Development of an occupational therapy intervention to improve sleep in people with schizophrenia spectrum disorders

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Contents

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Abstract

Sleep problems are very common in people with schizophrenia spectrum diagnoses, they cause considerable distress, and they impact negatively on quality of life, physical and mental health, and social functioning. Few non-pharmacological treatments are offered in practice, and therapies tested thus far tend to focus on insomnia processes more than on circadian dysregulation. Both insomnia and circadian dysregulation commonly occur in people with schizophrenia spectrum disorders. The presentation of sleep problems in this group is diverse, and social and occupational factors appear to contribute. It is suggested that occupational therapists have relevant skills to address such sleep problems.

This thesis presents work to develop an acceptable, safe and user-centred behavioural treatment for poor sleep, in people with schizophrenia spectrum disorders, to be delivered by an occupational therapist. This is the first programme of research that we are aware of that is pursuing this aim. Studies A and B evaluate existing evidence regarding interventions altering light exposure patterns to improve sleep in groups with high rates of circadian dysregulation. They present a meta-analysis with meta-regression, and a narrative synthesis of acceptability and adherence data. They describe evidence of positive effects of light exposure modifications on sleep, and areas where more research is needed. Despite many light therapy protocols appearing insufficiently flexible, acceptability appears to be high, and attrition low.

Study C is a mixed methods expert opinion study to support intervention development, based on the principles of Delphi methodology. Expert opinion emphasised the need for treatment personalisation, and this is reflected in the intervention developed. Study C is followed by a chapter describing the process of synthesis of background evidence and findings from Studies A-C, describing how these informed the intervention.

Study D surveys service users and staff, to identify potential implementation issues, including the demand for such an intervention, its acceptability, and barriers to referral. Findings identified significant demand for such an intervention and suggested increased staff training could improve sleep problem identification and referral. Finally, the protocol for feasibility testing of this intervention is presented. This mixed methods study evaluates both the acceptability of the intervention, and the feasibility of larger scale testing, and at the time of writing it is underway.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Copyright statement

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About the author

Sophie Faulkner is an experienced mental health occupational therapist whose interest in sleep research began when working on an acute mental health ward. Sophie began by completing The Clinical Scholar's scheme, conducting a qualitative focus group study on the role of the mental health occupational therapist in relation to sleep. Sophie then completed an HEE / NIHR funded MClinRes, focusing on experiences and perspectives on sleep problems in people with schizophrenia spectrum disorders, as preparation for the intervention-focused research presented in this thesis.

This work has been funded by HEE / NIHR through the Clinical Doctoral Research Fellowship, Integrated Clinical Academic Award, and is hosted by Greater Manchester Mental Health NHS Foundation Trust (GMMH). The award commenced on 01.04.2017 and is part-time at 60% whole time equivalent (WTE). Alongside completing this award, Sophie has worked in clinical services, and in research as an Attention Training Technique trials therapist. Sophie now works running and designing other studies, and on research capacity building, based in the Psychosis Research Unit, Greater Manchester Mental Health NHS Foundation Trust. Sophie is committed to remaining connected to clinical practice and aspires to develop a clinical-academic career.

When not researching sleep, circadian rhythm and mental health, Sophie can be found making and building things, drawing portraits, hosting board games evenings, exploring, dancing ferociously, and playing Beat-Saber.

Chapter 1: Background

1.1. Overview

This thesis presents work leading toward the development of a first-line occupational therapy intervention for poor sleep, in people with schizophrenia spectrum diagnoses (SzSD). It was decided to specifically target sleep in SzSD due to this group's high prevalence of sleep difficulties (Hombali et al., 2019; Winsky-Sommerer et al., 2019), combined with limited attention to sleep in this group in clinical practice and guidance (National Collaborating Centre for Mental Health, 2014; NICE, 2014, 2015c).

The existing skillset and professional objectives of occupational therapists are suited to delivering sleep treatment (Fung et al., 2013; Solet, 2014; Faulkner and Mairs, 2015; Green, 2015). For instance, environmental adaptation to address sleep environments, and the assessment and adjustment of occupational routines to address morning and evening routines. In recent years, sleep has become more recognised as a legitimate concern for occupational therapists (Picard, 2012; Green, 2015; Brown, 2016), but there are as yet relatively few studies of occupational therapy interventions for sleep. At the outset of this programme of work, I completed a scoping exercise searching for occupational therapy trials in schizophrenia (concluded or ongoing). Those found predominantly focused on either cognitive functioning or work (NHS, 2016), and none addressed sleep. This programme of research is the first we are aware of to develop an occupational therapy intervention to address sleep in people with SzSD.

This thesis will present a theoretical and empirical background to this work, rationales and additional methods for the studies in this research programme, and six theoretical and empirical papers. The papers include an editorial, two related evidence syntheses, an expert opinion study to support intervention development, service user and staff surveys on the need for such an intervention, and potential future implementation issues, and finally, the protocol for the intervention's ongoing feasibility study. This work will be considered together and used as the basis for proposals for further research.

1.2. Introduction

People with schizophrenia spectrum disorder diagnoses often experience problems with sleep onset, maintenance and timing. In many cases, these may be considered expressions of insomnia and / or circadian dysregulation. This chapter describes the physiology of healthy sleep and circadian rhythm, and how these processes can be interrupted, resulting in sleep difficulties such as insomnia and circadian rhythm sleep-wake disorders. The presentation of these problems in SzSD will be described. Existing treatments for poor sleep will then be discussed in terms of components, mechanisms of action, evidence of effectiveness, and how these types of treatments relate to the core skills of occupational therapists.

1.3. Normal sleep and circadian rhythm

Sleep is present in all mammals, and sleep or sleep-like states have been found in almost all animal species studied (Miyazaki et al., 2017). Sleep involves a complete or partial suspension of consciousness, and, in most animals, the suspension of outward activity. Although sleep often appears similar to rest, coma, or hibernation, it differs in terms of brain activity and how easily reversible this state is (Deboer, 2013). Although some have hypothesised that sleep evolved simply to conserve energy when the animal is not active, this has been shown not to be an adequate explanation (Kirsch, 2011). Since the discovery of polysomnography, evidence has accumulated for many different active functions of sleep, including: memory consolidation, flushing of brain metabolites (waste products), and dendritic spine remodelling (pruning excess connections formed during experience) (Miyazaki et al., 2017).

Another observable feature of sleep is that it usually occurs routinely and rhythmically in organisms, to fit in with that creature's relationship with the solar day (Hut et al., 2012). Sleep generally occurs during daylight in nocturnal creatures (e.g., mice, bats), during darkness in diurnal / day-active creatures (e.g., ducks, humans), and in daylight and in darkness in crepuscular creatures, whose most active periods are at dawn and dusk (e.g., domestic cats, deer). It has been advantageous for creatures to sleep in synchrony with the solar day, and to subconsciously predict and prepare for the forthcoming 24-hour light conditions through their internal clock; circadian rhythm evolved predominantly to help synchronise sleep propensity with the solar time (Roenneberg and Merrow, 2016).

All cells in the human body have a circadian rhythm. The 'master clock' in the human brain, the suprachiasmatic nucleus (SCN), is entrained by light exposure via the eyes (Duffy and Wright, 2005). The SCN then signals to peripheral clocks in other cells and tissues to maintain internal synchrony (Buijs et al., 2016). During jet lag, the SCN may adjust to the local time zone faster than the peripheral tissues, such as those of the gut and the liver, creating internal desynchrony, which accounts for the digestive symptoms in jet lag (Rajaratnam and Arendt, 2001).

Circadian rhythms continue in the absence of external time cues; in other words, they are self-sustaining (Wulff, 2012), as has been shown in many experiments (Duffy and Wright, 2005). In humans, an intrinsic / endogenous period length (day length of the internal clock) of approximately 24 hours has been demonstrated (on average 24.18 hours) (Czeisler et al., 1999). The intrinsic period length in humans has some normal inter-individual variation which contributes to individual differences in chronotype (lark vs owl), as discussed later. Circadian rhythms are entrained predominantly by light exposure, which is described as an environmental zeitgeber (time-giver), with earlier light exposure phase advancing the rhythm, and later light exposure phase delaying the rhythm (Gooley, 2017). There is also evidence of the roles of weaker zeitgebers in modulating sleep-wake rhythms, including food intake (Wehrens et al., 2017), activity (Hughes, 2018; Youngstedt et al., 2019) and social contact (possibly via effects on arousal) (Mistlberger and Skene, 2004). As these zeitgeber exposures are modified by a person's sleep-wake behaviours, the circadian system may feedback on itself (Roenneberg and Merrow, 1999).

Circadian rhythm interacts with sleep pressure to produce (usually) regularly timed bouts of sleep and wakefulness (Dijk DJ. and Landolt, 2019). Sleep pressure, or the homeostatic sleep drive, increases the longer a person has been awake. Sleep becomes harder to resist, sleep onset is more rapid, and involuntary microsleeps begin to occur as sleep pressure rises (Durmer and Dinges, 2005). In humans there are many neurotransmitters involved in sleep homeostasis, one of which is adenosine. Synaptic adenosine increases with increased sleep pressure and promotes sleep onset (Huang et al., 2014) (caffeine is, amongst other things, an adenosine receptor antagonist and so blocks adenosine's actions). Sleep pressure and circadian rhythm (the circadian alerting signal) act together to determine sleep propensity, such that a person is more likely to fall asleep at a time when the circadian wake promotion signal is lower. Whilst later in the day sleep pressure might be higher, the

circadian alerting signal counteracts this until shortly before habitual bedtime, reducing sleep propensity in the early evening (Borbély et al., 2016) (see Figure 1). Cognitive performance and subjective alertness also follow a circadian rhythm similar to sleep propensity, such that impairments caused by sleep deprivation which were clearly present in the daytime, were almost completely absent during the evening wake maintenance zone (Lo et al., 2012).

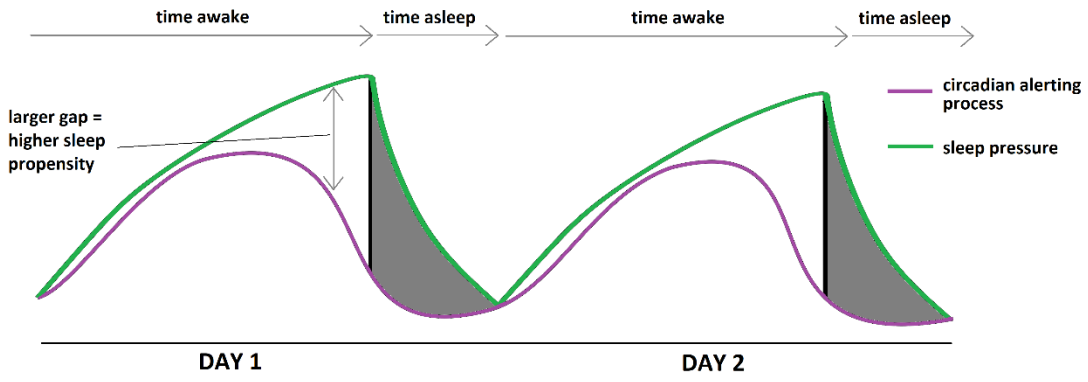

Figure 1: The two-process model

Sleep includes multiple different sleep stages; these states are distinguishable by their distinctive neurological activity detectable by polysomnography (described below) (Oliver and Datta, 2019). During normal sleep a person cycles through these different states in cycles of approximately 90 minutes, typically with several brief awakenings, or 'arousals' which are often not recalled (Roehrs and Roth, 2019). Different stages of sleep vary in their characteristics, and their known functions (see Table 1 and Figure 2).

There are many features of sleep microarchitecture with important known or hypothesised functions, too many to describe here. However, one which is pertinent to sleep in SzSD, is sleep spindles. Sleep spindles arise in NREM sleep and are involved in memory consolidation, coordination of activity between brain areas, and sensory gating; protecting NREM from disturbance by external stimuli (Fernandez and Lüthi, 2020). Sleep spindles have been found to be consistently reduced in schizophrenia. This reduction in spindles is associated with impaired cognition and positive symptoms, and may contribute to the impaired sensory gating which is found in schizophrenia (Manoach et al., 2016). Researchers have proposed directly

Table 1: Sleep stages and their characteristics

Sleep stage		Characteristics and functions
Non-REM sleep (NREM)	**Stage 1 (light sleep)**	▪ Usually the first stage of sleep entered, easy to wake from, might not feel like having been asleep if woken. ▪ Usually brief 1-5 min then moves to stage 2.
	Stage 2	▪ Body temperature drops, muscles relax, breathing and heart rate slow. ▪ Sleep spindles and K complexes occur on polysomnography (PSG) (short bursts of activity which help stay asleep). ▪ Usually 10-60 min, usually moves to stage 3 next. ▪ Involved in memory consolidation.
	Stage 3 (deep sleep / slow wave sleep)	▪ Delta frequency brain activity. ▪ Difficult to wake from. ▪ More deep sleep in the earlier part of the night. ▪ Deep sleep is 'prioritised' by the sleep deprived brain. ▪ Important for learning, memory, and bodily restoration.
Rapid eye movement sleep (REM)		▪ Muscles are paralysed, dreaming occurs, eyes make saccadic movements at intervals. ▪ More REM later in the night, so long sleep can result in increased amounts of REM. ▪ Looks similar to wake on PSG. ▪ Important for problem solving and memory processing.
Awakenings		Partial or complete awakenings between sleep stages are common and normal. These may or may not be recalled.

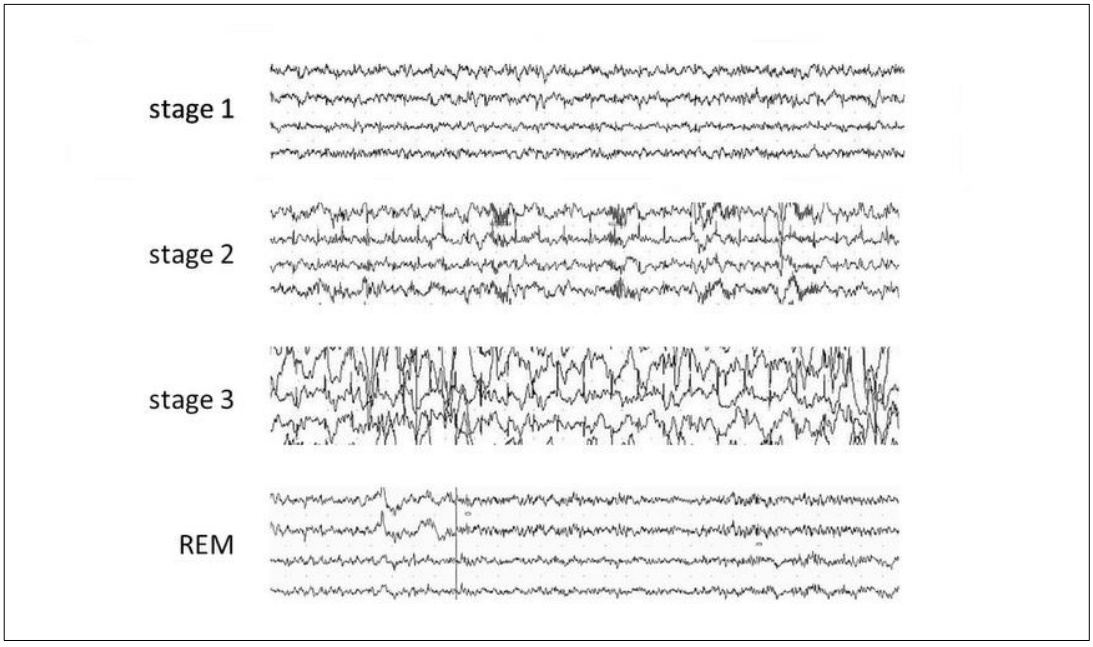

Figure 2: Polysomnographic patterns of different sleep stages

targeting spindle-related brain oscillations during sleep to improve memory in schizophrenia (Manoach et al., 2020). On a more immediate level, reduced sensory gating in schizophrenia highlights the importance of sleep environment and reducing or masking noise for this group.

1.3.1. Normal variations and individual differences

There is a great deal of normal variation in human sleep. The effects of personality and lifestyle differences account for some variation. Cultural and environmental differences account for some further variation, for instance, bi-phasic sleep (routine siestas) versus mono-phasic sleep (one sleep at night). However, the sleep system itself varies markedly between individuals. Some are earlier chronotypes (larks) or later chronotypes (owls), the majority are somewhere in between (neither lark nor owl). Adolescents and young people are more likely to be late types and, with age, chronotype becomes earlier (Danielsson et al., 2016b). A major contributor to being an early or late chronotype is the individual's intrinsic period length, with early-types usually having a shorter intrinsic period and late-types, a longer period (faster or slower running internal clocks, respectively) (Duffy et al., 2001). These differences may then be increased or reduced by the environment and behaviour, with self-exposure to artificial evening light and reduced daytime and morning natural light exposure increasing the proportion of people who are late-types, and magnifying the lateness of natural late-types. Poor light conditions (low daytime light, bright artificial evening light) may affect natural late-types to the extent that their entrainment with the solar day remains only through social cues (e.g., alarm use), or that entrainment is totally lost (Skeldon et al., 2017).

There is also some documented variability in sleep need between individuals. This includes both sleep duration required for unimpaired functioning, and also vulnerability to sleep loss (Ferrara and De Gennaro, 2001; Dongen et al., 2005). Sensitivity of the circadian system to light has been shown to vary (Chellappa et al., 2017; Phillips et al., 2019), as does caffeine metabolism and sensitivity (Clark and Landolt, 2017). The action of sleep pressure also varies based on differences in the PERIOD3 clock gene (Dijk and Archer, 2010). This is an active research area and various moderators of sleep pattern continue to be discovered.

1.4. Psychosis and schizophrenia spectrum diagnoses

Sleep parameters may be affected by mental illness, and sleep problems are more common in people with severe mental illnesses such as schizophrenia spectrum diagnoses (SzSD). Schizophrenia, schizoaffective disorder, schizotypal disorder, and delusional disorder are included within the category of SzSD (see Table 2). This group of conditions involves a range of disturbances of perception and thinking, collectively described as non-affective psychosis (National Collaborating Centre for Mental Health, 2014). Non-affective psychosis is so termed as it excludes bipolar disorder and severe depressive episodes with psychotic symptoms. It loosely corresponds to F20-29 diagnoses in Chapter V of the 10th edition of the International Classification of Diseases (ICD-10) published by the WHO (World Health Organisation, 1992).

SzSD are differentiated from a single acute psychotic episode; both ICD-10 and DSM-5 require some degree of continuity of symptoms (symptoms present to some degree for 6 months (American Psychiatric Association, 2013), or symptoms present most of the time for at least 1 month (World Health Organisation, 1992)).

Table 2: ICD-10 criteria for schizophrenia spectrum disorders

ICD-10 code and diagnosis	**Symptoms**	**Duration**	**Course**
F20 Schizophrenia	At least one 'first rank' positive symptom: thought echo, insertion or withdrawal, or broadcasting, delusions of control influence or passivity, hallucinatory voices, other persistent delusions, OR, at least 2 of: hallucinations, neologisms, breaks or interpolations in the train of thought, catatonic behaviour, "negative" symptoms.	Most of the time, or on most days, for >1 month	Continuous or episodic. Remission may be complete or incomplete.
F22 Persistent delusional disorders	Persistent delusion(s), but without meeting criteria for schizophrenia, without persistent auditory hallucinations, and persisting without disturbance of mood.	>3 months	Continuous.
F25 Schizoaffective disorders	Meets criteria for one of the specified affective disorders, AND, some of a specified list of schizophrenia symptoms present for most of the time. Both affective and psychotic symptoms occur together and are both prominent.	At least 2 weeks	Episodic.

The American Psychiatric Association's DSM-5 (5th edition of the Diagnostic and Statistical manual) and ICD-10 criteria for SzSD both require at least one "positive" symptom of psychosis. In DSM-5 these are: hallucinations, delusions, and disorganised thought or speech (American Psychiatric Association, 2013). ICD-10 is similar although it does not mention disorganised speech. Focusing on thoughts ICD-10 specifically mentions thought echo, insertion, withdrawal, broadcasting, passivity or control (World Health Organisation, 1992). Hallucinations are commonly auditory (such as voice hearing), but may also be visual, tactile, olfactory or gustatory, and commonly involve multiple senses (Lim et al., 2016). Delusions were previously defined as 'erroneous beliefs', but are now described as "fixed beliefs that are not amenable to change in light of conflicting evidence" (American Psychiatric Association, 2013; Heckers et al., 2013). Disorganised or abnormal motor behaviour (such as catatonia), and negative symptoms may also be present in SzSD (Heckers et al., 2013). Although research is often more focused on positive symptoms such as delusions and hallucinations, negative symptoms such as reduced emotional expression and motivation are common, cause significant functional impairment, often remain problematic even when positive symptoms are improved, and remain prominent later in the course of illness (National Collaborating Centre for Mental Health, 2014; Lieberman and First, 2018). Cognitive impairment is also common in SzSD (Sheffield et al., 2018), and is linked to poorer quality of life (Paudel et al., 2020).

SzSD continues to be controversial; there are researchers, clinicians and people with personal experience who question whether SzSD terms and diagnoses are the most helpful or informative means of description and classification. The British Psychological Society have, for instance, argued that psychotic experiences are more similar to other types of psychological problems such as anxiety, worry, or shyness, than is commonly accepted. They describe a continuum between psychotic experiences and normal experiences, similar to the continuum between normal variation in mood, and clinical depression (Cooke, 2017). It is accepted that it is normal to experience anxiety sometimes, but psychotic experiences are commonly viewed as being totally different to 'normal' experience, despite evidence that psychotic or psychotic-like symptoms are prevalent in people who do not meet criteria for any SzSD (Nuevo et al., 2012). There has been increased interest in describing SzSD in terms of the dimensions of symptoms rather than categories

(Potuzaka et al., 2012). This thesis presents no view on the reality or broader utility of the construct of schizophrenia or other SzSD, beyond that the group of people receiving these diagnoses have a high prevalence of particular types of sleep problems. At the same time, people with SzSD may be less likely to be offered non-pharmacological interventions, as psychosis is often viewed as 'more biological' than mood or anxiety symptoms (Andreou and Moritz, 2016). This was a further motivation to focus on developing an intervention for people with SzSD.

1.5. Sleep disorders

A range of sleep disorders are common in the general population, and even more common in people with SzSD. The main categories of these are each discussed below, first generally, and then in relation to SzSD.

1.5.1. Insomnia

Insomnia is defined in the International Classification of Sleep Disorders-Third Edition (ICSD-III) as difficulty falling asleep, or staying asleep, despite adequate opportunity, accompanied by daytime consequences, and which occurs 3 or more times per week for 3 or more months (Sateia, 2014). Insomnia is diagnosed based on self-report (history, and sometimes standardised measures), and without subjective complaint, a diagnosis of insomnia cannot be met.

Insomnia subtypes have long been debated. Insomnia can be described via symptoms (sleep onset vs sleep maintenance difficulties) (Waters et al., 2003), in terms of supposed causes (psychophysiological insomnia, idiopathic insomnia), or by objective sleep duration (paradoxical insomnia vs insomnia with short sleep duration) (Vgontzas et al., 2012; Castelnovo et al., 2019). Although these terms can be useful descriptively, research has not supported their reliability and validity to consistently distinguish genuine stable phenotypes, or as a means by which to select treatments (Benjamins et al., 2017); DSM-5 and ICSD-III have for now abandoned further subtyping. Subtypes based more on distress, reward sensitivity, and stress reactivity have been proposed based on large scale cross-sectional survey results (n=2224) (Blanken et al., 2019), although these findings have been criticised for reliance on subjective report, for the cross-sectional and observational nature of the data, and for lacking of clinical diagnostic utility (Ferini-Strambi et al., 2019).

Theories of insomnia propose processes by which insomnia becomes sustained and chronic, including 'sleep effort', neurobiological arousal, unhelpful behaviourally conditioned responses to sleep-related stimuli, and increased sleep-related anxiety (M. Perlis et al., 2010). Hyperarousal is widely held to be a factor in the development and maintenance of insomnia, with some people vulnerable to short term sleep disruption caused by stress (arousal), termed 'sleep reactivity' (Kalmbach et al., 2018). Similarly, those with slowed 'fear extinction' response (the unlearning of a conditioned fear response, when the stimulus is no longer predictive of the feared outcome), may also be more prone to develop insomnia (Perogamvros et al., 2020). In addition, theories emphasise the role of inappropriate coping behaviours (e.g., excess time in bed, increasing caffeine use) in maintaining insomnia (M. L. Perlis et al., 2010).

Many theories of insomnia and studies of the mechanisms underlying insomnia also emphasise the roles of beliefs and attitudes in causing and sustaining insomnia (Edinger and Wohlgemuth, 2001). These problematic sleep-related beliefs are measured using tools such as the Dysfunctional Beliefs and Attitudes about Sleep Scale, and include beliefs such as "Cannot function without a good night" and "Sleep is unpredictable" (Morin et al., 2007). Unhelpful sleep beliefs then lead to behavioural responses which promote and sustain insomnia, including safety behaviours and sleep effort (Fairholme and Manber, 2014). Experiences of poor sleep may then further reinforce some dysfunctional sleep beliefs, promoting maintenance of problems.

Metacognitive beliefs about sleep may also be important. These are beliefs and evaluations regarding one's own cognitive activity in relation to sleep, such as "not being able to rest my mind in bed means my thoughts are out of my control" and "Before I fall asleep, I should try and switch off my thoughts" (thought blocking). These unhelpful meta-cognitive sleep beliefs have been shown to be associated with worse subjective sleep (Sella et al., 2019), increased sleep reactivity to stress (Palagini et al., 2016), and more use of ineffective thought control strategies such as 'aggressive suppression' (Sella et al., 2019). It would be expected that dysfunctional meta-cognitive strategies such as thought blocking would probably impair sleep, and indeed this has been found (and by researchers outside the field of meta-cognitive research). Thought blocking, originally proposed as a helpful strategy, was either ineffective, or worse, resulted in *longer* time to sleep onset (Lemyre et al., 2020).

Insomnia in people with mental health conditions used to be described as 'secondary', whilst insomnia in someone otherwise apparently healthy was described as 'primary insomnia'. This distinction has since been abandoned as it implies a causal and temporal order that research does not support (Baglioni et al., 2011; Pritchett et al., 2012; Lunsford-avery et al., 2015); mental health conditions may be secondary to insomnia, both may be from a common cause, or they may be of unrelated causes, but now co-morbid and interacting.

1.5.1.1. Insomnia in SzSD

People with SzSD experience a diverse range of insomnia complaints, not all of which look obviously like insomnia to non-specialist clinicians. Chiu et al (2018) found that whilst 44.6% of people with insomnia and SzSD reported short sleep, poor sleep efficiency, and prolonged sleep onset latency ('classic severe insomnia' subtype). A further 55.4% had either normal or prolonged duration of sleep, but with poor sleep maintenance or onset, and with sleep-related daytime impairment. Similar findings came from the meta-analysis of actigraphic studies; people with SzSD had significantly longer sleep than controls (SMD=1.26, p=<0.001), but with longer sleep latency (SMD=0.74, p=<0.001) and more wake after sleep onset (SMD=0.90, p=0.002) (Meyer et al., 2020). Meta-analysis of polysomnographic studies by contrast did find shorter total sleep time in SzSD, alongside various other disturbances in sleep architecture (Chan et al., 2017). There is debate over whether some sleep abnormalities are caused by anti-psychotics rather than the disorder, and whilst these antipsychotics do appear to modify the type of abnormalities expressed (worsening some, improving others) (Monti and Monti, 2004), synthesis of polysomnographic evidence from untreated patients with psychosis shows that sleep abnormalities are present in both medication-withdrawn and medication-naïve patients (Chouinard et al., 2004).

One might assume that high levels of arousal and distress, and positive symptoms of psychosis, would contribute to arousal related insomnia processes, and that poor sleep would in turn contribute to worse psychotic symptoms. Observational and interventional studies have indeed found evidence of such a bi-directional relationship between positive symptoms of psychosis and sleep disturbance, both in SzSD (Reeve et al., 2015) and in first episode psychosis (Davies et al., 2017).

It has been proposed that current theories of insomnia are based predominantly on studies in insomnia without co-morbidity, and that some different beliefs and behaviours may be involved in sleep disturbance in severe mental illness (Chiu et al., 2015; Pearson et al., 2020). For instance, in people with insomnia without psychiatric co-morbidity, night-time worry about daytime consequences of poor sleep is a common sustaining factor; whilst clinicians working with people with psychosis note that worry about functional daytime consequences of poor sleep is less common in their clients, and that night-time worry more often relates to the contents of psychotic experiences (Waite, Myers, et al., 2015).

Beliefs and worries about sleep may also interact with fear of relapse, as people with SzSD have described seeing loss of sleep as a potential cause of relapse (Chiu et al., 2016; Faulkner and Bee, 2017). Fear of relapse is in itself linked to poorer emotional recovery and increased risk of relapse, potentially via activating a pattern of thinking or behaviour which itself accelerates relapse (e.g., social avoidance) (Gumley et al., 2015). It is possible that a similar process might become activated in relation to fear of relapse due to loss of sleep; if relapse is seen as a likely consequence of sleep loss then this could cause increased attentional focus on sleep, or excessively long time in bed seeking more sleep, resulting in poorer sleep, wellbeing and symptoms. Earlier qualitative work from which this thesis extends, has noted that some adults with psychosis expressed a belief in the need for an unusually long sleep in order to avoid relapse (Faulkner and Bee, 2017). People with SzSD can come to use sleep as an escape from distress (Faulkner and Bee, 2017; Waite et al., 2018), which can promote napping or excessive daytime sleep.

1.5.2. Circadian dysregulation, and circadian rhythm sleep-wake disorders

Circadian rhythm sleep-wake disorders (CRSWD) are diagnosed based on a chronic or recurrent pattern of sleep-wake rhythm disruption thought to be caused by a mismatch between a person's internal timing and the sleep-wake timing desired or needed for their life situation. This causes difficulty sleeping, daytime sleepiness, or both, which in turn causes daytime dysfunction. Except for jet-lag disorder, ICSD-III now requires that the disturbance should be present for at least 3 months (American Academy of Sleep Medicine, 2014; Sateia, 2014). Use of objective markers is encouraged but not necessarily required for the diagnosis of CRSWD. Passive monitoring of activity patterns (e.g., actigraphy) is used. Measuring dim

light melatonin onset (DLMO) gives a gold standard estimate of circadian phase, and although it is possible in the community (Rahman, 2015), the facilities to do this are rarely available in clinical services.

The list of diagnosable CRSWD includes rhythms that are too advanced, too delayed, or slower than the external day length, these have a regular rhythm, but which is asynchronous with the external environment, or which have limited or no discernible rhythm. Respectively, these are: advanced sleep-wake phase disorder (ASWPD), delayed sleep-wake phase disorder (DSWPD), non-24-hour sleep-wake phase disorder (Non-24), or irregular sleep-wake phase disorder (ISWPD) (see Figure 3).

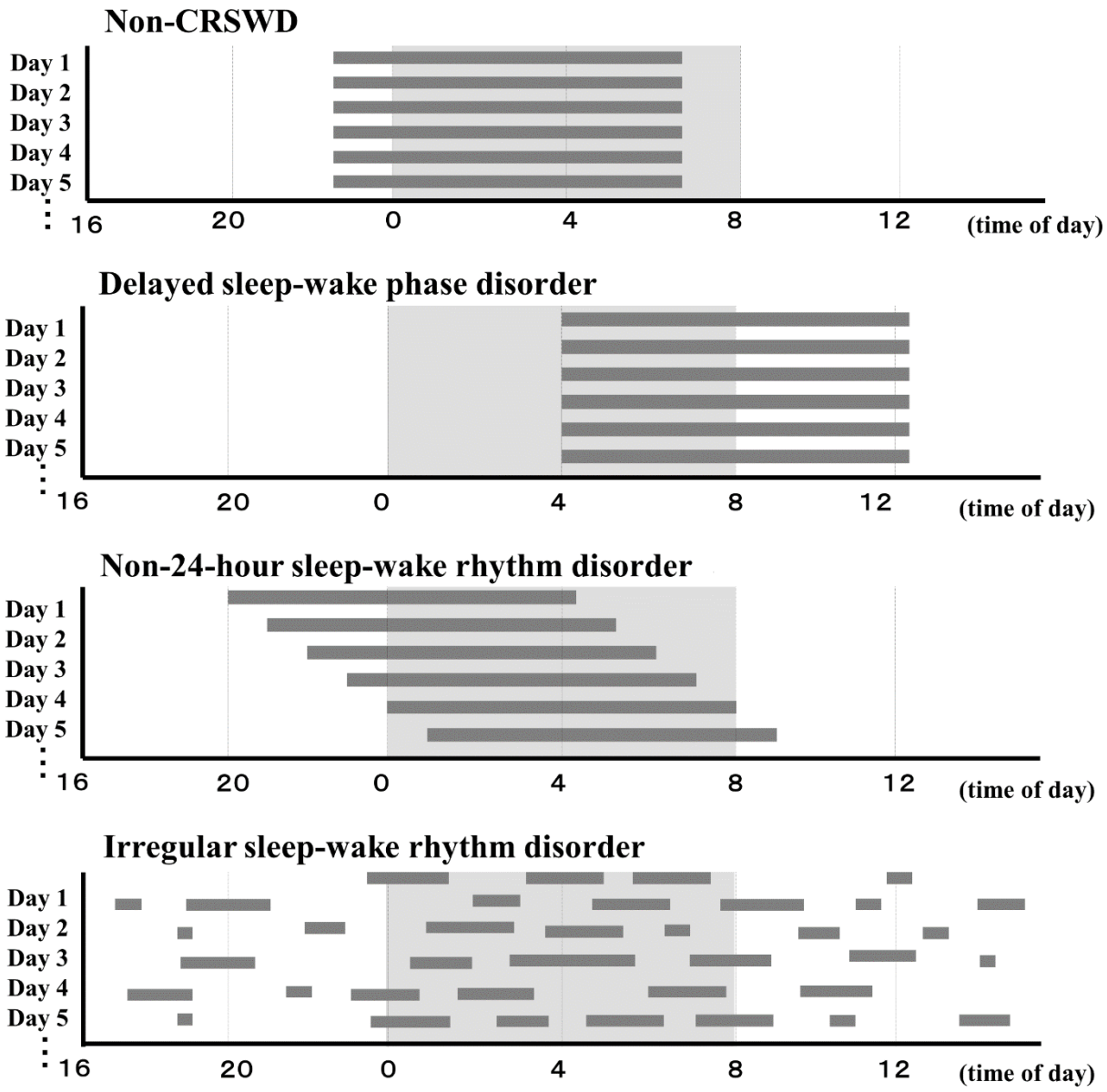

Figure 3: Sleep timing in CRSWD

CRSWD includes disorders which are 'intrinsic' - caused by individual factors such as the length of an individual's endogenous circadian period (a fast or slow clock). CRSWD can also be 'extrinsic' - due to environment or occupational routine, i.e. jet-lag and shift work disorder (NICE, 2013). There is interaction, and vulnerability to 'extrinsic' CRSWD varies based on individual factors; for instance, chronotype influences adaptation to shift work (Ritonja et al., 2019). Occupational and environmental factors can also worsen or conflict with individual predispositions (e.g., excess evening light exposure in DSWPD (Cho et al., 2015)). This thesis focuses on circadian dysregulation of predominantly intrinsic cause, which may be worsened or improved by environmental and occupational factors, but this thesis does not specifically address shift work or jet lag.

1.5.2.1. Circadian dysregulation in SzSD

Circadian dysregulation is more common in people with SzSD than in the general population (Wulff et al., 2010). Non-24-hour rhythms have been found in a large minority of people with schizophrenia, and not found in matched unemployed controls (20% vs 0%) (Wulff et al., 2012). Although the exact prevalence of non-24-hour rhythms in sighted individuals is not known, they is described as debilitating and *rare* (Mishima, 2017; Malkani et al., 2018). Studies have found rest-activity patterns to be mostly abnormal in SzSD, including very delayed, very advanced, irregular, and free running patterns (Pritchett et al., 2012; Wulff et al., 2012; Jagannath et al., 2013; Meyer et al., 2018). Despite this, people with SzSD are rarely diagnosed with CRSWD. ICSD-III suggests that the sleep problem must not be 'better explained' by another medical, neurological or mental disorder (American Academy of Sleep Medicine, 2014). Whilst the high prevalence of CRSWD-like presentations in SzSD suggests perhaps SzSD might partly 'explain' the circadian dysregulation, this diagnostic gap presents a challenge in terms of identification, treatment and research regarding CRSWD-like presentations in people with SzSD. It would be useful if these problems could be identified and referred to precisely. As CRSWD are perhaps not intended to be diagnosed in people with SzSD using current criteria, presentations otherwise meeting criteria for a CRSWD will be referred to in this thesis as ~CRSWD ("similar to CRSWD"), rather than CRSWD (people with SzSD can then be described as having ~DSWPD, ~ASWPD, ~IRSWPD or ~Non-24).

There appears to be a predisposition toward ~CRSWD in people with SzSD, most likely contributed to by abnormal neurotransmission or neurodevelopment. Genes which are involved in circadian rhythm have been found to be often affected in SzSD and other severe mental illnesses (Menet and Rosbash, 2011). It is suggested that these alterations, amongst other factors, may be causally involved in the development of ~CRSWD in SzSD (Jagannath et al., 2013). Exacerbating this vulnerability to ~CRSWD, people with SzSD show reduced engagement in social activities and active occupations (Hayes and Halford, 1996; Minato and Zemke, 2004), and are more likely to be socially excluded (Reddy et al., 2019). We know that routines, social contact, and social constraints (including alarm clock use) provide external pressure toward circadian entrainment; this has been shown via moderating the effects of timing of sleep opportunities and light exposure (Roenneberg and Merrow, 2016; Skeldon et al., 2017). There may also be a direct entraining effect (Mistlberger and Skene, 2004). Reduction in social integration and commitments can allow and encourage more irregular patterns of activity, further promoting poorer entrainment. Feeling sleepy or alert at the 'wrong' times can then further interfere with social engagement, and make it harder to access time-sensitive opportunities (Faulkner and Bee, 2017).

1.5.3. Parasomnias and sleep disordered breathing

The treatment developed within this project was never intended to directly address parasomnias or sleep disordered breathing (SDB), which are usually treated by specialist sleep services. There is less suggestion that these should fall within the remit of secondary care mental health services. However, it is noted that SDB and many parasomnias are at increased prevalence in SzSD compared to the general population (Kalucy et al., 2013; Klingaman et al., 2015; Reeve et al., 2019), so they are relevant to consider. SDB was found to be more than twice as prevalent in a sample with SzSD as in matched general population controls (Myles et al., 2018). Evidence suggests that increased rates of obstructive sleep apnoea (OSA) in SzSD are partly attributable to higher body mass index (BMI) due to reduced activity (a result of negative symptoms including reduced motivation, social isolation and daytime sedation) and increased appetite (e.g., due to antipsychotics and some antidepressants). Antipsychotics appear also to contribute as an independent risk factor to BMI, perhaps via effects on upper airway tone or respiratory control (Kalucy et al., 2013). Similarly, restless legs syndrome (RLS) is significantly more

common in schizophrenia (Kang et al., 2007), as are nightmares (Michels et al., 2014; Sheaves et al., 2015). There is of course some difficulty distinguishing RLS and the antipsychotic adverse effect akathisia in this group, and similarly, to what extent nightmares are a residual symptom or early warning sign of psychosis is unclear.

Because it is expected that a proportion of people with SzSD referred for problems with sleep onset, maintenance or timing will also have SDB or a parasomnia, the impact of these conditions, and to what extent the intervention should address or respond to these issues, will be considered (see Table 3).

Table 3: SDB, sleep-related movement disorders, and parasomnias

Condition / phenomenon	Description	Relevance to sleep treatment in SzSD
Obstructive sleep apnoea	Upper airway collapses during sleep, interrupting breathing, causing brief awakening. Causes sleepiness, and impacts cardiometabolic health, especially blood pressure. Treatment with continuous positive airway pressure (CPAP), dental devices, surgery or weight loss (Jordan et al., 2014).	The prevalence of OSA is higher in men with schizophrenia than without (Myles et al., 2018). Screening and referral advised.
Central sleep apnoea	Pauses in breathing during sleep caused by lack of respiratory drive (neurological), associated with heart failure. Often mixed with OSA. Less common (Momomura, 2012).	Screening and referral advised.
Restless legs syndrome (RLS)	Irresistible urge to move legs, accompanied by unpleasant sensations, particularly at rest, and worse at night. Treated with drugs (often dopamine agonists) (Aurora et al., 2012; Salminen and Winkelmann, 2018), or with non-pharmacological treatments but evidence is limited (Harrison et al., 2019).	RLS is common, and more so in schizophrenia (Kang et al., 2007). Caffeine reduction and exercise, may also improve symptoms (Harrison et al., 2019). Screening and referral advised.
Periodic limb movement disorder	Repetitive movements of lower limbs during sleep. Commonly co-occurs with RLS (Aurora et al., 2012).	Can affect interpretation of actigraphic assessment of sleep; movement may be detected during sleep.
REM sleep behaviour disorder	Movement during REM sleep, enacting dreams, more during later part of the night. Limited treatment options, mostly injury prevention strategies, and surveillance for development of Parkinson's and other associated conditions (Jung and St. Louis, 2016).	Screening and referral.
Sleep walking	Movement during non-REM sleep, common in children and can continue in adulthood (Loddo et al., 2019), worsened by stress. Can be caused by hypnotics (Iranzo, 2018).	If not improved through sleep treatment, refer as required.
Nightmare disorder	Frequent nightmares causing awakening, distress, and possibly delay returning to sleep. Dream content is recalled, occurs mostly later in the night (in REM sleep). Treated using imagery rehearsal therapy (IRT), relaxation, exposure, Prazosin (Augedal et al., 2013).	Nightmares are more common in SzSD (Michels et al., 2014). Improving sleep may improve nightmares, but specialist therapeutic input may be required.
Night terrors	Confused awakening with intense fear, possibly screaming, but limited or no dream content recalled. Happens earlier in the night (in non-REM sleep) (Loddo et al., 2019). Common in children, can occur in adulthood. Worsened by stress.	If not improved then refer as required.

1.5.4. The interaction of different sleep disorder processes

Although separate and distinct in aetiology and symptoms as described above, insomnia, CRSWD, parasomnias and SDB can co-exist and interact (see Figure 4). In neuropsychiatric disorders insomnia, ~CRSWD, SDB, and parasomnias are all at increased prevalence, so it is hypothesised that various complex interactions are likely.

Insomnia, ~CRSWD, SDB and parasomnias are typically studied as separate entities, although some authors have examined potential interactions and overlap. For example, insomnia processes and DSWPD (Richardson et al., 2015), insomnia and sleep apnoea (Sweetman et al., 2020), and insomnia and RLS (Broman et al., 2008). Unfortunately, much research side-lines, screens out, or ignores such co-morbidities and interactions.

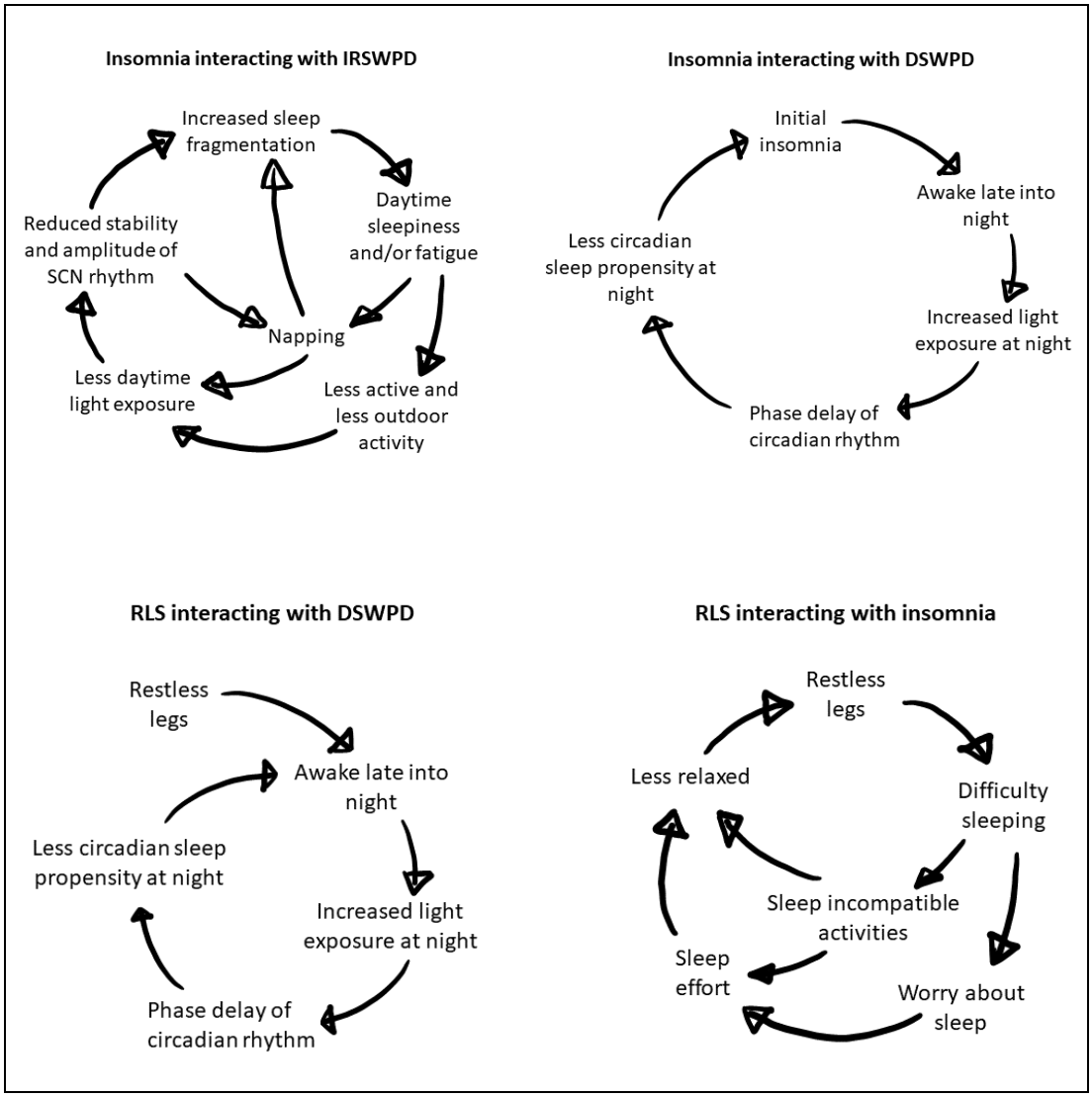

Figure 4: Potential interactions of CRSWD, insomnia and RLS

1.6. Impact of poor sleep and circadian dysregulation

Adequate sleep is a basic human need, without which the body and mind cannot function properly. Long term sleep disruption has been linked to hypertension, poorer cardiometabolic health outcomes, and increased weight (Medic et al., 2017). Lab studies and epidemiological work suggest a link between sleep loss and impaired insulin response, altered glucose metabolism, weight gain and development of type 2 diabetes (Spiegel et al., 2005). Shift work has been linked to increased cancer risk, which is thought to be due to the circadian dysregulation and sleep disruption caused by shift work (Haus and Smolensky, 2013).

Cognitive functioning is impacted by poor sleep and circadian rhythm; experimentally, sustained attention and working memory are impaired by both partial and total sleep deprivation (Lo et al., 2012). In students, insufficient sleep (Gomes et al., 2011) and irregularly timed sleep (Phillips et al., 2017) both predict poorer academic performance. As if short and mid-term impacts were not enough, disturbed sleep is a risk factor in the longer term for cognitive decline and Alzheimer's (Spira et al., 2014).

Sleep fragmentation and sleep deprivation have each been shown to increase plasma cortisol, with some sustained effects on levels and patterns of secretion persisting afterwards (Bonnet and Arand, 2003). In the short term, sleep disruption contributes to increased stress responsivity, emotional distress, and somatic pain (Medic et al., 2017), and impairs the ability to encode positive emotional memories (Van der Helms & Walker, 2009). Links have been established in the field of seasonal and non-seasonal depression between a shorter phase angle from melatonin onset to sleep, and reduced amplitude of melatonin rhythm, with lower mood (Alston et al., 2018). Sleep deprivation or restriction affects mood systems and causes depression-like states in rats (Novati et al., 2008). Overall, in the longer term, poor sleep in humans is associated with increased levels of psychiatric symptoms; mounting evidence suggests a potential causal role for sleep and circadian disturbance in the development of many neuropsychiatric conditions (Pritchett et al., 2012; Jagannath et al., 2013; Reeve et al., 2015; Waite et al., 2020).

1.6.1. Impact of sleep disturbance in SzSD

Problems with sleep and circadian dysregulation are common in people with SzSD (Wulff et al., 2012), and are present during phases of relative remission of symptoms

(Meyer et al., 2020). Indeed, rather than being secondary, sleep problems often precede and predict the onset of psychosis (Lunsford-avery et al., 2015; Reeve et al., 2015) and it is hypothesised that sleep deterioration may be causally involved in the progression of relapse (Reeve et al., 2015; Meyer et al., 2018; Waite et al., 2020).

Sleep, symptoms, and functioning are intertwined. It has been shown that improving sleep can improve psychotic-like symptoms in a large-scale analogue study (Freeman et al., 2017). Even without the possibility of improving sleep reducing psychotic symptoms, it is proposed that improving sleep would likely improve cognitive and functional performance (Wulff and Joyce, 2011) and quality of life (Ritsner et al., 2004; Hofstetter et al., 2005) for people with SzSD.

Overnight continuity of sleep (sleep maintenance) has been shown to predict subsequent daytime symptoms (Mulligan et al., 2016). Chaotic sleep patterns and poor sleep have been linked to poorer medication adherence (Afonso et al., 2014), perhaps due to the disorganised daily routines and poor social integration associated with poor sleep patterns. Sleep problems and reduced synchronisation of activity timing with the day-night cycle (becoming more erratic or more nocturnal) have been linked to reduced satisfaction with daily social and occupational routines (Eklund et al., 2010). There is also evidence that daytime napping is independently associated with cardiovascular morbidity in those with schizophrenia (Berry et al., 2021).

In summary, there are many links between poor sleep and negative health impacts. It has been proposed that poor sleep contributes to socioeconomic health inequalities (Laposky et al., 2016), and it seems plausible that sleep and circadian disturbance may be one of the contributing factors to the well-known physical health inequality and the mortality gap in SzSD (Laursen et al., 2011; Piotrowski et al., 2017).

1.6.2. Perspectives and preferences of people with SzSD

There has been limited research regarding the views and priorities of people with SzSD, or other severe mental illnesses for that matter, about sleep and sleep treatment, as summarised by my previous review (Faulkner and Bee, 2016). Those studies in that review, and some more recent work, do show that people with SzSD see sleep as important, and as impacting on various aspects of their social and occupational lives (Chiu et al., 2016; Faulkner and Bee, 2017). People with psychotic illnesses want to sleep better (Auslander and Jeste, 2002), and have

described the impact of poor sleep on their mental health, saying they felt it should be treated (Waite, Evans, et al., 2015).

Broken sleep, or sleep which was not experienced as 'deep', was described as a high priority for change by participants, as were prolonged sleep inertia and daytime sleepiness. Although some participants described sleep as something they wanted to work on, others believed efforts were futile (Faulkner and Bee, 2017). Importantly, clinicians sometimes come to the view that patients with psychosis are unmotivated toward improving their sleep patterns (Hansen et al., 2011; Faulkner and Mairs, 2015; Rehman et al., 2017). In reality, however, these patients may not seek help for numerous reasons, including the perceived inevitability of poor sleep as part of their illness (Chiu et al., 2016; Faulkner and Bee, 2017) or the assumption that sleep does not fall within the expertise and the remit of their mental health team (Faulkner and Bee, 2017).

1.7. Treatments for poor sleep

The following sections describe treatments for poor sleep, initially addressing these in terms of distinct intervention components rather than intervention packages. It is very often the case that these components are applied within multi-component complex interventions. The most widely studied of these is cognitive behavioural therapy for insomnia (CBTi), which incorporates many of the components discussed below (but usually not medication, and sometimes not addressing light). Sleep hygiene advice will also be mentioned; sleep hygiene consists of various advisory principles to improve sleep. The content can vary but usually includes factors like bedroom environment, caffeine, and regular sleep timing. Sleep hygiene advice overlaps with the contents of CBTi.

At the end of this section multi-component interventions generally, and CBTi specifically, will be discussed. It is acknowledged that there exist many other multi-component sleep interventions which are not covered here.

Interventions will be discussed generally, and with reference to SzSD.

1.7.1. Pharmacological treatment of insomnia

Drug treatments specifically to promote sleep (hypnotics) include the benzo-diazepines (nitrazepam, temazepam, diazepam, lorazepam), and the Z-drugs (e.g.,

Zaleplon, Zopiclone, Zolpidem). These promote GABA activity, which is sedating, thus aiding sleep (Agravat, 2018). However, side effects and tolerance are known issues, and there is much epidemiological evidence to suggest they may cause increased mortality (Kripke, 2016). Drug treatment of chronic insomnia is not recommended in NICE guidelines due to increased risk of falls, cognitive impairment, dependence and withdrawal (NICE, 2015b). Whilst the American Academy of Sleep Medicine does recommend some agents, it does so only with a 'weak' recommendation, whilst advising against others (M. J. Sateia et al., 2017).

As well as traditional hypnotics, other drugs have been used to treat insomnia. Anti-depressants such as the tricyclics (doxepin, amitriptyline, trimipramine) are sometimes prescribed off label to treat sleep (Wiegand, 2008), as is the serotonin antagonist and reuptake inhibitor Trazodone (Vijay et al., 2018). Perhaps more controversially, antipsychotics such as olanzapine and quetiapine are sometimes used in the absence of psychosis; however, due to the significant cardiometabolic and neurological side effects, this is not recommended (Buysse and Tyagi, 2017). Antihistamines, anticonvulsants, and plant extracts, such as valerian, have been used and tested to varying degrees as sleep treatments (Buysse and Tyagi, 2017), but none have revolutionised the treatment of insomnia, either due to limited efficacy, harms and drawbacks, or both. There is some optimism that newer hypnotics targeting the orexin system may be effective with fewer side effects, but this research is at a relatively early stage (Hoyer et al., 2020).

1.7.1.1. Melatonin in insomnia

Melatonin is relatively safe compared to common hypnotics, and it is licensed for treating short term insomnia in patients over 55 (Joint Formulary Committee, 2021). A recent network meta-analysis shows melatonin to be effective for reducing sleep onset latency in insomnia but not effective for improving subjective sleep quality or perceived severity of sleep problems (Baglioni et al., 2020). It should be noted that 3 of 11 studies included used sleep onset latency rather than DSM or ICD criteria to define insomnia, so these may have included some participants better described as having DSWPD.

1.7.2. Pharmacological treatment of circadian rhythm sleep-wake disorders

CRSWD is sometimes treated using hypnotic agents in practice, although again this is not recommended except in short term extrinsic CRSWD (e.g., short term shift

work, jet-lag) (Spiegelhalder K., Nissen C., 2017). DSWPD may particularly be approached with hypnotics if it is mistaken for insomnia disorder, as is common (Selsick and O'Regan, 2018). However, treatment of sleep onset insomnia in DSWPD using hypnotics will usually not address the underlying phase abnormality, so daytime sleepiness and poor sleep quality is likely to persist.

1.7.2.1. Melatonin in circadian rhythm sleep-wake disorders

Exogenous melatonin and melatonin agonists have both an acute sleep-promoting effect and a phase shifting effect. Acutely, they can facilitate sleep during the wake maintenance phase of the circadian rhythm (Alston et al., 2018), thus they are often proposed for use to treat CRSWD / ~CRSWD, rather than insomnia. The direction and magnitude of the phase shifting effects of melatonin follow a phase response curve in the same way as light exposure (Revell and Eastman, 2005). This makes melatonin more complex to prescribe than hypnotics for non-specialist prescribers due to the need to accurately assess or approximate circadian phase at baseline (Auger et al., 2015). For the same reasons, preparation type (e.g., release timing) significantly alters effects. There is meta-analytic evidence for the efficacy of melatonin in shortening sleep onset latency a small amount in children with neurodevelopmental disorders (Appleton et al., 2012), for treatment of short term insomnia in children and adolescents (Wei 2019), and for benzodiazepine withdrawal in adults with insomnia (Morera-Fumero et al., 2020). Perhaps surprisingly considering their mode of action, the evidence is, as yet, sparse for melatonin agonists in the treatment of many CRSWDs, including ASWPD and DSWPD (Williams et al., 2016). Some studies have shown positive effects of timed melatonin combined with light treatment (Dowling et al., 2008; Saxvig et al., 2014), one of which has demonstrated effects of melatonin and light were additive (Paul et al., 2011).

1.7.2.2. Pharmacological sleep treatment in SzSD

Sedative drugs are often used in SzSD (Baandrup et al., 2013). Apart from sleep hygiene advice, medication was reported as the most commonly used treatment approach by mental health professionals (Rehman et al., 2017). As benzodiazepines and Z-drugs are only recommended for short term use (NICE, 2004), they are unsuitable for those with persistent poor sleep in SzSD. In practice, Z-drugs are used frequently in inpatient settings, whilst efforts are made to avoid their use in

outpatients. There are concerns about the level of hypnotics prescription in inpatient settings, and research seeks to reduce their use (Novak et al., 2020). There is a small amount of positive evidence for the efficacy of hypnotics for sleep problems in schizophrenia (Kaskie et al., 2017; Oliveira et al., 2019); however, the same concerns regarding side effects, tolerance and mortality risk as described above still apply. Additionally, there are concerns regarding polypharmacy and drug interactions in this group as they are often already on many medications (Sarkar, 2016).

Importantly, many patients do not find sleep medications acceptable (Kaskie et al., 2017). Many people with SzSD prefer non-pharmacological or 'natural' treatments for sleep (Waters et al., 2015), as do people with severe mental illnesses more generally (Faulkner and Bee, 2016). They see hypnotics as undesirable and a last resort (Faulkner and Bee, 2017); this is a view with which clinicians (MacDonald et al., 2015) and many of the guidelines agree.

Some antipsychotic medications are potentially helpful for reducing arousal and assisting sleep onset (Monti and Monti, 2004; Stummer et al., 2018), and authors have recommended their use to target sleep if the patient also experiences psychosis (Buysse and Tyagi, 2017). If an antipsychotic is needed already, there is a logic to switching to a more sedative option if sleep onset is a problem. However, many patients complaining of sleep problems are already on sedative antipsychotics, and although they may improve sleep somewhat, they do not normalise sleep (Monti and Monti, 2004). Furthermore, even though taking a sedative medication can induce sleep, this might be at times which are out of synchrony with the person's internal rhythm, resulting in unrefreshing, broken or excessive sleep (e.g., falling asleep far before the individual's natural 'bedtime' then waking in the early hours, daytime napping or accidental daytime sleep).

People with SzSD have expressed feelings of disempowerment in their 'reliance' on antipsychotic medications to manage their sleep, feeling they are 'knocking themselves out'; many also suspected that psychotropic induced sleep was of poorer quality than 'natural' sleep (Faulkner and Bee, 2017). Similarly, mental health professionals have suggested that medications prescribed for psychosis might be responsible for causing sleep problems in some cases (Rehman et al., 2017).

1.7.2.3. Melatonin in SzSD

Melatonin has shown some promise in SzSD in two positive pilot trials (Shamir et al., 2000; Kumar et al., 2007). Although, for the reasons described above, its use may be challenging for non-sleep-specialist prescribers. Furthermore, estimating circadian phase is less reliable when rhythms are dysregulated and de-synchronised as sleep timing may not bear the normal relationship to melatonin phase (Wulff et al., 2012).

A large randomised open-label study of ramelteon (a potent melatonin 1 and 2 receptor agonist with a longer half-life than melatonin) in schizophrenia (n=120) has recently shown positive results (Mishra et al., 2020). However, the study's design and reporting are problematic. Generalisability is uncertain, as all participants were antipsychotic naïve or had not taken antipsychotics for a four-week period before the study. Participants were categorised into predominantly positive or predominantly negative symptom groups, and based on this, were allocated four weeks treatment with haloperidol 4 mg, or risperidone 2 mg (often a subtherapeutic dose). The precise criteria for categorisation went unspecified. Allocation to supplementation with ramelteon 8 mg "30 minutes before bedtime" was random. The primary outcome was change in serum melatonin level or 'melatonin level' (described differently in different parts of the paper), rather than a more clinically relevant outcome, such as improvement in sleep or behavioural aspects of circadian rhythm. Moreover, melatonin levels were compared between experimental and control groups separately for positive and negative symptom groups, and separately for three parameters (10am, 2am and urine levels) without adjustment of p values for any of the 6 resultant tests. There was no identification of the primary comparison, or reference to the power calculation. All melatonin levels increased (p 0.017 to <0.001 for intention-to-treat and per-protocol analyses). Sleep quality improved significantly more with ramelteon than with antipsychotic alone (PSQI improved a mean of around 1-2 points more with ramelteon, p 0.002 and 0.015, respectively), although criteria for clinically meaningful response were not specified. Assessment of adverse effects was inadequate, sought unsystematically by 'non-directive questioning' or by participants volunteering information.

Should evidence for pharmacological agents which target the underlying biological rhythms of sleep in SzSD improve in future, it may be advisable to combine these

with environmental and behavioural interventions such as those developed in this thesis.

1.7.3. Addressing caffeine, alcohol and other substances

Caffeine blocks the action of adenosine, and thus reduces the effect of sleep pressure, which is both how it reduces daytime sleepiness, and how it may impair night-time sleep (O'callaghan et al., 2018). Observational studies show reliable associations between caffeine use and poorer sleep; however, causality is difficult to untangle (Clark and Landolt, 2017). Although caffeine has been shown to produce changes in EEG (Clark and Landolt, 2017), and to lengthen the circadian period (Burke et al., 2015), there are few studies regarding the effect of reducing or abstaining from caffeine consumption in regular users (Sin et al., 2009; Irish et al., 2015). A recent study found no improvement in sleep measured by actigraphy (sleep duration, efficiency, or onset) during 1 week's abstinence, even when those who failed to adhere to abstinence were excluded from analysis (n=9 of 85) (Irish et al., 2020). The strength of evidence does not match the extent and confidence with which blanket caffeine reduction or abstinence advice is often promoted in sleep hygiene guidelines (fairly ubiquitously) (Stepanski and Wyatt, 2003). Synthesis of evidence from different sources suggests blanket avoidance advice may not be merited, but that those who are sensitive to caffeine may benefit from reduction or abstinence, and that evening use is problematic (Irish et al., 2015).

Alcohol reduction is also commonly advised in sleep hygiene guidelines. Alcohol shortens sleep latency (Irish et al., 2015) so it is common for people to attempt to use alcohol as a sleeping aid, (Schweizer et al., 2019) but this is inadvisable due to the sleep fragmentation, reduced total sleep time, slow wave sleep, and REM sleep caused by alcohol (Angarita et al., 2016). Alcohol use is also a risk factor for the development and worsening of sleep disordered breathing (Kolla et al., 2018). Alcohol reduction or abstinence does improve sleep, but does not normalise sleep in previously dependent individuals, who may require treatment for underlying sleep disorders (Brower, 2003).

Many other substances of abuse interfere with sleep, including cocaine and opiates, although, unfortunately, ceasing their use does not necessarily proportionately improve sleep (Angarita et al., 2016). Cannabis, which many also attempt to use as a sleep aid, does initially improve sleep by both subjective and objective measures.

However, in chronic use, tolerance develops to initial sleep-promoting effects (Angarita et al., 2016) and some evidence suggests that only undesirable effects on sleep architecture, such as reduction in slow wave sleep, persist (Bolla et al., 2008). During cannabis withdrawal, negative effects on sleep are then significant, various, and persistent (Gates et al., 2016).

Nicotine has stimulant effects on non-smokers, its administration (via dermal patch) reduces total sleep time and slow wave sleep, in chronic smokers similar difficulties are reported, and a dose-response relationship has been found (Garcia and Salloum, 2015). Nicotine abstinence is then strongly associated with increased sleep disturbance, to the extent that it is suggested that sleep treatment should feature within smoking cessation input (Ashare et al., 2017).

Overall, there is a lot of evidence regarding the negative effect of various substances of recreation and abuse on sleep, but evidence regarding the extent to which reducing or ceasing their use is likely to improve sleep in the short to mid-term is more mixed.

1.7.3.1. Addressing caffeine, alcohol and other substances in SzSD

There is a high comorbidity of substance abuse with SzSD (Hunt et al., 2018). People with SzSD cite many reasons for substance use, including managing symptoms such as sleeping difficulties (Asher and Gask, 2010). This was particularly common with use of cannabis. In one study 58.3% reported that cannabis helped them sleep better (Parshotam and Joubert, 2015) and in another study 25 out of 30 people reported that cannabis helped them to relax and sleep at night (Costain, 2008). Importantly, comorbid attention deficit hyperactivity disorder (ADHD) is disproportionately common in those with psychosis (Nourredine et al., 2021), which independently increases the risk of both substance misuse and sleep problems, and may confound or exaggerate the link between sleep problems and substance misuse.

Some experts advise addressing substance use using a harm-minimisation approach when treating sleep in SzSD (Waters et al., 2017). Based on evidence summarised from general population studies, any dramatic reductions or abstinence from illicit substances should be approached with the caveat that in many cases an initial worsening of sleeping problems might sometimes be expected before any improvement.

High levels of caffeine use is reported in SzSD, estimated at three times that of the general population (Topyurek et al., 2019). Research participants with SzSD have expressed using caffeine to counteract the sedating effects of antipsychotic medications (Thompson et al., 2014; Faulkner and Bee, 2017). Whilst caffeine use has been associated with poorer sleep in SzSD, it is highly correlated with smoking, which may be responsible for some of this effect (Gurpegui et al., 2004). The presence of high but varying levels of competing stimulating and sedating substances (e.g., caffeine, nicotine, antipsychotics, hypnotics), may lead to a situation where the normal circadian and homeostatic processes affecting sleep become less significant amongst the factors determining when sleep propensity occurs. On this basis it can be hypothesised that excessive caffeine use in combination with regular, or as needed, sedating oral medications, would increase the likelihood of irregular sleep timing and poor sleep, or at least that the timing of the use of these substances may be important. Chung et al did indeed find a significant association between later caffeine use, and more variability in total sleep time and sleep onset latency (K. F. Chung, Poon, et al., 2018); it is of course possible that the evening caffeine use was motivated by poorer sleep rather than vice versa. Although there is a rationale to believe that for some people with SzSD reducing caffeine use in would help to improve their sleep, we do not have enough evidence to conclude that all caffeine use is detrimental, as some evidence suggests it may have benefits for neurocognition (Núñez et al., 2015), which in some cases may outweigh any adverse effects on sleep.

1.7.4. Altering light exposure patterns

As mentioned, the human circadian rhythm is entrained via light exposure. Light exposure has been used to modify human circadian rhythms and sleep-wake patterns in laboratory settings, with established effects (Chang et al., 2012). The direction and extent of the effect of light exposure on circadian rhythms (and usually, as a result, timing of sleep propensity) depends on the timing, intensity, duration, and spectral composition of that light exposure (Gooley et al., 2010). As a simplification: brighter light, and more to the blue end of the spectrum, has a greater effect on phase shifting circadian rhythm, whilst dimmer, redder light has less impact. However, the manner by which brightness and spectral qualities of the light signal are integrated and weighed by the processing systems of the eye and the circadian system is complex, and study is ongoing. Longer exposure has more effect

than brief exposure but with a non-linear relationship (Chang et al., 2012), such that brief light exposure has proportionately more effect than longer exposures (Rahman et al., 2017). Also, light exposure history moderates the effect of later light exposures (Chang et al., 2011); for instance, bright blue-enriched morning light exposure can reduce undesirable effects of artificial evening light on melatonin suppression and phase delay (Münch et al., 2017).

Regarding colour spectra of light, the retinal cells contributing predominantly to circadian response are intrinsically photosensitive retinal ganglion cells (ipRGCs), which have maximum sensitivity to light of a spectrum around 480 nm (Lucas et al., 2014). However, research suggests non-visual responses driven by ipRGCs (such as circadian response) are affected by light in other colour spectra via colour discrimination via cones (Woelders et al., 2018). Thus, it may be too simplistic to say that only light around 480 nm impacts circadian rhythm. Although research in this field will likely evolve further in future, the metric of melanopic EDI (lux values weighted toward spectra which influence non-visual responses) is much more useful than photopic lux when considering impact on circadian rhythm and sleep (Brown et al., 2022).

Although research is ongoing, and the manner in which light impacts on sleep, circadian rhythm and human health is complex, we do have scientifically informed consensus recommendations to inform contemporary decisions affecting human health. These recommend 250 lux melanopic EDI in the daytime, melanopic EDI 10 lux during hte evening (3hrs before bed), and during sleep, as dark as possible, or a maximum of melanopic EDI 1 lux (Brown et al., 2022).

As well as phase delaying circadian rhythm, light exposure in the evening and night acutely suppresses melatonin expression interfering with sleep onset processes (Chang et al., 2012). In order to measure the unhindered rise in melatonin secretion (DLMO), dim light conditions (<30 lux) are required (Keijzer et al., 2014) (dim indoor lighting conditions). Bright light is also acutely alerting and reduces subjective sleepiness (Xu and Lang, 2018), thus bright light near bed time can cause sleep onset difficulties, or may be helpful when alertness and activity is desired, such as at the start of a work shift. Increased light exposure in the daytime can improve alertness (Cajochen, 2007; Xu and Lang, 2018), improve mood (Stephenson et al.,

2012), and a field PSG study has shown increased daylight exposure appears to have beneficial effects on subsequent sleep architecture (Wams et al., 2017).

In clinical studies, light exposure modification can be achieved through a range of means, including by changing behaviour (go outside, turn lights on or off, different timing of activities), by modifying the indoor light environment (architectural changes, window coverings, light bulbs), or via devices which deliver light directly (light boxes, light visors, dawn simulator alarms). Although more research attention has been paid to timed light exposure, timed darkness exposure is also an important part of the light-dark time cue signal. 'Dark therapy' can be achieved by turning off lights and using blackout blinds, or via 'virtual darkness' using amber tinted glasses (blue-blockers). Evening dark therapy has shown promising results in bi-polar mania (Barbini et al., 2005; Henriksen et al., 2016) and as an addition to CBTi (Janků et al., 2020).

Increasing light exposure (using natural light, environmental indoor light, or light boxes) has been studied in dementia, proposing to improve sleep and cognition, and reduce agitation and challenging behaviour. However Cochrane meta-analysis of studies found no effect on these outcomes (Forbes et al., 2014). A later meta-analysis found a small to medium sized effect (g=0.30) (van Maanen et al., 2016). This later review also found effects in CRSWD (g= 0.41) and insomnia (g=0.47), although there were some concerns regarding publication bias.

Light exposure is not a core component of CBTi, although some CBTi protocols have recently begun to include some recommendations regarding light exposure (Waters et al., 2017; Sheaves, Isham, et al., 2018a). Use of light therapy in practice for treatment of DSWPD and ASWPD has been recommended (Auger et al., 2015), partly due to its relatively limited side effect profile (Vols et al., 1991; Terman and Terman, 2005; Maruani and Geoffroy, 2019).

Similar to exogenous melatonin, ascertaining appropriate timing of light can present challenges for clinicians. It remains debatable whether the estimation of circadian phase via activity and sleep timing is adequate to guide timing of light treatment for sleep-phase normalisation, or whether the measurement of DLMO is necessary (Pullman et al., 2012; Keijzer et al., 2014; Lovato et al., 2016). Sleep timing may not accurately reflect underlying circadian phase for many reasons, including social

constraints, and also sleep disorders, thus there are some groups in which sleep timing does not accurately predict DLMO (and underlying circadian phase) (Wright et al., 2006).

1.7.4.1. Altering light exposure patterns in SzSD

Although light treatment has been utilised in treatment of depression (Golden et al., 2005; Oldham and Ciraulo, 2014a), it has rarely been studied as a treatment for circadian dysregulation and sleep problems in mental health conditions, and we are not aware of any studies of light therapy specifically targeting poor sleep in SzSD (see also in this thesis, Faulkner *et al.*, 2019). Sheaves et al did recently include a light therapy component in their adapted CBTi intervention in mixed acute psychiatric inpatients (Sheaves, Isham, et al., 2018a) with positive results (discussed in more detail below). Evidence regarding the effect of light modification on sleep in groups with ~CRSWD is examined in Chapter 4 (Study A) of this thesis.

As light is alerting and activating, and shifts circadian rhythm depending on its timing in relation to the time of the internal clock, there is clearly potential for light treatment to do some harm as well as some good through the same mechanisms. There has been one case study (n=1), and two small pilot studies, of light treatment in SzSD, and all targeted psychotic symptoms rather than sleep. The single case study describes a patient with schizoaffective disorder and seasonally recurring depression, it reports dramatic improvement in depression and functioning, but not in thought disorder, with daily 10,000 lux light box use at 7am, 30 min increasing to 45 min (Oren et al., 2001). In the first study, a single group pilot study (n=10), participants with schizophrenia received 1 hr of 10,000 lux light treatment (timing unspecified) for 4 weeks. This was associated with reduction in negative symptoms on the positive and negative symptoms scale (PANSS) during treatment, improved 'drive' (measured by VAS), and no change in other PANSS subscales (Aichhorn et al., 2007). Although the setting of recruitment is not stated, participants were on stable medication for 4 weeks so were probably outpatients who were not in acute crisis (in practice, acute crisis often results in changes or additions to medication).

The second study, a non-randomised controlled study (n=20), delivered 30 min per day of 5,000 lux light treatment for 5 days, to 10 patients with schizophrenia or schizoaffective disorder admitted to an acute ward. Participants were woken at a set time of 8am to receive light treatment, irrespective of their habitual wake time. No

statistically significant differences were detected, but there was a non-significant worsening of symptoms in the intervention group, and one intervention group participant was withdrawn due to increase in manic symptoms. Although the study was not designed to measure acceptability outcomes, the study's authors note that the intervention was not very acceptable due to the early waking (participants expressed reluctance, there was poor compliance, and prospective participants declined giving this reason). The authors acknowledge that timing of light should probably have been more personalised by habitual rise time or preference (Roopram et al., 2016). Some would argue for personalisation via measurement or estimation of circadian phase via DLMO or actigraphy. In addition, it might be argued to personalise the focus on increasing or reducing light exposure, depending on the mood state or arousal levels of the participant.

1.7.5. Addressing environmental factors

It is usually recommended that sleep environments are dark, cool and quiet (Sheaves and Espie, n.d.; Stepanski and Wyatt, 2003; NHS, 2020a), and evidence supports these recommendations. Light at night has been shown to interfere with melatonin secretion and cause circadian misalignment, even if the light is not bright (Cho et al., 2015; Touitou et al., 2017). Effects have been shown on sleep quality (increased light sleep and arousals) even in healthy sleepers, who were able to sleep despite the light (Cho et al., 2013).

Studies have demonstrated effects of noise on sleep (Basner and McGuire, 2018), including shortening, interrupting, or affecting sleep architecture (Muzet, 2007). Perhaps unsurprisingly, noise annoyance was more predictive of sleep disturbance than noise itself (van den Berg et al., 2014). If noise can be reduced at source or prevented by a sound insulated sleeping environment, this is obviously desirable, but this is not always possible. The use of white noise has shown promise for improving sleep in people exposed to intensive care unit (ICU) noise (Stanchina et al., 2005; Xie et al., 2009). In contrast, Reidy et al synthesised evidence on white noise including community samples finding results were more mixed, sometimes improving and sometimes worsening sleep (Riedy et al., 2021). Although these authors did not compare results in different environments, they note that studies should report background noise levels better. Perhaps noise masking may be beneficial on balance only if background noise is high.

Room temperature has been clearly demonstrated to affect sleep induction and maintenance, although the optimal room temperature also depends on nightclothes and bedding ('sleep microclimate') (Caddick et al., 2018). Humidity is less often discussed in sleep hygiene recommendations, but it interacts with temperature (lower humidity feels colder), and should optimally be 40-60% (Caddick et al., 2018); however, not everyone can measure or alter humidity at home.

Another aspect of the sleep environment which is sometimes discussed in advice is clutter; the notion that the sleep environment would be improved by removing stress-inducing stimuli (which might include clutter) is theoretically sound. Relatedly, removing objects which act as a prompt toward non-sleep activities is recommended as part of stimulus control (discussed in the section below).

1.7.6. Exercise

Exercise may alter sleep quality via stabilising or shifting circadian phase (Youngstedt et al., 2019), via effects on endocrine and metabolic functioning, via effects on the autonomic nervous system (Chennaoui et al., 2015), or via improving mental health (Mikkelsen et al., 2017). Some sleep advice still suggests avoiding evening physical activity (NHS, 2020a); however, increasingly studies have found a lack of evidence for this claim (Stutz et al., 2019). Unless a person subjectively experiences a problem sleeping soon after a particular type of exercise, exercise at any time should be promoted.

Exercise is a promising intervention which meta-analyses have suggested improves sleep with a small-to-moderate effect in general population samples (Kredlow et al., 2015), and with large effects in people with severe mental illnesses (Lederman et al., 2019), although these authors found no studies of exercise to improve sleep specifically in SzSD. Multiple meta-analyses have, however, shown an effect of exercise in negative symptoms in SzSD (Vogel et al., 2019). Due to the multiple other benefits of increased exercise, of course for physical health, but also for mental health and functioning, there is a good argument for including an increase in physical activity within behavioural changes to improve sleep, wherever the individual is able and willing (Firth et al., 2017; Weinstein et al., 2017; Vogel et al., 2019).

1.7.7. Timing of dietary intake

It has been proposed that the circadian pacemaker may be entrained partly by timing of dietary intake. Whilst it is unclear how and if dietary intake affects timing of the central clock (SCN), there are studies showing evidence of effects on blood glucose rhythms and the clock genes of the liver (Tahara and Shibata, 2016; Wehrens et al., 2017). Thus, timing of meals may have consequences regarding internal desynchrony; for instance, increased body fat is associated with later circadian timing of food intake (McHill et al., 2017). Alterations to dietary habits are a good method to improve other aspects of health, but they are not usually proposed as a primary method of improving insomnia or CRSWD; sleep hygiene advice often, but not always, includes advice not to have the last meal too near bed time (Stepanski and Wyatt, 2003; Irish et al., 2015). This may be more important if the last meal is large. Also, there is likely to be individual variability in how much recent eating disrupts sleep, for instance, patients with gastroesophageal reflux disease will be more affected by late eating (Piesman et al., 2007).

1.7.8. Therapeutic approaches to reduce arousal

As sleep difficulties can be caused by excessive arousal, various approaches which directly attempt to reduce arousal have been studied. Sedative medications, already mentioned above, attempt to reduce arousal to enable sleep. Similarly, people who self-medicate using alcohol or other depressant substances to aid sleep onset are often attempting to utilise their arousal reducing effects, often with poor long-term results.

Relaxation techniques directly target physiological and cognitive arousal. These include progressive muscular relaxation, imagery-based relaxation, music assisted relaxation, and combined approaches. Some authors consider relaxation one of the defining components of CBTi (van Straten et al., 2018), whilst others describe that CBTi can be with or without relaxation (Matthews et al., 2013). Some older evidence suggested moderate improvements in insomnia through use of relaxation (Haynes et al., 1974; Freedman and Papsdorf, 1976; Nicassion et al., 1982), but other evidence shows a lack of impact on perceived sleep-related functioning (Means et al., 2000), or a worsening in sleep (Ziv et al., 2008). There is a paucity of recent systematic reviews on relaxation for sleep, perhaps because more recent studies tend

to include relaxation as one of many components, and studies have not been designed to dismantle individual intervention components' effects.

Some protocols suggest practicing relaxation in the daytime, whilst others suggest practicing shortly before bed in order to facilitate sleep (De Niet et al., 2009; Waite, Myers, et al., 2015). Timing of relaxation may be important in determining its immediate and longer term effects. Furthermore, the intention with which relaxation is practiced is likely to influence effects; thus the manner of its introduction and the individual's underlying meta-cognitive beliefs may contribute. If relaxation is used as a strategy to try to 'empty' the mind or to 'block out' thoughts ready to sleep, for instance, this is likely to impair sleep, as these cognitive control strategies have been shown to be unhelpful (generally and in relation to sleep) (Lemyre et al., 2020). It should be noted that individual responses vary depending on internal processes often not explored during the presentation of relaxation instructions. For instance, relaxation induced anxiety can often occur in those with worry and anxiety related difficulties, due to fear of the return of negative emotion if worry and negative emotion abates during relaxation (Kim and Newman, 2019). Whilst relaxation has been endorsed for its ease of presentation with pre-recorded audio (De Niet et al., 2009), to understand and direct patients in the manner and intention of its use appears to be somewhat more complex and requiring of therapeutic skill.

It has been hypothesised that relaxation may improve sleep by teaching cognitive control and awareness, similarly to mindfulness (discussed below), rather than by acutely reducing physiological arousal (Haynes et al., 1974). In support of this idea, a recent review found that meditation based techniques were somewhat more effective than relaxation for reducing anxiety (Montero-Marin et al., 2019).

As well as formal approaches, the introduction of relaxing leisure or self-care activities within an evening wind-down period is widely recommended within sleep hygiene guidance and within multi-component sleep interventions (Stepanski and Wyatt, 2003; Berk, 2009; Harvey et al., 2011; Waters et al., 2017). Reading, listening to music, creative activities, and bathing may be recommended in preference of television watching, due to the short-wave light exposure from television. Similarly, pre-sleep computer games have been linked to delayed sleep, this is thought to be through a combined effect of light exposure and stimulating activity (Exelmans and Van den Bulck, 2015). Experimentally, just one night of pre-

sleep gaming (compared to passive film watching) resulted in a modest negative effect on sleep (Weaver et al., 2010). Late evening social media use can also result in late night light exposure. However, the viewing of novel and emotionally arousing content involved may interfere with sleep even more than the light exposure itself, and fear of missing out on social interactions whilst avoiding social media can equally cause arousal and interfere with sleep (Scott and Woods, 2018). Thus, the choice of less arousing activities, and the avoidance of arousing activities, depends heavily on the personal meaning and individual response to different activities, and although general rules may hold, the best approach cannot be rigidly prescribed.

1.7.8.1. Approaches to reduce arousal in SzSD

There have been many studies of various types of relaxation in SzSD; although, usually not targeting sleep, achieving a reduction in anxiety should theoretically improve sleep. A systematic review of randomised studies has found a reduction in state-anxiety following relaxation interventions in the 4 studies which measured anxiety. However, follow-up results were only reported for one study at 11 days post-intervention (Melo-Dias et al., 2019). A randomised controlled study conducted since this review (n=80) concurs in finding a short-term reduction in anxiety, but this effect was no longer evident at 3 months (Lu et al., 2020).

I found no studies specifically regarding the effect of addressing evening routine to improve sleep in SzSD, although successful trials of adapted CBTi in SzSD and related groups have included this component (Waite, Myers, et al., 2015; Waters et al., 2017; Sheaves, Isham, et al., 2018a). Authors noted that in inpatient settings patients should be provided with facilities to undertake their usual bedtime routines, including spiritual practices (Rodriguez and Messer, 2017), and that in the community, despite having more freedom to choose their activities, clients may need support to identify and plan evening activities (Waite, Myers, et al., 2015). This is understandable considering that people with SzSD have been found to have occupational deprivation, reduced engagement in activity (Hayes and Halford, 1996; Edwards et al., 2018), and reduced experience of anticipatory pleasure (Hayes and Halford, 1996; Nguyen et al., 2016), or difficulty converting anticipation into plans and expectations of valued activities actually occurring (Edwards et al., 2018).

1.7.9. Modifying cognitions and cognitive processes

Worry and anxiety can interfere with sleep, thus some therapies designed to reduce worry and anxiety have been proposed as a method to improve sleep, either alone or as part of a package. CBTi often contains cognitive components. The cognitive components contained within CBTi vary a great deal, and the level of evidence for these components is limited (Jansson-Fröjmark and Norell-Clarke, 2018). They include broad categories such as behavioural experiments to challenge sleep belief, and specific cognitive strategies such as paradoxical intention (try not to fall asleep), distraction, and 'thought stopping'. Based on what evidence there is, paradoxical intention has the best evidence base, whilst all other components have mixed or promising but inconclusive evidence, and thought suppression may be actively harmful (Jansson-Fröjmark and Norell-Clarke, 2018; Lemyre et al., 2020).

Mindfulness attempts to bring awareness to the present moment with an attitude of acceptance, practitioners suggest approaching a thought or experience with curiosity, and adopting an attitude of kindness. Mindfulness specifically involves the practice of meditation, directing attention toward the breath, sensations, or thoughts, and can involve movement. It has been proposed that mindfulness may improve sleep through reducing arousal, or through allowing letting go of goal-directed processing (Garland et al., 2016). A recent evidence synthesis suggested mindfulness produced similar results to other evidence based sleep treatments, and performed significantly better than non-specific active controls (e.g., attention controls) (Rusch et al., 2019). Taylor et al summarise promising initial evidence for a range of mindfulness based 'third wave' insomnia therapies in application to insomnia (where first wave = behavioural, second wave = cognitive, third wave = metacognitive). However, they acknowledge the duration of time required for ongoing practice of meditation skills is a disadvantage (Taylor et al., 2015).

Another 'third wave' therapy, meta-cognitive therapy (MCT), has been proposed as a method to improve sleep. MCT is very different from mindfulness, including in its relative brevity, and no requirement for ongoing meditation practice. A randomised trial of MCT to improve sleep began in 2009. Unfortunately, the trial stopped early due to insufficient recruitment (Morken, 2012); but results from those recruited will be reported soon (personal communication, 2020). Another randomised controlled

trial was recently registered by other investigators, and runs until 2022 (Callesen, 2020).

1.7.9.1. Modifying cognitions and cognitive processes in SzSD

It is not possible to comment on the efficacy or treatment effect contribution of cognitive components within adapted CBTi for poor sleep in SzSD as existing trials (reviewed below) do not examine the effects of different components (Myers et al., 2011; Freeman et al., 2015; Chiu et al., 2018; Hwang et al., 2019). Expert clinicians have suggested using behavioural experiments and cognitive restructuring (Waite, Myers, et al., 2015), distraction and challenging negative or unhelpful thoughts, or verbal suppression (repeating a mantra) (Waters et al., 2017), constructive worry (worry time), or worry postponement with distraction (Sheaves, Isham, et al., 2018a).

Thought suppression appears to be similarly problematic in people with SzSD as without (discussed above); cross-sectional work in people with and without psychotic disorders found 'aggressive suppression' to be more common in those with insomnia than without (Chiu et al., 2015). Similarly, people with schizophrenia used more maladaptive thought control strategies than those without (Morrison and Wells, 2000). Some evidence also suggests thought suppression is a risk factor for verbal auditory hallucinations (Jones and Fernyhough, 2006).

Qualitative findings suggest acceptability of mindfulness as an intervention for sleep in SzSD (Brown et al., 2010; Böge et al., 2020), but I did not find any studies examining effects of mindfulness on sleep in SzSD. Two systematic reviews examined mindfulness effects on various measures of symptoms and functioning in SzSD (not sleep), the first found insufficient evidence (Lam and Chien, 2016), and the later review summarised tentatively supportive evidence of positive effects (Hodann-Caudevilla et al., 2020). Although many state that mindfulness is not intended as a means of achieving relaxation (Bishop et al., 2004), mindfulness was described frequently in terms of relaxation, by participants in two separate mindfulness for schizophrenia groups (Brown et al., 2010; Böge et al., 2020), some of whom also reported using the recording to get to sleep (Brown et al., 2010).

There have been no studies of MCT or Attention Training Technique (ATT) (a large component of MCT) specifically targeting sleep in SzSD, but studies targeting general psychopathology have shown promising results (Morrison et al., 2014;

Knowles et al., 2016). The randomised study of ATT for SzSD, on which I worked as a trials therapist, will report results in 2022 (Parker, 2019).

1.7.10. Harnessing sleep pressure

Sleep restriction is a core component of CBTi and can be effective as a single component therapy (Miller et al., 2014; Kyle et al., 2015). Sleep restriction involves shortening time in bed (the 'sleep window') to match the duration the person is habitually asleep, such that time in bed awake is reduced, and sleep pressure increases. Napping should also be reduced or eliminated. The sleep window is then 'titrated' upwards only once sleep efficiency percentage reaches a certain level (what percentage varies by protocol) (Kyle et al., 2015). Thus sleep restriction can be used to move from a prolonged and broken sleep, to a more consolidated, and usually more refreshing, sleep (Maurer et al., 2018).

Sleep restriction protocols will specify a 'minimum sleep window', such that if the person has very short sleep at baseline (e.g., 2 hours) the sleep window will not be shortened below the minimum sleep window (e.g., 5 hours, this varies by protocol). Sleep restriction harnesses sleep pressure to increase sleep propensity at bedtime, thus improving sleep onset and sleep maintenance once in bed. Over time, this faster sleep onset will then improve the association between bed and sleep. Sleep restriction has long been thought to be one of the most potent components of CBTi by clinicians. This belief has been supported in a recent dismantling trial which showed reduced insomnia severity in people given sleep restriction compared to the regularisation of the sleep schedule alone (adjusted mean difference on the insomnia severity index (ISI) of -4.35 at 12 weeks, d=-1.36) (Maurer et al., 2020). Sleep restriction is, however, associated with significant daytime consequences in the short term whilst sleep time is restricted and sleep pressure is high (Kyle et al., 2014), and participants express how challenging a treatment it is to adhere to (Kyle et al., 2011).

Similar to sleep restriction, sleep compression reduces excess time in bed. It does this by slowly reducing down the sleep window toward the total amount of time asleep (Miller et al., 2014). This means that the initial impact of excess daytime sleepiness is not so great as with sleep restriction. Some suspect sleep compression may be easier to adhere to for this reason (Kyle et al., 2015).

There are some contraindications to the use of sleep restriction, such as seizure disorders (as sleep deprivation lowers the seizure threshold), and high mood (as sleep deprivation can induce higher mood or mania) (Morin et al., 2017). There is a lack of consensus in the literature regarding whether sleep restriction can or should be used in people with bipolar in the depressive or euthymic phase, or with people with schizophrenia or schizoaffective disorder. Sleep deprivation can cause mania (Lewis et al., 2018) and psychotic-like symptoms (Meyhöfer et al., 2017; Reeve et al., 2018). Some express or assume that sleep restriction therapy should therefore not be used at all in people with bipolar (Morin et al., 2017), or in SzSD (Norell-Clarke et al., 2015); however, others have used and recommend versions of sleep restriction therapy (Kaplan and Harvey, 2013; Harvey et al., 2015; Waite and Sheaves, 2020). Adaptations such as using a longer minimum time in bed window (Waite and Sheaves, 2020), or using an approach more akin to sleep compression (Waters et al., 2017), can be implemented with monitoring for adverse effects.

Increasing sleep efficiency is often the focus in use of sleep restriction in treatment of insomnia, however a higher sleep efficiency percentage should not be at the total expense of sleep duration and daytime functioning. A sleep efficiency of 95% is usually indicative of good sleep, but a state of sleep deprivation (chronically restricted sleep opportunity) can also result in very high sleep efficiency. High sleep efficiency, adequate sleep duration, and good self-reported sleep and sleep-related functioning should be the target.

Following stimulus control recommendations can equally result in a shortening of time in bed, and thus an increase in sleep pressure. Stimulus control includes the instruction to get out of bed if not falling asleep. Some instructions suggest getting up after a set period, commonly 15 minutes (Waite and Sheaves, 2020), whilst other manuals have altered this instruction to focus less on a specific period of time, and instead, on if the person realises they are not falling asleep (Bootzin and Perlis, 2011). Depending on the extent to which the person follows these rules, the sleep deprivation resulting can potentially still be quite significant. When stimulus control advice is given there is also usually no ‘minimum sleep window’ exception attached to this.

1.7.11. Altering behavioural associations (stimulus control)

One of the maintaining factors of insomnia is an association of the bed with non-sleep activities, or with distress (M. Perlis et al., 2010). In people with psychosis, the bed can become associated with traumatic experiences, worry, and fear, including that which is related to delusions or hallucinations; many people with psychosis have also experienced abuse, which may be associated with the bed or bedroom (Waite, Evans, et al., 2015; Waite, Myers, et al., 2015; Faulkner and Bee, 2017). By strengthening the association between bed and sleep, behaviourally conditioned physiological responses are then more likely to occur on cue, and sleep becomes more probable when the person gets into bed.

Stimulus control intends to improve behavioural associations between the bed and sleep, as well as requesting the person to get out of bed rather than spending prolonged time awake in bed during night-time awakenings. Stimulus control entails avoiding use of the bed, and if possible the whole bedroom, for non-sleep activities at other times of the day (Bootzin and Perlis, 2011). Sleep restriction also works partly via improving the association of bed with sleep, by reducing the opportunity to be in bed awake.

It should be noted that avoiding non-sleep activities in the bedroom is impossible to implement for many individuals, including those living in halls of residence, bedsits, some types of shared accomodation, and many institutional settings. These settings may not allow access to an appropriate space outside the bedroom to complete other activities, and some communcal spaces can be unsuitable for evening wind-down activities.

1.7.12. Behavioural feedback within sleep treatments

Some treatments for insomnia or ~CRSWD include behavioural feedback. This can be in the form of a sleep diary with which the patient can evaluate the effect of changes such as reducing caffeine consumption. Behavioural feedback can also utilise passive monitoring, such as activity tracking. This can be relevant in treatment of paradoxical insomnia, where the perception of a lack of sleep can drive sleep-related worry, thus sustaining poorer sleep quality. Showing clients passive monitoring feedback regarding their sleep can lessen their worry and improve their perception of their sleep (Tang and Harvey, 2006). Equally, however, passive monitoring feedback has the potential to do harm; when fake passive monitoring

feedback showing poor quality sleep was given to participants, this negatively biased daytime insomnia symptom reports (Gavriloff et al., 2018). This prompts caution regarding how passive monitoring of sleep is framed and used within an intervention.

Apart from attempting to measure sleep, passive monitoring can be useful when setting goals regarding daytime activity and adherence to time in bed schedules. Just as a sleep and activity diary may be reviewed in CBTi sessions (Manber et al., 2012), timing of activity and time in bed can be reviewed with less reliance on diary completion. Consumer devices and their associated apps often claim to improve sleep through allowing people to spot patterns and make changes (Bianchi, 2018). Whilst these claims have not been tested, there is evidence that consumer wearables can impact on engagement in physical activity, either alone or as part of an intervention (Brickwood et al., 2019).

Distinct from the type of behavioural feedback described above, is 'bio-feedback'. In 'bio-feedback' the person receives computerised feedback on when they produce brain activity conducive to sleep, to learn to deliberately produce this. Despite being researched for over 30 years, there is limited good quality evidence and results are mixed (Lovato et al., 2019; Melo et al., 2019).

1.7.13. Multi-component psychosocial and behavioural interventions

Many sleep treatments are multi-component, allowing for the fact that there are many diverse factors which may impact sleep. The most common multi-component sleep interventions are sleep hygiene advice and CBTi. The contents of sleep hygiene advice and CBTi overlap, to the extent that they can sometimes appear almost the same, except that sleep hygiene does not include sleep restriction therapy. The major difference is that CBTi is a structured program, even when facilitated by an app or similar, whilst sleep hygiene is usually not a structured program and is usually advice. The effects of sleep hygiene vs CBTi differ widely as is discussed below.

There are many other multi-component sleep treatments, combining various of the components described above, and others not discussed here (e.g., aromatherapy, acupuncture, hypnosis, binaural beats, weighted blankets, heated socks).

1.7.14. Sleep hygiene advice

Sleep hygiene advice may be tailored to the individual by the person or organisation offering it but is often generic. Sleep hygiene advice may sometimes be delivered

with some form of professional support along with the advice or may be one-off advice. Sleep hygiene is often used as the control condition within comparative intervention studies. This evidence shows it to be less effective than CBTi but there has not been a focused effort to ascertain if it has a better effect than placebo, sham advice or treatment as usual (K. F. Chung, Lee, et al., 2018). The relevance of various sleep hygiene advice items will vary depending on the type of sleep complaint, comorbidities, and individual differences; for instance, caffeine sensitivity varies, as may sensitivities to other sleep disturbing factors, and advice on napping may depend on the person's commitments and co-morbidities.

1.7.15. Cognitive Behavioural Therapy for insomnia

Many components of CBTi have been discussed at some length already. As a whole, CBTi is currently the best evidenced treatment for insomnia; it has been shown to be effective for insomnia with and without comorbidity (Espie and Kyle, 2009; Taylor and Pruiksma, 2014; Sweetman et al., 2020), effective when delivered digitally (Luik et al., 2019), and more effective in the long term than drug treatments (Wu et al., 2015). The effect sizes of CBTi from meta-analysis have been found in the ranges of g=0.29 to 0.98 depending on the measure used (van Straten et al., 2018), although some people do not respond (Taylor et al., 2015). There has been much work to determine what factors predict response to CBTi (Pruiksma et al., 2020) and brief behavioural treatment (Troxel et al., 2013) (which contains some elements of CBTi). Factors associated with adherence to CBTi have also been examined (Matthews et al., 2013), in order to potentially provide more personalised and targeted input in future.

Supplementing CBTi with evening use of blue-blocking glasses has been tested in participants with insomnia; this was associated with significantly longer total sleep time than CBTi alone (Janků et al., 2020). As well as in insomnia, CBTi has also been tested in DSWPD. CBTi showed no additional improvement compared to morning light therapy alone (given to both groups), but addition of CBTi showed more improvement in anxiety and depression (Danielsson et al., 2016a).

1.7.16 Transdiagnostic Sleep and Circadian Intervention (TranS-C)

A more recently developed multicomponent behavioural sleep intervention is TranS-C, which target multiple types of sleep and circadian problems, including not just insomnia, but also sleep timing issues and daytime sleepiness. Unlike in CBTi,

increasing sleep efficiency is not always the goal in TranS-C. TranS-C has been evaluated in an RCT (n=121) in people with serious mental illnesses, where it was associated with improvement in psychiatric symptoms, sleep and circadian functioning (Harvey et al., 2021). There were high rates of comorbidity of sleep problems in this sample, and promisingly, the number of co-morbid sleep and circadian problems did not moderate intervention effects (Sarfan et al., 2021).

TranS-C also reduced eveningness in adolescents with evening chronotype in a large RCT (n=176) (Dolsen et al., 2021), and has received preliminary evaluation in adolescents with ADHD and sleep problems (Becker et al., 2021)

1.7.16.1. Multicomponent sleep treatment in SzSD

CBTi or adapted CBTi has been tested in people with current hallucinations and delusions (Myers et al., 2011; Freeman et al., 2015), in stable patients with schizophrenia and other psychotic illnesses (Chiu et al., 2018), in patients with established psychosis (Hwang et al., 2019), and in young people classed as ultra-high risk of psychosis (Bradley et al., 2018). Similar multi-component interventions, Sleep and Circadian Intervention (TranS-C) and Sleep Treatment at Acute Crisis (STAC), which include elements of CBTi plus other sleep and circadian interventions, have been used in mixed groups of inpatients (Sheaves, Freeman, et al., 2018) and outpatients, respectively (Gumport et al., 2020). These studies all showed improvement in insomnia and sleep symptoms, and some found improvement in other psychotic and psychiatric symptoms (see Table 4).

Between study comparisons suggest larger effects from individual than group therapy (Waite et al., 2020), and within study sub-group analysis suggests better results in classic severe insomnia, than in those with poor sleep but normal or long sleep duration (Chiu et al., 2018). This latter group may represent a larger proportion of participants with ~CRSWD, which may explain reduced CBTi effects in this group.

In general non-pharmacological sleep interventions are viewed as more acceptable by people with severe mental illnesses (Faulkner and Bee, 2016), and those with SzSD (Waters et al., 2015; Faulkner and Bee, 2017). Participants positively appraised adapted CBTi, and found this type of approach highly acceptable,

especially the personalisation of the intervention, the practical 'doing' approach, and the empowering attitude of the therapist (Waite, Evans, et al., 2015).

1.7.17. Current guidance regarding sleep treatment in SzSD

Current NICE clinical guidance (CG178) for psychosis and schizophrenia does not mention assessment and treatment of sleep problems (NICE, 2014). Whilst brief insomnia guidance does exist, which recommends a range of assessment and treatment strategies including referral to specialist sleep services and CBTi (NICE, 2015a), these refer only to management in primary care, and do not discuss management in secondary care (specialist) mental health services. There is currently no NICE guidance for treatment of 'intrinsic' circadian rhythm disorders (ASWPD, DSWPD, Non-24 or ISWPD), only for 'extrinsic' shift-work and jet lag disorders (NICE, 2013). American Academy of Sleep Medicine guidance on treatment of circadian rhythm disorders makes only weak recommendations at present (Auger et al., 2015), except in the case of hypnotics for ISWPD in elderly people with dementia, which they strongly discourage.

1.7.18. Current practice regarding sleep in SzSD

Despite the acknowledged importance of sleep, sleep problems remain underdiagnosed and neglected in specialist mental health services (Jagannath et al., 2013; Rehman et al., 2017). Medication is often reported to be the most commonly provided intervention by mental health services, and non-pharmacological intervention often does not extend beyond sleep hygiene advice (Lyne et al., 2011; Peacey et al., 2012; Baandrup et al., 2013; Rehman et al., 2017). Although the current treatment on offer is limited, specialist mental health staff of various professions do recognise the importance and relevance of sleep; but they lack knowledge, confidence and tools to intervene (Faulkner and Mairs, 2015; O'Sullivan et al., 2015; Rehman et al., 2017), and lack a planned or structured approach (Faulkner and Mairs, 2015; Rehman et al., 2017).

Table 4: Studies of CBTi and related interventions for sleep in SzSD and closely related populations

Study	Sample / Population (% SzSD)	Allocation	Control	Intervention	Effect on sleep outcomes
Myers 2011	n=15. Outpatients, persistent persecutory delusions, psychosis diagnoses and insomnia (73%)	n/a - single group	n/a	Individual CBTi 4 sessions over up to 8 weeks	Reduced insomnia on ISI and PSQI from pre- to post-therapy
Freeman 2015	n=50. Outpatients, persistent distressing delusions / hallucinations, SzSD and insomnia (100%)	Random	Treatment as usual (TAU)	Individual CBTi 8 sessions over 10 weeks	Improved sleep on ISI and PSQI - large effect at 12 weeks and 24 weeks
Sheaves 2017	n=40. Acute psychiatric inpatients and insomnia (45%)	Random	TAU	STAC - CBTi, passive monitoring with feedback, light-dark exposure. 5+ sessions (9 average) over 2 weeks	Improved sleep on ISI at 2 weeks (large effect) and at 4 weeks (medium effect)
Chiu 2018	n=74. Outpatients with SzSD and insomnia (100%)	Not stated	TAU	Individual CBTi 4 sessions over 4-6 weeks	Improved PSQI, sleep hygiene behaviours scale, TST, SE and SOL at 6 weeks (pre-post).
Bradley 2018	n=12. Ultra-high-risk for psychosis outpatients, aged 18-24 and sleep problems (0%)	n/a - single group	n/a	Individual CBTi 8 sessions over 10 weeks	Improved sleep on ISI, Sleep-5 and PSQI - large effect at 12 weeks and 16 weeks
Harvey 2021	n=121. Adult outpatients with severe mental illness and sleep and circadian disruption(39%)	Random	TAU, wait-list	TranS-C - elements of CBTi and Interpersonal and Social Rhythm Therapy (IPSRT), chronotherapy, and motivational work. 8 sessions over 8 weeks	Reduction in sleep disturbance, and sleep related impairment, maintained at 6 month follow up.
Hwang 2019	n=63. People with schizophrenia in residential and rehab settings (100%)	Non-random	TAU	Group CBTi 4 sessions in groups of 2-9 patients	Improved sleep (ISI and PSQI), medium effect at 4 and 8 weeks. Small and medium effect on sleep quality, duration, efficiency and daytime dysfunction.

1.8. The role of the occupational therapist

There are a range of potential intervention strategies to address sleep, as described above. Very many of these relate to the person's habits and routines, engagement in alerting or relaxing activities, timing of sleep opportunities (or lack thereof), and timing of environmental exposures (particularly light exposure). Authors in a range of occupational therapy specialisms have described the relevance of the profession's existing skill set to these aspects of sleep treatment (Fung et al., 2013; Solet, 2014; Faulkner and Mairs, 2015; Green, 2015). For instance, occupational therapists' environmental adaptation skills can address sleep environments, occupational therapists work with activities and routines, which can be applied to addressing morning, evening, and daytime routines, exercise, and occupation-focused strategies to personalise and adhere to sleep schedule recommendations. Occupational therapy assessments in mental health are likely to cover many zeitgebers, or behavioural and environmental determinants of circadian entrainment; including an assessment of sleep and circadian rhythm is opportune amongst these topics, whereas other disciplines do not routinely undertake any similar assessment.

Occupational therapists work using a number of modalities, which are sometimes used collectively or individually to describe or *define* the role. Although a comprehensive and universally agreed definition of occupational therapy has proven elusive, most literature agrees regarding the types of approaches occupational therapists commonly utilise (see Table 5), and most also acknowledge variability in the exact nature of the role depending on context (Hardaker et al., 2007; Pentland et al., 2018).

Some of the first people to describe themselves as occupational therapists worked in 'asylums', as they were then called, they discovered the benefits of introducing opportunities for productive activity to their patients (Meyer, 1922; Reed et al., 2017). In the 1990s and 2000s increasingly occupational therapists rebelled against stereotypes such as 'craft technician', 'knitting lady', or 'kitchen skills trainer', and occupation as a means of intervention fell out of favour (Kinn and Aas, 2009). More recently though, occupational therapy has re-embraced the power of occupation (Muñoz et al., 2016; Dai Davies, 2019), and definitions of occupational therapy, including working *through* or *upon* meaningful occupations, can be seen in current literature.

Table 5: Common approaches, skills and values of occupational therapists

Approach or modality	**Description**	**Examples**
Use of occupation or activity as a medium of therapy	Occupation as an intervention tool (Creek, 2003; Roley et al., 2008)	▪ Introducing a relevant personally meaningful activity to begin to engage a person with catatonic depression. ▪ Working on finger flexion through an occupation.
All approaches which aim to improve activity or occupational performance	Occupation as an outcome (Creek et al., 2005), "Occupational therapy aims to improve your ability to do everyday tasks if you're having difficulties." (NHS, 2020b)	▪ Assessment and referral for the right therapy or service to meet the occupational need identified. ▪ Delivering anxiety management techniques to enable social or work goals.
Rehabilitative model. Meaningful occupation may be the agent of change, the target of change, or neither.	▪ To improve skills or functioning (Kinn and Aas, 2009) ▪ Intervention regarding daily living skills (Hardaker et al., 2007) ▪ Skills training, education (Pentland et al., 2018)	▪ Direct provision of a daily living skills intervention. ▪ Collaborative goal setting to support a client to improve their work-readiness via education or volunteering. ▪ Working on finger flexion, through exercises or occupation.
Compensatory / adaptive model. Occupational performance is the target of change	The modification of activities, provision of equipment or environmental adaptation (Pentland et al., 2018)	▪ Prescription of equipment such as raised toilet sets, bath aids, grab rails. ▪ Designing activities tailored to clients' interests and abilities. ▪ Modification of a work environment for a person with sensory processing issues.
Commonly cited core skills of occupational therapists:	Functional assessment, activity analysis, environmental assessment (physical and social environment), grading, teaching and coaching, listening and interviewing, group-work, use of occupational therapy models, occupational formulation (College of Occupational Therapists, 2016).	
Commonly cited values and perspectives of occupational therapists:	▪ "The foundational idea that doing can be therapeutic" (Pentland et al., 2018). ▪ Holistic assessment and practice (including mental and physical health) (Hardaker et al., 2007). ▪ Emphasis on complexity / complex systems dynamics, and interrelatedness (Kielhofner, 2008; Roley et al., 2008). ▪ Empowering individuals, promoting independence, and 'client centred' practice (Taylor, 2003). ▪ Prevention, and promotion of wellbeing as opposed to treatment of disease (Reitz, 1992). ▪ Emphasis on functioning and quality of life over symptoms.	

1.8.1 Balance and rhythm of rest and activity in the beginnings of occupational therapy

Early descriptions of occupational therapy emphasised the importance of natural rhythms and balance, including not just the balance of occupations (work, rest and play) but also rest activity rhythms (Meyer, 1922). Whilst the notion of occupational balance has remained a focus for occupational therapists (e.g., productivity, leisure, self-care), natural rhythms of rest and sleep have received little attention (Green, 2015). Occupational therapy became focused on agency, action and participation; focusing on conscious daytime activity, to the exclusion of rest and sleep (Nurit and Michal, 2003; Iwama, 2015).

As a result of neglecting rest and sleep, activity timing and rest-activity rhythm also remained neglected. Yet, when considering occupation, time and rhythm are fundamentally important (Green, 2008). Furthermore, internal and external time both impact on occupational performance; wellbeing and optimal functioning are best achieved when internal and external time are in harmony and synchrony.

1.8.2. Occupational therapy's involvement in sleep

In recent years, sleep is becoming recognised as a legitimate concern for occupational therapists, receiving increased coverage in literature (Green, 2015), and within therapist training (Brown, 2016), but there are as yet few studies of occupational therapy interventions for sleep. There have been studies and evaluations of CBTi delivered by occupational therapists (Berger, 2012; Eakman et al., 2017), with promising initial results showing recruitment, delivery and retention were feasible (Eakman et al., 2017), and outcomes improved from pre- to post-intervention (Berger, 2012; Eakman et al., 2017). Occupational therapists have studied delivery of a sound producing pillow versus meditation versus sleep hygiene in poor sleepers (Gutman et al., 2017), music with movement to improve sleep in dementia (Lai et al., 2016), and use of weighted blankets in inpatient mental health (Champagne et al., 2015). The only occupational therapy sleep interventions which were occupation based were in community dwelling older adults and nursing home residents. Perhaps surprisingly, there were none in people with severe mental illnesses. Leland et al found that community dwelling older adults receiving an occupation based intervention increased their night-time sleep when they ceased napping, whilst those not receiving occupation based intervention slept less in total when they ceased napping (Leland et al.,

2016). Similarly, Kuck et al found that social activation and mobilisation improved nursing home residents' subjective sleep quality (Kuck et al., 2014).

I have communicated with occupational therapists practicing in sleep specific roles in services in the UK, mainland Europe, USA, Australia and Canada, practicing in mental and physical health settings, and across the age range (personal communications, 2016-present). Anecdotally, colleagues report a gradual and continuing increase in the number of occupational therapists incorporating sleep assessment and interventions into their practice, and in development of sleep specific roles. However, previous work suggests occupational therapists feel there is a lack of evidence to direct their practice in relation to sleep (Faulkner and Mairs, 2015), and recent communications suggest this remains the case. Chapter 2 presents a short editorial arguing the case for increased attention toward sleep from occupational therapy researchers and practitioners, highlighting the relevance of sleep as a specialism for occupational therapists, and sleep knowledge as relevant for occupational therapists working in a range of fields.

1.9. Background summary and rationale for this research

Sleep and circadian rhythm problems in SzSD are serious, have wide-ranging consequences, and are highly prevalent. They constitute a modifiable treatment target for non-pharmacological intervention, and one which many patients are keen to address.

Understanding of circadian rhythms has progressed significantly in recent years, but this knowledge has not yet been adequately applied in real world interventions. Interventions studied in SzSD remain more informed by theories of insomnia and CBTi, with its longer established evidence base, than by the science of circadian rhythms.

It is acknowledged that adherence to sleep schedule recommendations to improve insomnia presents a particular challenge in people with limited daytime occupation (Troxel et al., 2012). Behavioural interventions to modify zeitgeber exposure and manipulate sleep pressure require a high level of engagement, and some changes in routine must be ongoing, not temporary. Such whole-lifestyle changes should be appropriately embedded within the context of meaningful occupational engagement, to fit within existing or desired routines. Occupational therapists already address limited or unbalanced occupational routines in a personalised manner and could bring these skills to apply in sleep and circadian interventions. This thesis presents the development of a personalised occupational therapy intervention to

address poor sleep in SzSD, examination of demand and acceptability, and the preparations for feasibility testing which is now underway.

1.9.1. Overall aims of the thesis:

1) To develop an acceptable, user-centred behavioural treatment for poor sleep, in schizophrenia spectrum disorders, suitable for delivery by an occupational therapist working within secondary care mental health services.

2) To prepare a study protocol to assess the acceptability and feasibility of the developed intervention.

3) To identify and explore, prospectively, any potential implementation issues which might affect further testing and clinical use of this intervention in secondary care mental health settings.

Chapter 2: Editorial - The relevance of sleep for occupational therapy

2.1. Paper 1: “Sleep and occupational performance are inseparable: Why occupational therapy practice and research should consider sleep and circadian rhythm”

Paper number: 1

Page of thesis: 64

This paper is published in British Journal of Occupational Therapy.

Faulkner, S. M., (2022) ‘Sleep and occupational performance are inseparable: Why occupational therapy practice and research should consider sleep and circadian rhythm’, British Journal of Occupational Therapy, 85(5), pp 305-307

Sleep and occupational performance are inseparable: Why occupational therapy practice and research should consider sleep and circadian rhythm

Sleep is essential for human health, and recovery from injury and disease. Inadequate sleep is linked to worse physical and mental health, from increased diabetes risk, to worse cognitive decline (Chaput et al., 2020). Sleep is of particular relevance to occupational functioning; it affects cognitive performance, from alertness and attention, to executive functioning and learning (Tkachenko and Dinges, 2018), and affects physical performance from basic cardiorespiratory functioning to sports performance (Charest and Grandner, 2020). Sleep timing and patterns also affect social inclusion and occupational routines; predictably timed nocturnal sleep is usually preferable, whilst erratically timed or reversed sleep can interfere with people's ability to make social or work plans (Faulkner and Bee, 2017).

Normal sleep is characterised by a cessation of activity, dramatic changes in brain activity, and loss of conscious awareness of external stimuli (although the right stimuli will still wake the person). Core body temperature and heart rate drop especially during slow wave sleep (deep sleep), and during Rapid Eye Movement (REM) there is muscle atonia, which prevents people from acting out their dreams (Roehrs and Roth, 2019). Healthy sleep-wake cycles follow a circadian rhythm (as do many other biological processes), this rhythm is set by the circadian clock (in mammals, the suprachiasmatic nucleus, SCN), which controls timed changes in production of neurotransmitters, including a rise in melatonin in the evening before sleep. This internal pacemaker produces an approximately 24-hour rhythm which continues in the absence of any environmental cues, and which synchronises with the external time of day through regular light exposure (Roenneberg and Merrow, 2016).

Sleep pressure, or sleep drive, builds up with longer time spent awake (Milinski et al., 2021), but this sleep drive can be resisted for some time in situations of acute stress. Although this was no doubt useful during our evolution, many modern sources of stress are not improved by remaining awake and vigilant. Stress can lead to short term insomnia. Insomnia may then be maintained by changes to behaviour such as extending time in bed, cancelling daytime activities, and coping strategies such as caffeine use (Perlis et al., 2010).

Sleep can also be disturbed due to circadian dysregulation; regular daylight exposure, and darkness at night is needed for good circadian entrainment, and this can be lacking when

spending most time indoors in artificial lighting. Circadian dysregulation does not just affect shift-workers, but can affect teenagers (whose natural rhythm is later), older people (who's natural rhythm can become less robust), and people with particular neuropsychiatric diagnoses which appear linked to poorer circadian rhythm (such as schizophrenia) (Jagannath et al., 2013). Poor circadian entrainment can affect people who because of illness or disability find it difficult to get outdoors on a regular basis, and who may have limited 'social cues' (such as work or social commitments) to promote a regular rhythm.

Sleep is a relevant consideration for occupational therapists on two levels; firstly, sleep knowledge should inform occupational therapy practice and research across specialities, and secondly, sleep treatment should become more established as a specialism for occupational therapists. Sleep is intrinsically linked to many areas which occupational therapists are well equipped to address, such as the physical and social environment, the timing and type of activities undertaken, and optimising performance capacity, see Figure 1. These areas all provide potential targets for occupational therapy interventions for sleep improvement. Furthermore, it is relevant for us to understand the interactions of sleep with these areas, in order to avoid unintended consequences.

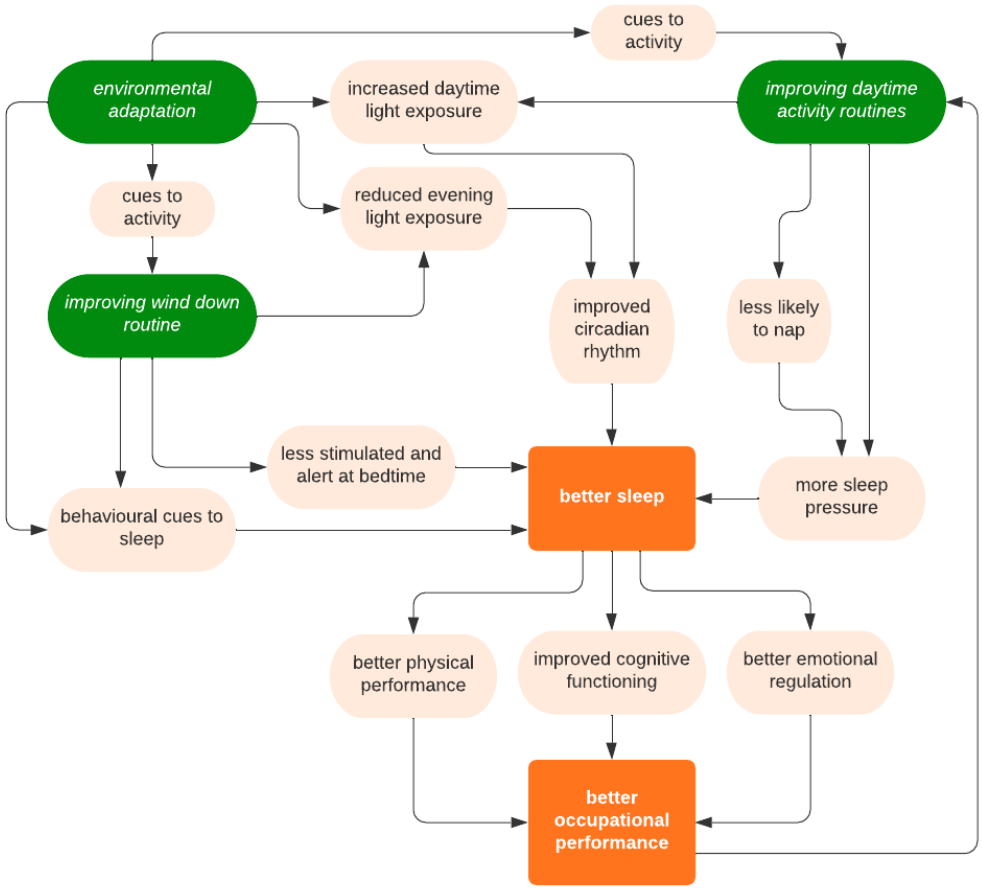

FIGURE 1: Impact of occupational therapy interventions on sleep and occupational performance

Some examples of how sleep knowledge is relevant for occupational therapists in 'non-sleep' specialities are now explored. Firstly, a person's performance in assessments may be affected by whether they are sleep deprived, and whether they have recently woken up and are experiencing sleep inertia (Werts et al., 2006). Without such awareness functional assessments may be inaccurate. Secondly, recovery will be optimised by promoting a good sleep environment, and practices. For example, enforced early morning bathing for all on hospital wards should be questioned by occupational therapists, more personalised timing may better promote independence and enhance recovery. Thirdly, occupational therapists in a range of fields are well placed to identify sleep difficulties; excessive sleepiness may be picked up during functional assessment, prompting screening or referral for sleep apnoea assessment. Insomnia, problems with sleep hygiene, or maladaptive sleep behaviours, may be picked up when assessing daily routines, occupational therapists might signpost clients, refer for treatment, or provide self-help advice. Fourthly, failure to recognise possible sleep

difficulties may lead to waste of resources, trying to treat the problems caused by poor sleep, as though they are caused by other factors.

Occupational therapists have a relevant contribution to make to the development, testing and delivery of biopsychosocial treatments to improve sleep. Cognitive Behavioural Therapy for insomnia (CBTi) has been successfully delivered by occupational therapists (Eakman et al., 2022). Occupational therapists have relevant skills for delivering CBTi and related behavioural sleep interventions, for instance, CBTi calls for restricting time in bed, avoiding non-sleep activities in bed, and avoiding napping (Perlis et al., 2010) - the ability to work with clients to address the type, timing and location of activities is very relevant to supporting these goals (e.g., avoiding napping is easier when engaging in activity). Occupational therapists can use their skills in environmental assessment and adaptation to optimise the sleep environment (temperature, safety, toileting needs, positional supports), to improve daytime light exposure, and reduce evening and night-time light. Many components of existing sleep interventions involve behaviour changes which are easy to specify, but hard to initiate for clients. They might involve doing the opposite of what the sleep deprived person feels like doing, and changing longstanding habits can be challenging. Many occupational therapists are well practiced in use of behaviour change techniques such as graded goal setting, use of environmental supports, motivational work, and using personalisation to make goals relevant and meaningful.

Occupational therapy research about sleep fits in one way or another with each of the top 10 research priorities (Royal College of Occupational Therapists and James Lind Alliance, 2020). For instance, priority 6 - addressing sleep may be a means of being more inclusive of both physical and mental health, and priority 8 - improving sleep may reduce hospital admissions in people whose conditions are exacerbated by poor sleep. There are a many potentially fruitful areas of research in which occupational therapists could have a useful contribution; such as research on interventions to increase physical activity to improve sleep. Research in mice has demonstrated that the content of wake time alters sleep drive, with more engaging exploratory activity producing more sleep drive than a repetitive compulsive activity (Milinski et al., 2021). Occupational therapists may be well positioned to contribute toward research to identifying the characteristics of daytime activity in humans which best promotes healthy build-up of sleep drive, so that this knowledge can be incorporated in future sleep interventions.

Research on light exposure interventions to improve sleep has so far been focused on use of light boxes, and with little attention to how this fits within the person's daily routine, and little personalisation in terms of utilising occupational opportunities to obtain light exposure. This might make these light exposure treatment protocols unsustainable (Faulkner et al., 2020). Occupational therapists are well placed to develop and test personalisable occupationally embedded protocols to improve daily light exposure.

Research on sleep and circadian rhythm has moved on a huge amount in the last twenty years, for example, the retinal cells responsible for detection of light by the circadian system (distinct from the vision-producing rods and cones) were only discovered in 2002 (Hattar et al., 2002). In order to remain evidence based in our practice, it is necessary to have a current and active engagement with research evidence. Occupational therapists should not be satisfied with basic general knowledge of sleep; an in-depth understanding of normal sleep, circadian rhythm, and insomnia processes are relevant to support expert clinical practice in most if not all occupational therapy specialities. There is a lot to know about sleep, circadian rhythm, and its interactions with the environment and our habits and routines, and occupational therapists are ideally placed to both use and create this knowledge.

References:

Chaput, J. P., Dutil, C., Featherstone, R., Ross, R., Giangregorio, L., Saunders, T. J., Janssen, I., Poitras, V. J., Kho, M. E., Ross-White, A. and Carrier, J. (2020) 'Sleep duration and health in adults: an overview of systematic reviews.' Applied physiology, nutrition, and metabolism = Physiologie appliquee, nutrition et metabolisme, 45(10) pp. S218–S231.

Charest, J. and Grandner, M. A. (2020) 'Sleep and Athletic Performance: Impacts on Physical Performance, Mental Performance, Injury Risk and Recovery, and Mental Health.' Sleep Medicine Clinics, 15 pp. 41–57.

Eakman, A. M., Schmid, A. A., Rolle, N. R., Kinney, A. R. and Henry, K. L. (2022) 'Follow-Up Analyses From a Wait-List Controlled Trial of Occupational Therapist–Delivered Cognitive–Behavioral Therapy for Insomnia Among Veterans With Chronic Insomnia.' The American journal of occupational therapy, 76(2).

Faulkner, S. and Bee, P. (2017) ‘Experiences, perspectives and priorities of people with schizophrenia spectrum disorders regarding sleep disturbance and its treatment: a qualitative study.’ BMC Psychiatry, 17(1) p. 158.

Faulkner, S. M., Dijk, D. J., Drake, R. J. and Bee, P. E. (2020) ‘Adherence and acceptability of light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuropsychiatric illness: a systematic review.’ Sleep Health. Elsevier Ltd, 6 pp. 690–701.

Hattar, S., Liao, H. W., Takao, M., Berson, D. M. and Yau, K. W. (2002) ‘Melanopsin-containing retinal ganglion cells: Architecture, projections, and intrinsic photosensitivity.’ Science, 295(5557) pp. 1065–1070.

Jagannath, A., Peirson, S. N. and Foster, R. G. (2013) ‘Sleep and circadian rhythm disruption in neuropsychiatric illness.’ Current Opinion in Neurobiology, 23(5) pp. 888–894.

Milinski, L., Fisher, S. P., Cui, N., McKillop, L. E., Blanco-Duque, C., Ang, G., Yamagata, T., Bannerman, D. M. and Vyazovskiy, V. V. (2021) ‘Waking experience modulates sleep need in mice.’ BMC Biology. BMC Biology, 19(1) pp. 1–14.

Perlis, M. L., Smith, M. T., Jungquist, C., Nowakowski, S., Orff, H. and Soeffing, J. (2010) ‘Cognitive-Behavioral Therapy for Insomnia.’ In Attarian, H. P. and Schuman, C. (eds) Clinical Handbook of Insomnia. Springer Science+Business Media, pp. 281–296.

Roehrs, T. and Roth, T. (2019) ‘The sleep-wake cycle: An overview.’ In The Behavioral, Molecular, Pharmacological, and Clinical Basis of the Sleep-Wake Cycle. Elsevier Inc., pp. 2–16.

Roenneberg, T. and Merrow, M. (2016) ‘The circadian clock and human health.’ Current Biology. Elsevier Ltd, 26(10) pp. R432–R443.

Royal College of Occupational Therapists and James Lind Alliance (2020) Top 10 priorities for occupational therapy research in the UK.

Tkachenko, O. and Dinges, D. F. (2018) ‘Interindividual variability in neurobehavioral response to sleep loss: A comprehensive review.’ Neuroscience and Biobehavioral Reviews. Elsevier, 89(March) pp. 29–48.

Werts, A. T., Ronda, J. M., Czeisler, C. A. and Wright, K. P. (2006) ‘Research Letter: Effects of Sleep Inertia on Cognition.’ JAMA, 295(2) pp. 163–165.

Chapter 3: Methodology

This chapter presents methodological discussion relating to the primary and secondary studies conducted as part of this PhD. First, the overall aims and structure of this work is set out in relation to the research pathway for development and evaluation of complex interventions. Then, methodological issues relevant to these studies are discussed. Details of specific methods used are presented in Chapters 4-9 (in papers, and in supplementary content preceding papers where relevant).

3.1. Overall aims of the thesis:

1) To develop an acceptable, user-centred behavioural treatment for poor sleep, in schizophrenia spectrum disorders, suitable for delivery by an occupational therapist working within secondary care mental health services.

2) To prepare a study protocol to assess the acceptability and feasibility of the developed intervention.

3) To identify and explore prospectively, any potential implementation issues which might affect further testing and clinical use of this intervention in secondary care mental health settings.

3.2. Studies and papers in this thesis

The empirical work and papers of this PhD are shown below in chronological order of delivery and presentation:

Ch 2) Editorial on the relevance of sleep for occupational therapy
Ch 4, Study A) Meta-analysis on light therapies to improve sleep
Ch 5, Study B) Systematic review on adherence and acceptability
Ch 6, Study C) Mixed methods expert opinion study to support intervention design
Ch 7) Synthesis, development of intervention and design of study protocol
Ch 8, Study D) Surveys on potential future implementation issues
Ch 9) Feasibility study protocol

Details of the aims of these studies and how they fit within the overall research programme are given below in Table 6.

Table 6: Studies, aims and purpose within this programme of research

Chapter / Study	Study	Key Aims	Purpose within this programme of research
Ch4 **Study A**	**Meta-analysis of the effect of light-dark interventions:**	▪ To examine the effect of interventions altering light exposure patterns on sleep quality, duration and timing, in populations with circadian dysregulation. ▪ To examine moderators of effectiveness.	To identify efficacious techniques from interventions in similar populations to the target group.
Ch5 **Study B**	**Narrative review of acceptability of and adherence to light-dark interventions**	To examine evidence regarding adherence and acceptability in studies of light or dark interventions using various delivery devices and protocols to improve sleep in intrinsic circadian rhythm sleep-wake disorders and neuropsychiatric illness.	▪ To inform the potential acceptability of light-based intervention components within the multi-component sleep intervention in development. ▪ To inform design of light-based components, identifying any factors which might impact upon acceptability and adherence.
Ch 6 **Study C**	**Intervention development expert opinion study**	To examine and explore expert opinions regarding the appropriate components, format, length and other attributes of an occupational therapy intervention to improve sleep in people with schizophrenia spectrum disorders.	To inform the co-design of the intervention by myself, my supervisors and PPI contributors.
Ch 8 **Study D**	**Implementation focused surveys**	To examine presence of and awareness of different types of sleep problems, readiness to refer or be referred, factors associated with help-seeking, treatment preferences, and staff confidence and knowledge to identify and improve sleep problems.	To inform future study and clinical implementation of the intervention developed, and similar interventions.

3.3. Review methodology

The first stage of this PhD was to examine and synthesise relevant evidence. Apart from the background summarised in Chapter 1, more focused and formal evaluation of the evidence was undertaken. This focused on light therapies in populations experiencing similar sleep problems to those with SzSD, their effects (and potential effect moderators), and adherence and acceptability (and factors affecting adherence and acceptability). Rationales for the topics of focus are presented in Chapters 4 and 5.

There are many designs of evidence synthesis, appropriate to different research aims and evidence types. Table 7 summarises some of the main types. This is followed by a discussion of the types of review potentially relevant to the topics addressed in this thesis, and the rationale for the methodological decisions taken.

Table 7: Types of evidence synthesis that may be applied to evaluation of an intervention

Review type	**Evidence type and how identified and selected**	**Pro's (+) and con's (-)**
Traditional (non-systematic) "narrative review"	▪ No systematic search or inclusion criteria. ▪ Any study type, opinion pieces, theoretical background, other reviews.	+ quick + story-based structure may be more readable - bias
Scoping review	▪ Varied in systematicity of search and inclusion, can balance comprehensiveness with time available. ▪ Any primary study.	+ quicker than systematic review + more flexible allowing change of inclusion criteria, in light of early findings - limitations in guidelines for the method, as yet
Systematic review with narrative synthesis	▪ Systematic search and pre-defined inclusion. ▪ Any primary study type. ▪ Not opinion pieces.	+ exhaustive inclusion + transparency re: inclusion + can synthesise un-meta-analysable data - unstandardised synthesis method
Systematic review with meta-analysis	▪ Systematic search and pre-defined inclusion. ▪ Usually only intervention studies with a control group. ▪ Not qualitative data.	+ synthesis of summary effect - less meaningful if studies are diverse - excludes some data (e.g., observational, qualitative) - more resource intensive than narrative synthesis
Meta-analysis with meta-regression	▪ As above. ▪ Can choose to only include studies with the moderator of interest if	As above, and: + allows examination of moderator variables (e.g., dose, location, participant characteristics)

Review type	Evidence type and how identified and selected	Pro's (+) and con's (-)
	meta-regression is the primary aim.	- less informative re: moderators than IPD meta-analysis
Individual Patient Data (IPD) meta-analysis	▪ Systematic search and pre-defined inclusion. ▪ Controlled studies where raw data can be accessed.	+ allows more examination of the effect of moderator variables than meta-analysis with meta-regression - limitations of raw data availability - very resource intensive
Network meta-analysis	▪ Systematic search and pre-defined inclusion. ▪ Controlled studies or equivalence trials.	+ avoids equating different controls + appropriate where active controls or 3 group designs are used - large number of studies needed - resource intensive
Qualitative meta-synthesis	▪ Systematic search and pre-defined inclusion. ▪ Qualitative studies only.	+ overview of qualitative work - often too few studies available - without raw data, can be skewed by the authors' interpretive filter

To address the questions under consideration some review types were inappropriate - non-systematic reviews can play a role in theory development but do not give confidence that all relevant studies are included, and they can easily be biased (Cipriani and Geddes, 2011). We conducted scoping searches and found that there appeared to be too few qualitative or mixed methods studies for a qualitative meta-synthesis, or any systematic review design including exclusively qualitative results.

Scoping the literature, and expert advice, indicated that the intervention we envisaged would potentially include light therapy, so it was of interest to evaluate the efficacy of light therapy, and to identify factors predicting better or worse effect, to inform design. Meta-analysis can estimate intervention effect size, and meta-regression can give an indication of therapy or patient variables associated with better or worse effects (Smith and Egger, 2008). However, there are some limitations to acknowledge. Meta-analysis, although identified in the hierarchy of research methodologies as a more valid source of evidence than individual trials, rests on various assumptions about the nature of the trials involved. For instance, there should be sufficient trials of sufficient quality to yield meaningful outcomes. If differences in samples, intervention or trial methodology, illness, or context, introduce enough heterogeneity to affect the results, these differences should be identifiable and capable of being acknowledged or addressed to avoid introducing bias. The primary purpose of meta-analysis is to see the overall effect of an intervention; sub-group comparisons and meta-regressions using only aggregated data should be interpreted cautiously as other variables

may co-vary with any variable of interest within studies (Thompson and Higgins, 2002; Sun et al., 2010), and can introduce confounding. For this reason Individual Patient Data (IPD) meta-analysis is preferable to answer questions regarding relationships between intervention and participant variables, as variables that vary within studies can contribute to analyses, as well as those which vary between studies (Smith and Egger, 2008). Unfortunately, in this instance, IPD were not readily available and attempting to obtain and analyse IPD for all the studies involved was impractical, would have excluded several studies, and was beyond the resource scope of this PhD.

Efficacy is not the only important outcome of trials, and the quantitative measures of acceptability (e.g., recruitment, attrition, satisfaction) are often unhelpfully limited, and not included within traditional meta-analyses. For this and other reasons it is increasingly accepted that randomised controlled trials and meta-analytic synthesis of effects are not the only useful evidence to consider when making policy or healthcare decisions (Dixon-Woods, 2006). To examine acceptability and adherence, data must be extracted and examined which is more often in the incorrect format for meta-analysis, and not convertible, so narrative synthesis may be the only option. Narrative synthesis within a systematic review can bring the benefits of systematic search, inclusion, and quality appraisal, and a systematic process of data extraction and synthesis, whilst allowing the flexibility to include all data types. Relationships and variation within and between studies can be explored through narrative synthesis methods, and this is a suitable means of exploring factors shaping implementation (Popay et al., 2006). As some data would be expressed numerically (adherence and attrition), and other data we anticipated would be qualitative (acceptability), a mixed methods review, or mixed studies review, was undertaken (Pluye and Hong, 2014).

3.4. Research pathway for complex interventions

MRC Guidance on developing and testing complex interventions asserts that interventions should be developed based on evidence and theory, followed by feasibility work. Feasibility work should examine both intervention-related procedures and acceptability, and trial related procedures, acceptability and recruitment (Craig et al., 2008), before full-scale evaluation of efficacy and effectiveness. Adequate preparation can therefore avoid waste by ensuring that interventions and trial methodologies are not impractical or unacceptable, before larger scale

studies are undertaken to evaluate them (Czosnek et al., 2020; Matthews and Simpsons, 2020).

The work in this thesis relates predominantly to the "Development" phase of the research process, with some preparations for "Feasibility / piloting" (prospective examination of factors which may affect implementation, and feasibility study protocol) (see Figure 5).

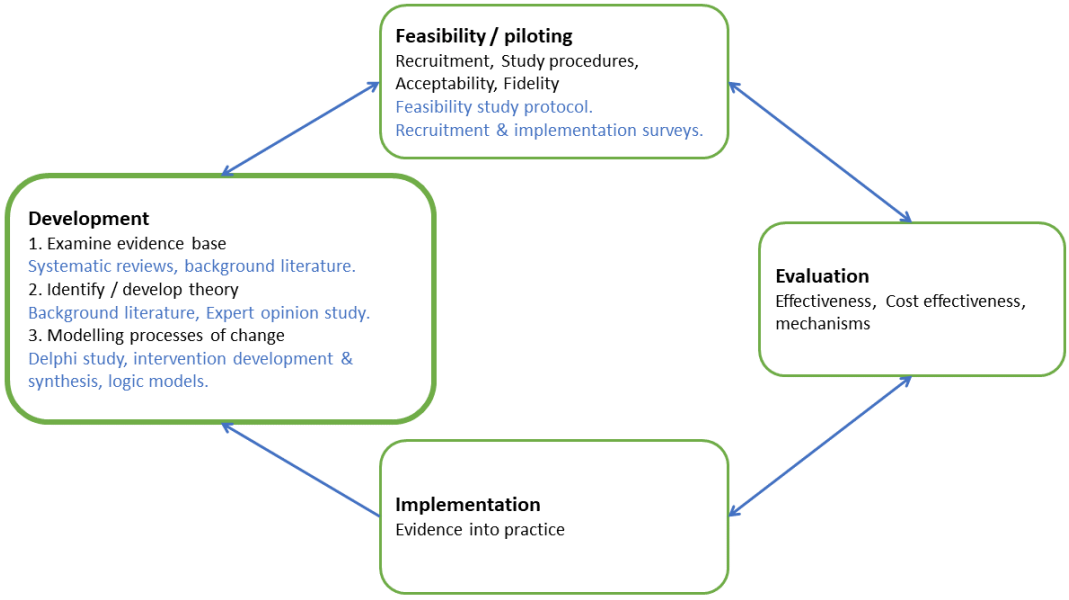

Figure 5: Complex intervention research phases in this PhD

*concepts from MRC Complex Interventions Guidance (Craig et al., 2008)

The work contributing to the 'development' phase includes evaluation of existing evidence, an expert opinion study, and synthesis of primary and secondary findings (see Figure 6).

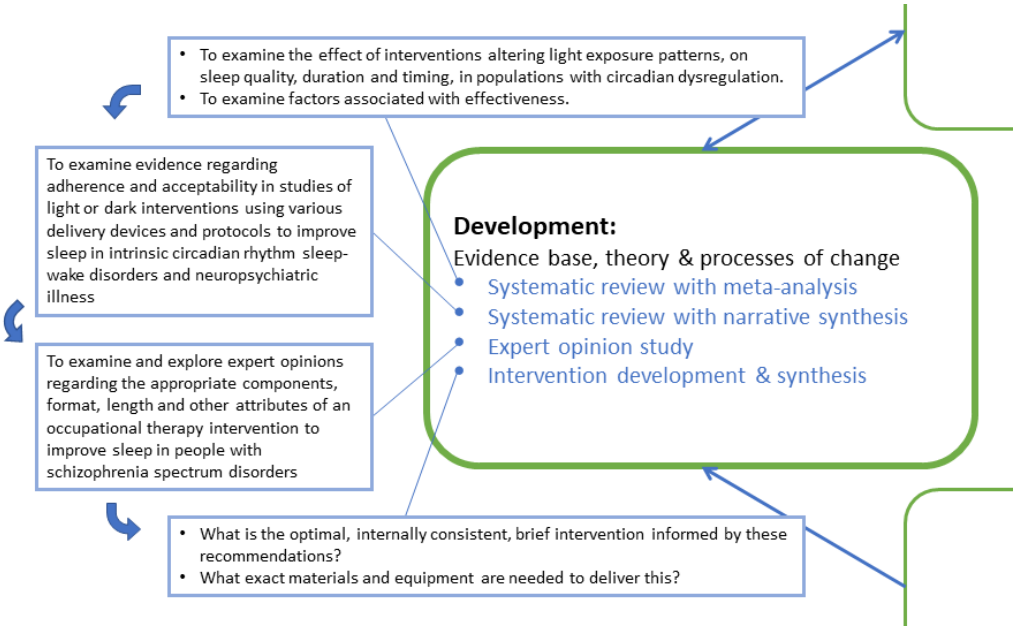

Figure 6: Intervention development work in this thesis

3.5. Complex sleep interventions

Complexity has many potential dimensions (Craig et al., 2019) such as number of intervention components and their interactions, or level of individual tailoring (see Table 8). Behavioural sleep interventions often involve complexity in many dimensions, such as being multi-component, requiring multiple and difficult behavioural changes, and including individual tailoring. Individual tailoring may be by design or may be unavoidable due to individual life circumstances of individuals. Even apparently 'simple' single component non-pharmacological sleep interventions, such as 30 minutes morning light box use, may be more appropriately understood as complex, once the user has embedded this into their daily schedule, with the knock-on effects this entails. This is discussed in Study B. The behavioural sleep intervention developed in this PhD includes more than one component, modified by consideration of individual circumstances, context, and problem type, and thus is complex.

Table 8: What makes complex interventions complex

Dimension of complexity	Example from 'single component' morning light therapy
Number of components and their interactions	1. Light exposure, 30 min, 8am. (necessitates 2, 3 and 4) 2. Awaken in time for light exposure 3. Sit, stand or face light for 30 min 4. Make modifications to routine to fit this in
Number and difficulty of behaviours required	Difficulty waking and method(s) used (alarms etc) will vary between individuals.
Number of groups or organisational levels targeted by the intervention	Not applicable, intervention can be considered on an individual level (although implementation might benefit from considering organisational factors such as staff awareness or training).
Number and variability of outcomes	Different sleep outcomes may be targeted, e.g., earlier sleep onset, improved sleep maintenance, reduction of sleep inertia. Long term outcomes may be targeted e.g., improved functioning or QoL.
Degree of flexibility or tailoring of the intervention permitted (Craig et al., 2019)	Tailoring (e.g., of timing, duration or brightness) brings an increase in complexity (protocol to select correct time etc). However, a lack of tailoring may still bring heterogeneity in both the effect and difficulty of the intervention. 8am is earlier for some than others depending on their routine as baseline.

3.5.1. Examining intervention packages versus examining components in isolation

MRC complex interventions guidance describes a process of developing and evaluating a complex intervention as a whole (Craig et al., 2008), but this is not the only possible approach. A disadvantage of only examining the whole intervention is that some elements may be inactive. Another approach to multi-component complex interventions is to examine individually the intervention components in terms of efficacy (Petticrew, 2011), or similarly, to review evidence for individual components. Unfortunately, in their review of sleep hygiene advice components, Irish's group found that there was limited interventional research for the individual components (Irish et al., 2015). Alternatively, contributions of individual elements can be examined in a 'dismantling trial' or 'deconstruction trial', where one or more active elements are removed from one treatment arm in order to assess their contribution (Carrico and Antoni, 2008; Kellett et al., 2018). The precision of such estimates depends on the size of the sample, which therefore implies a large trial for precise estimation.

There is a lack of dismantling trials for behavioural sleep intervention components, and certainly none conducted in SzSD, thus it would not be possible to base decisions for

including a component on such evidence. It was decided to develop and examine a package of components together rather than separately, as it is expected that the mechanisms of various components will combine. For instance, time in bed restriction and avoiding napping, might not be expected to work without simultaneously avoiding caffeine consumption late in the day (or at least avoiding increasing caffeine to stay awake longer and follow time in bed restriction). Moreover, people who experience psychosis often have many co-morbid sleep disorders and sleep interfering factors (Reeve et al., 2019), making it more difficult to isolate a sample with a singular problem amenable to a more focused single component intervention. Previous qualitative work with this group also found patients felt there was a need for a 'whole lifestyle' intervention (Faulkner and Bee, 2017).

Avoiding inclusion of 'incompatible' elements is an important consideration. Individually separate elements might be beneficial, but some of these may interact in a harmful way. This particularly applies to the different manners in which a sleep intervention might address worry or thoughts, where utilising a coherent model is important to avoid conflicting messages and demands on recipients of the intervention. For example, Acceptance Commitment Therapy (ACT) has been described as incompatible with CBT, as CBT encourages systematic examination and change of negative thoughts, whilst ACT encourages their acceptance (Thompson et al., 2017). Similarly MCT discourages analysis of negative thoughts and encourages leaving them alone, in contrast to CBT which has an incompatible focus on appraisal of these thoughts (Wells, 2009). Although harms of 'interactions' of intervention components might usually be linked to drug interactions, non-pharmacological psychological or behavioural intervention components can also interact in undesirable ways.

It is easily conceivable that careless combination of behavioural and environmental components could equally be harmful. For instance, improving brightness of lighting in the non-bedroom areas of the home might be helpful to improve daytime light exposure, getting out of bed if not asleep might be helpful to improve the association between bed and sleep might be helpful to reduce association of wakefulness with bed. If, however, the person therefore gets out of bed and goes to sit in a now extra-brightly-lit area, this increases light exposure at night, and is likely to be counterproductive (Touitou et al., 2017). It was decided for this reason to use logic models to illustrate the possible interactions of intervention components during design and planning of evaluation of complex interventions models (Moore et al., 2015). The likely interaction of these elements also underlined the value of

evaluating acceptability of the combined intervention, which might be different to the acceptability of components presented individually. Qualitative and repeated measures data now being collected as part of the feasibility study (see Chapter 9, protocol) will help in future to further clarify interactions between components in terms of effects and acceptability.

3.6. Expert opinion and consensus methods in intervention and guideline development

Development of complex interventions has often utilised expert opinion or expert consensus. This process may be informal, and arrived at via meetings and communications. Sometimes the contributors are known to each other, as is often the case for consensus statements by pre-existing organisations (e.g., (Nathaniel et al., 2015; M. Sateia et al., 2017)), or some methods can enable anonymity of participants. Use of formal methods improve the validity of conclusions compared to informal discussion, by reducing the effect of dominant individuals and social pressures to reach agreement (Murphy et al., 1998; Cook and Birrell, 2007). Table 9 provides examples of expert consensus methods, and some of the reasons for selection of methodology in Chapter 6.

Table 9: Choice of a consensus method

Consensus development method:	**Why used / why not used in this study:**
Informal - face to face	× Impractical - international participants
Informal - remote, video conference	× Lack of anonymity, too many participants
Informal - remote, email / messenger	× Lack of anonymity, too time consuming
Nominal Group Technique	✓ Allows completion in one day, avoids attrition, avoids excluding those without technological access or literacy
RAND-UCLA Appropriateness Model (Nair et al., 2011)	× Requires a core panel to conduct a systematic literature review with evidence synthesis together

Consensus development method:		Why used / why not used in this study:
Delphi study	…with open questions first round.	✓ To allow generation of ideas we might not be familiar with including from practice experience and from participants who have awareness of different literature than the investigators.
	…with set options from first round based on literature.	× Suitable if all potential options can reasonably be known by investigators, or if another study precedes the Delphi to generate these options.
	…with face to face / videocall first round.	× Appealing to engender sense of 'team', but sacrifices anonymity and creates scheduling pressure. Time zones problematic.
	…where participants are anonymous from each other and readers.	✓ In order that participants cannot guess the source of ideas or quotes by knowing other's work. Less likely to bias responses for perception of others.
	…where participants are anonymous even from researchers.	× Not practical to ensure participants have desired expertise if anonymous. Researcher would not then have been able to interview participants.
	…moving from open questions to voting / rating.	✓ Rating of ideas generated earlier. Assess level of consensus / endorsement numerically.
	…including open questions through to last round.	✓ Allows further exploration of reasons behind controversies / disagreements and responses to dilemmas identified. Retains some elements of a conversation or debate whilst retaining anonymity.

There are criticisms of the Delphi method, and of basing recommendations on expert opinion or consensus generally, including that, as the sample is purposively selected, the selection involved introduces bias, and that results may not be 'reliable' in terms of being replicated by another panel (Keeney et al., 2001). Whilst Delphi studies which aim to forecast are of course concerned with reliability (Rowe and Wright, 1999), this is perhaps less true of those making intervention recommendations. It is not necessary to suggest the exact same results would be produced by another panel, any more than that the same exact results should be produced by two qualitative studies on the same topic (Mays et al., 2005). The results may be transferable without being statistically generalisable (Gale et al., 2013). It does, however, seem likely that many commonly endorsed ideas and suggestions might re-occur if experts fitting similar categories were selected, but their balance and discussion might differ somewhat. Again, it can be difficult to address complexity using this methodology, as rating of individual components may not automatically take account of potential interactions.

3.7. Implementation theory

This thesis develops an intervention and does some preliminary work to examine possible factors which might affect its later implementation. This kind of work is necessary because

often interventions are developed and found to be effective, yet they fail to be translated into clinical practice (Damschroder et al., 2009). This wastes research resources and does not provide patient benefit. Application of theoretical frameworks during intervention development and implementation aims to ensure relevant approaches and considerations are not missed (Michie et al., 2011), and can suggest avenues for investigation during feasibility work (Michie et al., 2014). Three related and overlapping fields of theoretical research are relevant: implementation theory, behaviour change theory, and acceptability research.

Implementation theories have mapped the different factors which can affect the uptake of new interventions. There are a large number of factors which can affect implementation of individual and service level interventions; the Consolidated Framework for Implementation Research (CFIR) synthesised many theories describing common and unique factors (Damschroder et al., 2009), although this list focuses on organisational factors rather than individual client factors. This thesis focuses more on individual client factors than organisational factors, although it does touch on factors potentially affecting staff referral behaviour.

Behaviour change theory is relevant within implementation, because implementation requires behaviour change by staff (Michie et al., 2014). This is perhaps more pronounced where staff must deliver the change in practice themselves, but even with an individual therapy accessed by referral there is referral behaviour and support of the client during and after. The surveys in Study D sought to identify any areas in which future behaviour change efforts might focus, for instance, on education and training (knowledge of sleep), environmental re-structuring (referral process), or persuasion (perspectives regarding particular types of intervention) (Michie et al., 2011). Behaviour change theory is considered further in Chapter 7 during intervention development, but in relation to how the intervention might promote behaviour change in the participant.

Acceptability of an intervention affects implementation (Glasgow R E et al., 1999; *www.RE-AIM.org*, 2019). The Theoretical Framework of Acceptability (Sekhon et al., 2017) was thus used to inform data extraction in Study B, and informs the topic guide in the acceptability interviews in Study D. Considerations of acceptability in these papers relate mostly to acceptability to the client; however, professional's perspectives are of course important also. The impact of professionals on uptake of the intervention is explored in the mixed methods expert opinion study, which contains questions influenced by the RE-AIM framework,

around Reach, Adoption and Implementation (Glasgow R E et al., 1999; *www.RE-AIM.org*, 2019). Reach is then addressed further in the surveys (Study D) which assessed presence and identification of relevant sleep problems in the population, and readiness to refer / be referred.

3.8. Survey methodology

Study D presents a survey-based study, detailed methods are presented in that chapter. Below is a discussion of methodological considerations of use of this type of approach for this type of question.

3.8.1. Aims and designs of surveys

Survey methods can be used to explore, describe or explain phenomena, and may be longitudinal or cross-sectional (Jann and Hinz, 2016). The cross-sectional surveys presented in Chapter 8 aim to roughly describe staff confidence in relation to sleep, explore presence and awareness of sleep problems, and explore reasons service users and staff might have for referral or non-referral for Light-Dark and Activity Rhythm Therapy (L-DART) or similar interventions.

Although there are some potential limitations to confidence in representativeness (discussed below and in the paper), these surveys serve to give some indication of the prevalence of different types of sleep problems, and clinician awareness of these. What is less affected by representativeness are the aims around qualitative exploration; for example, 'what reasons are given / endorsed for reluctance to access treatment'.

3.8.2. Bias

When designing surveys, potential sources of bias should be considered; bias may come from the sample selected (discussed further below), or from the questions and how they are asked. A number of sources of bias were considered during survey design, including social desirability bias, and context effects. Social desirability bias has been shown to be reduced by self-administration of surveys, and by anonymity (Tourangeau, 2017). Beyond this, phrasing and wording (Näher and Krumpal, 2012), and ensuring where potentially sensitive questions or response options are presented, that their relevance is obvious, may improve accurate disclosure (Krumpal, 2013). For instance, offering "I need help to address my illicit drug use first…" embedded as an option amongst other potentially less stigmatised response options, may improve disclosure. Social desirability bias can also cause people to respond in

ways not just to present themselves in a positive light, but to express a more positive view of the researcher or a group to which the researcher belongs (Dahlgren and Hansen, 2015). In our surveys, this might explain more positive comments about occupational therapists, whilst criticisms can perhaps be assumed to be representative and candid.

Context effects have been shown based on order of questions, where more specific questions can influence what is considered in answering more general questions subsequently presented (Cowles, E., & Nelson, 2015). For instance, 'would you like to be referred…' was presented before questions about specific potential barriers and preferences, which might otherwise prime the person to give a different response than they would if asked without priming.

3.8.3. Sampling and representativeness

For descriptive statistics in a cross-sectional survey to be an accurate representation of the population, requires a representative sample (Jann and Hinz, 2016). There are a number of sampling strategies which aim to achieve representativeness, some are summarised in Table 10.

Table 10: Sampling strategies

Sampling strategy	**Description**
Simple random sampling	All of the population is available to sample from, and a random selection is made, using a method such as a random number table.
Stratified sampling	The desired sample is broken down into categories based on specific features (e.g., demographics), and a sample is sought which is similarly distributed to the population between these categories.
Cluster sampling	Random samples are drawn from pre-existing groups within the population, e.g., if the population is all inpatient staff, but we sample from certain wards. The clusters may differ from each other (e.g., male and female wards), and staff in those clusters may have things in common (intracluster homogeneity). We could try to select a representative collection of clusters, and to assess intracluster homogeneity.
Systematic selection	The population are placed in an ordered list (e.g., alphabetically, or by a stratification feature such as age) a random number is selected and cases are sampled at that interval (e.g., every 5th case) instead of at random.

Representativeness can be achieved if there is a 100% response rate using a randomly selected sample, although in practice this is rarely the case. The methods for selecting a random sample do not address response bias. Even with a good (but not 100%) response rate, respondents may differ systematically from non-responders (Cowles, E., & Nelson, 2015). As an alternative means of assessing representativeness of a sample, methods of evaluating non-response bias are recommended (Johnson and Wislar, 2012). Comparing respondents to the sampling frame (aggregated routine data on Trust service users), or to external data sources (other research), are potential means of assessing non-response bias (Johnson and Wislar, 2012) which were suitable for this study.

This is even more important in anonymous survey research with an open invite where it is not possible to know how many may have seen the advert and so no reliable estimate of response rate is possible (Eysenbach and Wyatt, 2002).

We considered the ways in which volunteers might differ from the population in relation to variables not measured in our demographic data, based on what might be salient about the invitation materials (Cowles, E., & Nelson, 2015). As the staff survey advert mentions sleep, occupational therapy, and a therapy for people with schizophrenia spectrum disorders, it is possible staff with an interest in one or more of these topics might be more likely to participate. This might explain, for instance, higher levels of knowledge of sleep in the respondents than non-respondents. It is possible that more service users with sleep problems would choose to participate than without as they may feel more personally interested in the topic. Perhaps it is less likely that the sample would specifically favour particular types of sleep problems, although it is theoretically possible there could be a correlation between enjoying online surveys and some types of sleep problems, for instance, mediated by particular personality types.

Drawing samples from the lists available (a sampling frame) not the whole population can create a coverage error (Cowles, E., & Nelson, 2015). To reduce this error it is important to consider whether the lists available exclude any members of the total population in a way that is not random, and the possible impact of this. For the staff survey, it is possible that very new members of staff who do not have network access yet, or staff on long-term sickness absence, will be excluded. However, this does not damage the relevance of the results.

For the service user survey, the study team does not have direct access to the sampling frame; the research team can only indirectly reach those who have previously given permission to be directly contacted about research, those whose involved clinician passes on the study details to them, and those attending settings where research recruiters are working. These processes may potentially generate sampling biases toward different types of clients, including through 'gatekeeping' by clinicians, who preferentially recruit some types of clients over others. For instance, clinicians are reported to be more likely to ask clients they think are likely to say yes (Patterson et al., 2011), or more likely to refer clients who are 'reliable', fitting their idea of a 'good' participant (Guillemin et al., 2017). Clinicians may be less likely to refer those they perceive to be vulnerable or in need of protection from burden (Witham et al., 2015). Clinicians are expected to balance their duty to protect their clients from harm, whilst also promoting the client's right to choose where it comes to research (Bond Sutton et al., 2003); however, they may already be too overwhelmed by other responsibilities and decisions to be able to take on this additional decision making, meaning that only the most 'obvious candidates' are referred. Furthermore, retaining information about potentially many different studies is challenging for clinicians who have many elements to their roles (Bucci et al., 2015). Thus any clients who are not able to be quickly signposted to a study, without the clinician doing extra work explaining, may be less likely to be referred.

Potential sampling bias due to lack of access is not a problem unique to this study, not unique to survey research, nor even unique to mental health research; it is beyond the scope of this PhD to completely resolve this. To try to reduce the impact of 'gatekeeping' on representativeness, we encouraged recruiters to approach any client who does not mind being asked, not just someone they predict will say yes, and not to focus just on their most literate patients, offering verbal completion if literacy is a barrier or if verbal response is preferred. We reinforced to gatekeepers not to specifically approach people who do or don't have a sleep problem, but to ask anyone, and we used direct promotion to potential participants where this was approved, including via posters, Trust mailouts, and service user groups.

3.9. Manualisation of complex interventions and feasibility testing

It is reasonably accepted that feasibility testing should precede larger scale testing. It is common for feasibility studies to mirror the design of later efficacy studies, whilst their main aims are different. The methods selected may focus on examining the feasibility of the intervention, or may also focus on the feasibility of trial methods. Unless a study is acting as

an internal pilot (Lancaster et al., 2004), it is not essential, and sometimes not desirable, for the design to be identical to the randomised controlled trial (RCT) which might follow (Arain et al., 2010). For instance, feasibility studies may contain qualitative data collection which may then be omitted or have a different focus in a later RCT. Chapter 5 (acceptability and adherence of light therapy review) addresses the lack of measurement of feasibility and acceptability outcomes, including adherence or treatment fidelity, even in small scale early-stage trials of light treatment. A similar lack of measurement of feasibility outcomes was also found in reviewed studies of occupational therapy sensory integration interventions (Blanche et al., 2011). Assessment of factors such as 'dose', therapy adherence, or intervention fidelity, necessarily requires more thought with a personalised multi-component intervention, and requires a manual for comparison. However, these complex client centred interventions can be challenging to manualise, and as yet few occupational therapy interventions have been manualised (Nelson and Mathiowetz, 2004).

Blanche et al emphasise the importance of a multi-step manualisation process for complex interventions, including manual refinement through a feasibility study (Blanche et al., 2011). They describe creating a Stage 1 manual, which is then refined to create a Stage 2 manual following a feasibility study. This thesis presents development of a Stage 1 manual and a protocol for a feasibility study which will inform the Stage 2 protocol in the future.

"Adherence" to complex interventions is often assessed via attendance (Burton et al., 2010; Aschbrenner et al., 2016). Whilst in some cases this may be appropriate (for instance, where there are few behavioural requirements between sessions), in other cases researchers find it necessary to separately operationalise 'adherence' beyond attendance at sessions (Nock and Ferriter, 2005). Adherence and attendance have been operationalised separately in CBTi, where there are many behavioural requirements before effects would be expected (Matthews et al., 2012; Cui and Fiske, 2020). Attendance does not capture the full range of behaviours and efforts actually required of therapists and their clients in order to bring about the change processes targeted, and attendance may reflect adherence, but does not necessarily indicate anything more than the ability to tolerate the presence of the therapist (usually not expected to be sufficient to bring about change). In the following review of light therapy intervention acceptability and adherence, and in formulating a protocol to measure adherence and acceptability of L-DART, we hoped to capture 'adherence' beyond mere attendance of therapist sessions. Adherence to behaviour changes following sessions is arguably more

important in these types of interventions, as the main supposed mechanisms of change are behaviours and environmental exposures, rather than coming directly from anything interpersonal occurring in the therapy session itself (see Figure 18 in Chapter 7 for a logic model illustrating this).

Acceptability also entails much more than tolerance of attending sessions. Sekhon et al describe various aspects of acceptability, including attitudes, feelings, values and ethics; coherence (how easy it is to understand the intervention); perceived efficacy and opportunity costs (Sekhon et al., 2018). The review in Chapter 5 and the feasibility study protocol utilised these constructs to guide data extraction, and the qualitative question schedule for intervention study participant interviews. To evaluate all these aspects of acceptability requires additional questions and study procedures that may not be part of a larger scale efficacy study. This underscores that early feasibility work, in some cases, should not identically resemble the larger scale work planned later.

3.10. Outcome measurement in sleep research

Sleep outcome measurement is relevant in two parts of this thesis: selection of outcomes for synthesis in the meta-analysis, and selection of study outcomes to pilot the use of in the feasibility study protocol. The main focus of a feasibility study should usually be around feasibility outcomes such as acceptability, adherence, and intervention fidelity (Arain et al., 2010); however, potential future outcomes should also be piloted (Whitehead et al., 2014). This enables assessment of acceptability of these measures, completion rates, burden and any issues with face validity. Below is a discussion of objective, pseudo-objective and self-reported sleep measurements, followed by a discussion of methodological issues with the measurement of sleep-related outcomes in research.

3.10.1. Measures of sleep

Sleep can be measured objectively via polysomnography, can be interred via proxies such as movement (actigraphy, wearables or bed-sensors), or measured subjectively through self-report.

3.10.1.1. Polysomnography, actigraphy and wearables

The gold standard of sleep measurement is generally considered to be polysomnography (PSG) (Sadeh, 2011). PSG involves measuring brain activity through electroencephalogram (EEG) electrodes worn on the head during sleep, the resulting signals can then be analysed to

identify the sleep stages. PSG is often done in a sleep lab, but can be done at home to detect sleep disordered breathing (Kapur et al., 2000). Even when done at home, however, polysomnography is necessarily somewhat invasive due to the inconvenience and discomfort of applying and wearing the electrodes, which can itself disrupt sleep (Marino et al., 2013). When used to detect parasomnias, EEG is often combined with video.

Movement (and in some protocols, body position) can be used as a proxy to estimate sleep vs wake through actigraphy. Actigraphy uses accelerometers to detect movement. Actigraphy devices are generally worn on the wrist, and sometimes on the body (Razjouyan et al., 2017). Probable sleep is then inferred from reduced movement, and changes in body-position. Actigraphy may use an 'event marker' button, pressed when the person is about to try to sleep, and again on waking, or may be combined with a sleep diary, which can improve accuracy (Vallières and Morin, 2003).

There are an increasing range of consumer wearables which also utilise accelerometery, often offering sleep tracking alongside fitness tracking or step counting. The major differences between actigraphy and consumer wearables concern data availability and cost; actigraphy makes raw data available, but this is not available on demand to the wearer (requiring researcher visits to download data from the devices). A benefit of many consumer wearables is their provision of constant access to data (usually by syncing with a mobile device), allowing continuous feedback (Guillodo et al., 2020). This data, however, comes pre-processed using the proprietary algorithms of that company, thus presenting periods of 'sleep', 'wake' and sometimes inferred sleep stages, rather than raw data such as activity counts per axis. This pre-processing enables devices to export a smaller dataset to the user, conserving battery life and storage, but can make it difficult for researchers to analyse, interpret and compare between studies. Consumer devices were found, in a rigorous systematic review, mostly to over-estimate sleep duration. They also perform worse in patient populations than in healthy controls (Baron et al., 2018). Indeed we are aware of cases where consumer wearables detected little or no sleep in some participants with SzSD (Meyer, 2020). It is implausible that this was completely accurate based on existing knowledge of the effects of prolonged total sleep deprivation, so this likely represents broken or restless sleep being classified as 'wake'.

Poorer performance in clinical groups may be explained by the fact that the main intended use of consumer wearables is by the general public, so the devices and algorithms may be

built with healthy users in mind. As these wearables are intended and marketed as wellbeing aids for the general consumer, their algorithms and associated data displays are focused around the most prevalent problems in the general population, such as short sleep due to lifestyle, and insomnia (Johnson et al., 2018; Chaput et al., 2020), rather than CRSWD or hypersomnia.

A weakness of any attempt to assess sleep via body movement is that people with insomnia may appear to be asleep, but have differences in cortical arousal and sleep structure compared to good sleepers. These differences can be detected by polysomnography, and are experienced by the person (M. Perlis et al., 2010), but are often missed by actigraphy.

Other methods and devices utilise additional data channels, such as heart rate detection, environmental or bed mounted devices, sound detection, and even ultrasound (Perez-Pozuelo et al., 2020), or combine data from different channels, such as wearables with mobile phone use data (Meyer et al., 2018; Martinez et al., 2020) to improve accuracy. This is a rapidly developing field which is not possible to comprehensively summarise here.

3.10.1.2. Self-report measures

Self-report measures include those that are completed for the current time, or a shorter duration, and repeated over a period (such as Ecological Momentary Assessment [EMA]), or retrospective - completed based on memory of that phenomenon over a longer period.

A very common type of 'repeated measure' for sleep is the sleep diary, which is usually meant to be completed every morning (although with paper, there is nothing to prevent participants completing sleep diaries all at once based on recollection prior to meeting the researcher or therapist). Sleep diaries typically request reporting of time into and out of bed, sleep onset and offset time, other factors, such as awakenings, and sleep quality, and can cover factors such as alcohol or caffeine use (Carney et al., 2012).

EMA of sleep has been undertaken using mobile apps (Staples et al., 2017; Meyer et al., 2018) or wearable research devices (Mulligan et al., 2016) programmed to administer a short measure, or collection of questions at intervals, reducing recall bias (Shiffman et al., 2008) and collecting repeated measures or 'time series' data.

Retrospective measures include taking a sleep history via interview, as would often be done in clinical practice, and the vast range of standardised self-reported sleep measures. These

will typically ask questions relating to a preceding period of days or weeks, asking either about self-reported objective sleep (sleep duration, interruptions, timing), or self-evaluation of sleep (satisfactions with sleep, sleep quality), or both. Some may act as a general barometer of sleep, such as the PROMIS-SD (Yu et al., 2011). Some screen for particular sleep disorders, as does the STOP-Bang (F. Chung et al., 2018) and the MOS Sleep Scale (Hays et al., 2005). Others combine self-evaluation of sleep with more descriptive self-reported objective items, such as the Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989).

3.10.2. Sleep Parameters

Using measures of sleep over time, such as a sleep diary or actigraphy, a number of sleep parameters can be calculated, which are commonly used in evaluation of sleep disorders and their treatment (see Table 11).

Table 11: Common sleep parameters, their standard use and abbreviations

Sleep parameter	**Description**
Sleep onset latency (SOL) / sleep latency (SL)	Length of time from getting into bed with the intention to sleep to sleep
Total sleep time (TST)	Total duration of sleep excluding any mid-sleep awakenings (may or may not include naps)
Time in bed (TIB)	Self-explanatory, however, if used to calculate sleep efficiency this should exclude time spent in bed not attempting to sleep (e.g., doing other activities).
Wake after sleep onset (WASO)	Duration off all awakenings within the sleep period.
Sleep efficiency (SE / SE%)	The proportion of time spent attempting to sleep which is spent actually asleep. SE% is targeted in treatment of insomnia. SE% can calculated as follows: *SE% = TST / TIB (× 100)* To be clearer, use 'duration of sleep episode' (DSE), DSE = SOL + TST + WASO + time attempting to sleep after final awakening (TASAFA) (Reed and Sacco, 2016).
Awakenings	Number of times the person awakens. May be based on self-report, PSG, or actigraphy. Awakenings based on PSG and self-report will differ as many awakenings are not remembered.
Sleep continuity	The extent to which sleep is continuous and broken by fewer or shorter awakenings, there are multiple measures of sleep continuity.
Sleep inertia	The extent, duration, or both, of sleepiness and impaired performance after waking / attempt to wake. Related or overlapping with the concept of 'difficulty waking'.
Mid-sleep point	Self-explanatory. May be used to estimate circadian phase.
Acrophase	The average timing of peak activity measured using actigraphy.

Sleep parameter	Description
Amplitude	The difference in activity between most and least active periods, higher amplitude activity rhythm being associated with better sleep and more active awake time. Amplitude of the signal of SCN can also be referred to, which can vary.
Inter-day stability	The regularity of the rhythm of sleep-wake or rest-activity timing between consecutive days.
Intra-daily variability	Amount of varying between active and non-active periods within a day. More intra-daily variability might be due to more broken sleep, or more periods of inactivity or sleep during the day.
L5	Amount of activity during the 5-hour period with the least activity, related to sleep continuity.
M10	Amount of activity during the 10-hour most active period, related to intra-daily variability, amplitude and absolute level of activity.
Sleep quality	Sleep quality is usually based on self-report using a single item to evaluate sleep quality (e.g., Likert scale from very good to very poor). Sometimes the total score on a composite measure such as the Insomnia Severity Index (ISI) or Pittsburgh Sleep Quality Index (PSQI) is described as being a measure of 'sleep quality'. Occasionally 'sleep quality' is used as a global description of 'better' or 'worse' sleep measured by PSG or actigraphy.

3.10.3. Methodological issues in the measurement of sleep outcomes

A key factor which makes sleep outcomes uniquely problematic is that what is often targeted by a sleep intervention, is the state or activity of the brain during a period in which the person (ideally) loses consciousness and the ability to recall. With other mental processes it is sometimes possible to ask the person; however, loss of conscious and amnesia make self-report necessarily limited. Even though periods of wakefulness are remembered, when they are interspersed with complete or partial sleep, people's estimation can be quite inaccurate (Rotenberg et al., 2000).

Polysomnography provides a partial solution; analysis of brain activity can indicate sleep state, although sleep quality or depth may not always be completely represented by this (Gabryelska et al., 2019). Furthermore, polysomnography must be applied ready for the planned sleep period, so it will miss unintentional daytime naps. Set up requires specialist skills, and takes time, so it necessarily cannot capture sleep under totally naturalistic circumstances, as its application alters the pre-sleep routine and affects physical comfort. Levels of cortical arousal during NREM sleep may be detectable through power spectral analysis of EEG, with some differences detectable between good sleepers versus people with insomnia (Svetnik et al., 2017). However, findings are as yet inconsistent and work is

ongoing (Kaplan et al., 2017; Gabryelska et al., 2019). Thus in many cases self-report, despite its limitations, may remain a gold standard measure of sleep quality (Pilcher et al., 1997; Harvey and Tang, 2012). Furthermore, cost and participant burden, create barriers to use of sleep EEG in the community and in applied health research, and studies of CBTi rarely measure sleep via polysomnography nor sleep EEG spectral analysis (Mitchell et al., 2019).

Often of even more interest is detecting improvement in 'sleep-related daytime dysfunction' or 'sleep-related impairment'. Whilst reporting daytime impairment does not suffer from participant amnesia, it should be acknowledged that these functional impact ratings measure impairments, which although associated with sleep disturbance (Buysse et al., 2010), are also associated with other factors (e.g., mood) as well as with sleep disturbance. For instance, fatigue and cognitive difficulties are affected by mood, especially if they are self-rated. So, it may be difficult to attribute daytime functioning issues specifically to sleep disturbance, as functioning may be influenced by the presence of other dysfunctions, themselves related to sleep in complex ways.

Apart from being important to the patient themselves, subjective sleep quality is actually often more influential upon functioning and health than more objectively measured sleep (Pilcher et al., 1997; Harvey and Tang, 2012). The studies in this thesis have therefore prioritised self-reported sleep over measures based on passive monitoring of movement, but retained movement-based passive monitoring as an additional source of data. Passive monitoring has the advantage of being in some respects less burdensome, and of creating a longitudinal record of variations in sleep and patterns over time. This can be useful on an individual level to identify when changes occurred. There are some unique challenges in how to best translate rest-activity rhythms measured via actigraphy into numerical variables for outcome measurement, and the correct interpretation of these variables (Gonçalves et al., 2015). Additional challenges and uncertainties apply to the interpretation of the pre-processed outputs from consumer wearables.

Self-reported sleep measures vary widely in their content and approach to measurement, and can be categorised as those which involve self-evaluation, and those which involve self-reporting of more objective phenomena (or a mixture of both), both have advantages and disadvantages. Self-evaluation involves making a subjective judgement of one's sleep, which determines the score, for instance, rating sleep quality between very good and very poor. Questions or measures involving self-reported objective or pseudo-objective phenomena

require remembering and reporting, for instance, reporting average sleep onset latency and duration in the last week. 'Self-reported objective' outcome measures then assign scores or ratings to these answers according to their own criteria, for instance, assigning more points for shorter time to fall asleep.

Some of my other work, completed alongside this PhD, has shown how one of the most widely used sleep measures, the PSQI, is more sensitive in its scoring of self-reported objective features of classic insomnia (e.g., short sleep, long sleep onset latency) than those of circadian rhythm sleep-wake disorders (daytime sleepiness, mistimed sleep) or hypersomnia (excessive sleep) (Faulkner and Sidey-Gibbons, 2019) (see Appendix 1). Because of this, it appears to perform poorly as a global measure of sleep, in people with SzSD. Where sleep problems are heterogenous in type, as in SzSD, a self-evaluation-based measure may be more appropriate. Broadly phrased sleep self-evaluation questions may be sensitive to a range of problems without having to specify them. For this reason, the feasibility study protocol selected a primary sleep outcome which uses self-evaluation, rather than self-reported objective sleep characteristics.

3.10.4. Secondary outcome measurement in preventative or wellbeing focused interventions

Staff and patients have linked improved sleep with improved functioning and quality of life in qualitative studies (Faulkner and Mairs, 2015; Faulkner and Bee, 2017; Rehman et al., 2017), but identification, operationalisation and measurement of relevant changes may be challenging. There are a number of challenges relevant to sleep interventions, many of which apply equally to other 'preventative', or 'wellbeing' interventions. Firstly, some outcomes of interest might not be expected to improve until much later. It is more challenging and costly to measure outcomes of interventions intended to have more long-term impact than those which offer immediate symptom relief. PPI suggestions were conflicted regarding ideal follow-up length, as balancing the burden of overly long follow-up with the time period over which improvements might be expected was challenging.

Secondly, the course of improvement in self-evaluated constructs such as 'quality of life' or 'life satisfaction' may not always bear a direct relationship to improvement or deterioration in this construct; self-evaluation of quality of life is greatly influenced by expectations (Wan et al., 1997; Adamson et al., 2004). People may describe their health is good 'all considered', or that their quality of life is good 'for someone with their condition'. Increasing

expectations, and changes in one's perceived 'peer group', can have an effect (is the person comparing themselves to their healthy friends or only people they have met who have SzSD?). If a person begins to set new goals and raises their expectations this would be seen as a good thing, but this may initially be reflected in *worse* self-evaluation of quality of life. Equally, there could be the opposite effect, where something about the intervention may reduce people's expectations (although we don't anticipate this), producing the opposite effect.

Staff and patients suggest poor sleep worsens psychotic symptoms (Faulkner and Mairs, 2015; Faulkner and Bee, 2017; Rehman et al., 2017), and scientific and theoretical background supports this link (Waite et al., 2020). A third challenge is that average effect sizes of sleep interventions upon psychotic-like symptoms are present but small in a large non-clinical sample (students) (Freeman et al., 2017). These effects, if present in clinical populations, have not been detectable in small to medium scale RCTs of sleep treatment in psychosis (Freeman et al., 2015; Hwang et al., 2019) at intervention end point or follow-up (24 weeks / 8 weeks, respectively). Although average effects might be small, if sleep is causally involved in the process of relapse, what might be ideal in some ways to measure (although more difficult) is the extent to which improving sleep lessens likelihood, frequency or severity of relapse over future months or years after intervention. Sleep disturbance is cited as a precursor to deterioration in psychosis by patient perception (Eisner et al., 2014; Chiu et al., 2016) and by passive monitoring studies (Mulligan et al., 2016; Henson et al., 2020). Measurement of changes in the frequency of occurrence of relatively infrequent events are challenging however, requiring large sample sizes and long followup periods to detect significant differences (Jacobson et al., 2001). Further to this, relapse in psychosis varies in its definition, and can be difficult to clearly demark from 'stability' or 'wellness' (which may not be the same thing), making detecting 'events' difficult (Gleeson et al., 2010; Eisner et al., 2013).

A fourth challenge is the presence of external confounders such as alterations in medication, living circumstances, and other therapeutic input received. Various confounders may be affected by sleep interventions, such as if medication changes are implemented due to other team members becoming more aware of the person's sleep, or if other interventions are delayed until after the course of sleep therapy, which they may not be in a control group.

3.11. Patient public involvement

When conducting health research, such as that to develop interventions, patient public involvement (PPI) is important, and significant PPI was included within the work completed for this thesis. Relevant aspects of PPI will now be discussed in more detail.

Good PPI can make the difference between research being 'to', 'about' or 'for' patients and the public, and research which is 'with' or 'by' patients and the public (INVOLVE, 2012). The distinction between research *participation* and research *involvement* has practical significance, partly because formal ethical approval is required in order to conduct research, but not to complete PPI (although ethical issues should still be considered). PPI may be completed during the planning of the research project, throughout it, and during dissemination of results. The distinction between PPI and research participation is often clear, but can be ambiguous when the aims of research themselves include gaining patient or public perspectives to inform future research. Sometimes research (Waters et al., 2015; Faulkner and Bee, 2017) and PPI consultation (James Lind Alliance, n.d.) can both achieve the same aim, or they can do so together (see Table 12). People can even take on dual roles as PPI contributors and research participants, such as where a research participant takes on a PPI role within the research team to assist with analysing anonymised data (Boote et al., 2002).

PPI can be consultative, collaborative, or user controlled (Wilson et al., 2015). There is some variation in how consultation and collaboration are defined; some describe the difference as collaboration involving power sharing (Telford et al., 2002), some describe collaboration as involving an ongoing relationship (INVOLVE, 2012). Describing differences in these approaches in terms of a hierarchy of collaboration, with collaborative PPI, and user-controlled research gives 'more empowerment' (Boote et al., 2002), this can imply that 'mere' consultation is inferior or not valuable. Actually, these different models of engagement serve different functions, do not need to be ranked, and often co-exist. I argue that if consultation is meaningful, and the PPI contributors input appropriately influences the research, that consultation also empowers those involved. I emphasise below that good consultation is equally important, fills a different need, and may appeal to different people by making lesser demands of PPI contributors than thoroughly entwined strategies.

Table 12: Aims which should be met by PPI, by research, or by either or both

Research related aim	Met by PPI or research?	Example from this thesis
To evaluate the effectiveness of a treatment	Research	▪ Meta-analysis reports effect of light treatment on sleep in intervention studies
To understand acceptability of a treatment	PPI and / or research	▪ Systematic review of acceptability reported in light therapy studies. ▪ Expert opinion study reports, expert views regarding acceptability of intervention components. ▪ PPI input on intervention and materials during development. ▪ PPI input on idea of developing this type of intervention before project funding
To understand experiences of a problem you intend to research further	PPI and / or research	▪ Service user participant experiences in expert opinion study ▪ PPI contributors' experiences discussed in meetings to inform decisions
To understand utility or appropriateness of an outcome measure for use in research	PPI and / or research	▪ Mixed methods study on use of PSQI with people with SzSD ▪ PPI contributors discussing what outcomes to measure, examining potential measures.
To improve participant info sheet	PPI	▪ PPI comments on drafts

Examples of PPI where PPI contributors collect or analyse data are usually described as collaborative. In these cases PPI can resemble citizen science, which similarly involves the lay public (contributors / volunteers / citizens) in collection and analysis of data (Eitzel et al., 2017). One distinction between citizen science and PPI is that there is something about the PPI contributor's personal experience perspective which uniquely qualifies them to contribute (Grundy, 2018), which is not necessarily the case in citizen science.

Personal experience can not only enable people to contribute views or perspectives, but also (after training) to gather and analyse qualitative data (Grundy et al., 2016), giving a different perspective than that of the researcher without personal experience. In this type of collaborative PPI, contributors might be described as 'lived experience researchers' or 'service user researchers', in recognition of the person having specialist research skills enabling them to complete the role. In this case, collaborative PPI does not resemble citizen science, as the person contributing has relevant personal experience, but is not 'lay', and would not be able to complete the role if they were 'lay'. PPI input in data analysis has been

cited as being perhaps especially relevant to qualitative research, where the perspective of the researcher is acknowledged as shaping the findings (Telford and Faulkner, 2004).

PPI has become ubiquitous in health research over the last 10-20 years (Mathie et al., 2014), and there are many well established arguments for PPI. Pragmatically, researchers assert that involvement of those with relevant personal experience results in better research, more relevant research, and avoids wasting resources (Telford and Faulkner, 2004; Wilson et al., 2015). Morally and politically, they assert variously that patients and the public should be involved in research, as publicly-funded research should be as egalitarian, accountable, and inclusive as possible (Telford et al., 2002; Ives et al., 2013; Madden and Speed, 2017). PPI is now embedded and required within most health and research organisations' policies (Wilson et al., 2015).

Although it is accepted that PPI is valuable, PPI remains underreported (Price et al., 2018), and poorly understood by many (Mathie et al., 2014), and evidence of the worth and impact of PPI is limited (Madden and Speed, 2017). Limited evidence is not evidence of limited impact, of course. Some benefits of PPI which have been empirically examined include improved intelligibility and content of written research materials (Knapp et al., 2011) and changes to organisational or professional attitudes (Crawford et al., 2002). Compared to other aspects of research methods however, there is limited evidence to guide how best to conduct PPI.

There is a lack of clarity regarding how best to evaluate PPI, and some evaluations have not taken into account the complex ways PPI can intertwine with research processes (Wilson et al., 2015). Wilson at al summarise features of those studies which have evaluated PPI, which led to better PPI; they concur however with other authors that there is a lack of evidence and consensus regarding what creates effective PPI (Wilson et al., 2015; Madden and Speed, 2017). Some factors associated with better PPI include: Time to establish relationships, mutual understanding and trust, developing a shared understanding of the purpose of the PPI between researcher(s) and contributor(s), and clear yet flexible descriptions of roles (Wilson et al., 2015).

A thorny issue in the PPI literature is that of 'representativeness'. Many have suggested PPI contributors with the characteristics of the studied population should be involved in order to ensure the relevance of research questions and methods to those intended to benefit from that

research. INVOLVE suggest it is more helpful to think of seeking perspectives than seeking representativeness (INVOLVE, 2012). So PPI contributors bring relevant perspectives, which are likely different from those of the researchers. These can aid reflection and shape the research, but no-one in the team should assume the views of the PPI contributors represent the views of the whole population studied; for this, a larger survey of views would be required.

Representativeness is a valid concern within a research sample and can be approached through stratification, but it must be considered differently ethically in relation to PPI. Seeking representation of underrepresented groups within those fulfilling job roles may require positive discrimination (Noon, 2010). To effectively and ethically implement 'selection criteria' would require discrimination on the basis of race, gender or other protected characteristics (probably to turn away non-minority applicants, but this is discrimination nevertheless). I concluded it was inappropriate for a PhD researcher seeking PPI contributors to undertake positive discrimination, and that if it should be implemented, should involve in-depth discussion with human resources departments. Ongoing involvement roles in this project were therefore filled on a volunteer basis, people who came forward were involved if they had relevant experience (which for this project was specified in relation to experience of psychosis and of sleep problems). To get more diverse views, more views were sought from other existing groups.

Related to 'representativeness', is the idea of avoiding 'professionalisation' of PPI contributors. Those who caution against 'professionalisation' suggest that through learning research skills or gaining topic specific knowledge, lay contributors become less representative, and less 'lay' (Boote et al., 2002). It has even been suggested that PPI contributors *should not* be involved in data collection and analysis, and that researchers should *avoid* providing training in research, suggesting if contributors see PPI as a route to a research career they will have "incentive […] to become more expert, which compromises the integrity of PPI" (p184, Ives et al., 2013). If we are willing to actively discriminate against PPI contributors on the basis of their research knowledge, we should be comfortable describing PPI contributors as a commodity that can be 'used up' and should be discarded once no longer 'lay'. This runs counter to the idea of PPI as valuing and empowering patients and the public, and would make ongoing, embedded, PPI impossible. I dispute that providing knowledge and training to people with personal experience destroys the value of

their personal experience perspectives. There may arise a need to seek 'research naïve' views on certain questions then, such as how something might be perceived by someone not familiar with the research methods, but this does not diminish the role of the trained or experienced PPI contributor / lived experience researcher, which is much more than to give a research naïve perspective.

Having advocated for the value of in-depth involvement, it is also undesirable to suggest *only those* with the capacity or desire to devote many hours to collaboration in research processes should be involved, as this would exclude the voices of many who are either not that interested in research methods, don't have time, or don't have the capacity to acquire certain skills for whatever reason. Thus, consultative PPI should not be devalued and described as 'lesser', for someone who does not want to collaborate in an in-depth way in research data analysis, being consulted on research topic prioritisation for instance. Insisting on more 'empowerment' (responsibility) may be unwelcome and unhelpful to some, PPI roles should be flexible and responsive to the individuals involved (INVOLVE, 2012).

3.11.1. PPI during initial design of the research programme (pre-award)

This programme of research was prompted by findings from my previous qualitative research with schizophrenia spectrum patients, as well as experience with and feedback from service users during my clinical work. In both cases patients highlighted their desire for non-pharmacological help to improve their sleep. A small Research Design Service bursary was secured to further involve service users in the early design of these studies.

Ten service users and carers contributed, over three discussion groups, to discuss the research aims and overall design of the research programme. People were recruited through Trust patient groups, voluntary sector organisations, the INVOLVE website, and Twitter. Those involved in previous work who had consented to future contact were also approached. Contributors gave feedback on a range of areas including the aims and scope of the proposed plan, the overall methods, and the lay summary included in the application.

3.11.2. Overview of PPI during this PhD

The PPI during the PhD included three elements, with differing levels of entwinement and commitment required from those involved:

1) One-off meetings and written communications with individuals and groups (consultation)
2) Ongoing involvement from a core group of PPI contributors (consultation and involvement in the conduct of the research)
3) Lived experience researcher undertaking qualitative data collection and analysis (involved in the conduct of the research)

3.11.2.3. One-off meetings and communications

This element was not included in the initial plan, which had been to recruit one longstanding involvement group and for this to be the source of all PPI input. Through experience and discussions with service users, this was revised to allow both the ongoing group and additional one-off involvement interactions with a more informal approach. This allowed, for instance, visiting already existing groups to consult, and involvement of contributors who were not interested in ongoing involvement work, allowing both broad and deep involvement from different sources.

3.11.2.4. Ongoing involvement from a core group of PPI contributors

We advertised and originally sought to recruit 3-4 contributors (for the advert used to see Appendix 1), 4 individuals expressed interest and spoke or met with myself on one or more occasions, but we were only able to retain 2 longstanding regular contributors. We also undertook wider consultation with others outside this core group at intervals, on a more one-off basis requiring less commitment, and enabling direct access to more diverse views.

To develop relationships and mutual trust we planned and conducted meetings with regular contributors throughout the research process for updates and staying in touch, not just at the key points where most PPI was planned. Although the intention of this was mostly around maintaining relationships, actually once meeting there were often areas where PPI contributors' comments helped the researcher reflect differently on the current work. We tried to achieve shared understanding of roles by writing a role description included within the initial advert (see Appendix 2). We did not write a 'person specification', nor did we interview, as we felt this would deter potential contributors.

3.11.2.5. Lived experience researcher

In the feasibility study protocol included in this thesis, we have included a substantial role in data collection and analysis for a researcher with personal experience, who also through his

role has contact with a wider group of service users, so may bring personal and second-hand personal experience perspectives.

3.11.2.6. Focus of PPI across studies in this PhD

Patient involvement during this PhD has focused on the expert opinion study and feasibility testing of the intervention, rather than the systematic reviews. One off consultations were undertaken during the study design and refinement for both of these studies. Ongoing contributors were involved in decisions between rounds of the mixed methods expert opinion study, interpreting data and construction of questions for the next round. These PPI contributors were consulted during decisions regarding how to utilise the findings of the expert opinion study, to create a coherent intervention, and in reviewing intervention materials, including the educational content and worksheets, and their opinions regarding outcome measure selection. During the expert opinion study and intervention development, meetings with the regular PPI contributors were equally as frequent as those with supervisors (on average every 1.5 months), and PPI contributors were involved in dissemination by commenting on presentations and by co-authoring of the expert opinion study paper. Further details of PPI in particular studies of this thesis can be found in the sections preceding those papers and in the papers themselves.

Chapter 4: Study A - Meta-analysis on light therapies to improve sleep

This chapter presents a meta-analysis of controlled studies of interventions altering light exposure to improve sleep in groups with high rates of circadian dysregulation. Its purpose within this thesis was to inform inclusion of light-based intervention components within the multi-component sleep intervention in development. As such, the aims were:

1. To examine the effect of interventions altering light exposure patterns, on sleep quality, duration, and timing, in populations with circadian dysregulation.
2. To examine factors associated with effectiveness.

The rationale for the broad methodological choices made was presented in Chapter 3. Below is presented a rationale for conducting this specific meta-analysis within this programme of research, signposting to additional methods details in the published paper and its supplements (Appendix 3 to this thesis).

4.1. Rationale for this topic focus

This systematic review focuses on interventions altering light exposure in populations which commonly experience circadian dysregulation or sleep-wake timing issues. A review examining light was chosen for the following reasons:

- A review of behavioural interventions more broadly was considered, but CBTi in populations with psychiatric and other comorbidities has been recently and adequately reviewed (Geiger-Brown et al., 2015; van Straten et al., 2018).
- Scoping searches showed that a review including 'behavioural sleep interventions' more broadly defined would predominantly include CBTi studies, and so would add little new knowledge to the field.
- Another possible topic, occupational therapy interventions for sleep, was considered but not pursued due to a restricted evidence base; although increasing, this literature remains too sparse to facilitate useful synthesis.
- It was unclear to what extent a review summarising the effect of a collection of complex interventions could inform the development of a novel complex intervention, as there was

unlikely to be enough evidence facilitate analysis of the potential contribution of different components.

Instead, one core component, light therapy, was prioritised. There were no reviews of the effects of interventions altering light exposure on sleep or circadian disturbance in samples with psychiatric illnesses. This review would therefore be informative regarding whether our provisional intention to include a light-exposure based element in the intervention was well founded.

4.2. Summary of additional methods in supplementary files

The supplement to the published paper includes additional details of the methods. Please find below a more concise summary of this content.

- Supplement S1: Changes from protocol:

Reports minor changes to outcomes, meta-regressions we were unable to complete, sensitivity analysis modifications, and the decision to report adherence, attrition, and acceptability in a separate paper (Study B).

- Supplement S2: Example search, MEDLINE database, Ovid interface
- Table S3: Full detail inclusion criteria with common synonyms
- Table S4: Outcomes and their relevance in included populations:

Rationales are given for synthesis of outcomes between populations, or not, e.g., for the outcome 'sleep timing' in ASWPD, *phase delay* is desired, whilst *phase advance* is desired in DSWPD, thus synthesis of these without consideration of the desired direction of change would be illogical.

- Table S5: Constructs, hierarchy of outcomes, and considerations in synthesis:

There are multiple relevant but distinct sleep outcomes presented in studies of light treatment (e.g., total sleep time, sleep latency, sleep quality). It is possible to amalgamate all outcomes into 'better' or 'worse' sleep, as has been done by other authors (van Maanen et al., 2016); however, we elected to present outcomes relating to distinct constructs separately. This decision was made on the theoretical basis that different effects on different outcomes might be expected, and because the relevance of change on these different outcomes to different groups and individuals varies (for some longer sleep is desirable, for others sleep duration is adequate and does not need extending, but sleep timing is unsatisfactory). Supplement Table

S5 gives justification for the constructs of interest, and the hierarchy of outcomes measuring these constructs (determining which outcome was used when both were available).

4.3. Paper 2, study A: "Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: A systematic review and meta-analysis"

Paper number: 2

Page of thesis: 107

This paper has been published in Sleep Medicine Reviews.

Faulkner, S. M., Bee, P. E., Meyer, N., Dijk, D. J. and Drake, R. J. (2019) 'Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: A systematic review and meta-analysis.' Sleep Medicine Reviews, 46 pp. 108–123.

Supplements to this paper are in Appendix 3 of this thesis.

Author contributions:
The review protocol was designed by SF with supervisory input from DJD, PB & RD. Search, screening, data extraction and data analysis were conducted by SF. Risk of bias assessment was conducted by SF and NM. The manuscript was drafted by SF. DJD, PB, RD and NM gave input regarding structure, content, and style.

Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: a systematic review and meta-analysis

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Conflicts of interest:

The authors have no conflicts of interest to declare.

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Summary

Circadian dysregulation causes sleep disturbance and impacts quality of life and functioning. Some interventions target circadian entrainment through modifying light exposure, but existing reviews of light interventions for sleep improvement include few studies in psychiatric populations. We examined effect of light interventions on sleep quality, duration and timing, and effect moderators. We included controlled studies in intrinsic circadian rhythm disorders (such as advanced or delayed sleep) and in neuropsychiatric disorders with assumed high prevalence of circadian dysregulation (such as affective and psychotic disorders). Articles were identified through database searching: 40 studies reporting 49 relevant intervention comparisons met inclusion criteria. Meta-analysis showed improvements in sleep continuity (ES=-0.23, p=0.000), self-reported sleep disturbance (ES=-0.32, p=0.014), and advancement of delayed sleep timing (ES=-0.34, p=0.010). Although the small number of studies limited meta-regression, evening light avoidance was associated with greater increase in total sleep time. Effects of light on sleep and circadian outcomes have received limited attention in studies in psychiatric disorders, but results were promising in these groups. These findings invite further refinement and testing of light interventions to improve sleep in psychiatric disorders, with improved assessment and specification of problems, and the development and implementation of light schedule interventions for delayed sleep.

Keywords

Bright light treatment; dark treatment; dawn simulation; circadian rhythm sleep disorders; insomnia; co-morbid insomnia; mental illness; dementia; delayed sleep phase disorder; affective disorders; psychosis.

Glossary

Suprachiasmatic nucleus (SCN): the brain's internal master clock, cells in the SCN oscillate with a period of approximately 24hr, and are entrained to external time by environmental cues

Zeitgeber: from German "time-giver"; environmental cues which entrain circadian rhythms; light is the strongest zeitgeber for entraining circadian rhythms

Introduction

Circadian rhythms exert a strong influence on sleep propensity, alertness and performance, modulating these each day (1). Circadian rhythms are entrained to the external day-night cycle by environmental cues, of which the light-dark cycle is by far the strongest influence (2). When circadian rhythms are well entrained, the suprachiasmatic nucleus (SCN) oscillates in time with the external day-night cycle, and all other bodily tissues and organs are synchronised by the SCN's rhythmic signal. Circadian dysregulation has been connected to various negative physical and mental health consequences, and of course, to poor sleep (3). As circadian rhythms are known to be entrained by light exposure, interventions that modify light exposure patterns to reduce sleep disturbance have strong theoretical support. Light and darkness also influence sleep and arousal processes more acutely, through 'direct', non-circadian pathways, which may contribute toward therapeutic effects (4).

In circadian rhythm sleep disorders (CRSDs) such as delayed sleep phase disorder (DSPD) or advanced sleep phase disorder (ASPD), interventions may aim to normalise timing of sleep. Interventions may equally aim to improve sleep quality or duration by improving the synchronisation between circadian phase and sleep-wake timing where these are out of phase (5). Interventions may aim to increase the amplitude of the SCN rhythm, which can become reduced in older age and in neurodegenerative disorders (6). Symptoms of circadian dysregulation also frequently occur in the context of neuropsychiatric disorders; for instance irregular sleep wake disorder (ISWD) is common in dementia (7). 'Free-running' rhythms (non 24hr sleep wake disorder) most commonly occur due to eye or optic nerve damage. Non 24hr rhythms can be observed in time-cue free environments in sighted participants (8), but occur under free-living conditions in sighted people with schizophrenia (9) and rapid-cycling bipolar disorder (10).

Circadian dysregulation impacts negatively on quality of life, on occupational and social engagement (11–13), and on cognitive functioning (14). Although causality is challenging to investigate, evidence suggests circadian dysregulation and poor sleep exacerbate psychiatric symptoms (15–17). Circadian dysregulation very often precedes other symptoms, and some evidence suggests a causal role in development of illness (18,19). There is much hope that treating circadian dysregulation and reducing sleep disturbance might improve functioning and reduce suffering in a range of conditions. Indeed, some studies which reduced insomnia via psychological intervention, reported a reduction in psychiatric symptoms (20–22); these effects have been shown to be mediated by reductions in sleep disturbance (20).

Historically sleep problems have been neglected in groups with neuropsychiatric disorders due to diagnostic overshadowing (23), and assumptions that sleep problems are purely secondary to psychiatric symptoms. Unfortunately sleep problems often persist even if affective or psychotic symptoms are well-controlled (24,25). There is increasing recognition that sleep problems require independent attention irrespective of co-morbid conditions. In accordance with this the 'primary' / 'secondary' insomnia distinction was removed from DSM-5 and ICSD-3 (26). Circadian dysregulation disorder definitions have not been similarly modified; the ICSD-3 stipulates for diagnosis of CRSD the sleep disturbance must not be "better explained" by another medical, neurologic or mental disorder. Further, it contains no category for CRSD secondary to another disorder (27). Studies which examine circadian dysregulation in samples with neuropsychiatric disorders find high prevalence of patterns similar to ASPD, DSPD, ISWD and non-24hr (6,9,24), but usually CRSD terminology is not applied.

Previous meta-analyses of studies of light treatment for sleep improvement in CRSD (without co-morbidity) and in dementia were inconclusive, and limited by small participant and trial numbers (28,29). Despite the high levels of circadian dysregulation symptoms in populations

with severe mental illness, no meta-analysis has yet included studies in these groups. In the meta-analysis by Van Maanen et al (2016) (30) broad inclusion criteria were used, including any reported or diagnosed sleep disorder or complaint. The authors identified studies in groups as diverse as renal patients, brain injury, and mid-winter insomnia in the sub-arctic, yet no studies targeting sleep in samples with co-morbid mental illness which met inclusion criteria were found.

Evidence syntheses of the effects of light in seasonal and non-seasonal mood disorders have shown effects on improvement in mood (31,32), but the effects on sleep are less well understood.

This review presents a synthesis of the effects of light schedule interventions on circadian rest-activity patterns and sleep, across dementia, CRSD, and psychotic, affective and personality disorders. Acknowledging the lack of measurement of circadian dysregulation and application of CRSD terminology in existing research in psychiatric disorders, our inclusion criteria are operationalised specifically to ensure studies in these groups are not excluded.

Our aims are: 1) To examine the effect of interventions altering light exposure patterns on sleep and rest-activity parameters, in populations diagnosed with, or at risk of, circadian dysregulation. 2) To examine predictors of effect size.

Methods

The protocol for this review was prospectively published on Prospero, and is available at: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017072387. For changes from protocol see Supplement S1.

Search, screening and inclusion

Systematic searches were performed using keywords and subject headings in MEDLINE, Embase, PsycInfo, and AMED (via Ovid), and CINAHL (via EBSCO). Searches were run in August 2017, from database inception. Truncation (*), wildcards, and the (adj) adjacent operator were used to capture terminology variants.

Searches were limited to human studies, and a trial filter was applied; 10% of articles excluded by the trial filter were screened to confirm no relevant studies were being filtered. Database searches were supplemented by reference checking relevant reviews and contacting key authors in the field. Only peer-reviewed publications of primary research were included. For an example search strategy see Supplement S2.

We included populations with intrinsic CRSDs, and those with other conditions strongly associated with circadian dysregulation. We identified and specified a list of conditions a priori based on the background literature; amongst them were dementia, psychotic disorders and affective disorders (see Tables 1 & S3).

During screening we encountered studies where participants were not formally diagnosed with DSPD or ASPD, but where inclusion criteria specified suggested that most participants had DSPD or ASPD. After discussion we included these studies and planned a sensitivity analysis on the effect of their removal. We excluded groups at-risk of (not currently presenting with) mental disorders, 'extrinsic' CRSDs, specifically jet-lag disorder and shift work disorder, and problems occurring due to very unusual light environments (e.g. space flight, arctic winter).

Table 13: Inclusion criteria

Study type	Intervention study (not observational and correlational studies) Exclude: case studies (<5 people)
Population	Intrinsic CRSD (DSPD, ASPD, ISWD or Non-24hr) OR Psychiatric or neurodegenerative disease with high levels of circadian dysregulation: dementia, psychotic disorders, personality disorder, affective disorders (bi-polar or unipolar, seasonal or non-seasonal) AND Over 70% of the sample meet the above criteria, or subgroups reported Adults or adolescents (over 13)
Intervention	Interventions altering light exposure (amount, timing, or spectral qualities) as a core (not optional) component, with primary or secondary aim of improving sleep. Examples: light boxes, light visors, dark treatment, amber glasses, increasing daylight exposure, increasing or decreasing indoor lighting.
Comparison	Control group without the light/dark intervention
Outcome	Self-reported, clinician reported, or objectively measured sleep or rest-activity variables (Sleep onset latency, maintenance, quality, depth, timing, duration, rest-activity patterns)

*CRSD=circadian rhythm sleep disorder, DSPD=delayed sleep phase disorder, ASPD= advanced sleep phase disorder, ISWD irregular sleep wake disorder, Non-24hr=non-24hr sleep wake phase disorder, SCN=suprachiasmatic nucleus.

Results were de-duplicated and screened; one third of results were independently screened by another researcher. Authors of relevant conference abstracts were contacted to seek

publications. Potentially relevant studies were assessed for eligibility using the full text. All those where there was ambiguity were assessed by another researcher. An additional 10% of randomly selected full texts were independently assessed by another researcher to check consistency in application of the inclusion criteria. After familiarisation we found inconsistency only between categories "include" / "unsure" and "exclude" / "unsure" -- not between "include / "exclude", therefore we were satisfied that all relevant studies were being identified. Uncertainty was resolved through discussion, and consulting a third researcher where needed. Where multiple papers reported on the same study all were included and data were combined.

Data Extraction

Population, setting, intervention and outcomes data were extracted and cross-checked by another researcher. Mean, standard deviation (SD) and sample size were extracted, or where required calculated (from confidence intervals (CIs) and standard errors (SEs)), or requested from authors. Where outcome measures were scaled in the opposite direction (e.g. higher = better, higher = worse) effect sizes were reversed. Clock times (hours, minutes) were converted to decimal hours or total minutes.

Risk of Bias assessment

Methodological quality in controlled studies was appraised during data-extraction using the Cochrane risk of bias tool. Participant blinding is a pervasive difficulty in light/dark treatment (interventions are by nature perceptible) and this affected overall risk of bias assessments across studies. It was therefore decided to use gradations of 'low / medium / high', to capture more information than 'low / high' quality ratings. Studies were

independently assessed by a second researcher, discrepancies were resolved through discussion.

Analysis

There are various sleep outcomes, many of which are dissimilar, and therefore not amenable to pooling. The relevance of outcomes in each group was based upon the known complaints of that population and relevance was noted a-priori to guide synthesis (see Table S4).

To reduce risk of bias in outcome extraction, a hierarchy of outcome measures for each construct was determined a priori, in case multiple measures were reported (e.g. TST actigraphy and self-report), so the preferred measure for that construct was pre-determined (see Table S5).

Where studies included multiple relevant comparisons (for instance morning light / afternoon light / placebo) each was included individually, as differences in effects depending on intervention features were of interest. To avoid double counting the control group was split accordingly (33).

Meta-analyses and meta-regressions were run in Stata 14. Standardised mean differences (SMDs) were used due to inclusion of multiple outcome measures, the random effects model was used to allow for heterogeneity (34). Meta-regression covariates were planned in advance. To avoid applying meta-regression with too few trials (35) we set a lower limit of 10 comparisons. Covariates were tabulated and visually inspected for collinearity and confounding to avoid misinterpretation of associations (e.g. if only studies in certain diagnoses used afternoon light, population effects and intervention effects cannot be separated). We did not run meta-regressions for participant characteristics for which we had only a study mean, such as age or mean baseline sleep quality, because without individual patient data results may be misleading (35).

The following sensitivity analyses were run for each meta-analysis:

1) Removing and examining any striking outliers
2) Removing studies at high risk of bias
3) Removing studies with neuropsychiatric diagnosis but no sleep inclusion criteria.
4) Removing studies where diagnosis was assumed not formally assessed

Sub-group analyses and differences in outcomes between populations

It was our assumption on embarking on this review that there is some commonality in mechanisms of sleep disturbance between groups and therefore that there may be commonality in intervention effects. Research in animal models and from genetic studies suggests the mechanisms causing circadian dysregulation may be similar across diagnostic groups (36,37). Although our primary aim was to examine effects across diagnostic groups, we have examined sub-group differences (38). We examined differences first using overall tests for heterogeneity between sub-groups for each meta-analysis. We then examined sub-grouped forest plots and for those where CIs did not overlap (33) we examined differences statistically using the method described by Bornstein et al (39).

Results

Search results

3,319 unique results were returned, resulting in 320 potentially relevant studies for which full-text was retrieved and assessed for eligibility. 48 articles reporting on 40 studies met inclusion criteria.

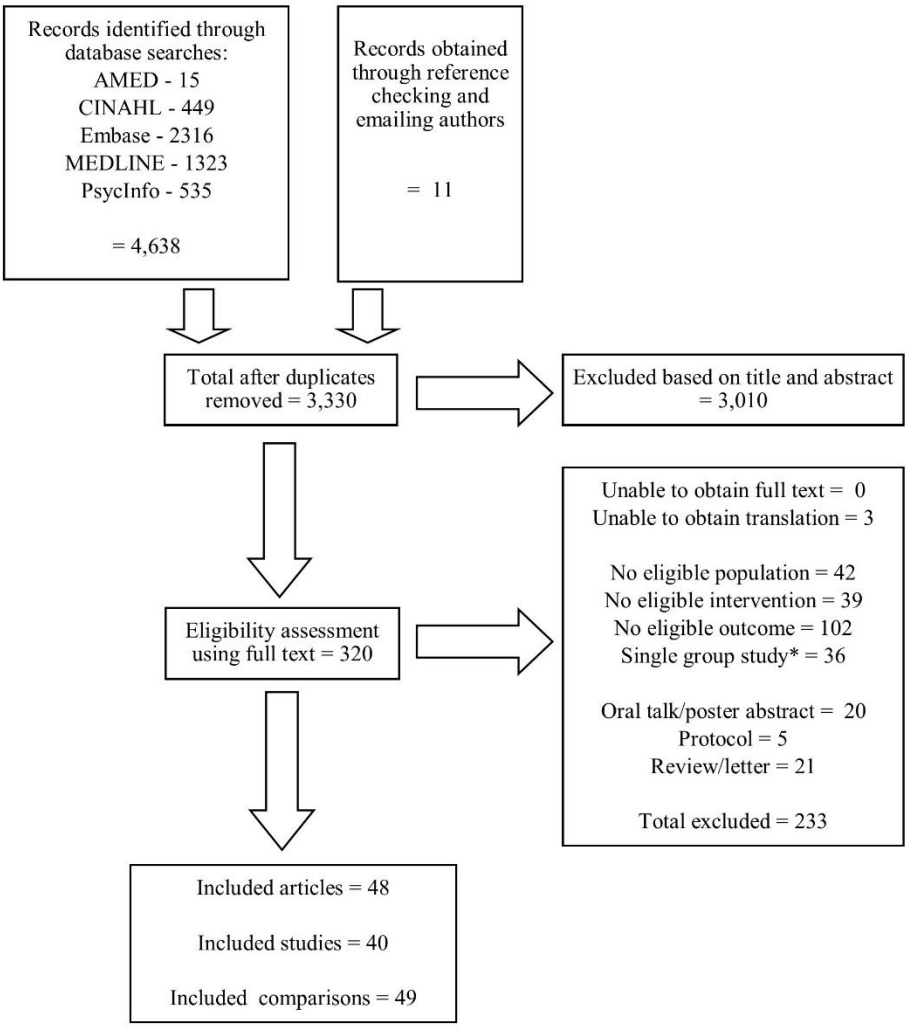

Figure **7** shows the flow of articles through search and screening.

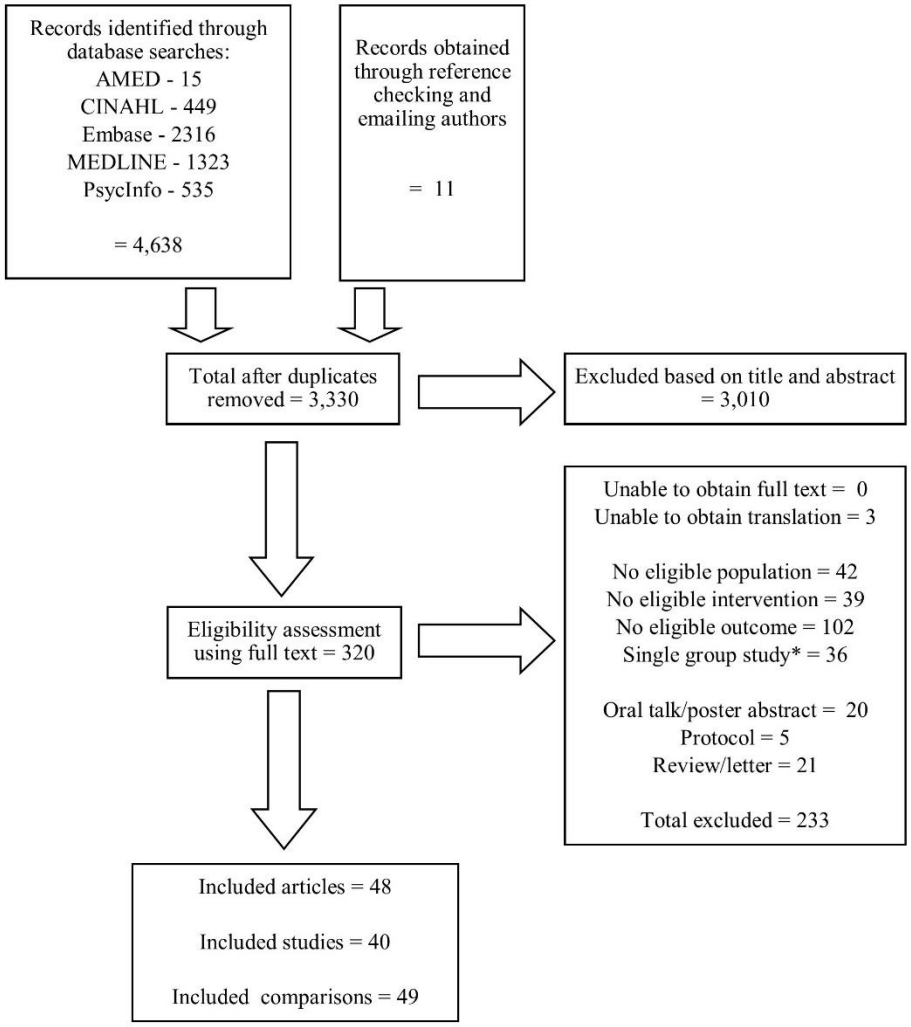

Figure 7: PRISMA flow diagram for search, screening and inclusion

*Includes controlled trials with the wrong comparison, e.g. both groups gave the same light exposure and modified another component.

Study Characteristics

There were 40 controlled studies reporting on 49 relevant intervention comparisons (see Table 14). Studies in non-dementia populations were conducted in participant's own homes, with the exception of five inpatient studies (40–44). Studies in dementia were based in institutions, with the exception of four in private residences (45–48). The most commonly used intervention was the light box, followed by bright indoor light, outdoor light, or light from a combination of sources. Light visors, dawn simulation, and light avoidance were

infrequently used. Many interventions were single component. The most common additional components were sleep schedule recommendations and sleep hygiene advice. Some studies combined morning light exposure and evening light avoidance. A small minority of studies combined light exposure with exogenous melatonin (49,50), cognitive behavioural therapy for insomnia (CBT-i) (40,51) or wake therapy (44). Many interventions did not describe including any maintenance advice or treatment.

Population groupings were decided after data-extraction and before analysis. The two studies in seasonal affective disorder (SAD) both included hypersomnia, hence the category "SAD with hypersomnia". Certain outcomes and measurement methods were more common within certain diagnostic groups, for instance actigraphy was most commonly used in dementia (Table S6 summarises outcomes and measurement methods per study).

Risk of bias assessment

Many studies attempted participant blinding, but difficulties were understandably common. To counter this some studies assessed the participants' intervention expectations to determine whether this accounted for outcomes. Rates of attrition were highly variable. Allocation methods were sometimes unclearly reported (see Table S7).

Publication bias

Funnels plots were generated for each analysis. None appeared skewed (52) and statistical testing suggested no publication bias (53). However, due to the small number of studies and limited variation in trial size for many analyses, it is difficult to accurately interpret these plots and tests.

Table 14: Characteristics of included studies, grouped by diagnosis

Author(s) & Year	**N=**	**Design**	**Population** (+sleep disturbance)	**Age** mean (SD) / (range)	**Setting**	**Country**	**Intervention(s)** *** dark highlight text = light reduction component**	**Light timing selection**	**Intensity**	**Spectral properties / light source**	**Length (days)**	**Control condition**
Campbell et al 1993 (54)	16	controlled	ASPD	70.4 (4.85)	at home	UK	• evening light box • watch TV during	via bio-marker	4000lux	white	12	dim light box
Figueiro et al 2015 (55)	8	crossover	ASPD	70 (4.5)	at home	USA	• blue flashing light mask in early sleep	via bio-marker	not stated	blue LEDs 480nm	7	red flashing light mask 640 nm
Lack et al 2005 (56)	25	controlled	ASPD	51.2 (36-68)	outpatient	Australia	• evening light box, 4hrs • whilst watching TV in the lab	set time	2,500lux	white	2	<100lux red light
Palmer et al 2003 (57)	47	controlled	ASPD	(60-86)	at home	USA	• evening light box 2.5hrs	via sleep-timing	265lux	white fluorescent	28	dim light box (2lux)
Ando et al 1999 (58)	10	controlled	DSPD	33.5 (10.7)	at home	USA	• dawn simulation light mask	via sleep-timing	500lux	not stated	12	0.1lux
Cole et al 2002 (59)	54	RCT	DSPD	25 (6)	at home	USA	• bright-dawn simulation mask • advance sleep timing • avoid naps • avoid evening light	via sleep-timing	2700lux	white	26	dim red light mask
Geerdink et al 2016 (60)	39	RCT, quasi-random	DSPD	22.0 (6.3)	at home	Netherlands	• morning blue light pulses • advance sleep timing • avoid light at night	via sleep-timing	2306 melanopic lux	blue (460nm, 80nm)	9	amber light, avoid light at night, advance sleep schedule
Gradisar et al 2011 (51)	40	RCT	DSPD	14.6 (1.0)	at home / outpatient	Australia	• light box on awakening • advance wake time 30min day • CBT-i	via sleep-timing	1000lux	broad-spectrum / outdoors	56	wait list control
Lack et al 2007 (61)	18	RCT	DSPD	28.2 (10.6)	at home	Australia	• morning blue light box	via sleep-timing	65 µW/ cm2	470nm (blue)	7	unclear if no treatment or red light
Lack et al 2007b (62)	16	RCT	DSPD	29 (18-56)	at home	Australia	• light box on awakening • advance wake time	via sleep-timing	2500lux	incandescent tungsten	7	dim light
Langevin et al 2014 (63)	10	RCT	DSPD	16.3 (15-18)	at home	Canada	• morning blue light via spectacle mounted LEDs • eliminate light after 9pm	via sleep-timing	2000lux	400< X < 750nm	22	orange light of same brightness
Saxvig et al 2014 (49) (64)	40	RCT	DSPD	20.7 (3.1)	at home	Norway	• morning light box • placebo melatonin • advance rise time 1hr each day	via sleep-timing	10,000lux	not stated	14	morning dim red light, placebo melatonin, advance rise time

Author(s) & Year	**N=**	**Design**	**Population** (+sleep disturbance)	**Age** mean (SD) / (range)	**Setting**	**Country**	**Intervention(s)** *** dark highlight text = light reduction component**	**Light timing selection**	**Intensity**	**Spectral properties / light source**	**Length (days)**	**Control condition**
							• morning light box • melatonin • advance rise time 1hr each day	via sleep-timing	10,000lux	not stated		
							• morning light box • melatonin • advance rise time (re-randomised for 2nd phase)	via sleep-timing	10,000lux	not stated		no treatment
Avery et al 1998 (58)	11	RCT	SAD	33.0 (10.0)	at home	USA	• dawn simulation lamp • darken bedroom, block out light, turn off nightlights • avoid daylight before 8am • avoid direct sunlight in the daytime (sunglasses)	set time	250lux	white	7	red dawn, 1.5hr, 2lux
Avery et al 2002 (65)	50	controlled	SAD	37.3 (6.1)	at home	USA	• dawn simulation lamp • wake at 6:00am • darken bedroom avoid morning light before 8am	set time	250lux	white	7	dim red dawn
Bogen et al 2016 (66)(43)	57	RCT	Depression	15.4 (1.6)	inpatient	Germany	• morning light box	via MEQ	10,000lux	white	14	dim light (100–150lux)
Esaki et al 2017 (67)	20	RCT	Depression (+sleep)	41.6 (7.3)	at home	Japan	• amber glasses 8pm til bed, remove only once in the dark	set time	n/a	n/a	14	clear glasses
Kragh et al 2017 (44)(68)	64	RCT	Depression	38.4 (12)	inpatient	Denmark	• morning light box • wake therapy (total sleep deprivation), in a lighted area	via MEQ	10000lux	white	63	TAU (medication, exercise, talking therapies)
Lieverse et al 2011 (69)	89	RCT	Depression	69 (6.6)	at home	Netherlands	• morning light box • adherence monitoring via wearable device	preference	7500lux	pale blue	21	red light (50lux)
McEnany et al 2005 (70)	29	RCT	Depression	37.5 (27-46) 55.9 (45-76)	at home	USA	• light visor 1hr on awakening	via sleep-timing	2500lux	krypton incandescent	26	light blocking glasses for 1hr before bed
Barbini et al 2005 (41)	32	controlled	Other MH – bipolar mania	38.2 (8.8)	inpatient	Italy	• enforced darkness 6pm-8am • quiet - noise deadened • staff supervision	set time	n/a	n/a	3	TAU, drug therapy alone
Bromundt et al 2013 (71)	14	crossover	Other MH – borderline personality disorder	30.1 (6.0)	at home	Switzerland	• morning light box • rising by 9am	preference	8000lux	not stated	21	TAU, waitlist control
Henriksen et al 2016 (42)	19	RCT	Other MH – bipolar mania	36.0 (17.3)	inpatient	Norway	• amber glasses 6pm till bed, and before 8am	set time	n/a	n/a	7	clear glasses

Author(s) & Year	**N=**	**Design**	**Population** (+sleep disturbance)	**Age** mean (SD) / (range)	**Setting**	**Country**	**Intervention(s)** *** dark highlight text = light reduction component**	**Light timing selection**	**Intensity**	**Spectral properties / light source**	**Length (days)**	**Control condition**
Sheaves et al 2018 (40) (72)	40	RCT	Other MH – mixed acute inpatients (+sleep)	40 (13)	inpatient	UK	• morning light box / natural light • adapted CBT-i • dark in evening and at night • activity tracking wearable for motivation and feedback	via MEQ	10,000lux / outdoors	light box / outdoor light	14	TAU
Sit et al 2017 (73)	46	RCT	Other MH – bipolar depression	44.7 (14.5)	at home	USA	• mid-day light box; titrated from 15min to 60min per day • adherence monitoring via machine	set time	7,000lux	4,000K white fluorescent	42	red light box(50lux)
Ancoli-Israel et al 2002 (74)	34	RCT	Dementia	85.7 (7.3)	nursing home	USA	• am light box • staff supervision	set time	2,500lux	cool-white	18	dim light, less than 50lux, red light
							• pm light box • staff supervision	set time	2,500lux	cool-white		
Burns et al 2009 (75)(76)	46	RCT	Dementia (+sleep)	83.6 (7.9)	nursing homes	UK	• am light box • staff supervision	set time	10000lux	full spectrum	14	100lux standard fluorescent light
Connell et al 2007 (77)	20	RCT	Dementia	79.7 (8.3)	nursing home	USA	• daytime natural light • group outdoor activity: social, horticultural, creative, singing • facilitated by nurse	convenience	natural light	outdoor light	14	indoors, similar activities

Author(s) & Year	N=	Design	Population (+sleep disturbance)	Age mean (SD) / (range)	Setting	Country	Intervention(s) • * dark highlight text = light reduction component	Light timing selection	Intensity	Spectral properties / light source	Length (days)	Control condition
Dowling et al 2005 (78)(79)	70	RCT (crossover in phase 2)	Dementia (+sleep)	84 (10)	long-term care	USA	• morning outdoor / indoor light • light boxes to supplement when required	set time	~2,500lux	not stated	70	indoor light (150-200lux) usual activities
							• afternoon outdoor / indoor light • light boxes to supplement when required	set time	~2,500lux	not stated		
							• am or pm outdoor / indoor light • light boxes to supplement when required (am/pm groups merged after crossover in phase 2)	set time	~2,500lux	not stated		
Dowling et al 2008 (50)	50	RCT	Dementia (+sleep)	86 (10)	long-term care	USA	• morning outdoor / indoor light • light boxes when required • melatonin	set time	2,500lux	not stated	70	usual activities placebo melatonin
							• morning outdoor / indoor light • light boxes when required • placebo melatonin	set time	2,500lux	not stated		
Fontana Gasio et al 2003 (80)	13	RCT	Dementia (+ sleep)	86.8 (4.5)	inpatient	Switzerland	• environmental dawn-dusk simulation, set to participants sleep timing	via sleep-timing	<400lux	halogen with diffuser	21	dawn-dusk simulation using 15w red bulb
Friedman et al 2012 (45)	54	RCT	Dementia	77.9 (8.1)	at home	USA	• morning light box • read or watch TV, during • sleep hygiene info • compliance aid and explanation	via sleep-timing	~4,200lux	full spectrum	14	dim red light (filter added to same light)
Lyketsos et al 1999 (81)	15	RCT crossover	Dementia	80.8 (8.7)	residential care	USA	• morning bright light box • staff supervision	convenience	10,000lux	full spectrum	28	dim blinking light
McCurry et al 2005 (46)	36	RCT	Dementia (+sleep)	77.8 (8.1)	at home	USA	• evening natural light / light box • sleep hygiene • regularise sleep times • reduce naps • daily walking (30min) • reduce light at night	convenience	2,500lux	fluorescent	28	dementia education and carer support
McCurry et al 2011 (47)	70	RCT	Dementia (+sleep)	82.2 (8.5)	at home	USA	• evening light box • sleep hygiene leaflet • reduce light at night	convenience	2,500lux	full spectrum	56	sleep hygiene leaflet

Author(s) & Year	**N=**	**Design**	**Population** (+sleep disturbance)	**Age** mean (SD) / (range)	**Setting**	**Country**	**Intervention(s)** • *** dark highlight text = light reduction component**	**Light timing selection**	**Intensity**	**Spectral properties / light source**	**Length (days)**	**Control condition**
							• evening light box • natural light • walking (30minutes) • sleep hygiene leaflet • reduce light at night	convenience	natural light	full spectrum		
Mishima et al 1998 (82)	22	RCT crossover	Dementia (+sleep)	81 & 78	inpatient	Japan	• light box 9-11am • carer supervision	set time	5000-8000lux	full spectrum	14	dim light (300lux)
Nowak et al 2008 (83) (84)	20	RCT	Dementia	85.9 (6.24)	nursing home	USA	• blue green light cap visor	set time	12,000lux	blue-green	14	dim red light cap visor
Ouslander et al 2006 (85)	173	cluster crossover study	Dementia	83.2 (9.0)	nursing home	USA	• evening light box 2hrs • activity and exercise • avoid naps • regularise sleep times • reduce noise and continence related disruptions at night	convenience	1,467lux	full spectrum	17	TAU / waitlist control
Sloane et al 2007 (86)	60	cluster crossover	Dementia	<65=6 65-79=28 >80=32	long-term care	USA	• indoor light 7am-11am	set time	~2500lux	not stated	21	standard indoor light (~>500lux)
							• indoor light 4pm-8pm	set time	~2500lux	not stated		
							• all day indoor light 7am-8pm	set time	~2500lux	not stated		
Sloane et al 2015 (48)	17	RCT crossover	Dementia	65-79=6 >80=11	at home	USA	• all day indoor artificial light	preference	13,000K	blue white / 470nm	42	daytime 2700K (yellow-white) lamps & red light box
Van Someren et al 1999 (87)(88)	22	repeated measures crossover	Dementia	79 (9.4)	long-term care	Netherlands	• day time indoor artificial light	convenience	790-2190lux	not stated	28	TAU

*N=number of participants included in meta-analyses, RCT=randomised controlled trial, n/a=not applicable, TAU=treatment as usual, MH=mental health conditions, ASPD=advanced sleep phase disorder, DSPD=delayed sleep phase disorder, SAD=seasonal affective disorder, CBT-i=cognitive behavioural therapy for insomnia

Outcomes

The effect of intervention compared to control condition was statistically significant for six outcomes; all in the desirable direction (see Table 3). Effects on sleep timing (in DSPD), self-reported sleep disturbance, and sleep continuity disruption were robust to all sensitivity analyses. Effects on sleep onset latency (SOL), total sleep time (TST), and sleep quality were statistically significant in the main analysis but not in all sensitivity analyses (see supplements S8-S20 for additional forest plots and S21 for sensitivity analyses).

Table 15: Effect of interventions altering light exposure patterns on sleep outcomes

	Included			Effect				Heterogeneity	
Outcome	N_s	N_c	n (Ix/Cx)	Direction of effect with Ix	SMD (g)	95% CI	p=	I^2%	p=
Sleep timing in ASPD	4	4	52/52	Earlier (undesirable) (n.s)	-0.15	-0.54; 0.23	0.439	0.0	0.602
Sleep timing in DSPD	8	10	137/118	**Earlier (desirable)**	**-0.34**	-0.60, -0.08	**0.010**	46.0	0.054
Sleep inertia	3	3	74/69	Less sleep inertia (n.s)	-0.26	-0.59, 0.08	0.132	37.9	0.200
Self-reported daytime sleepiness	4	4	55/49	Less daytime sleepiness (n.s)	-0.34	-0.74, 0.06	0.092	44.2	0.146
Sleep onset latency (SOL)	6	8	138/131	**Shorter SOL**	**-0.27**	-0.52, -0.02	**0.033**	54.9	0.030
Sleep quality (on VAS)	5	7	113/107	**Higher sleep quality**	**0.28**	0.00, 0.55	**0.046**	52.5	0.049
Self-reported sleep disturbance (questionnaire)	5	7	119/116	**Less sleep disturbance**	**-0.32**	-0.58, -0.06	**0.015**	0.0	0.525
Total sleep time (TST)	27	34	703/492	**Longer TST**	**0.15**	0.03, 0.27	**0.015**	57.6	0.000
Sleep Efficiency (SE%)	15	19	427/364	Higher SE% (n.s)	0.14	-0.01, 0.28	0.063	5.1	0.393
Sleep continuity disruption	20	24	672/509	**Less sleep disruption**	**-0.23**	-0.36, -0.10	**0.000**	30.9	0.125

Rhythmicity of rest activity rhythm	6	10	252/123	Lower rhythmicity (n.s.)	-0.06	-0.28, 0.16	0.585	5.6	0.389
Amplitude of rest activity rhythm	11	16	463/314	Higher amplitude (n.s)	0.03	-0.11, 0.18	0.644	11.4	0.323
Carer reported daytime sleep propensity	10	14	439/299	Less daytime sleepiness (n.s)	-0.13	-0.28, 0.02	0.096	13.4	0.307

N_s= number of studies, N_c= number of comparisons, n (Ix/Cx)=number of participants in combined intervention and control groups, n.s.=not significant, ASPD=advanced sleep phase disorder, DSPD=delayed sleep phase disorder.

Delaying sleep timing in advanced sleep phase disorder (ASPD)

Samples were middle aged or older, and community based (see **Table 14**). There were few studies and samples were small. All interventions gave evening light or light during early sleep, none restricted morning light. Effects were homogeneous. All studies measured the first-choice outcome – rise time. The pooled effect was non-significant, and in the wrong direction (toward even earlier sleep) (effect size (ES)=-0.15, p=0.602). To examine if this suggested *harm*, we made post hoc examination of baseline imbalance and pre-post effect. Intervention groups indeed had earlier average rise time at baseline which persisted after intervention, and there was no significant pre-post effect in either direction in the intervention group (ES=0.32, p = 0.111).

Advancing sleep timing in delayed sleep phase disorder (DSPD)

All studies in DSPD measured sleep timing. Samples in DSPD were young and community based, exclusion of co-morbidities varied widely. All interventions increased light exposure in the morning, and three involved some instruction to avoid or reduce evening light exposure. Effects were homogeneous (χ^2= 6.00 (d.f. = 8), p = 0.648, I^2= 0.0%), with the exception of Langevin et al (2014) (63) which was an extreme outlier. This study was small (n=10) with highly selective exclusion criteria compared to others, and used spectacle mounted LEDs rather than a light box, likely

increasing ‘dose’ of light reaching the circadian photoreceptors (including this study increased heterogeniety, χ^2 = 16.67 (d.f. = 9), p = 0.054, I^2= 46.0%)

The pooled effect was significant, and in the direction intended (earlier sleep timing). Sensitivity analysis removing the extreme outlier reduced the effect size slightly (-0.34 to -0.32), but it remained statistically significant (p = 0.015) (

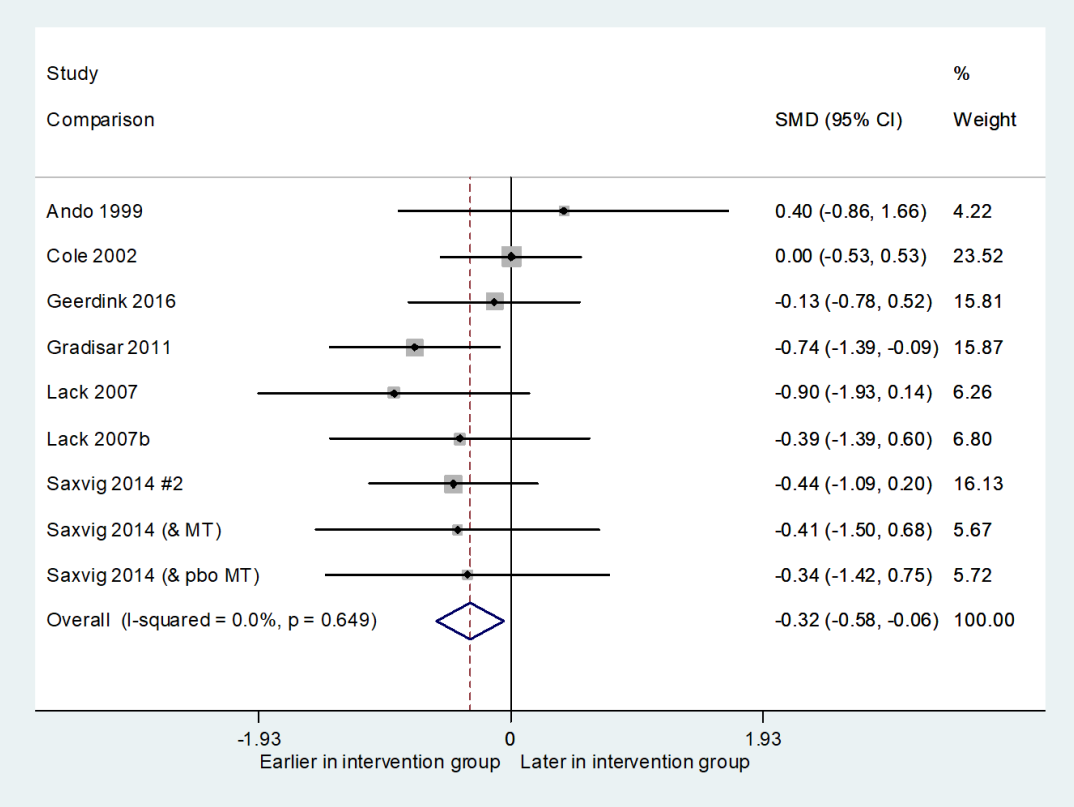

Figure **8**). This effect size can be translated to 25 minutes earlier sleep timing (using the pooled SD to convert overall SMD back into hours / minutes, whilst excluding SMD of the outlier in which sleep onset was 1.5 hours earlier (63)).

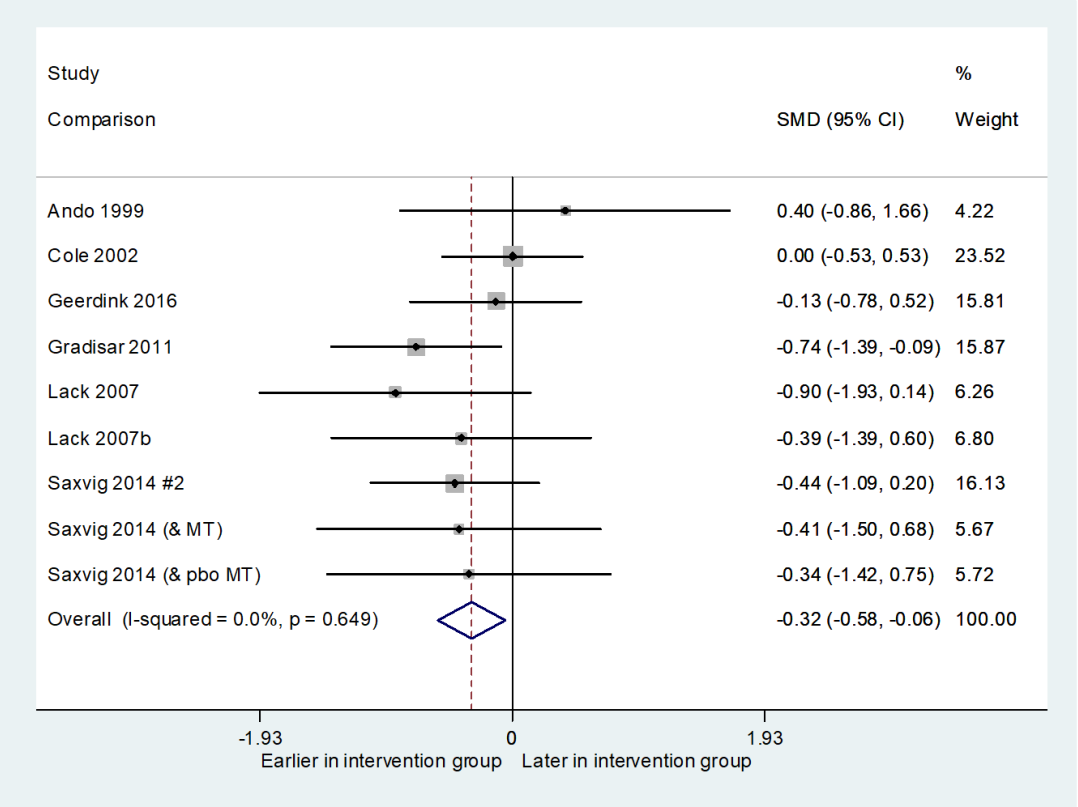

Figure 8: Effect of morning light interventions on sleep timing in DSPD

Sleep Inertia

Only three studies reported on sleep inertia: these were in DSPD (n=2) and SAD with hypersomnia (n=1). The summary effect was small and non-significant.

Self-reported daytime sleepiness

Only studies in DSPD reported daytime sleepiness (n=4), all interventions supplemented morning or pre-awakening light. Effects were heterogeneous (χ^2 = 5.38 (d.f. = 3), p = 0.142, I^2 = 44.2%); mostly attributable to the same outlier as above (63) (after its removal, χ^2 = 1.40, (d.f. = 2), p = 0.496, I^2 = 0.0%). The effect was non-significant (ES= -0.34, p=0.092).

Sleep Onset Latency (SOL)

Six studies reported SOL. Samples were community based. Age varied and depression samples were older than DSPD samples. Most interventions were similar, giving 30-60 minutes light box in the morning. Esaki et al (2017) instead reduced evening blue light exposure using amber glasses (67). Gradisar et al (2011) included CBT-i and light (51), and Saxvig et al (2014) gave melatonin in some groups (49). Effects were heterogeneous (χ^2 = 15.51 (d.f. = 7), p = 0.030, I^2 = 54.9%).

The pooled effect was significant (p=0.033), with ES -0.27; equivalent to 5.5 minutes shorter SOL. Significance was altered by sensitivity analysis excluding assumed (not diagnosed) DSPD (p=0.078) (see Table S21). Sub-group analysis suggested larger effects in DSPD (ES= -0.46, p= 0.006), than in depression (ES=-0.01, p=0.946).

Sleep quality

Self-reported sleep quality (visual analogue scale; VAS) was measured in DSPD and depression. Most samples were young. Most interventions were morning or pre-awakening light, some included nighttime light avoidance. One intervention instead used amber glasses in the evenings (67).

Effects were heterogeneous, even within diagnostic groups (χ^2 = 12.62 (d.f. = 6) p = 0.049, I^2 = 52.5%). Heterogeneity was reduced by removing the same outlier (63) (χ^2 = 5.50 (d.f. = 5) p = 0.358, I^2= 9.0%). The pooled ES of 0.28 toward improved sleep quality was statistically significant (p=0.046), but was altered by sensitivity analyses (ES 0.18 to 0.38, p=0.013 to 0.266). The ES of 0.28 translates to 0.25 points improvement on a 5-point Likert scale (using the pooled SD to convert overall SMD back to VAS).

Self-reported sleep disturbance (composite measures)

Composite measures of self-reported sleep disturbance (e.g. insomnia severity index (ISI)) were used in DSPD, inpatient mental illness, and bipolar depression (inpatients). Most interventions gave early morning bright light (>2500lux), except Sit et al (2017) gave early afternoon bright light (73). Saxvig et al (2014) added melatonin in some groups (49), and Sheaves et al (2018) also gave CBT-i (89). Effects were homogeneous (χ^2 = 5.15 (d.f. = 6), p = 0.525, I^2 = 0.0%).

The pooled effect was an ES of -0.32 (lower sleep disturbance) (p=0.015), (Figure 3) which was robust to all sensitivity analyses, and can be translated to a 1.26 points reduction in ISI score.

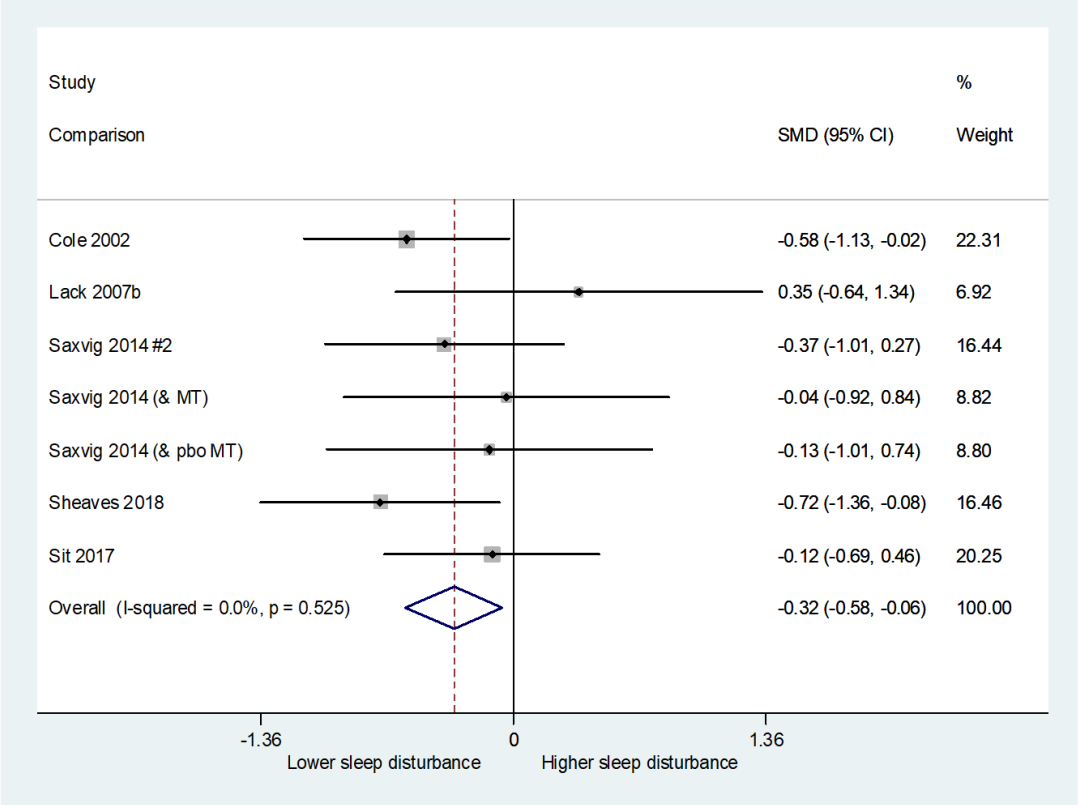

Figure 9: Effect of light schedule interventions on self-reported sleep disturbance

Total Sleep Time (TST)

TST was measured in most studies. Results were heterogeneous across diagnostic groups (χ^2 = 68.21 (d.f. = 33), p = 0.000, I^2 = 51.6%), and within all groups except dementia (χ^2= 4.34, p=0.996, I-squared = 0.0%) and depression (χ^2 = 0.89, p=0.642, I^2 = 0.0%). The populations with largest ES were most heterogeneous. Heterogeneity remained after removal of two extreme positive outliers (41,63). There was a small ES of 0.15 toward longer sleep (p=0.015) (

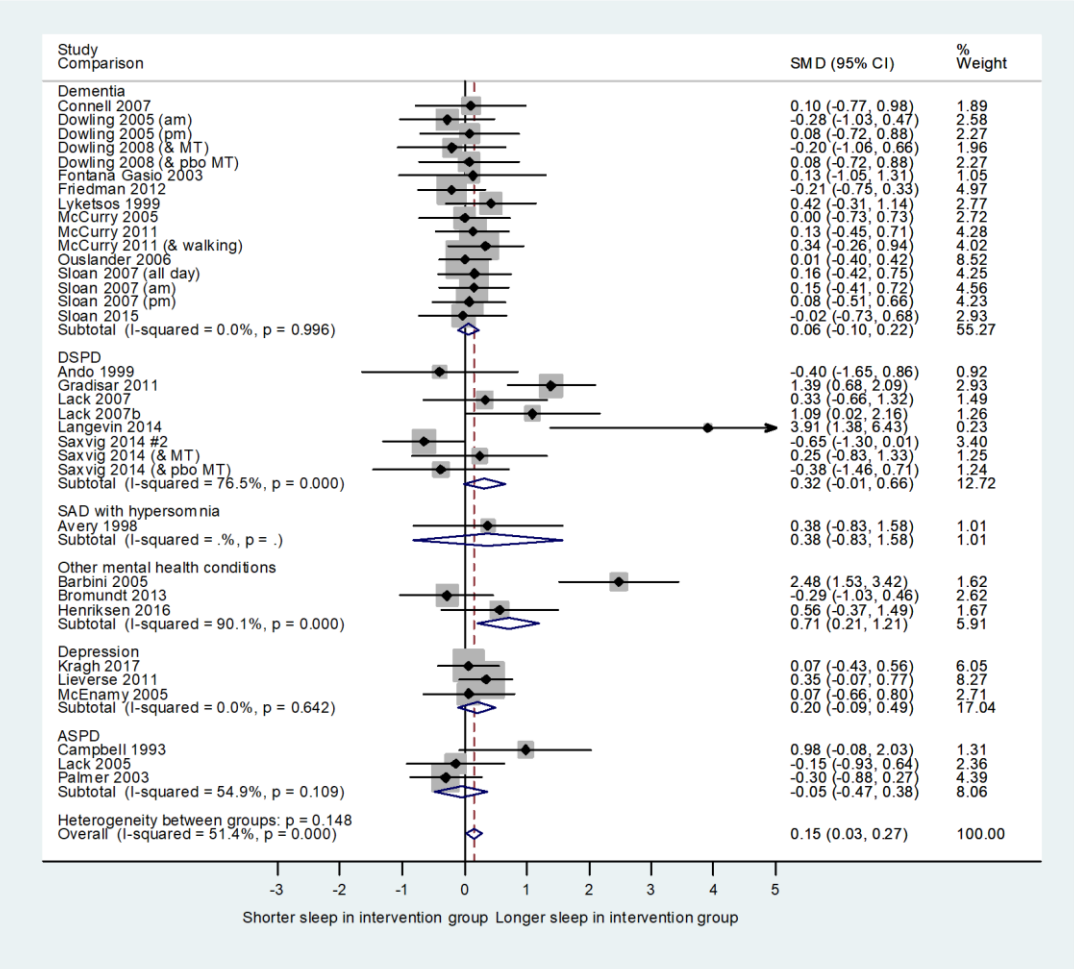

Figure 10). Sensitivity analyses removing positive outliers reduced significance (p=0.097), and as did removing studies in samples without sleep disturbance inclusion criteria (perhaps counterintuitively) (p=0.209). Removing studies at high risk of bias increased the ES (=0.20) and significance (p=0.002). Additional post hoc sensitivity analysis excluding studies with longer average TSTs at baseline had

minimal effect on results (adequate examination of the impact of baseline TST would require individual patient data).

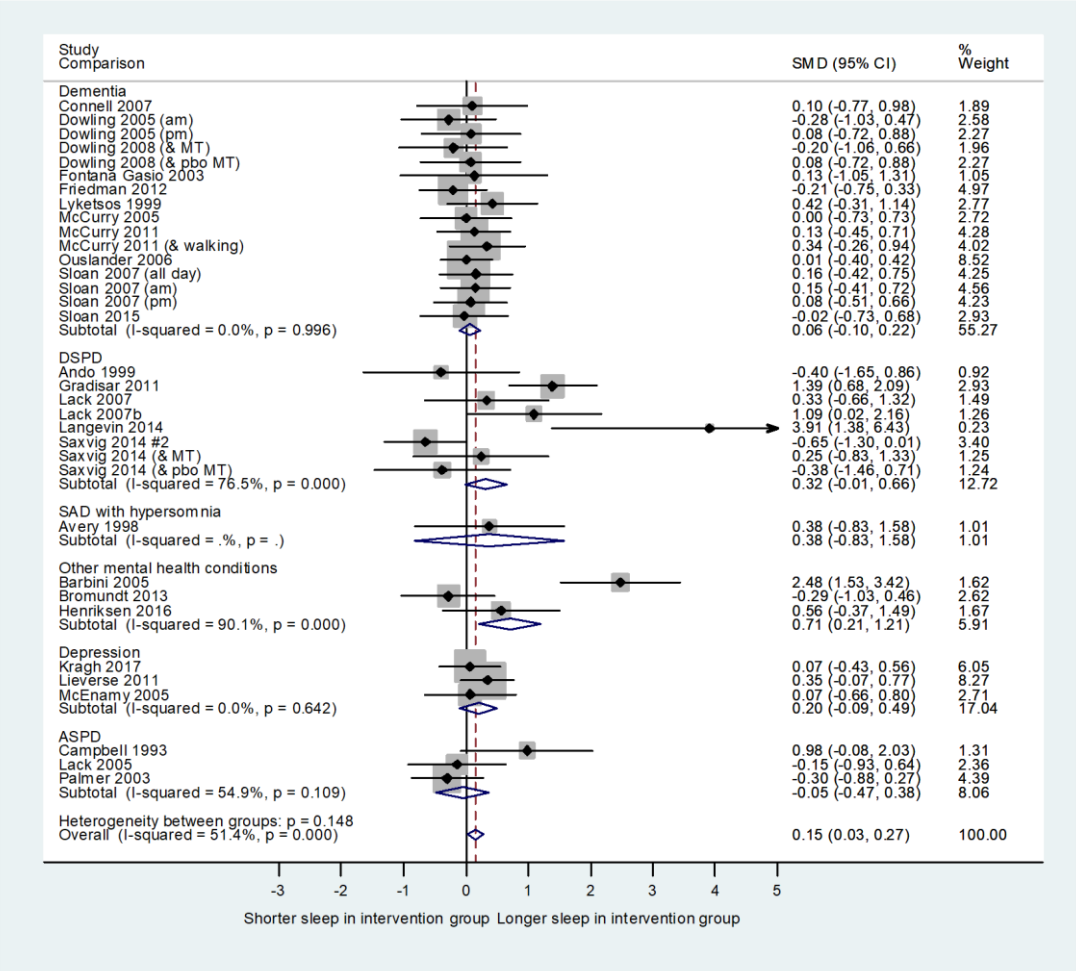

Figure 10: Effect of light schedule intervention on total sleep time (TST)

Sleep Efficiency (SE%)

All diagnostic groupings except 'other mental health conditions' measured SE%. Effect sizes were relatively homogenous despite clinical heterogeneity in intervention and population characteristics (χ^2 = 18.98 (d.f. = 18) p = 0.393, I^2 = 5.1%). The pooled effect was small and non-significant (ES= 0.14, p=0.063). Sensitivity analyses affected the overall result slightly as statistical significance varied (ES=0.10 to 0.15, p=0.045 to 0.330).

Sleep continuity disruption

Sleep continuity disruption was measured in many diagnostic groups. Light intensity and duration varied, one study used amber glasses (42). Results were heterogenous between groups, whilst within the dementia sub-group results were homogeneous (χ^2 = 10.59 (d.f. = 17) p = 0.877, I^2 = 0.0%).

The pooled ES of -0.23 was highly statistically significant (p=0.000) (reduced sleep disruption), this translated to 6.1 minutes less wake time after sleep onset, or 1.44 less awakenings per night (using pooled SD to convert back from SMD). ES varied significantly between diagnostic groups (see section below), with larger ES in mental illness and ASPD (-1.45, -0.75 and -0.50), and homogeneous, small, non-significant effects in dementia (ES= -0.12, p=0.089) (Figure 5). Sensitivity analyses made little difference to results (ES= -0.20 to -0.27, p=<0.000 to p= 0.038).

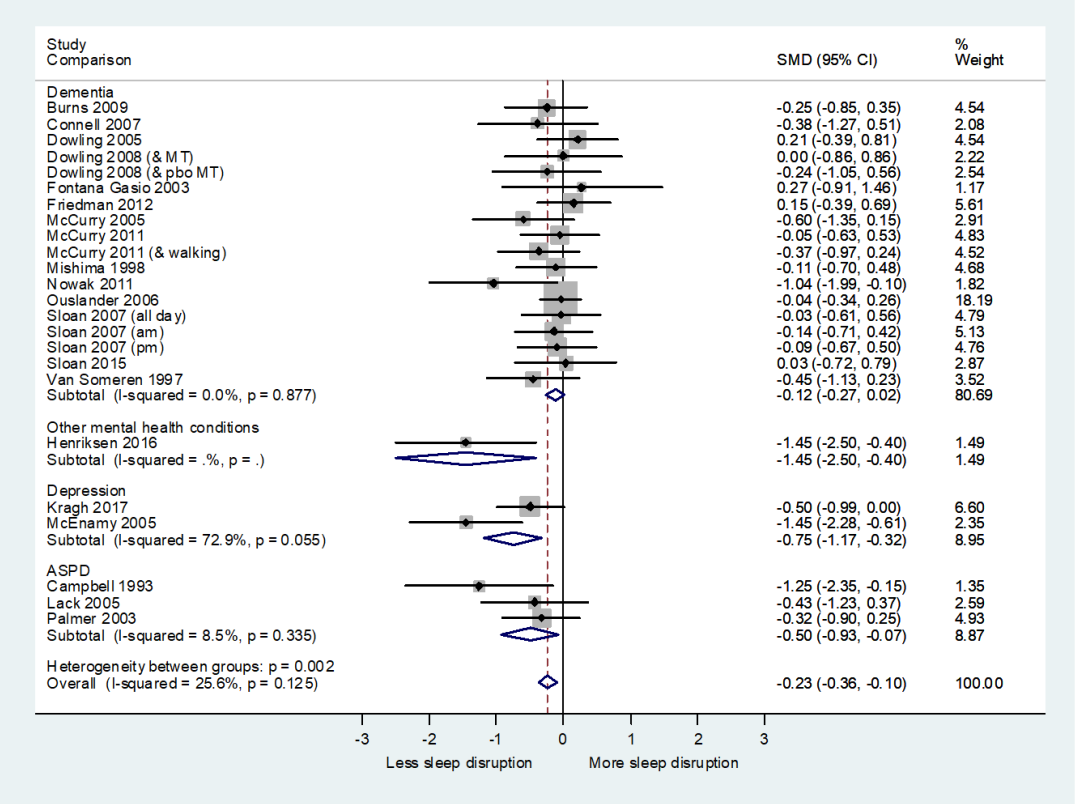

Figure 11: Effect of light schedule interventions on sleep continuity disruption

Rhythmicity of rest activity rhythm

Rhythmicity was only measured in dementia. Light administration, timing, intensity and duration varied; none reduced light as the primary intervention. Rhythmicity was always derived from actigraphy, but algorithms varied including non-parametric and parametric approaches (extended cosine model). Results were reasonably homogenous (χ^2 = 9.54 (d.f. = 9), p = 0.389, I^2= 5.6%). The pooled effect was non-significant (p=0.585) and close to the line of no effect (ES= -0.06).

Amplitude of rest activity rhythm

Amplitude was only measured in dementia. Metrics varied; relative amplitude was most common, but other metrics such as percentage of activity in night-time were also reported. Results were not significantly heterogeneous (χ^2 = 16.94 (d.f. = 15) p = 0.323, I^2 = 11.4%), nor was the effect significant (ES = 0.03, p= 0.644).

Carer reported daytime sleep propensity

Self-reported sleepiness was not available for samples with dementia, so carer reported daytime sleep propensity was examined (assessed through behavioural observations suggesting sleepiness or nodding off). Heterogeneity was low (χ^2 = 15.01 (d.f. = 13) p = 0.307, I^2 =13.4%) and the pooled effect non-significant (ES= -0.13, p=0.096) despite the large number of comparisons (n=13) and participants (438 / 299) included.

Follow up points

Few studies presented data for follow-up points. Studies varied in terms of inclusion of maintenance therapy or advice, and many ceased intervention completely, so these results could not be synthesised.

Differences between outcomes depending on population

Results for sub-groups are presented in Table 4. CIs for outcomes overlapped substantially in all cases except TST and sleep continuity. The overall test for heterogeneity between sub-groups was likely to be invalid due to within group heterogeneity. Where CIs did not overlap, or only just overlapped, we tested for differences between subgroups using the method described in Bornstein et al (2009), and found no statistically significant differences.

Intervention effect moderators

There were too few studies to run meta-regressions for some outcomes, and sometimes planned covariates varied insufficiently or were too confounded with other features. Insufficient reporting of season prevented meaningful examination of latitude or season (without season, latitude does not describe baseline light environment). Features related to intervention 'dose' (intensity, duration) were mostly well reported, and varied, allowing meta-regression; but we found no significant associations between 'dose' features and effects (see Table S22). Spectral composition of light, or bulb type was reported too infrequently to permit analysis (see supplement S1). Variability in effects based on intervention type (e.g. light box, natural light, light restriction) was examined using sub-group analysis, results are presented in supplements S23-34. Due to small numbers and many confounders further interpretation was resisted. Pm light exposure (versus am) was associated with a greater reduction in carer reported daytime sleep propensity in dementia (Coefficient =-0.5007139, p= 0.019). Interventions with a sleep schedule component were also associated with less deterioration of rest activity rhythm amplitude in dementia (Coefficient = 0.4587271, p= 0.010).

The strongest association was between interventions including light avoidance/reduction, and greater increase in TST (Coefficient = 0.6477418, p= 0.004). The association was greatest when light was avoided not just at night but

from afternoon or evening (Coefficient = 1.48552, p= 0.000) (

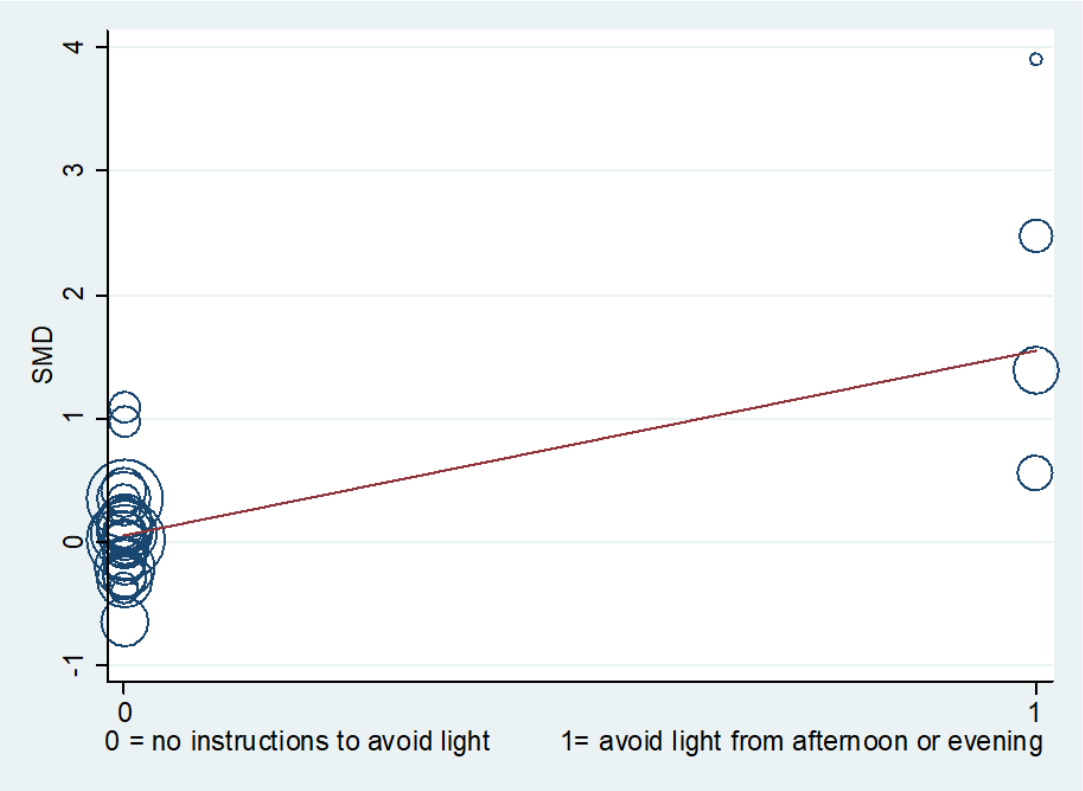

Figure 12). On other outcomes, interventions including light avoidance also performed better but associations were non-significant. To examine whether differences in effects on TST were population related, meta-regressions were re-run excluding groups where no interventions involved light reduction; associations remained highly significant (Coefficient = 0.6944778, p= 0.006, and, Coefficient =1.69882, p=0.009).

Table 16: Intervention effects in diagnostic sub-groups

	Outcome (only listing those relevant and with data)	**Studies reporting / total studies**	**SMD (g)**	**95% CI**	**p=**
ASPD	Sleep timing	4 / 4	-0.15*	-0.54, 0.23	0.439
	TST	3 / 4	-0.05*	-0.47, 0.38	0.823
	SE%	3 / 4	-0.02*	-0.47, 0.43	0.929
	Sleep continuity disruption	3 / 4	-0.50	-0.93, -0.07	0.023
	Rhythmicity of rest activity	0 / 4			
DSPD	Sleep timing	8 / 8	-0.34	-0.60, -0.08	0.010
	Sleep inertia	2 / 8	-0.04	-0.45, 0.37	0.845
	Self-reported daytime sleepiness	4 / 8	-0.34	-0.74, 0.06	0.092
	SOL	4 / 8	-0.46	-0.79, -0.13	0.006
	Sleep quality (on VAS)	3 / 8	0.21	-0.13, 0.55	0.217
	Self-reported sleep disturbance	4 / 8	-0.29	-0.61, 0.04	0.087

	TST	6 / 8	0.31	-0.03, 0.65	0.070
	SE%	2 / 8	-0.07*	-0.47, 0.32	0.720
	Rhythmicity of rest activity	0 / 4			
Depression	SOL	2 / 5	-0.01	-0.39, 0.36	0.946
	Sleep quality (on VAS)	2 / 5	0.39	-0.07, 0.84	0.094
	TST	3 / 5	0.20	-0.09, 0.49	0.174
	SE%	2 / 5	0.27	-0.09, 0.64	0.139
	Sleep continuity disruption	3 / 5	-0.75	-1.17, -0.32	0.001
SAD with hypersomnia	Sleep inertia	1 / 2	-0.68	-1.28, -0.11	0.02
	TST	1 / 2	0.38*	-0.83, 1.58	0.541
Other mental health conditions	Self-reported sleep disturbance	2 / 4	-0.39	-0.82, 0.04	0.078
	TST	2 / 4	0.71	0.21, 1.21	0.005
	Sleep continuity disruption	1 / 4	-1.45	-2.50, -0.40	0.007
Dementia	TST	10 / 16	0.06	-0.10, 0.22	0.460
	SE%	7 / 16	0.17	-0.01, 0.36	0.066
	Sleep continuity disruption	14 / 16	-0.12	-0.27, 0.02	0.089
	Rhythmicity of rest activity	6 / 16	-0.06*	-0.28, 0.16	0.585
	Amplitude of rest activity rhythm	11 / 16	0.03	-0.11, 0.18	0.644
	Carer report daytime sleep propensity	6 / 16	-0.13	-0.28, 0.02	0.096

TST=total sleep time, SE%=sleep efficiency percentage, SOL=sleep onset latency, VAS=visual analogue scale, DSPD=delayed sleep phase disorder, ASPD=advanced sleep phase disorder, *opposite direction to desired effect.

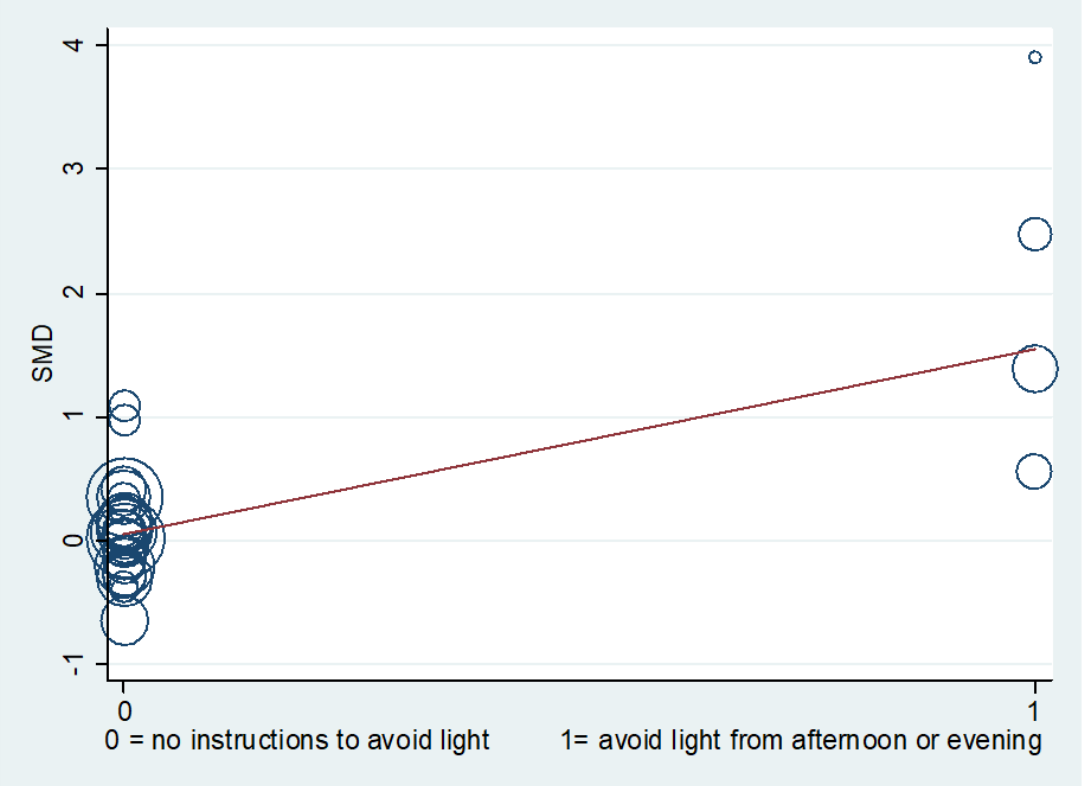

Figure 12: Bubble plot - light avoidance from afternoon or evening associated with greater increase in total sleep time

Discussion

Summary of findings

We found studies of light schedule interventions to improve sleep in a range of populations, but there were relatively few studies in samples with mental illnesses which targeted and measured sleep and circadian disturbances. This despite the fact that circadian dysregulation is acknowledged to be important in this group (36). Many studies in mental illness were excluded because they reported no sleep outcomes, and when present sleep outcomes were usually secondary. Interventions predominantly involved a circumscribed period of light exposure, most commonly from a light box at a set time each day. Some interventions were more complex and included modifications to both morning and evening light levels, personalisation of light schedules, or light from multiple sources.

Overall, the effects of light schedule interventions on sleep outcomes were positive. We found evidence of small but statistically and clinically significant improvements in sleep continuity disruption, self-reported sleep disturbance, and sleep timing in DSPD, that were robust to sensitivity analyses. We found less conclusive evidence of improvements in SE%, SOL, and self-reported sleep quality; and a small increase in TST. These findings are broadly in agreement with previous meta-analytic findings where different sleep outcome types were pooled, and where study inclusion required diagnosis or specification of sleep problems at baseline (30). The current review contributes a synthesis of evidence in psychiatric diagnoses, and separate analysis of various sleep and rest-activity outcomes.

Effects in sleep phase disorders

Basic research has found reasonably consistent effects of light interventions on circadian phase, the direction and magnitude of which depend on timing, intensity, spectral properties, and duration of light exposure (90–92). Our findings confirm that the phase advancing effects of morning light established in laboratory settings can be replicated to some degree in the home in DSPD. This finding builds on previous syntheses in DSPD where reported effects were also positive but less conclusive (29). We found a shortening of SOL, and an average advance in sleep timing of 25 minutes, suggesting morning light intervention may be sufficient for some participants, whilst others will require some additional intervention. Basic research suggests that increasing morning light for phase advance, or evening light for phase delay, should be more effective if light is also avoided during the opposite period (morning/evening) (93). Whilst across all studies those including light avoidance gave greater increase in TST, we were not able to definitely establish superiority of effects for adding evening light avoidance to morning light exposure from the studies in DSPD.

Our findings did not support increased evening light exposure to phase delay sleep in ASPD, and no studies in ASPD included morning light avoidance, but the total number of participants in this analysis was small.

Effects on sleep continuity and sleep disturbance

Light exposure interventions improved sleep continuity, self-reported sleep disturbance, and sleep quality (although the latter was affected by removing an outlier, and by removing studies without sleep inclusion in sensitivity analysis). This is consistent with findings in shift work: attempts to sleep out of phase with circadian rhythm are understood to incur increased disruptions (94), whilst increasing circadian alignment can improve sleep quality (95). Sleep continuity should be considered as a potential outcome in more studies, because it is important to patients (13), has been

linked to next-day symptoms (96), may be amenable to change, and can be assessed with actigraphy or self-report.

Effect on Total Sleep Time (TST)

The most commonly reported parameter was TST (27/40 studies). Our primary analysis showed a small average effect toward longer sleep (ES = 0.15, p=0.015). This effect size is similar to the effect sizes found by Van Maanen et al (2016) (effect of light therapy on 'all sleep problems' and 'other sleep problems'). Changes to mean TST are difficult to interpret without individual patient data, or sub-grouping by baseline sleep duration. In many diagnostic groups, an individual's sleep may be short, long, or already of normal (optimal) duration but poor quality, thus the desirable direction of change varies. Chiu et al (2018) stratified participants with schizophrenia and other psychoses by sleep duration at baseline (<6hrs, 6-10hrs, >10hrs) and found that intervention with CBT-i (compared to control condition) increased TST in those with short sleep and reduced TST in those with long sleep (both desirable), the mean value however obscured both effects. We recommend that studies of light schedule interventions consider stratifying participants by baseline TST, and that a future review on this topic might examine this outcome using individual patient data.

Effect on Sleep Efficiency (SE%)

Another commonly reported but difficult-to-interpret metric is SE%; SE% is influenced by SOL, sleep fragmentation, and unwanted early awakening. Inconsistencies in how SE% is calculated are common, and persist despite efforts at standardisation (97,98). Furthermore, although higher SE% is an accepted intervention target in insomnia studies, it is not clear if very high SE% (>90%) should always be viewed positively. Very high SE% (mean 96.6%) was found to be

a feature of sub-type “insomnia with hypersomnia” in people with psychotic illnesses, who had excessively long sleep and a subjective complaint of sleeping poorly (21).

Baseline light exposure patterns as an effect moderator

We hypothesised that if baseline light exposure patterns were already close to optimal, that alterations during intervention may make less of a difference. We were not able to examine this due to sparse reporting. Future studies should report season or months of intervention in order that future syntheses may examine whether season and latitude moderate intervention effects. Some studies in institutions examined baseline light levels in the environment, but none examined individuals’ dynamic light exposure at baseline. It is possible that variability of baseline light exposure accounts for some heterogeneity of effects.

The signal received from daily light exposure patterns can be described as high or low amplitude; high amplitude being bright days and dark nights, and low amplitude being quite similar light levels throughout. The modern light environment for many individuals involves rather dimly lit days spent indoors, artificially elongated days with artificial light in the evening, and darkness only when it is time to sleep. Modelling describes how this low amplitude signal with evening light, delays and de-stabilises circadian rhythms (99). By contrast reverting to a more natural light-dark signal was found to improve circadian rhythms and sleep (2). This research suggests that normalising light schedules by reducing artificial evening light would improve sleep, our findings agree with this, and suggest interventions were more effective if they included evening light avoidance / reduction.

Studies in dementia compared to in other populations

There were distinct differences in approaches to intervention and outcome selection between studies in dementia and in other conditions. For instance, studies in dementia almost always used actigraphy, were more likely to specify some sleep disturbance inclusion criteria, and often set sleep as a higher priority amongst their stated aims. Only studies in dementia modified the living environment to alter overall daytime light levels, and more often used natural light, or light from a range of sources. Despite more studies focusing on sleep, intervention effects in dementia were notably smaller and less significant than in other groups (and similar to in a previous meta-analysis (28)). Caution is advised interpreting sub-group analyses of differences in treatment effects based on sample characteristics (38); associations are observational and other factors may explain differences. The use of parametric circadian analysis may have contributed to poor measurement, as non-parametric methods have since been shown to detect change better (88). It is also possible that interventions were insufficiently personalised, as interventions were commonly applied to whole institutions.

Studies in mental illness

Although twelve studies in mental illness were included, each only contributed a small amount of data, reporting few sleep outcomes, usually with sleep as a secondary aim. Sleep outcomes are often neglected in mental health intervention research; for instance studies in bipolar disorder seldom measure sleep, despite these interventions often containing components targeting sleep (100). Though it was not our aim to compare effects between diagnostic groups, some of the largest effects were seen in mental illness samples (such as sleep continuity disruption in depression, ES=-0.75, TST in other mental health conditions, ES=0.71). This suggests that light schedule interventions which have previously focused primarily on affective symptoms might consider also targeting and measuring sleep outcomes.

Research links a more regular diurnal rhythm to better mental wellbeing and functioning (11). A regular rhythm is also described as important by people with mental health conditions, in order to support social integration, functioning, and wellbeing (13,101,102). We had therefore identified regularity of rhythm as a relevant outcome in these groups, and planned to examine effects on regularity and amplitude, but these metrics were only reported in dementia (see Table S6). We recommend that future studies in mental illness measure rest-activity timing and rhythm, as well as sleep quality and amount.

Co-morbid circadian dysregulation

Relatively few studies in mental illness were included despite broadening criteria to capture more studies. Without broadening criteria only 4/12 studies in mental illness, and 7/16 in dementia would have been included, as only these specified sleep inclusion criteria. Interpretation of the current review is therefore contingent on the assumption that sleep problems are prevalent enough in the included neuropsychiatric populations that sleep disruption criteria would not have changed the samples too greatly. Although sensitivity analyses found no consistent or marked difference between studies with or without sleep inclusion criteria, the relevance of studies without them can of course be questioned, and there may be a difference in effect which we were unable to detect. Furthermore, sleep problems in our included neuropsychiatric samples would most likely also have had non-circadian causes: anxiety and arousal processes of insomnia, environmental interruptions, and the impact of affective or psychotic symptoms. Better assessment and description of the different types and causes of sleep disturbance in populations with neuropsychiatric disorders would allow more targeted intervention using the most relevant components. Although more reporting of secondary sleep outcomes in mental health

interventions is welcome the field needs more intervention trials targeting specific types of sleep disturbance and circadian dysregulation as primary outcomes.

Conclusions

This review highlights promising initial findings regarding the effects of altering patterns of light exposure on sleep in groups experiencing, or potentially experiencing, circadian dysregulation. This is despite some intervention protocols not appearing to be optimised according to current theoretical understanding, and despite only a few studies selecting participants specifically for presence of relevant sleep and circadian problems. Our findings suggest that small but clinically meaningful improvements in some sleep parameters can be achieved through altering light exposure patterns in some groups. To achieve greater effects, light exposure interventions may be further optimised and better targeted to particular types of sleep and circadian problems, and appropriately combined with other behavioural elements.

Practice Points:

- Our findings support the use of morning light exposure to advance sleep timing and hasten sleep onset in delayed sleep phase disorder; average effects are small so in many cases other intervention components may be required in addition.
- Interventions altering light exposure may be helpful for improving sleep continuity or sleep disturbance in groups with circadian dysregulation; appropriate light schedule alterations will depend upon the group.
- Enhancing evening darkness to promote sleep may be useful; evidence is as yet weak but side effects are few (as long as risk of falls is mitigated).

Research agenda:

- Studies in psychiatric populations should consider targeting sleep outcomes, as findings are promising but research is sparse.
- Studies should consider altering light-dark exposure patterns over the whole day or during multiple periods.
- There should be mores studies of evening light avoidance/reduction.
- Controlled studies aiming to phase advance or phase delay sleep timing should compare the effects of using timed light exposure and timed light avoidance, with 'single component' light exposure or light avoidance.
- In groups where sleep and circadian rhythm problems are diverse, samples should be stratified by type of sleep problem, particularly where the desired effects differ (e.g. delayed versus advanced sleep, short versus long sleep).
- Studies should report season of intervention delivery; and may consider examining individual participant's baseline light exposure patterns.

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References:

1. Dijk D-J, von Schantz M. Timing and consolidation of human sleep,

wakefulness, and performance by a symphony of oscillators. J Biol Rhythms [Internet]. 2005 Aug [cited 2014 Nov 4];20(4):279–90. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16077148

*2. Wright KP, McHill AW, Birks BR, Griffin BR, Rusterholz T, Chinoy ED. Entrainment of the human circadian clock to the natural light-dark cycle. Curr Biol [Internet]. 2013;23(16):1554–8. Available from: http://dx.doi.org/10.1016/j.cub.2013.06.039

3. Sharma A, Tiwari S, Singaravel M. Circadian rhythm disruption: Health consequences. Biol Rhythm Res [Internet]. 2016;47(2):191–213. Available from: http://dx.doi.org/10.1080/09291016.2015.1103942

4. Hubbard J, Ruppert E, Gropp C, Bourgin P. Non-circadian direct effects of light on sleep and alertness : Lessons from transgenic mouse models. Sleep Med Rev [Internet]. 2013;17(6):445–52. Available from: http://dx.doi.org/10.1016/j.smrv.2012.12.004

5. Hasler BP, Buysse DJ, Kupfer DJ, Germain A. Phase relationships between core body temperature, melatonin, and sleep are associated with depression severity: Further evidence for circadian misalignment in non-seasonal depression. Psychiatry Res [Internet]. 2010;178(1):205–7. Available from: http://dx.doi.org/10.1016/j.psychres.2010.04.027

6. Van Someren EJW. Circadian and sleep disturbances in the elderly. Exp Gerontol. 2000;35(9–10):1229–37.

7. Zee P, Vitiello M. Circadian Rhythm Sleep Disorder: Irregular Sleep Wake Rhythm Type. Sleep Med Clin. 2009;4(2):213–8.

8. Czeisler CA, Duffy JF, Shanahan TL. Stability, precision, and near 24 hour

period of the human circadian pacemaker. Science (80-). 1999;284(JUNE):2177–81.

*9. Wulff K, Dijk D-J, Middleton B, Foster RG, Joyce EM. Sleep and circadian rhythm disruption in schizophrenia. Br J Psychiatry [Internet]. 2012 Apr [cited 2014 Oct 20];200(4):308–16. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3317037&tool=pmcentrez&rendertype=abstract

10. Wehr TA. Bipolar mood cycles and lunar tidal cycles. Mol Psychiatry [Internet]. 2018;23(4):923–31. Available from: http://dx.doi.org/10.1038/mp.2016.263

*11. Margraf J, Lavallee K, Zhang X, Schneider S. Social rhythm and mental health: A cross-cultural comparison. PLoS One. 2016;11(3).

12. Leufstadius C, Erlandsson L-K, Eklund M. Time use and daily activities in people with persistent mental illness. Occup Ther Int [Internet]. 2006 Sep;13(3):123–41. Available from: http://doi.wiley.com/10.1002/oti.207

13. Faulkner S, Bee P. Experiences, perspectives and priorities of people with schizophrenia spectrum disorders regarding sleep disturbance and its treatment: a qualitative study. BMC Psychiatry [Internet]. 2017;17(1):158. Available from: DOI 10.1186/s12888-017-1329-8

14. Benca R, Duncan MJ, Frank E, McClung C, Nelson RJ, Vicentic A. Biological rhythms, higher brain function, and behavior: Gaps, opportunities, and challenges. Brain Res Rev [Internet]. 2009;62(1):57–70. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc6&NEWS=N&AN=2009-18310-001

*15. Wulff K, Gatti S, Wettstein JG, Foster RG. Sleep and circadian rhythm disruption in psychiatric and neurodegenerative disease. Nat Rev Neurosci. 2010;11(8):589–99.

16. Kecklund G, Axelsson J. Health consequences of shift work and insufficient sleep. BMJ. 2016;355(i5210).

17. Short MA, Louca M. Sleep deprivation leads to mood deficits in healthy adolescents. Sleep Med [Internet]. 2015;16(8):987–93. Available from: http://dx.doi.org/10.1016/j.sleep.2015.03.007

18. Menet JS, Rosbash M. When brain clocks lose track of time: Cause or Consequence of neuropsychiatric disorders. Curr Opin Neurobiol. 2011;21(6):849–57.

19. Lunsford-avery JR, Lebourgeois MK, Gupta T, Mittal VA. Actigraphic-measured sleep disturbance predicts increased positive symptoms in adolescents at ultra high-risk for psychosis : A longitudinal study. Schizophr Res [Internet]. 2015;164(1–3):15–20. Available from: http://dx.doi.org/10.1016/j.schres.2015.03.013

20. Freeman D, Sheaves B, Goodwin GM, Yu LM, Nickless A, Harrison PJ, et al. The effects of improving sleep on mental health (OASIS): a randomised controlled trial with mediation analysis. The Lancet Psychiatry [Internet]. 2017;4(10):749–58. Available from: http://dx.doi.org/10.1016/S2215-0366(17)30328-0

21. Chiu VW, Ree M, Janca A, Iyyalol R, Dragovic M, Waters F. Sleep profiles and CBT-I response in schizophrenia and related psychoses. Psychiatry Res [Internet]. 2018;268(July):279–87. Available from: https://doi.org/10.1016/j.psychres.2018.07.027

22. Ye Y, Zhang Y, Chen J, Liu J, Li X, Liu Y, et al. Internet-Based Cognitive Behavioral Therapy for Insomnia (ICBT-i) Improves Comorbid Anxiety and Depression—A Meta-Analysis of Randomized Controlled Trials. PLoS One [Internet]. 2015;10(11):e0142258. Available from: http://dx.plos.org/10.1371/journal.pone.0142258

23. Palmese LB, DeGeorge PC, Ratliff JC, Srihari VH, Wexler BE, Krystal AD, et al. Insomnia is frequent in schizophrenia and associated with night eating and obesity. Schizophr Res [Internet]. 2011 Dec [cited 2014 Oct 27];133(1–3):238–43. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=21856129

24. Melo MCA, Abreu RLC, Linhares Neto VB, de Bruin PFC, de Bruin VMS. Chronotype and circadian rhythm in bipolar disorder: A systematic review. Sleep Med Rev [Internet]. 2017;34:46–58. Available from: http://dx.doi.org/10.1016/j.smrv.2016.06.007

25. Bersani FS, Iannitelli A, Pacitti F, Bersani G. Sleep and biorythm disturbances in schizophrenia, mood and anxiety disorders: A review. Riv Psichiatr. 2012;47(5):365–75.

26. Sateia MJ. International classification of sleep disorders-third edition highlights and modifications. Chest. 2014;146(5):1387–94.

27. American Academy of Sleep Medicine. International classification of Sleep Disorders, 3rd edition (ICSD-3). Darien: IL; 2014.

28. Forbes D, Blake CM, Thiessen EJ, Peacock S, Hawranik P. Light therapy for improving cognition, activities of daily living, sleep, challenging behaviour, and psychiatric disturbances in dementia. Cochrane Database Syst Rev

[Internet]. 2014;(2). Available from: http://doi.wiley.com/10.1002/14651858.CD003946.pub4

29. Auger RR, Burgess HJ, Emens JS, Deriy L V, Thomas SM, Sharkey KM. Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders. J Clin Sleep Med [Internet]. 2015;11(10):1199–236. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26414986%5Cnhttp://www.ncbi.nlm.nih.gov/pubmed/26414986

*30. van Maanen A, Meijer AM, van der Heijden KB, Oort FJ. The effects of light therapy on sleep problems: A systematic review and meta-analysis. Sleep Med Rev [Internet]. 2016;29:52–62. Available from: http://dx.doi.org/10.1016/j.smrv.2015.08.009

31. Golden RN, Gaynes BN, Ekstrom RD, Hamer RM, Ph D, Jacobsen FM, et al. The Efficacy of Light Therapy in the Treatment of Mood Disorders : A Review and Meta-Analysis of the Evidence. Am J Psychiatry. 2005;162(April):656–62.

*32. Penders TM, Stanciu CN, Schoemann AM, Ninan PT, Bloch R, Saeed SA. Bright Light Therapy as Augmentation of Pharmacotherapy for Treatment of Depression: A Systematic Review and Meta-Analysis. Prim Care Companion CNS Disord [Internet]. 2016;18(5). Available from: https://www.jstor.org/stable/1164588?seq=1#page_scan_tab_contents

33. Higgins J, Green S (eds). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011] In: The Cochrane Library [Internet]. Chichester: John Wiley & Sons, Ltd.; 2011. Available from: www.handbook.cochrane.org.

34. Harris RJ, Bradburn MJ, Deeks JJ, Altman DG, Harbord RM, Sterne JAC. Metan: Fixed- and random-effects meta-analysis. Stata J. 2008;8(1):3–28.

35. Thompson SG, Higgins JBT. How should meta-regression analysis be undertaken and interpreted? Stat Med. 2002;21(11):1559–73.

*36. Jagannath A, Peirson SN, Foster RG. Sleep and circadian rhythm disruption in neuropsychiatric illness. Curr Opin Neurobiol [Internet]. 2013 [cited 2014 Nov 4];23(5):888–94. Available from: http://dx.doi.org/10.1016/j.conb.2013.03.008

*37. Harvey AG, Murray G, Chandler RA, Soehner A. Sleep Disturbance as Transdiagnostic: Consideration of Neurobiological Mechanisms. Clin Psychol Rev. 2011;31(2):225–35.

38. Sun X, Briel M, Walter SD, Guyatt GH. Is a subgroup effect believable? Updating criteria to evaluate the credibility of subgroup analyses. BMJ. 2010;340(7751):850–4.

39. Borenstein M, Hedges L, Higgins J, Rothstein H. Introduction to meta-analysis. New Jersey, USA: John Wiley & Sons, Ltd; 2009.

40. Sheaves B, Isham L, Bradley J, Espie C, Barrera A, Waite F, et al. Adapted CBT to Stabilize Sleep on Psychiatric Wards: a Transdiagnostic Treatment Approach. Behav Cogn Psychother. 2018;(April):1–15.

41. Barbini B, Benedetti F, Colombo C, Dotoli D, Bernasconi A, Cigala-Fulgosi M, et al. Dark therapy for mania: A pilot study. Bipolar Disord. 2005;7(1):98–101.

42. Henriksen TE, Skrede S, Fasmer OB, Schoeyen H, Leskauskaite I, Bjørke-Bertheussen J, et al. Blue-blocking glasses as additive treatment for mania: A

randomized placebo-controlled trial. Bipolar Disord. 2016;18(3):221–32.

43. Bogen S, Legenbauer T, Gest S, Holtmann M. Lighting the mood of depressed youth: Feasibility and efficacy of a 2 week-placebo controlled bright light treatment for juvenile inpatients. J Affect Disord. 2016;190:450–6.

44. Kragh M, Martiny K, Videbech P, Møller DN, Wihlborg CS, Lindhardt T, et al. Wake and light therapy for moderate-to-severe depression – a randomized controlled trial. Acta Psychiatr Scand. 2017;136(6):559–70.

45. Friedman L, Spira AP, Hernandez B, Mather C, Sheikh J, Ancoli-Israel S, et al. Brief morning light treatment for sleep/wake disturbances in older memory-impaired individuals and their caregivers. Sleep Med. 2012;13(5):546–9.

46. McCurry SM, Gibbons LE, Logsdon RG, Vitiello M V., Teri L. Nighttime Insomnia Treatment and Education for Alzheimer's Disease: A randomized, controlled trial. J Am Geriatr Soc. 2005;53(5):793–802.

47. McCurry S, Pike K. Increasing Walking and Bright Light Exposure to Improve Sleep in Community-Dwelling Persons with Alzheimer's Disease: Results of a Randomized, Controlled Trial. J Am Geriatr Soc [Internet]. 2011;59(8):1393–402. Available from: http://onlinelibrary.wiley.com/doi/10.1111/j.1532-5415.2011.03519.x/full

48. Sloane P, Figueiro M, Cohen L, Reed D, Williams C, Preisser J, et al. Effect of home-based light treatment on persons with dementia and their caregivers. Light Res Technol. 2015;47(2):161–76.

49. Saxvig IW, Wilhelmsen-Langeland A, Pallesen S, Vedaa Ø, Nordhus IH, Bjorvatn B. A randomized controlled trial with bright light and melatonin for

delayed sleep phase disorder: Effects on subjective and objective sleep. Chronobiol Int. 2014;31(1):72–86.

50. Dowling GA, Burr RL, Van Someren EJW, Hubbard EM, Luxenberg JS, Mastick J, et al. Melatonin and bright-light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease. J Am Geriatr Soc. 2008;56(2):239–46.

51. Gradisar M, Dohnt H, Gardner G, Paine S, Starkey K, Menne A, et al. A Randomized Controlled Trial of Cognitive-Behavior Therapy Plus Bright Light.pdf. Sleep [Internet]. 2011;34(12):1671–80. Available from: http://dx.doi.org/10.5665/sleep.1432

52. Sterne JAC, Harbord RM. Funnle plots in meta-analysis. Stata J. 2004;4(2):127–41.

53. Steichen TJ, Egger M, Sterne JAC. sbe19.1: Tests for bias in meta-analysis. Stata Tech Bull Stata Tech Repr vol 8. 1998;44(3–4):84–5.

54. Scott S Campbell, Dawson D, Anderson MW. Alleviation of sleep maintenance insomnia with timed exposure to bright light. J - Am Geriatr Soc. 1993;41:829–36.

55. Figueiro MG. Individually tailored light intervention through closed eyelids to Promote Circadian Alignment and Sleep Health. Sleep Heal. 2015;1(1):75–82.

56. Lack L, Wright H, Kemp K, Gibbon S. The treatment of early-morning awakening insomnia with 2 evenings of bright light. Sleep. 2005;28(5):616–23.

57. Palmer CR, Kripke DF, Savage HCJ, Cindrich LA, Loving RT, Elliott JA. Efficacy of Enhanced Evening Light for Advanced Sleep Phase Syndrome.

Behav Sleep Med. 2003;1(4):213–26.

58. Katsuhisa Ando, Kripke DF, Cole RJ, Elliot JA. Light mask 500 lux treatment for elayed sleep phase syndrome. Vol. 23, Progress in neuro-psychopharmacology & biological psychiatry. 1999. p. 15–24.

59. Cole RJ, Smith JS, Alcalá YC, Elliott JA, Kripke DF. Bright-light mask treatment of delayed sleep phase syndrome. J Biol Rhythms. 2002;17(1):89–101.

60. Geerdink M, Walbeek TJ, Beersma DGM, Hommes V, Gordijn MCM. Short blue light pulses (30 Min) in the morning support a sleep-advancing protocol in a home setting. J Biol Rhythms. 2016;31(5):483–97.

61. Lack L, Bramwell T, Wright H, Kemp K. Morning blue light can advance the melatonin rhythm in mild delayed sleep phase syndrome. Sleep Biol Rhythms. 2007;5(1):78–80.

62. Lack L, Wright H, Paynter D. The treatment of sleep onset insomnia with bright morning light. Sleep Biol Rhythms. 2007;5(3):173–9.

63. Langevin RH, Laurent A, Sauvé Y. Preliminary assessment on the effectiveness of the Luminette® in adolescents with a delayed sleep phase syndrome (DSPS): Randomized single blind placebo-controlled study. Med du Sommeil [Internet]. 2014;11(2):91–7. Available from: https://www.scopus.com/inward/record.uri?eid=2-s2.0-84901654831&doi=10.1016%2Fj.msom.2014.03.003&partnerID=40&md5=5d7ccbe0a24ebfa91a811148ee50dff6

64. Wilhelmsen-Langeland A, Saxvig IW, Pallesen S, Vedaa Ø, Nordhus IH, Bjorvatn B. A randomized controlled trial with bright light and melatonin for

delayed sleep phase disorder: Effects on subjective and objective sleepiness and cognitive function. J Biol Rhythms. 2013;28(5):306–21.

65. Avery DH, Bolte MA, Ries R. Dawn Simulation Treatment of Abstinent Alcoholics With Winter Depression. J Clin ps. 1998;59(1):35–44.

66. Bogen S, Legenbauer T, Gest S, Holtmann M. Morning bright light therapy: A helpful tool for reducing comorbid symptoms of aff ective and behavioral dysregulation in juvenile depressed inpatients? A pilot trial. Z Kinder Jugendpsychiatr Psychother. 2017;45(1):34–41.

67. Esaki Y, Kitajima T, Takeuchi I, Tsuboi S, Furukawa O, Moriwaki M, et al. Effect of blue-blocking glasses in major depressive disorder with sleep onset insomnia: A randomized, double-blind, placebo-controlled study. Chronobiol Int [Internet]. 2017;34(6):753–61. Available from: https://doi.org/10.1080/07420528.2017.1318893

68. Kragh M, Møller DN, Wihlborg CS, Martiny K, Larsen ER, Videbech P, et al. Experiences of wake and light therapy in patients with depression: A qualitative study. Int J Ment Health Nurs. 2017;26(2):170–80.

69. Lieverse R, Van Someren EJ, Nielen MM, Uitdehaag BM, Smit JH, Hoogendijk WJ. Bright light treatment in elderly patients with nonseasonal major. Arch Gen Psychiatry. 2011;68(1):61–70.

70. McEnany GW, Lee KA. Effects of light therapy on sleep, mood, and temperature in women with nonseasonal major depression. Issues Ment Health Nurs [Internet]. 2005;26(7):781–94. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc4&NEWS=N&AN=2005-10414-009

71. Bromundt V, Wirz-Justice A, Kyburz S, Opwis K, Dammann G, Cajochen C. Circadian sleep-wake cycles, well-being, and light therapy in borderline personality disorder. J Pers Disord [Internet]. 2013;27(5):680–96. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=22928852

72. Sheaves B, Freeman D, Isham L, McInerney J, Nickless A, Yu L-M, et al. Stabilising sleep for patients admitted at acute crisis to a psychiatric hospital (OWLS): Psychol Med. 2017;48:1694–704.

73. Sit DK, McGowan J, Wiltrout C, Diler RS, Dills J, Luther J, et al. Adjunctive bright light therapy for bipolar depression: A randomized double-blind placebo-controlled trial. Am J Psychiatry. 2017;175(2):131–9.

74. Ancoli-Israel S, Martin JL, Kripke DF, Marler M, Klauber MR. Effect of light treatment on sleep and circadian rhythms in demented nursing home patients. J Am Geriatr Soc. 2002;50(2):282–9.

75. Burns A, Allen H, Tomenson B, Duignan D, Byrne J. Bright light therapy for agitation in dementia: A randomized controlled trial. Int Psychogeriatrics. 2009;21(4):711–21.

76. Sutherland D, Woodward Y, Byrne J. The use of light therapy to lower agitation in people with dementia. Nurs Times. 2004;100(45):32–4.

77. Connell BR, Sanford JA, Lewis D. Therapeutic Effects of an Outdoor Activity Program on Nursing Home Residents with Dementia. J Hous Elderly [Internet]. 2007;21(3–4):194–209. Available from: http://www.tandfonline.com/doi/abs/10.1300/J081v21n03_12?journalCode=wjhe20#.UjW4Kz_fKSo

78. Dowling GA, Mastick J, Hubbard EM, Luxenberg JS, Burr RL. Effect of timed bright light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease. Int J Geriatr Psychiatry. 2005;20(8):738–43.

79. Dowling GA, Hubbard EM, Mastick J, Luxenberg JS, Burr RL, Someren EJW Van. Effect of morning bright light treatment for rest–activity disruption in institutionalized patients with severe Alzheimer's disease. Int Psychogeriatrics. 2005;17(2):221–36.

80. Fontana Gasio P, Kräuchi K, Cajochen C, Van Someren E, Amrhein I, Pache M, et al. Dawn-dusk simulation light therapy of disturbed circadian rest-activity cycles in demented elderly. Exp Gerontol. 2003;38(1–2):207–16.

81. Lyketsos CG, Veiel LL, Baker A, Steele C. A randomized, controlled trial of bright light therapy for agitated behaviors in dementia patients residing in long-term care. Int J Geriatr Psychiatry. 1999;14(7):520–5.

82. Mishima K, Hishikawa Y, Okawa M. Randomized, dim light controlled, crossover test of morning bright light therapy for rest-activity rhythm disorders in patients with vascular dementia and dementia of alzheimer's type. Chronobiol Int. 1998;15(6):647–54.

83. Nowak L, Davis J. Qualitative analysis of therapeutic light effects on global function in alzheimer's disease. West J Nurs Res. 2011;33(7):933–52.

84. Nowak L. The effect of timed blue-green light on sleep-wake patterns in womenwith alzheimer's disease. Wayne State University. 2008.

85. Ouslander JG, Connell BR, Bliwise DL, Endeshaw Y, Griffiths P, Schnelle JF. A nonpharmacological intervention to improve sleep in nursing home patients:

Results of a controlled clinical trial. J Am Geriatr Soc. 2006;54(1):38–47.

86. Sloane PD, Williams CS, Mitchell CM, Preisser JS, Wood W, Barrick AL, et al. High-Intensity Environmental Light in Dementia: Effect on Sleep and Activity. J Am Geriatr Soc [Internet]. 2007;55(10):1524–33. Available from: http://doi.wiley.com/10.1111/j.1532-5415.2007.01358.x

87. Van Someren EJ, Kessler A, Mirmiran M, Swaab DF. Indirect Bright Light Improves Circadian Rest-Activity Rhythm Disturbances in Demented Patients. Biol Psychiatry. 1997;41:955–63.

*88. Van Someren EJW, Swaab DF, Colenda CC, Cohen W, McCall WV, Rosenquist PB. Bright light therapy: Improved sensitivity to its effects on rest-activity rhythms in Alzheimer patients by application of nonparametric methods. Chronobiol Int. 1999;16(4):505–18.

89. Sheaves B, Isham L, Bradley J, Espie C, Barrera A, Waite F, et al. Adapted CBT to Stabilize Sleep on Psychiatric Wards: A Transdiagnostic Treatment Approach. Behav Cogn Psychother. 2018;46(6):661–75.

90. Chang A-M, Santhi N, St Hilaire M, Gronfier C, Bradstreet DS, Duffy JF, et al. Human responses to bright light of different durations. J Physiol [Internet]. 2012;590(13):3103–12. Available from: http://doi.wiley.com/10.1113/jphysiol.2011.226555

91. Santhi N, Thorne H, van der Veen D, Johnsen S, Mills S, Hommes V, et al. The spectral composition of evening light and individual differences in the suppression of melatonin and delay of sleep in humans. J Pineal Res. 2012;53(1):47–59.

92. Gooley JJ, Rajaratnam SMW, Brainard GC, Kronauer RE, Czeisler CA,

Lockley SW. Spectral responses of the human circadian system depend on the irradiance and duration of exposure to light. Sci Transl Med. 2010;2(31).

93. Minors DS, Waterhouse JM, Wirzjustice A. A Human Phase Response Curve to Light. Neurosci Lett. 1991;133(1):36–40.

94. Wright KP, Bogan RK, Wyatt JK. Shift work and the assessment and management of shift work disorder (SWD). Sleep Med Rev [Internet]. 2013 Feb [cited 2014 Oct 13];17(1):41–54. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22560640

95. Boudreau P, Dumont GA, Boivin DB. Circadian Adaptation to Night Shift Work Influences Sleep , Performance , Mood and the Autonomic Modulation of the Heart. PLoS One. 2013;8(7).

96. Mulligan LD, Haddock G, Emsley R, Neil ST, Kyle SD, Mulligan LD, et al. High Resolution Examination of the Role of Sleep Disturbance in Predicting Functioning and Psychotic Symptoms in Schizophrenia : A Novel Experience Sampling Study High Resolution Examination of the Role of Sleep Disturbance. J Abnorm Psychol [Internet]. 2016;125(6):788–97. Available from: doi.org/10.1037/abn0000180

97. Carney CE, Buysse DJ, Ancoli-israel S, Edinger JD, Krystal AD, Lichstein KL, et al. The Consensus Sleep Diary : Standardizing Prospective Sleep Self-Monitoring. Sleep. 2012;35(2):287–302.

98. Reed DL, Sacco WP. Measuring sleep efficiency: what should the denominator be? J Clin Sleep Med. 2016;12(2):263–6.

*99. Skeldon AC, Phillips AJK, Dijk D-J. The effects of self-selected light-dark cycles and social constraints on human sleep and circadian timing: a modeling

approach. Sci Rep [Internet]. 2017;7(45158). Available from: http://www.nature.com/articles/srep45158

100. Harvey AG, Kaplan KA, Soehner AM. Interventions for sleep disturbance in bipolar disorder. Sleep Med Clin. 2015;10(1):101–5.

101. Samalin L, Bellivier F, Giordana B, Yon L, Milhiet V, El-Hage W, et al. Patients' perspectives on residual symptoms in bipolar disorder: a focus group study. J Nerv Ment Dis [Internet]. 2014;202(7):550–5. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=24921420

102. Bradley J, Freeman D, Chadwick E, Harvey AG, Mullins B, Johns L, et al. Treating Sleep Problems in Young People at Ultra-High Risk of Psychosis: A Feasibility Case Series. Behav Cogn Psychother. 2018;46(3):276–91.

4.4 Additional discussion

Preface

This additional discussion was added after the publication of the article in section 4.3, and is presented separately as it is not in the published paper.

Clinically heterogenous interventions and controls

It is noted in the paper that the interventions tested vary in duration, intensity, timing, and method of application of light, this limits the ability to estimate an effect size from the summarised results, as interventions with different features are likely to have different effects. The pooling of these effects would be more meaningful if interventions were more similar, but we feel the existing similarities do make pooling

informative at least to the broad effect of light interventions, and direct future research.

Similarly, due to the limited number of studies available, it was not practical to limit inclusion by type of control condition. Controls included treatment as usual, waitlist control, and sham light therapy/dark therapy. The varied effects of these control conditions likely impacted on the estimated effect sizes of the active interventions. Future syntheses, once more primary data is available, might benefit from sub-grouping studies by control condition, or having specific inclusion criteria around the nature of the control condition.

Study quality and sample size

Risk of bias and study quality were described in the paper and in supplement S7, it is relevant to acknowledge the possible impact of lack of concealment of allocation on outcomes, particularly self-reported outcomes. For instance participants might have felt social pressure to report better outcomes if they were in the intervention arm of the study (Dahlgren and Hansen, 2015).

Although the funnel plot did not detect publication bias, the average sample size of studies was small (mean n = 37.9, median n = 33). Publication bias may have influenced results, as smaller studies may be run with fewer resources, and investigators may be less incentivised to publish negative or inconclusive results, without a large grant funder requiring and facilitating this.

Studies including other active intervention components

Although the majority of studies were of light exposure alterations alone (n=25), a large minority included some other component (n=15), the most common being sleep schedule alterations (n=7), followed by exercise / activity (n=3), CTBi (n=2), sleep hygiene advice (n=2), melatonin (n=2), and wake therapy (n=1). These components

may have contributed toward the observed improvements in sleep. In particular, CBTi, exercise, and melatonin have an evidence base regarding sleep improvement, as summarised in Chapter 1. We ran meta-regressions regarding the effect of inclusion of melatonin, sleep schedule components, and CBTi within the intervention arm (Table S22), and all but one were none-significant, suggesting effects were somewhat similar with or without these additional components. For 'amplitude of rest activity rhythm', inclusion of a sleep schedule component was associated with more improvement, or less deterioration (coefficient 0.4587271, $p = 0.010$).

It is difficult to entirely separate the effects of light exposure, especially from sleep schedule alterations, based on these results, and also based on how light exposure is applied. Timed light exposure near the start or the end of the day, may influence sleep schedule (e.g. the person wakes in time for light exposure). Due to the supposed mechanisms of the effect of light upon circadian rhythm, recommending timed light, without considering sleep schedule, would be inadvisable. The next chapter explores in more detail the complex nature of light schedule alterations, through their interaction with daily routine, baseline light exposure, and sleep timing.

Chapter 5: Study B - Systematic review on adherence and acceptability

This chapter presents a systematic review with narrative synthesis of acceptability and adherence in studies of light therapy to improve sleep in groups with high rates of circadian dysregulation. Its purpose within this thesis was to inform regarding potential acceptability and adherence related issues for light-based intervention components which could be included in the intervention being developed.

Its aim was:

- To examine evidence regarding adherence and acceptability in studies of light or dark interventions, using various delivery devices and protocols, to improve sleep in intrinsic CRSWD and neuropsychiatric illness.

Rationales for the broad methodological choices made were presented in Chapter 3. Below is a rationale for conducting this particular synthesis, within this programme of research, followed by some additional methods detail not included in the published paper.

5.1. Rationale for topic focus and study types included

Study A (meta-analytical review) discussed why the selected populations, interventions, and outcomes were of interest. As well as wishing to know whether light is potentially effective in these groups, we wanted to know about acceptability and adherence, to inform our intervention. It was decided to include single group and qualitative or mixed methods studies in this synthesis, because randomisation was not required to assess acceptability and adherence related factors (Craig et al., 2008), and qualitative or mixed methods can be effective for examining acceptability (Sekhon et al., 2018). It might be argued that focusing only on qualitative or mixed methods studies would be more relevant to the question; however, we were aware from scoping searches that there would be too few studies of light therapy using qualitative methods. It was decided to examine all qualitative and quantitative data reported on these outcomes irrespective of study type.

Even though some studies may not provide rich data, it was also felt that highlighting gaps in reporting, and what attention adherence and acceptability has been accorded in existing literature, was in-itself worthwhile. The data reported could then inform our intervention, and the manner in which it was collected and reported could inform the design of our feasibility study procedures, if appropriate. Possible areas in which we anticipated this review could inform the intervention manual and the feasibility study protocol were: means of adherence management and facilitation, means of monitoring and reporting adherence, measurement and reporting of acceptability, intervention or contextual factors which appear to be acceptable or unacceptable, safety and adverse effects, and means of monitoring of adverse effects. Existing work was not of course the only source on which these decisions would be based, as

theory, guidelines, other evidence, and expert opinion are also relevant; but approaches taken in reviewed studies formed a relevant point of reference.

5.2. Additional detail on data-extraction and synthesis methods

Data extraction and synthesis is described briefly in the manuscript and the below section gives more detail.

5.2.1. Data extraction

Data extraction was initially performed by importing full texts into Nvivo (di Gregorio, 2011), in order to facilitate linking back to the original data. This was done for all data extracted but was particularly important for the acceptability and adherence data, because, as expected, this data was not presented in a standardised format between studies. This meant that frequent reference back to the original data was required during synthesis. Coding the source text during data extraction enabled an audit trail when queries arose.

5.2.2. Data synthesis

Synthesis of the qualitative and quantitative data was undertaken using a narrative approach (Mays et al., 2005), with qualitative and quantitative data on each topic being presented together and then integrated through interpretation. In order to generate numerical summaries (for instance, of the number of studies taking different approaches to adherence management), directed content analysis was used. Directed content analysis is suitable where there is substantial existing theory regarding relevant codes based on which to extract data (Hsieh and Shannon, 2005). We used the Theoretical Framework of Acceptability (Sekhon et al., 2018) to influence the initial framework for data extraction. We additionally created new codes where some data which appeared relevant to acceptability and adherence did not fit neatly with the initial codes, extracting data under the new codes of *personalisation*, and *intervention burden*.

In the few cases where quantitative summaries with descriptive statistics were possible, these were provided. The Wilcoxon signed-rank test was used to assess between group attrition differences, as this test is suitable for matched pair data (Rosner et al., 2006) (the pairs being attrition rates in the intervention and control arms of each study).

It was not possible to extract sufficient acceptability or adherence related outcomes to attempt any numerical examination of relationships between, for instance, percentage adherence and effect, thus no meta-regression was attempted.

5.3. Paper 3, study B: "Adherence and acceptability of light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuropsychiatric illness: a systematic review"

Paper number: 3

Page of thesis: 169

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Supplements to this paper are in Appendix 4 of this thesis.

Author contributions:

The review protocol was designed by SF with supervisory input from DJD, PB and RD. Search, screening, data extraction, risk of bias assessment and data analysis were conducted by SF. The manuscript was drafted by SF, with input from DJD, PB and RD regarding structure, content, and style.

Adherence and acceptability of light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuropsychiatric illness: systematic review

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Abstract

Sleep problems and circadian misalignment affect health and wellbeing, and are highly prevalent in those with co-morbid neuropsychiatric disorders. Interventions altering light exposure patterns of affected individuals are a promising non-pharmacological treatment option; shown by previous meta-analyses to improve sleep, and often described as minimally invasive. To best translate laboratory based mechanistic research into effective treatments, acceptability and barriers to adherence should be understood, but these have not yet been systematically evaluated. Here we examined evidence regarding adherence and acceptability in studies of light or dark interventions using various delivery devices and protocols, to improve sleep in intrinsic circadian rhythm sleep wake disorders and neuropsychiatric illness. Attrition during intervention was low, and reported experiences were largely positive, but measurement and reporting of self-reported experiences, expectations, and adverse effects were poor. Approaches to management and measurement of adherence were varied, and available light monitoring technology appeared under-exploited, as did mobile technology to prompt or track adherence. Based on these findings we suggest recommended reporting items on acceptability and adherence for future investigations. Few studies assessed baseline light exposure patterns, and few personalised interventions. Overall, many applied studies exhibited an approach to light schedule interventions still reminiscent of laboratory protocols, this is unlikely to maximise acceptability and clinical effectiveness. For the next phase of translational research, user acceptability and adherence should receive increased attention during intervention design and study design. We suggest framing light therapies as complex interventions, and emphasise the occupationally embedded (daily activity routine embedded) context in which they occur.

Keywords

Satisfaction, Burden, Phototherapy, Dark therapy, Evidence synthesis, Complex intervention

The health benefits of adequate sleep and of a well synchronised circadian rhythm are well established [1,2]. However, there are many populations in which sleep problems and circadian rhythm disturbances remain highly prevalent [3–5]. It is known that light exposure can be used to modify the timing of circadian rhythms in controlled settings [6], and light interventions have shown potential to improve sleep in real-life settings [7,8].

Light interventions often use a range of special devices, including light boxes, light visors or glasses, dawn simulation devices, or amber (blue blocking) glasses. Interventions can also target indoor lighting, increase natural light exposure (encouraging going outside), or involve dark therapy / light reduction by dimming, turning off or blocking out light. Some interventions aim to shift circadian phase and sleep timing, whilst others aim to increase circadian amplitude and stability of circadian rhythm. Some target sleep alongside high or low mood.

The effects of light depend on the intensity, spectral composition, duration and of timing of light exposure. Importantly, the direction of effects, i.e. an advance or delay in circadian phase, depends on the timing of light exposure [9,10]. To facilitate or cue light exposure that is correctly timed and of adequate duration, modifications to the daily routine (lifestyle, occupational routine[1]) will often be needed. These are not often considered within light therapy protocols and the most convenient and effective fit or compromise between current life circumstances and optimal light exposure might require some personalisation. Adherence to light interventions may therefore not come equally easily to all potential users.

Some activities and environments support adherence to light exposure and bring their own separate health benefits (e.g. daytime outdoor exercise [10]), whilst other activities compete with light exposure recommendations. For instance when reducing evening light exposure is recommended, night-time electronic media use presents a powerful temptation, through its combination of alerting light and engaging and alerting emotional content [11]. Thus like most behavioural interventions, light regimes depend on the participant's adherence across a range of settings and activities. Despite this

[1] Occupational routine is used here to refer to all of the meaningful activities in which a person is engaged throughout the day, including vocational activities, leisure and self-care or 'maintenance' activities. Occupation is sometimes distinguished from mere 'activity' by individual or societal value, meaning or purposefulness [129].

light exposure interventions are *typically* not referred to or described as complex interventions (interventions with several interacting components which are highly context dependent [12]).

Light exposure interventions are promoted as a non-invasive, low cost option [13], whilst at the same time having a definite biological action comparable to a drug [14]. However light exposure is applied over a prolonged period of time (typically 30 minutes or more, daily); this entails a considerable treatment burden of time, effort, and organisation in order to adhere [15,16]. Some burden may be unavoidable [17], but burden can impact upon adherence, health, wellbeing and quality of life [15,16], and should not be ignored.

It is an accepted principle that intervention acceptability is important to consider when developing and evaluating complex interventions [12,18], particularly in interventions involving behaviour change and self-management [19]. Acceptability is a determinant of intervention implementation in practice, and thus should be studied [20–22]. Equally there are many potential methods to increase intervention adherence (bring about behaviour change)[23], methods used should be examined as some means can transfer into clinical practice (such as education, role modelling, or environmental change), whilst other methods (such as financial incentives) probably cannot. Intervention acceptability can relate to a number of factors, described within the Theoretical Framework of Acceptability. These factors include burden; attitudes, feelings, values and ethics; coherence (how easy it is to understand the intervention); perceived efficacy; opportunity costs (within which we include, likelihood and severity of side-effects) [19]. These acceptability factors will influence recruitment, attrition, and adherence.

As circadian rhythm sleep interventions are moving from the lab, to the clinic, and to the home, translation and implementation are critical. Here we provide an analysis of user acceptability of light interventions to improve sleep in intrinsic circadian rhythm disorders and neuropsychiatric conditions. We analyse user perspectives on prospective expectations and retrospective acceptability, recruitment and attrition, adherence, and adverse effects.

Methods

Search and screening

MEDLINE, Embase, PsycInfo, and AMED (via Ovid), and CINAHL (via EBSCO) were searched using keywords and subject headings. Searches were supplemented by reference checking and contacting key authors.

We identified populations in which sleep is frequently disrupted and in which circadian dysregulation is assumed to be prevalent; we included studies in the following populations: intrinsic circadian rhythm sleep-wake disorders (CRSWDs), dementia, psychotic disorders, affective disorders and personality disorders. We included any intervention which altered light exposure patterns, such as those using light boxes, visors, natural light, light avoidance or blue-blocking glasses. We specified studies with the (primary or secondary) aim of improving sleep (Table A1). We made no exclusion based on context of intervention delivery (home, hospital, clinic, lab).

Results were de-duplicated and screened and one third of results were independently screened by another researcher. Full texts were assessed where potentially relevant; where there was ambiguity these were assessed by another researcher. Ten percent of randomly selected full texts were independently assessed by another researcher to check consistency in application of the inclusion criteria. In cases of multiple study publications data were combined.

The protocol for this review was prospectively published on Prospero, available at: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017072387. For changes from this protocol see Appendix A2. This review accompanies a meta-analysis examining treatment effects upon sleep parameters published elsewhere [8] and includes the same controlled studies but adds single group and qualitative studies.

Data Extraction and analysis

Population, setting and intervention data were coded in Nvivo, which was used both to manage and organise the original source text for quantitative data extraction, facilitating checking. Nvivo was also used for some basic qualitative analysis.

Qualitative analysis used a directed content analysis approach (an approach to qualitative analysis which involves categorisation and counting) [24], for instance, different approaches to adherence management were coded, categorised and counted (see Table 2) [25]. Data excerpts were coded relating to the following a priori topics, influenced by the Theoretical Framework of Acceptability [19]: 1) therapy expectations (prospective), 2) acceptability and/or satisfaction (retrospective), 3) adherence (amount/reasons for), and adherence management approaches, 4) recruitment, 5) attrition during intervention (amount/reasons for), and 6) adverse effects. These categories were all deemed of interest as they may influence or reflect acceptability. Excerpts could be coded to multiple topics where relevant. Occurrences of different types of content were compared between categories (e.g. population, setting or intervention categories). During analysis new themes related to both acceptability and adherence were developed [24], including 'intervention burden', and 'personalisation'.

Quantitative data relating to these topics were converted into comparable formats where possible, (e.g. percentage of total participants) and analysed using descriptive statistics, and the Wilcoxon signed-rank test to assess between group attrition differences.

Results

Studies included

There were 89 articles reporting on 77 studies, of which over half included a control group, and only two were qualitative (see Figure 1). We found studies in advanced sleep wake phase disorder (ASWPD) [26–31], delayed sleep wake phase disorder (DSWPD) [29-40], mixed CRSWD [44–46], dementia [44-75], depression [79–85], seasonal affective disorder (SAD) [86–94], bipolar affective disorder [95–97], borderline personality disorder [98], mixed mental health conditions [99], post-partum depression [100], post-traumatic stress disorder (PTSD) & depression [101]. The mean sample size was 37 participants, with most studies in the 11-20 participant range, and only 8 with n>100 (see Table 1 for a summary and Appendices A3-4 for full details of included studies).

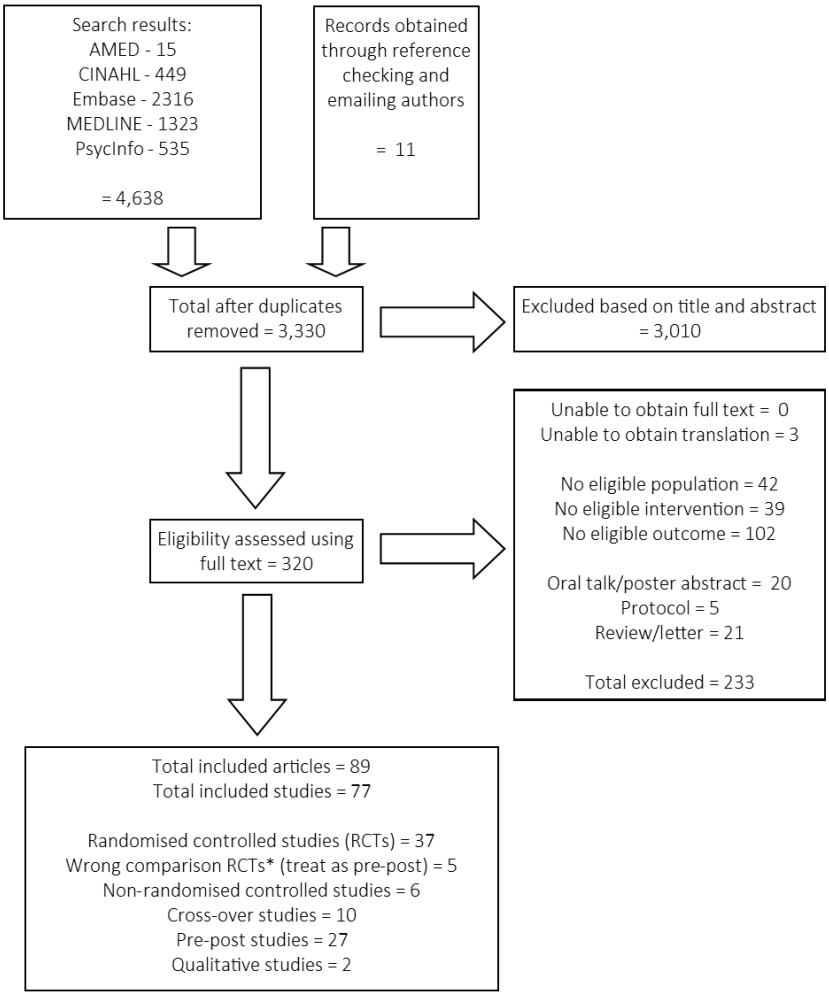

Figure 1: PRISMA flow diagram, about here. Sub-text to Figure 1: *Wrong comparison RCT = no group without the light intervention of interest, for instance "light", VS "light + exercise". These studies were treated as single group within analyses.

Intervention features (including personalisation) and burden

Bright light treatment via a light box was the most commonly applied intervention (n=47), this was most commonly given in the morning (n=32). Some studies examined environmental light exposure modifications or outdoor light exposure (n=27), most often in dementia (n=22). Interventions were usually applied for between 30min and 2hrs per day (n=59). Most studies used white (25%), or cool white light (28%), or did not describe colour spectra (30%), 9% used blue/green light and 8% used outdoor light. Only four examined timed light avoidance as the primary intervention (2 of which in bipolar mania), but some included this as an additional component (n=23). Protocols were mostly over a short period, although a minority

gave light exposure for over a month (1-5 days n=5, 6-10 days n=11, 11-30 days n=40,, >30 days n=14. See also Appendix Figure A1). In CRSWD the primary outcomes were always sleep outcomes, whilst in mental health disorders more studies stated primary aims around mood and secondary aims around sleep (n=13) or had multiple unranked aims (n=5) (6 had sleep as the primary aim). In dementia most studies stated sleep as a primary aim (n=24) whilst some stated agitation or behaviour as primary or unranked aims (n=3, n=5 respectively) (see Appendix Table A3).

Light box exposure requires participants to remain in location. Some protocols specified direction of gaze, whilst others did not. Wearable glasses/visors for light delivery or light avoidance allow relatively free movement. The level of inconvenience of included interventions was therefore highly variable, as was the 'dose' of light delivered. Some proof-of-concept studies used prolonged light box exposure (4hrs, delivered in a sleep lab [28]), whereas other protocols simply modified the participant's light environment by modifying lights in their place of residence.

Most studies intervened at a set (clock) time, within a set time range, at staff's convenience, or did not state how intervention timing was determined (n=47, 61%). Some personalised timing, mostly based on habitual sleep timing (n=17), occasionally based on participant preference (n=3), and occasionally based on objectively assessed circadian phase (Dim Light Melatonin Onset [DLMO] (n=3), or Core Body Temperature (n=-1), in DSWPD and ASWPD), or self-reported diurnal preference (Morningness-Eveningness Questionnaire [MEQ] (n=3), in depression (n=2) and mixed mental health (n=1)). Overall phase assessment or estimation was more common in CRSWD, sometimes used in mental health conditions, and least common in dementia.

Eleven studies measured dynamic light exposure using wearable monitors; however baseline light exposure was used to verify an increase in exposure in the intervention group, rather than to personalise interventions. Other methods of personalisation were occasionally reported, such as personalised placement of lights within the home [71], choices given regarding models of blue-blocker glasses [97], 'titration' of light exposure in response to adverse effects or tolerability [67,95,97]. Occasionally studies described embedding light exposure as part of an activity collaboratively selected with the participant [99,101]. See Appendix Table A5.

We have attempted to distinguish between those self-administration studies which simply instructed participants (n=27), and those which also provided education and a rationale (n=12). Studies which gave light within a multi-component 'talking' based therapy more often described giving explanation and education (e.g. Cognitive Behavioural Therapy for Insomnia [CBT-I] plus light exposure). Assessment of the levels of education or explanation provided was difficult as reporting of how and by whom interventions were introduced was often brief and unclear. In studies which attempted participant blinding and used a dim-light or red-light control condition (29 studies), as opposed to 'treatment as usual' / no light intervention (14 studies), we inferred that participants must not have been given too comprehensive an education regarding light, circadian rhythm and sleep, as they would have been unblinded by the knowledge of brighter and/or more blue spectrum light acting more upon the circadian system or mood.

Table 1: Summary of included studies and of reporting on acceptability and adherence

		ASWPD	DSWPD	mixed CRSWD	dementia	depression	SAD	bipolar	other MH*	total	/ (%)
	total studies in population	6	12	3	32	8	9	3	4	77	
	total n=	120	349	262	1409	356	193	97	86	2872	
	average n=	20	29	87	44	45	21	32	22	37	
study design:	control / comparison	4	10	0	19	6	4	3	1	47	61%
	pre-post	2	2	3	13	2	3	0	2	27	35%
	qualitative studies	0	0	0	0	1	1	0	0	2	3%
intervention:	am light box/lamp	n/a	7	2	15	4	4	0	2	34	44%
	mid-day/afternoon light box/lamp	0	0	0	9	1	0	1	0	11	14%
	eve. light box/lamp	5	n/a	0	4	0	3	0	0	12	16%
	dawn simulation /pre-waking light	n/a	2	0	1	1	5	0	0	9	12%
	am light mask/glasses	n/a	2	0	2	1	0	0	0	5	6%
	eve. light mask/glasses	1	n/a	0	0	0	0	0	0	1	1%
	indoor light	0	0	1	7	2	4	0	1	15	19%
	outdoor light	0	0	0	7	0	0	0	1	8	10%
	light avoidance (main component)	0	1	0	0	1	0	2	0	4	5%
includes:	sleep schedule instructions	0	7	3	5	2	1	0	1	19	25%
	light avoidance	1	8	0	7	1	0	2	1	20	26%
reports on:	expectations	0	2	1	0	3	3	2	0	11	14%
	acceptability	1	1	0	0	1	3	1	1	8	10%
	recruitment	1	8	0	7	3	1	1	2	23	30%
	attrition	4	9	1	19	6	4	3	3	49	64%
	adherence	4	8	0	22	4	4	2	3	47	61%
	adverse effects	1	4	0	8	6	0	2	1	22	29%

*Darker colour indicates better coverage / more studies proportionally. MH = mental health (borderline personality disorder x1, mixed MH x1, post-partum depression x1, PTSD & depression x1). ASWPD=advanced sleep-wake phase disorder, DSWPD=delayed sleep-wake phase disorder, CRSWD=circadian rhythm sleep-wake disorder, SAD=seasonal affective disorder

Pre-therapy expectations and perceptions

Reported therapy expectations related exclusively to expectations of efficacy. There were no pre-therapy perspectives regarding compatibility with values, anticipated burden, or confidence in ability to adhere.

Efficacy expectations were rated in order to check for expectancy bias. Some studies reported measuring expectations, but did not report results [79,91], or reported only on differences in expectations in the intervention and control groups [34,84,86]. Three studies, all of dawn simulation (for SAD mood - primary outcome, sleep - secondary outcome (n=2) or DSWPD sleep - primary outcome (n=1), reported mean and standard deviation for therapy efficacy expectations. Within these the average treatment efficacy expectation was 3.1-3.3 (0-5, 5=complete improvement) for the active treatment groups, and 2.7-3.1 for the control intervention groups [33,87,89]. In the two cases where expectations of bright dawn simulation were compared to dim-red dawn simulation both treatments were rated as reasonably credible, with slightly higher expectation ratings in the intervention groups (3.2 VS 2.7, 3.35 VS 3.1). Two other studies of bright light box treatment in bipolar (mood - primary outcome, sleep - secondary outcome) and mixed CRSWD (sleep - primary outcome) reported expectations using categories [45,95] (see Table A6), similarly to the middling numerical expectation ratings, a 'moderate effect' was most endorsed. Overall this suggests that prior to treatment most participants expected a moderate effect, although the data are very limited.

Two studies asked about knowledge of blue-blocking (amber) glasses in participants with bipolar, excluding participants with prior knowledge to ensure blinding (2 of 20, 2 of 40, respectively) [81,97].

No studies explored pre-therapy expectations, beliefs or knowledge qualitatively.

Post-therapy satisfaction, attitude and perspectives

Four studies assessed satisfaction with the intervention through satisfaction questionnaires [30,97,99], or by asking about recommending the intervention [83]. A limitation is that none specified whether questionnaires were anonymous, so response bias is possible. Two studies in depression and SAD qualitatively explored various aspects of acceptability within treatment experience as a whole [93,102]. Overall these few studies found high levels of acceptance and / or satisfaction with these interventions. Where ratings were given for both an active and control condition, the active condition was rated more favourably on all items [30,97]. Reasons given or endorsed for satisfaction with interventions included: the comfort of amber glasses [97] and ease of use of a light box [30]. Time taken to receive light treatment was mentioned as a drawback [83,93], although this could also be experienced as pleasant quiet time [83] if the social environment was one of mutual respect and few disruptions [93] (see Table A7). Some studies in dementia measured caregiver and staff satisfaction [49,60,61,64], or reported caregivers and staff's inferences regarding participant satisfaction [103], which was generally positive. However views of participants with dementia were never directly ascertained. Interestingly, studies in both dementia and affective disorders referred to the light treatment being "calming", discerned either by participant, carer or research staff report [59,64,83,91,93].

Six studies inferred acceptability from participants' intention to continue use after the study. All of these studies described a high proportion of participants who stated a wish to continue use of the treatment after the study [30,83,93,97], kept study devices [30], or bought their own devices [83].

Recruitment and attrition

Most studies (56 of 77) did not report the number of potential participants approached, possibly because the early stages of recruitment involved clinicians (non-study staff) who did not record refusals. In studies reporting this, a mean of 76% (SD 14%) of those approached agreed to participate.

Most studies reported on attrition (67%). In the 52 studies reporting, mean attrition was 17% (SD=16%) during the intervention (we did not include attrition during follow up as this reflects on acceptability of assessments or study procedures rather than the interventions). Twenty-five studies itemised attrition by reasons and these studies reported an average 5% (SD=6%) attrition due to intervention related factors

such as non-adherence, “refused”, poor acceptability or side-effects. Five studies clearly reported that there was no attrition and 22 studies reported attrition but did not give numbers per reason. Fourteen controlled studies gave separate figures for attrition from the active intervention and control groups. Within these studies attrition was higher in the control groups (intervention attrition: median = 2.91%, IQR = 0.00%-6.09%, control attrition: median = 7.13%, IQR = 0.00%-19.63%), a Wilcoxon signed-rank test showed active intervention was associated with lower attrition ($p = 0.0141$), suggesting attrition was not predominantly caused by active elements of the intervention but by elements recreated in control interventions, and by other non-intervention study factors (see Table A8). Whilst causality cannot be inferred, studies with higher attrition from the intervention included 2 in depression (10%, 31%), of which one included wake therapy (31%), attrition from light + CBTi in DSWPD was also higher than others (13%).

Adherence to therapy

Adherence to light exposure interventions was measured via self-report, by caregiver or researcher observation, and occasionally via remote monitoring methods such as light monitors on actigraphy devices. Adherence was described in relation to how closely actual light exposure resembled intended light exposure, or how many participants were classified as ‘adherent’, or both. Although most studies discussed methods of encouraging and monitoring adherence (70 of 77), many studies (n=29) gave no information on levels of adherence, whilst a further 20 either gave only general comments (e.g. “adherence was good”), or reported relationships of adherence and other variables, but did not report adherence itself. Few studies reported levels of adherence (24 of 77), although adherence was high in those studies (mean 88% (SD=11%), range 65%-100%). Because of limited reporting it is not possible to draw any conclusions regarding potential predictors of adherence. For instance ‘explanation/education’ appears linked to lower % of participants being adherent (75% vs 93-94%), but as this approach was used more within studies containing other (non-light) behavioural intervention components, it may be the inclusion of many components rather than the method of encouraging adherence which is linked to lower adherence.

Methods to encourage adherence (including monitoring adherence) were similarly varied, ranging from constant supervision (or indeed enforcement), to merely

instructing participants to self-administer. Relatively few studies utilised anything in between, such as reminders, or remote monitoring of adherence (see Table 2, A9 and A10).

Table 2: Approaches to adherence management, frequency and examples

Approach to adherence management:	n (%) of studies using	Example (direct quotes):
supervision	24 (31.2%)	"A nurse was seated nearby […] to make sure that the distance from the light source did not become greater than 0.5 m, that the patient did not have their eyes closed for long periods, and that the face was directed towards the lamp." [68] (light box in dementia) "The outdoor program was offered at an existing outdoor space, directly accessible from the facility dining room […] study staff also actively encouraged residents to attend activity programs…" [75] (outdoor light in dementia)
enforcement	3 (3.9%)	"[Participants were] seated in a geri-chair facing the light box and restrained by a tray." [66] (light box in dementia)
instruction only	20 (26.0%)	"Participants were instructed to use the lighting device every night for the next 28 consecutive days for 2 to 3 hr before the time they usually go to bed […]" [30] (light box in ASPD)
explanation / education	13 (16.9%)	"Participants received education regarding the time of their DLMO and the importance of administering light treatment at a particular time in the morning, which may have motivated them and enhanced compliance with light treatment." [36] (light box in DSWPD)
reminders	4 (5.2%)	"In order to encourage compliance […] research staff maintained daily telephone contact with subjects during the treatment interval." [26] (light box in ASPD)
environmental	8 (10.4%)	"For the intervention condition, 13,000K (blue-white) compact fluorescent light bulbs (Philips Lighting, Eindhoven, NL) were placed in table and floor lamps added to the participant's home in the area where the participant spent most of his/her time." [71] (environmental light in dementia)
self-report log	3 (3.9%)	"Participants recorded time and duration of use on a daily log." [100] (light visor in post-partum depression)
time-stamp machine/remote adherence monitoring	4 (5.2%)	"To monitor adherence, patients recorded their daily light therapy sessions on the corresponding self-report form and called the time-stamped machine […]. At every clinic visit […] [researchers] downloaded the light sensor and sensitivity data recorded by the logger device to confirm appropriate, missed, or ill-timed sessions." [95] (light box in bipolar depression)

Although most studies gave no information regarding the reasons for adherence or non-adherence, 29 reported to varying degrees on this. Many gave only a brief comment without directly linking to their data, whilst others itemised reasons given for non-adherence or for ceasing intervention completely. Methods used to gain this information were very rarely described, suggesting that mostly assessment was not systematic and that this information was volunteered by participants. Reasons given for non-adherence included: due to adverse effects, lack of time / other commitments / forgot. In those studies requiring advance of sleep phase for early light exposure - failure to be out of bed and have light on time were mentioned as reasons for non-adherence. In studies requiring clinic attendance or remaining in hospital - travel to clinic and hospital discharge were given as barriers. In studies in dementia, non-adherence was described behaviourally in terms of difficulty remaining seated, wandering off, agitation or closing eyes.

Adverse effects

Few studies described the methods they used to assess adverse effects in detail, if at all. For this reason, although 51/78 studies reported no adverse effects (or reported 'no serious adverse effects', 2 studies), it was often not possible to confidently distinguish between studies where no adverse effects occurred, where no adverse effects were identified, or where adverse effects might have been identified but not reported in the manuscript. It should also be noted that most studies were not powered to detect rare adverse effects, which requires large trials or observational studies [104]. Only 6/47 studies reported separate numbers for adverse effects in the active intervention versus control condition, limiting conclusions.

Nonetheless, available data suggest that adverse effects were infrequent. Twenty-five studies reported adverse effects: in most cases these were mild and short-lived, or ceased with stopping or reducing the intensity of the intervention. Fifteen of these studies reported numbers of participants experiencing different adverse effects (others described but said for instance 'some'), there were 505 participants in these studies and within these the most common side effects were headache (16.4%, n=83 participants), restlessness, agitation or irritability (8.7%, n=44), and tiredness (6.9%, n=35), whilst all others were uncommon (0.2% - 1.6%) (Appendix Table A12). It is

important to bear in mind that most of these studies did not distinguish between side effects of active and control interventions.

A few studies described methods to reduce adverse effects, such as offering choices of models of amber glasses to participants with bipolar to avoid mechanical discomfort [97], or giving the option to reduce brightness and increase duration if participants with dementia appeared troubled by brightness [67]. Such contingencies, however, were not commonly reported.

The adverse effects most frequently reported across studies were headache (9 studies), eye strain or discomfort (5 studies), and restlessness / agitation / irritability (4 studies, 2 = dementia, 1 = depression, 1= post-partum depression). Early awakening was reported exclusively in studies of dawn-simulation (5 of 5 studies). Mechanical discomfort was also reported in some studies using glasses or visors to deliver the light or virtual darkness (3 studies). Headache was reported spontaneously by few participants (3%-7%, 7 studies), whilst in studies which used checklists or interviews to assess side effects, they were much more common (30%-80%, 3 studies). Participants experiencing 'severe' headaches, or headaches prompting discontinuation of treatment occurred in 5 studies (mean 5.9% of participants within those studies) (see Tables A11, A12 and A13).

Hypomania was reported in two participants in total [89,102], neither of which in studies focused specifically on bipolar disorder (n=1 in seasonal depression, n=1 in moderate-severe depression). This represents low rates of hypomania despite 24 studies including participants with affective disorders (718 participants, 2 cases = 0.3% hypomania) and study 1 increasing light for bipolar depression (46 participants). It would not be expected for light reduction (5 studies) to trigger mania, and it did not. One participant with bipolar mania began to experience bipolar depression while using blue blocking (amber) glasses, in response to this the length of daily wear time was reduced, and the depressive episode then remitted.[97]. Three studies of early morning light for delayed sleep reported adverse effects which they attributed to the sudden change to sleep schedule causing sleep deprivation, rather than the light manipulation itself.

Discussion:

The principal findings of this systematic review were that attrition during intervention was low, experiences were largely positive insofar as they were reported, but that measurement and reporting of self-reported experiences, expectations, and adverse effects were poor. Adherence to light treatment was often not measured or reported, and approaches to encouraging adherence were very varied. Adverse effects were not rigorously reported but, apart from headache, appeared uncommon. 0.3% of those with affective disorder were reported to develop hypomania.

Limitations

The diverse samples and interventions included within this review limited synthesis. Future reviews focused on acceptability might benefit from selecting narrower intervention and/or population criteria, and maybe also from broadening the included study or publication types (e.g. observational studies and/or grey literature). A further limitation is the low levels of reporting on the constructs examined. Thus some findings are vulnerable to reporting bias and only tentative claims are possible.

Despite inclusion of many feasibility and single group studies in real-life contexts, relatively few investigated acceptability and adherence, which might have informed the design of larger effectiveness studies. Methods of measurement and reporting on the factors examined by this review were also highly variable.

Only 8 (10%) of studies asked participants views on the acceptability of interventions, and only 2 (3%) investigated their experiences using qualitative methods. This is a common gap in evaluations of other health behaviour interventions [105], yet guidelines stress the importance of such information in underpinning translation of an efficacious treatment into an effective treatment in practice[12,18].

Presentation of light interventions to participants

The way self-administered light interventions were introduced by researchers or clinicians was usually reported very briefly. This makes it difficult to replicate their work, and suggests that as a field we view the manner of introduction of light interventions as unimportant. However, intervention coherence and comprehension by the participant is an aspect of acceptability that is probably important for

adherence (education is one means of influencing behaviour[23]), and for secondary outcomes such as satisfaction and sense of empowerment [19]. More detailed reporting of how and by whom self-administration protocols are introduced might improve evaluation of reproducibility and feasibility.

The attraction of masking treatment allocation from participants by not educating them about the effects of different colour, strength and timing of light must be set against the potential value of intervention coherence, and perhaps better adherence through improved participant understanding. Increasing media attention and public awareness of light and circadian rhythm, may make masking allocation to active intervention versus a placebo-control from participants increasingly unrealistic. Researchers may need to accept trials, with allocation masked from assessors but not participants, as is more accepted in the study of other behavioural and psychological treatments [106].

An involved and personalised explanation requires staff training and expertise to deliver it, which is not without cost [20]. Better reporting would help to clarify what is required in different situations, and when, if ever, following concrete instructions without explanation is enough.

Adherence monitoring and management

Adherence monitoring and management represent challenges within translational research. Optimising adherence to protocol may maximise efficacy but if this cannot be delivered in real settings then it is not relevant to test in effectiveness studies aiming to create generalizable findings [12]. Adherence monitoring is however a different matter; providing feedback on adherence could contribute toward 'persuasion' or 'training', improving motivation or influencing behaviour socially initially [23]; then once benefits are felt, motivation would hopefully increase. Adherence monitoring is also important to ascertain what 'dose' of intervention was actually received to cause the observed effect, to aid in interpretation of studies with positive or negative results[22]. Whilst some labour-intensive methods used in some research studies may be impractical or intrusive within real life interventions, adherence monitoring can be incorporated clinically (adherence can be reported to a clinician, the user, or a third party). There are many technologies which appear underutilised as yet for remote adherence monitoring and encouragement. These

range from text reminders, to wearable light sensing technology, and internet connected devices and environments. Although wrist worn light sensors can produce unreliable data due to distance from the eye, devices worn on the upper body may best balance acceptability for everyday wear, and relatively accurate estimation of light reaching the eyes [107]. Furthermore, examining the dynamic light exposure of an individual at baseline might enable more targeted light exposure recommendations. This would minimise burden by identifying and requiring only those changes expected to have maximum impact, fitting with calls for 'minimally disruptive medicine' [108].

Treatment burden and personalisation

The time required to receive light treatment varied widely, whilst environmental modifications and dawn simulation represent the lowest time burden, light boxes remain the most used. Light box protocols varied in duration of exposure per day and total length of treatment in days; whilst reducing time spent reduces burden, this also reduces the 'dose' of light received, and thus can only be reduced so far before all treatment effect would be lost. Apart from duration, another potential determinant of adherence and the burden of intervention is how the intervention is embedded within the individual's daily routine and lifestyle; however this was rarely discussed. Few studies personalised light exposure timing, either in relation to personal preferences and lifestyle, or in relation to circadian phase (assessed or estimated). Research has shown sleep timing to predict circadian phase in DSWPD [109]. Although personalisation based on phase was more common in CRSWD, even in these studies few offered gradual progression from current to desired/required sleep-wake schedule. As a consequence, adherence would be most challenging for those individuals with the worst sleep phase abnormalities, and may potentially result in exposure during the wrong portion of the phase response curve (see paragraph below and Figure 2). It is likely that personalised timing of light interventions is equally or even more important in neuropsychiatric disorders, due to the diverse sleep disorder presentations within these groups [110,111]. Relationships between sleep timing and circadian phase in neuropsychiatric populations require further examination, and existing knowledge in CRSWD should be utilised.

Light interventions have been conceptualised as being similar to drugs: the light intervention delivers a controlled 'dose' of biologically active light which at

baseline, and in the control condition, is not present. It may be more appropriate to conceptualise light interventions as modifying an existing light exposure pattern, which requires a quantification of the light exposure pattern at baseline. Daytime, evening and night-time light exposure levels vary between individuals significantly based on occupational, environmental and lifestyle factors [112–114]. Thus light interventions are much more like dietary interventions; everyone has a dietary intake at baseline, a diet too low in protein is improved by more protein, whilst a diet already too high in protein will not be improved by more protein. Everyone has a light consumption at baseline. What manipulations are likely to be beneficial as well as tolerable will depend upon baseline light exposure patterns, circadian phase, sleep timing, and other aspects of lifestyle and occupational routines, such as when the person has free time, and activities which might be sacrificed to fit in light therapy (see Figure 2). These examples demonstrate potential problems with interventions applied in an insufficiently personalised manner, in terms of excessive intervention burden, likely difficulties in adherence, and inefficient (or at worst counterproductive) user efforts.

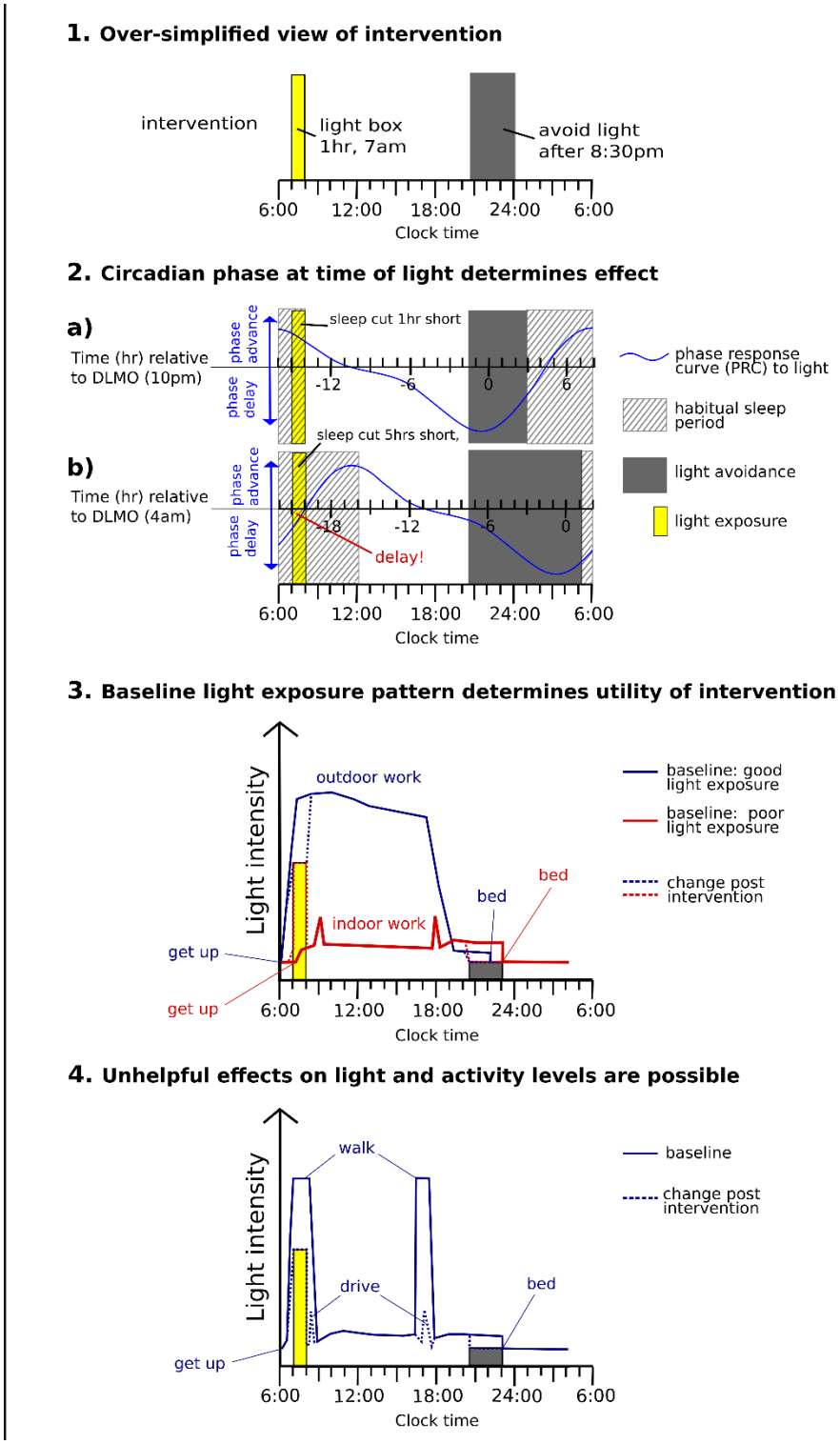

Figure 2: The same light and dark intervention represents a different manipulation depending on baseline circadian phase, light exposure pattern and occupational routine. DLMO = dim light melatonin onset (onset of melatonin production under dim light). Phase response curve (PRC) to light (predicted phase shifting impact of light at DLMO relative times)

1. The intervention is intended to be the same for all individuals. Typically this type of intervention would be intended to either: advance circadian phase, improve sleep quality and regularity, or to lift mood.

2. a) An individual with slight phase delay/normal at baseline, habitual sleep 1am-8am, DLMO at 10pm. 7am bright light is during the phase advance portion of the PRC (advances in circadian phase), the person must wake one hour earlier than usual to use the light box. Avoiding light from 8:30pm until bed 1am (5.5hrs) occurs during the most phase delaying portion of the PRC (prevents much delay of circadian phase).
2. b) An individual with extreme phase delay at baseline, habitual sleep 5am-12pm, DLMO at 4:00am. Waking at 7am in the middle of their habitual sleep period to use a bright light box would be onerous, lead to sleep deprivation, and occurs during the phase delay portion of the PRC (expected to cause *further delay* in circadian phase). Avoiding light from 8:30pm until bed (9.5hrs) seems excessive, and unnecessary as most gains are to be found after midnight in the more delaying portion of this person's PRC.
3. For someone with excellent light exposure patterns at baseline, for instance who usually works outdoors during the morning and daytime, and who already reduces light in the evening, the manipulation effected by the intervention is minimal, so little or no benefit would be expected, whilst for someone exposed to low morning and daytime light, and more evening light at baseline, the manipulation brought about, and therefore the benefits, may be much greater.
4. Where a person usually walks (outdoors) to work or school at 7am, staying inside to use a light box may reduce morning light exposure (even bright light boxes are dimmer than most daylight). Having set off later at 8am if they now drive to work, they are missing bright light exposure (7am & 4:30pm), and missing exercise. The overall effect of the modifications the person has made to their daily routine to fit in light box use, would likely do more harm than good.

Adverse effects

The current review suggests these were infrequent and mostly temporary and reversible, agreeing with another recent evidence synthesis of light interventions in mood disorders [115]; however confidence in this finding is limited by poor reporting of methods of assessment of side effects. Headache and eyestrain appear to be the most common adverse effects. Adverse effects of light exposure alterations may compare favourably to those of behavioural sleep treatments with a sleep restriction component [116,117], and certainly appear preferable to the known adverse effects of hypnotics, which are not recommended for long term use and can cause addiction [118,119].

Agitation, restlessness or anxiety were reported in 4 studies, and hypomania in only two participants, supporting the potential for an over-activation response in a minority of cases. Case reports have documented patients with bipolar depression developing mixed mood states with morning but not midday light [120]. Interestingly, the opposite effect, of light exposure being calming, was also spontaneously reported (studies in SAD=1, depression=1, dementia=2), this is perhaps surprising as light

exposure is generally believed to be acutely alerting [121]. It is worth considering whether adverse effects of light exposure might be more common if light is given at a non-optimal time considering the individual's current circadian phase, sleep pattern, and light exposure history, and if other aspects of education or personalisation might reduce adverse effects. More research is however needed; current evidence is insufficient to conclude with any certainty regarding adverse effects, particularly of long-term use.

The future of light and circadian interventions research

Short-term, highly controlled light interventions have been tested extensively. This has enabled the understanding of mechanisms and development of models. For improvement of sleep and health however, light exposure changes should in many cases be recommended indefinitely, intermittently, or with seasonal recurrence. It is important therefore to think of light in terms of health behaviour change, and to focus on improving light exposure with minimal disruption to people's lives. This should include an increased focus on environmental light (which has received limited attention outside of dementia). We are by no means the first to advocate for increased attention toward characteristics of artificial lighting, including brightness and spectral composition, within the modern light environment. Even though research efforts are ongoing to find the optimal exposures, and best technology to deliver these, there are already recommendations based on existing knowledge[122–124], which could be further utilised within intervention research.

Reviews of light interventions thus far have shown small-moderate effect sizes for sleep outcomes in a range of disorders [7,8]. This encourages light intervention's supplementation with other components. There is increasing evidence for circadian effects of behavioural interventions in exercise, meal timing, and caffeine consumption [125–127]. Thus, future trials may investigate interventions targeting more aspects of the daily routine, utilising multiple zeitgebers.

Long term use of light exposure modifying interventions can be time intensive. We recommend that light exposure is occupationally embedded (embedded within occupational routines). This could mean considering what activity the person will do during light box exposure, and how their surrounding routine is affected, or could include environmental changes in the home, hospital, or workplace (as have been

studied in other groups [128]). Interventions could be optimized to best fit routines, personal values, and social context. The experience of the time spent can be negative; described in terms of inconvenience. By contrast the experience can be of a meaningful pause in which to plan for the day, 'time out' to read or to socialise, or potentially a helpful prompt to take exercise.

We have compared the varied approaches taken within reviewed studies, considering the utility of differing approaches in furthering understanding of acceptability and adherence in studies of light interventions. Based on this a range of reporting recommendations have been drawn (see below).

Recommended reporting items for studies of light schedule interventions

Aims:

- Does the study aim to examine mechanisms (focus on internal validity), or examine feasibility or effectiveness (focus on external validity and generalisability)? Or where on this continuum does the study lie?

Recruitment:

- Proportion of those eligible and approached who participated.
- Numbers declining itemised by reasons for declining (including 'reason withheld')

Introduction of intervention:

- How was the intervention introduced, by whom, in what format was information given, how much time was spent?
- Which mechanisms of action were explained and how? Was any information withheld to maintain credibility of a placebo?

Intervention burden:

- What was required of participants: including location, position, direction of gaze, and any recommended or prohibited activities.
- If the participant needs to make any calculations or decisions in order to 'titrate' or grade their timing or duration of exposure, describe these.
- Describe any ongoing support available to participants.
- If possible, assess and describe alterations to daily occupational routines which participants made in order to adhere to light intervention, and their views on these changes.

Personalisation (where present):

- Describe whether and how the protocol was personalised in its application to individuals
- Describe any options regarding mode of administration (equipment, positioning) and any optional intervention components.
- Were personalisation choices made by participants, clinicians or both together? Based upon what considerations?

Adherence management:

- Specify any incentives (financial or otherwise) given for intervention adherence?
- Describe any strategies used to encourage adherence (e.g. reminders, self-monitoring, was adherence monitoring set up so as to encourage adherence?).

Adherence levels:

- Describe adherence measurement/monitoring methods (e.g. passive light exposure monitoring, self-report, researcher observation).
- Report amount of adherence (average), and variability in adherence.
- Report adherence in terms of both duration and correct timing separately.
- For multiple discrete intervention components report adherence to each separately.

- Where flexibility or self-adjustment is allowable, report levels of adherence to the 'minimum' amount, as well as average amounts of exposure/avoidance.

Adherence reasons:

- Where possible measure and report barriers and facilitators to adherence through qualitative methods or questionnaires.
- Report reasons for discontinuation (e.g. adverse effects, convenience, no reason given).

Expectations, acceptability and satisfaction

- When was satisfaction assessed? (before/during/after treatment)
- Were satisfaction questionnaire responses anonymous? Give percentage response.
- Was there any pattern to nonresponse?
- For quantitative: List response options and scales. Who administered measures?
- For qualitative: Who interviewed the participant (was it the therapist who delivered the intervention or a separate person?)
- Provide access to question schedule / topic guide.
- Consider examining and reporting on the domains within the Theoretical Framework of Acceptability [19].

Adverse effects:

- How were adverse effects assessed? How frequently? By whom?
- Consider assessing and reporting in the following categories: headache, eyestrain / discomfort, mechanical discomfort from wearables (as opposed to the light itself), mood (high/low), energy levels (high/low), sleep onset, offset or maintenance, other (list)
- Report numbers of participants experiencing each side-effect, and numbers of occurrences.

Conclusion

Measurement and reporting of many indicators of acceptability of light therapy is inconsistent or limited. Nevertheless, the high recruitment rates from among those approached, low attrition (which is well documented), reasonable adherence, positive satisfaction ratings and infrequent or mild side effects reported, indicate that these interventions are attractive and acceptable.

Light treatment interventions appear often to be still too closely based upon laboratory protocols originally designed to explore mechanisms, and to be too often examined in a way fitting for simple interventions. This review advocates for the reconceptualization of light interventions as complex behaviour change interventions, and for increased attention to the individual circumstances, experience and views of the user of the intervention. Improved measurement and reporting of

acceptability and adherence related factors may help to optimise adherence, reduce burden and improve user experiences. This may in turn contribute toward improved intervention effectiveness.

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References:

1. Luyster FS, Strollo PJ, Zee PC, Walsh JK. Sleep: A Health Imperative. *Sleep*. 2012;35(6):727-734. doi:10.5665/sleep.1846

2. Roenneberg T, Merrow M. The circadian clock and human health. *Curr Biol*. 2016;26(10):R432-R443. doi:10.1016/j.cub.2016.04.011

3. Zambotti M De, Goldstone A, Colrain IM, Baker FC. Insomnia disorder in adolescence: diagnosis, impact, and treatment. *Sleep Med Rev*. 2018;39(June):12-24. doi:10.1016/j.smrv.2017.06.009.Insomnia

4. Baglioni C, Nanovska S, Regen W, et al. SLEEP AND MENTAL DISORDERS: A META-ANALYSIS OF POLYSOMNOGRAPHIC RESEARCH. *Psychol Bull*. 2016;142(9):969-990. doi:10.1037/bul0000053

5. Leng Y, Musiek ES, Hu K, Cappuccio FP, Yaffe K. Association between circadian rhythms and neurodegenerative diseases. *Lancet Neurol*. 2019;18(3):307-318. doi:10.1016/S1474-4422(18)30461-7

6. Duffy JF, Wright KP. Entrainment of the human circadian system by light. *J Biol Rhythms*. 2005;20(4):326-338. doi:10.1177/0748730405277983

7. van Maanen A, Meijer AM, van der Heijden KB, Oort FJ. The effects of light therapy on sleep problems: A systematic review and meta-analysis. *Sleep Med Rev*. 2016;29:52-62. doi:10.1016/j.smrv.2015.08.009

8. Faulkner SM, Bee PE, Meyer N, Dijk DJ, Drake RJ. Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: A systematic review and meta-analysis. *Sleep Med Rev*. 2019;46:108-123. doi:10.1016/j.smrv.2019.04.012

9. Czeisler CA, Kronauer RE, Allan JS, et al. Bright Light Induction of Strong (Type 0) Resetting of the Human Circadian Pacemaker. *Science (80-)*. 1989;244.

10. Khalsa SBS, Jewett ME, Cajochen C, Czeisler CA. A phase response curve to single bright light pulses in human subjects. *J Physiol*. 2003;549(3):945-952. doi:10.1113/jphysiol.2003.040477

11. Scott H, Woods HC. Fear of missing out and sleep: Cognitive behavioural factors in adolescents' nighttime social media use. *J Adolesc*. 2018;68(July):61-65. doi:10.1016/j.adolescence.2018.07.009

12. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. *Developing and Evaluating Complex Interventions: Update*.; 2019. www.mrc.ac.uk/complexinterventionsguidance.

13. Terman M, Terman JS. Light Therapy for Seasonal and Nonseasonal Depression: Efficacy, Protocol, Safety, and Side Effects. *CNS Spectr*. 2005;10(8):647-663. doi:10.1017/s1092852900019611

14. Wirz-Justice A. Light and dark as a "drug." *Prog Drug Res*. 1987;31:383-342.

15. Eton D, Ramalho de Oliveira D, Egginton J, et al. Building a measurement framework of burden of treatment in complex patients with chronic conditions: a qualitative study. *Patient Relat Outcome Meas*. 2012:39. doi:10.2147/prom.s34681

16. Sav A, King MA, Whitty JA, et al. Burden of treatment for chronic illness: A concept analysis and review of the literature. *Heal Expect*. 2015;18(3):312-324. doi:10.1111/hex.12046

17. Mair FS, May CR. Thinking about the burden of treatment. *BMJ*. 2014;349(November):g6680. doi:10.1136/bmj.g6680

18. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: new guidance. *MRC*. 2008.

19. Sekhon M, Cartwright M, Francis JJ. Acceptability of health care interventions: A theoretical framework and proposed research agenda. *Br J Health Psychol*. 2018;23(3):519-531. doi:10.1111/bjhp.12295

20. Glasgow R E, Vogt T M, Boles S M. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999;89(9):1322-1327.

21. www.RE-AIM.org. www.re-aim.org. Published 2019. Accessed June 17, 2019.

22. Hull L, Goulding L, Khadjesari Z, et al. Designing high-quality implementation research: Development, application, feasibility and preliminary evaluation of the implementation science research development (ImpRes) tool and guide. *Implement Sci*. 2019;14(1):1-20. doi:10.1186/s13012-019-0897-z

23. Michie S, Stralen MM van, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6(42). doi:doi:10.1186/1748-5908-6-42

24. Hsieh H-F, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15(9):1277-1288. doi:10.1177/1049732305276687

25. Morgan DL. Qualitative Content Analysis: A Guide to Paths Not Taken. *Qual Health Res*. 1993;3(1):112-121.

26. Scott S Campbell, Dawson D, Anderson MW. Alleviation of sleep maintenance insomnia with timed exposure to bright light. *J - Am Geriatr Soc*. 1993;41:829-836.

27. Figueiro MG. Individually tailored light intervention through closed eyelids to Promote Circadian Alignment and Sleep Health. *Sleep Heal*. 2015;1(1):75-82. doi:10.1016/j.sleh.2014.12.009.Individually

28. Lack L, Wright H. The effect of evening bright light in delaying the circadian rhythms and lengthening the sleep of early morning awakening insomniacs. *Sleep*. 1993;16(5):436-443. doi:10.1093/sleep/16.5.436

29. Lack L, Wright H, Kemp K, Gibbon S. The treatment of early-morning awakening insomnia with 2 evenings of bright light. *Sleep*. 2005;28(5):616-623. doi:10.1093/sleep/28.5.616

30. Palmer CR, Kripke DF, Savage HCJ, Cindrich LA, Loving RT, Elliott JA. Efficacy of Enhanced Evening Light for Advanced Sleep Phase Syndrome. *Behav Sleep Med*. 2003;1(4):213-226. doi:10.1207/S15402010BSM0104

31. Suhner AG, Murphy PJ, Campbell SS. Failure of timed bright light exposure

to alleviate age-related sleep maintenance insomnia. *J Am Geriatr Soc*. 2002;50(4):617-623. doi:10.1046/j.1532-5415.2002.50154.x

32. Katsuhisa Ando, Kripke DF, Cole RJ, Elliot JA. Light mask 500 lux treatment for elayed sleep phase syndrome. *Prog Neuropsychopharmacol Biol Psychiatry*. 1999;23:15-24.

33. Cole RJ, Smith JS, Alcalá YC, Elliott JA, Kripke DF. Bright-light mask treatment of delayed sleep phase syndrome. *J Biol Rhythms*. 2002;17(1):89-101. doi:10.1177/074873002129002366

34. Rosenthal NE, Joseph-vanderpool JR, Levendosky AA, et al. Phase-Shifting Effects of Bright Morning Light as Treatment for Delayed Sleep Phase Syndrome. *Sleep*. 1990;13(January):354-361.

35. Saxvig IW, Wilhelmsen-Langeland A, Pallesen S, Vedaa Ø, Nordhus IH, Bjorvatn B. A randomized controlled trial with bright light and melatonin for delayed sleep phase disorder: Effects on subjective and objective sleep. *Chronobiol Int*. 2014;31(1):72-86. doi:10.3109/07420528.2013.823200

36. Danielsson K, Jansson-Fröjmark M, Broman JE, Markström A. Cognitive Behavioral Therapy as an Adjunct Treatment to Light Therapy for Delayed Sleep Phase Disorder in Young Adults: A Randomized Controlled Feasibility Study. *Behav Sleep Med*. 2016;14(2):212-232. doi:10.1080/15402002.2014.981817

37. Danielsson K, Jansson-Fröjmark M, Broman JE, Markström A. Light Therapy With Scheduled Rise Times in Young Adults With Delayed Sleep Phase Disorder: Therapeutic Outcomes and Possible Predictors. *Behav Sleep Med*. 2016;16(4):325-336. doi:10.1080/15402002.2016.1210150

38. Esaki Y, Kitajima T, Ito Y, et al. Wearing blue light-blocking glasses in the evening advances circadian rhythms in the patients with delayed sleep phase disorder: An open-label trial. *Chronobiol Int*. 2016;33(8):1037-1044. doi:10.1080/07420528.2016.1194289

39. Geerdink M, Walbeek TJ, Beersma DGM, Hommes V, Gordijn MCM. Short blue light pulses (30 Min) in the morning support a sleep-advancing protocol in a home setting. *J Biol Rhythms*. 2016;31(5):483-497. doi:10.1177/0748730416657462

40. Gradisar M, Dohnt H, Gardner G, et al. A Randomized Controlled Trial of Cognitive-Behavior Therapy Plus Bright Light.pdf. *Sleep*. 2011;34(12):1671-1680. http://dx.doi.org/10.5665/sleep.1432.

41. Lack L, Bramwell T, Wright H, Kemp K. Morning blue light can advance the melatonin rhythm in mild delayed sleep phase syndrome. *Sleep Biol Rhythms*. 2007;5(1):78-80. doi:10.1111/j.1479-8425.2006.00250.x

42. Lack L, Wright H, Paynter D. The treatment of sleep onset insomnia with bright morning light. *Sleep Biol Rhythms*. 2007;5(3):173-179. doi:10.1111/j.1479-8425.2007.00272.x

43. Langevin RH, Laurent A, Sauvé Y. Preliminary assessment on the effectiveness of the Luminette® in adolescents with a delayed sleep phase syndrome (DSPS): Randomized single blind placebo-controlled study. *Med du Sommeil*. 2014;11(2):91-97. doi:10.1016/j.msom.2014.03.003

44. Okawa M, Uchiyama M, Ozaki S, Shibui K, Ichikawa H. Circadian rhythm sleep disorders in adolescents: Clinical trials of combined treatments based on chronobiology. *Psychiatry Clin Neurosci*. 1998;52(5):483-490. doi:10.1046/j.1440-1819.1998.00449.x

45. Yamadera H, Takahashi K, Okawa M. A multicenter study of sleep-wake rhythm disorders: Therapeutic effects of vitamin B12, bright light therapy, chronotherapy and hypnotics. *Psychiatry Clin Neurosci*. 1996;50:203-209.

46. Yamadera W, Sasaki M, Itoh H, Ozone M, Ushijima S. Clinical features of circadian rhythm sleep disorders in outpatients. *Psychiatry Clin Neurosci*. 1998;52(3):311-316. doi:10.1046/j.1440-1819.1998.00395.x

47. Ancoli-israel S, Gehrman P, Martin JL, et al. Increased Light Exposure Consolidates Sleep and Strengthens Circadian Rhythms in Severe Alzheimer ' s Disease. *Behav Sleep Med*. 2003;1(1):22-36. doi:10.1207/S15402010BSM0101

48. Ancoli-Israel S, Martin JL, Kripke DF, Marler M, Klauber MR. Effect of light treatment on sleep and circadian rhythms in demented nursing home patients. *J Am Geriatr Soc*. 2002;50(2):282-289. doi:10.1046/j.1532-5415.2002.50060.x

49. Figueiro MG, Hunter CM, Higgins PA, et al. Tailored lighting intervention for persons with dementia and caregivers living at home. *Sleep Heal*. 2015;1(4):322-330. doi:10.1016/j.sleh.2015.09.003

50. Fontana Gasio P, Kräuchi K, Cajochen C, et al. Dawn-dusk simulation light therapy of disturbed circadian rest-activity cycles in demented elderly. *Exp Gerontol*. 2003;38(1-2):207-216. doi:10.1016/S0531-5565(02)00164-X

51. Friedman L, Spira AP, Hernandez B, et al. Brief morning light treatment for sleep/wake disturbances in older memory-impaired individuals and their caregivers. *Sleep Med*. 2012;13(5):546-549. doi:10.1016/j.sleep.2011.11.013

52. Gibson RH, Gander PH, Dowell AC, Jones LM. Non-pharmacological interventions for managing dementia-related sleep problems within community dwelling pairs: A mixed-method approach. *Dementia*. 2017;16(8):967-984. doi:10.1177/1471301215625821

53. Ito T, Yamadera H, Ito R, Endo S. [Effects of bright light on cognitive disturbances in Alzheimer-type dementia]. *Nippon Ika Daigaku Zasshi*. 1999;66(4):229-238.

54. Ito T, Yamadera H, Ito R, Endo S. Effects of vitamin B on bright light on cognitive and 12 sleep–wake rhythm in Alzheimer-type dementia. *Psychiatry Clin Neurosci*. 2001;55:281–282.

55. Kobayashi R, Fukuda N, Kohsaka M, et al. Effects of bright light at lunchtime on sleep in patients in a geriatric hospital II. *Psychiatry Clin Neurosci*. 2001;55(3):287-289. doi:10.1046/j.1440-1819.2001.00864.x

56. Koyama E, Matsubara H, Nakano T. Bright light treatment for sleep-wake disturbances in aged individuals with dementia. *Psychiatry Clin Neurosci*. 1999;53(2):227-229. doi:10.1046/j.1440-1819.1999.00483.x

57. Lyketsos CG, Veiel LL, Baker A, Steele C. A randomized, controlled trial of

bright light therapy for agitated behaviors in dementia patients residing in long-term care. *Int J Geriatr Psychiatry*. 1999;14(7):520-525. doi:10.1002/(SICI)1099-1166(199907)14:7<520::AID-GPS983>3.0.CO;2-M

58. Martin JL, Marler MR, Harker JO, Josephson KR, Alessi C a. A Multicomponent Nonpharmacological Intervention Improves Activity Rhythms Among Nursing Home Residents With Disrupted Sleep / Wake Patterns. *J or Gerontol*. 2007;62(1):67-72. doi:10.1093/gerona/62.1.67

59. Burns A, Allen H, Tomenson B, Duignan D, Byrne J. Bright light therapy for agitation in dementia: A randomized controlled trial. *Int Psychogeriatrics*. 2009;21(4):711-721. doi:10.1017/S1041610209008886

60. McCurry SM, Gibbons LE, Logsdon RG, Vitiello M V., Teri L. Nighttime Insomnia Treatment and Education for Alzheimer's Disease: A randomized, controlled trial. *J Am Geriatr Soc*. 2005;53(5):793-802. doi:10.1111/j.1532-5415.2005.53252.x

61. McCurry S, Pike K. Increasing Walking and Bright Light Exposure to Improve Sleep in Community-Dwelling Persons with Alzheimer's Disease: Results of a Randomized, Controlled Trial. *J Am Geriatr Soc*. 2011;59(8):1393-1402. doi:10.1111/j.1532-5415.2011.03519.x.Increasing

62. Mishima K, Hishikawa Y, Okawa M. Randomized, dim light controlled, crossover test of morning bright light therapy for rest-activity rhythm disorders in patients with vascular dementia and dementia of alzheimer's type. *Chronobiol Int*. 1998;15(6):647-654. doi:10.3109/07420529808993200

63. Mishima K, Okawa M, Hishikawa Y, Hozumi S, Hori H, Takahashi K. Morning bright light therapy for sleep and behaviour disorders in elderly patients with dementia. *Acta Psychiatr Scand*. 1994;89:1-7.

64. Nowak L. The effect of timed blue-green light on sleep-wake patterns in womenwith alzheimer's disease. *Wayne State Univ*. 2008.

65. Ouslander JG, Connell BR, Bliwise DL, Endeshaw Y, Griffiths P, Schnelle JF. A nonpharmacological intervention to improve sleep in nursing home patients: Results of a controlled clinical trial. *J Am Geriatr Soc*. 2006;54(1):38-47. doi:10.1111/j.1532-5415.2005.00562.x

66. Satlin A, Volicer L, Ross V, Herz L, Campbell S. Bright Light Treatment of Behvaioural and Sleep Disturbances in Patients with Alzheimers Disease. *1Am J Psychiatry*. 1992;149:1028-1032.

67. Sekiguchi H, Iritani S, Fujita K. Bright light therapy for sleep disturbance in dementia is most effective for mild to moderate Alzheimer's type dementia: a case series. *Psychogeriatrics*. 2017;17(5):275-281. doi:10.1111/psyg.12233

68. Skjerve A, Holsten F, Aarsland D, Bjorvatn B, Nygaard HA, Johansen IM. Improvement in behavioral symptoms and advance of activity acrophase after short-term bright light treatment in severe dementia. *Psychiatry Clin Neurosci*. 2004;58(4):343-347. doi:10.1111/j.1440-1819.2004.01265.x

69. Sloane PD, Williams CS, Mitchell CM, et al. High-Intensity Environmental Light in Dementia: Effect on Sleep and Activity. *J Am Geriatr Soc*. 2007;55(10):1524-1533. doi:10.1111/j.1532-5415.2007.01358.x

70. Calkins M, Szmerekovsky JG, Biddle S. Effect of Increased Time Spent Outdoors on Individuals with Dementia Residing in Nursing Homes. *J Hous Elderly*. 2007;21(3-4):211-228. doi:10.1300/J081v21n03

71. Sloane P, Figueiro M, Cohen L, et al. Effect of home-based light treatment on persons with dementia and their caregivers. *Light Res Technol*. 2015;47(2):161-176. doi:10.1177/1477153513517255.Effect

72. Van Someren EJ, Kessler A, Mirmiran M, Swaab DF. Indirect Bright Light Improves Circadian Rest-Activity Rhythm Disturbances in Demented Patients. *Biol Psychiatry*. 1997;41:955-963.

73. Chong M, Tan K, Tay L, Wong Y, Ancoli-Israel S. Bright light therapy as part of a multicomponent management program improves sleep and functional outcomes in delirious older hospitalized adults. *Clin Interv Aging*. 2013;8:565-572. doi:10.2147/CIA.S44926

74. Colenda CC, Cohen W, McCall WV, Rosenquist PB. Phototherapy for Patients with Alzheimer Disease with Disturbed Sleep Patterns: Results of a Community-Based Pilot Study. *Alzheimer Dis Assoc Disord*. 1997;11(3):175-178.

75. Connell BR, Sanford JA, Lewis D. Therapeutic Effects of an Outdoor Activity Program on Nursing Home Residents with Dementia. *J Hous Elderly*. 2007;21(3-4):194-209. doi:10.1300/J081v21n03

76. Dowling GA, Mastick J, Hubbard EM, Luxenberg JS, Burr RL. Effect of timed bright light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease. *Int J Geriatr Psychiatry*. 2005;20(8):738-743.

77. Dowling GA, Burr RL, Van Someren EJW, et al. Melatonin and bright-light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease. *J Am Geriatr Soc*. 2008;56(2):239-246. doi:10.1111/j.1532-5415.2007.01543.x

78. Fetveit A, Skjerve A, Bjorvatn B. Bright light treatment improves sleep in institutionalised elderly - An open trial. *Int J Geriatr Psychiatry*. 2003;18(6):520-526. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed6&NEWS=N&AN=2003255958.

79. Bogen S, Legenbauer T, Gest S, Holtmann M. Lighting the mood of depressed youth: Feasibility and efficacy of a 2 week-placebo controlled bright light treatment for juvenile inpatients. *J Affect Disord*. 2016;190:450-456. doi:10.1016/j.jad.2015.09.026

80. Dietzel M, B Saletu, O.M. Lesch, W Sieghart, M Schjerve. Light Treatment in Depressive Illness, Polysomnographic, sychometric and Neuroendocrinological Findings. *Eur Neurol*. 1986;25(suppl 2):93-103.

81. Esaki Y, Kitajima T, Takeuchi I, et al. Effect of blue-blocking glasses in major depressive disorder with sleep onset insomnia: A randomized, double-blind, placebo-controlled study. *Chronobiol Int*. 2017;34(6):753-761. doi:10.1080/07420528.2017.1318893

82. Jacobsen FM. Waking in a lighted room. *Biol Psychiatry*. 1990;27(3):372-374.

doi:10.1016/0006-3223(90)90011-P

83. Kragh M, Møller DN, Wihlborg CS, et al. Experiences of wake and light therapy in patients with depression: A qualitative study. *Int J Ment Health Nurs.* 2017;26(2):170-180. doi:10.1111/inm.12264

84. Lieverse R, Van Someren EJ, Nielen MM, Uitdehaag BM, Smit JH, Hoogendijk WJ. Bright light treatment in elderly patients with nonseasonal major. *Arch Gen Psychiatry*. 2011;68(1):61-70.

85. McEnany GW, Lee KA. Effects of light therapy on sleep, mood, and temperature in women with nonseasonal major depression. *Issues Ment Health Nurs.* 2005;26(7):781-794. doi:10.1080/01612840591008410

86. Avery DH, Eder DN, Bolte MA, et al. Dawn simulation and bright light in the treatment of SAD: A controlled study. *Biol Psychiatry*. 2001;50(3):205-216. doi:10.1016/S0006-3223(01)01200-8

87. Avery DH, Bolte MA, Ries R. Dawn Simulation Treatment of Abstinent Alcoholics With Winter Depression. *J Clin ps*. 1998;59(1):35-44. doi:10.4088/JCP.v59n0109

88. Avery DH, Kouri ME, Monaghan K, Bolte MA, Hellekson C, Eder D. Is dawn simulation effective in ameliorating the difficulty awakening in seasonal affective disorder associated with hypersomnia? *J Affect Disord*. 2002;69:231-236. doi:10.1016/S0165-0327(00)00360-8

89. Avery DH, Bolte MAP, Cohen S, Millet MS. Gradual Versus Rapid Dawn Simulation Treatment of Winter Depression. *J Clin Psychiatry*. 1992;53:359-363.

90. Ciesielczyk K, Pracka D, Pracki T, Tafil-Klawe M. Changes of sleep quality and mood disorders under the influence of phototherapy on patients with seasonal affective disorders SAD. *Psychiatr Pol*. 2004;38(6):1105-1114.

91. Meesters Y, Dekker V, Schlangen LJM, Bos EH, Ruiter MJ. Low-intensity blue-enriched white light (750 lux) and standard bright light (10 000 lux) are equally effective in treating SAD. A randomized controlled study. *BMC Psychiatry*. 2011;11(1):17. doi:10.1186/1471-244X-11-17

92. Partonen T, Appelberg B, Kajaste S, Partinen M, Harma M, Laitinen J. Effects of light treatment on circadian rhytniciety in seasonal affective disorder. *1European Psychiatry*. 1992;7:141-142.

93. Rastad C, Wetterberg L, Martin C. Patients' Experience of Winter Depression and Light Room Treatment. *Psychiatry J*. 2017;2017:1-11. doi:10.1155/2017/6867957

94. Winkler D, Pjrek E, Praschak-Rieder N, et al. Actigraphy in patients with seasonal affective disorder and healthy control subjects treated with light therapy. *Biol Psychiatry*. 2005;58(4):331-336. doi:10.1016/j.biopsych.2005.01.031

95. Sit DK, McGowan J, Wiltrout C, et al. Adjunctive bright light therapy for bipolar depression: A randomized double-blind placebo-controlled trial. *Am J Psychiatry*. 2017;175(2):131-139. doi:10.1176/appi.ajp.2017.16101200

96. Barbini B, Benedetti F, Colombo C, et al. Dark therapy for mania: A pilot

study. *Bipolar Disord*. 2005;7(1):98-101. doi:10.1111/j.1399-5618.2004.00166.x

97. Henriksen TE, Skrede S, Fasmer OB, et al. Blue-blocking glasses as additive treatment for mania: A randomized placebo-controlled trial. *Bipolar Disord*. 2016;18(3):221-232. doi:10.1111/bdi.12390

98. Bromundt V, Wirz-Justice A, Kyburz S, Opwis K, Dammann G, Cajochen C. Circadian sleep-wake cycles, well-being, and light therapy in borderline personality disorder. *J Pers Disord*. 2013;27(5):680-696. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=22928852.

99. Sheaves B, Isham L, Bradley J, et al. Adapted CBT to Stabilize Sleep on Psychiatric Wards: A Transdiagnostic Treatment Approach. *Behav Cogn Psychother*. 2018;46(6):661-675. doi:10.1017/S1352465817000789

100. Swanson L, Burgess H, Zollars J, Arnedt J. An Open-Label Pilot Study of a Wearable Home Morning Light Therapy for Postpartum Depression. *Arch Womens Ment Health*. 2018. doi:https://doi.org/10.1007/s00737-018-0836-z

101. Haynes PL, Kelly M, Warner L, Quan SF, Krakow B, Bootzin RR. Cognitive Behavioral Social Rhythm Group Therapy for Veterans with posttraumatic stress disorder, depression, and sleep disturbance: Results from an open trial. *J Affect Disord*. 2016;192:234-243. doi:10.1016/j.jad.2015.12.012

102. Kragh M, Martiny K, Videbech P, et al. Wake and light therapy for moderate-to-severe depression – a randomized controlled trial. *Acta Psychiatr Scand*. 2017;136(6):559-570. doi:10.1111/acps.12741

103. Sutherland D, Woodward Y, Byrne J. The use of light therapy to lower agitation in people with dementia. *Nurs Times*. 2004;100(45):32-34.

104. MacMahon S, Collins R. Reliable assessment of the effects of treatment on mortality and major morbidity, I: clinical trials. *Lancet*. 2001;357(9253):455-462. doi:S0140-6736(00)03651-5 [pii]\n10.1016/S0140-6736(00)03651-5

105. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework. *BMC Health Serv Res*. 2017;17(1):1-13. doi:10.1186/s12913-017-2031-8

106. van Straten A, van der Zweerde T, Kleiboer A, Cuijpers P, Morin CM, Lancee J. Cognitive and behavioral therapies in the treatment of insomnia: A meta-analysis. *Sleep Med Rev*. 2018;38:3-16. doi:10.1016/j.smrv.2017.02.001

107. Aarts MPJ, van Duijnhoven J, Aries MBC, Rosemann ALP. Performance of personally worn dosimeters to study non-image forming effects of light: Assessment methods. *Build Environ*. 2017;117:60-72. doi:10.1016/j.buildenv.2017.03.002

108. May C, Montori VM, Mair FS. We need minimally disruptive medicine. *BMJ*. 2009;339:b2803. doi:10.1136/bmj.b2803

109. Lovato N, Micic G, Gradisar M, et al. Can the circadian phase be estimated from self-reported sleep timing in patients with Delayed Sleep Wake Phase Disorder to guide timing of chronobiologic treatment? *Chronobiol Int*.

2016;33(10):1376-1390. doi:10.1080/07420528.2016.1220386

110. Chiu VW, Ree M, Janca A, Iyyalol R, Dragovic M, Waters F. Sleep profiles and CBT-I response in schizophrenia and related psychoses. *Psychiatry Res*. 2018;268(July):279-287. doi:10.1016/j.psychres.2018.07.027

111. Wulff K, Porcheret K, Cussans E, Foster RG. Sleep and circadian rhythm disturbances: multiple genes and multiple phenotypes. *Curr Opin Genet Dev*. 2009;19(3):237-246. doi:10.1016/j.gde.2009.03.007

112. McFadden E, Jones ME, Schoemaker MJ, Ashworth A, Swerdlow AJ. The relationship between obesity and exposure to light at night: Cross-sectional analyses of over 100,000 women in the breakthrough generations study. *Am J Epidemiol*. 2014;180(3):245-250. doi:10.1093/aje/kwu117

113. Leger D, Bayon V, Elbaz M, Philip P, Choudat D. Underexposure to light at work and its association to insomnia and sleepiness. A cross-sectional study of 13296 workers of one transportation company. *J Psychosom Res*. 2011;70(1):29-36. doi:10.1016/j.jpsychores.2010.09.006

114. Cho YM, Ryu SH, Lee BR, Kim KH, Lee E, Choi J. Effects of artificial light at night on human health: A literature review of observational and experimental studies applied to exposure assessment. *Chronobiol Int*. 2015;32(9):1294-1310. doi:10.3109/07420528.2015.1073158

115. Maruani J, Geoffroy PA. Bright Light as a Personalized Precision Treatment of Mood Disorders. *Front Psychiatry*. 2019;10(March):1-9. doi:10.3389/fpsyt.2019.00085

116. Kyle SD, Morgan K, Spiegelhalder K, Espie C a. No pain, no gain: an exploratory within-subjects mixed-methods evaluation of the patient experience of sleep restriction therapy (SRT) for insomnia. *Sleep Med*. 2011;12(8):735-747. doi:10.1016/j.sleep.2011.03.016

117. Kyle SD, Miller CB, Rogers Z, Siriwardena AN, Macmahon KM, Espie CA. Sleep restriction therapy for insomnia is associated with reduced objective total sleep time, increased daytime somnolence, and objectively impaired vigilance: implications for the clinical management of insomnia disorder. *Sleep*. 2014;37(2):229-237. doi:10.5665/sleep.3386

118. Brandt J, Leong C. Benzodiazepines and Z-Drugs: An Updated Review of Major Adverse Outcomes Reported on in Epidemiologic Research. *Drugs R D*. 2017;17(4):493-507. doi:10.1007/s40268-017-0207-7

119. NICE. Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia, NICE technology appraisal guidance 77. 2004. guidance.nice.org.uk/ta77.

120. Sit D, McGowan J, Wiltrout C, et al. Light therapy for bipolar depression: A randomized, double-blind, parallel placebo-control trial. *Neuropsychopharmacology*. 2014;39:S566-S567. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed12&NEWS=N&AN=71714856.

121. Vandewalle G, Maquet P, Dijk DJ. Light as a modulator of cognitive brain function. *Trends Cogn Sci*. 2009;13(10):429-438. doi:10.1016/j.tics.2009.07.004

122. Lucas RJ, Peirson SN, Berson DM, et al. Measuring and using light in the melanopsin age. *Trends Neurosci*. 2014;37(1):1-9. doi:10.1016/j.tins.2013.10.004

123. CIE. *CIE System for Metrology of Optical Radiation for IpRGC-Influenced Responses to Light*.; 2018.

124. Khademagha P, Aries MBC, Rosemann ALP, van Loenen EJ. Implementing non-image-forming effects of light in the built environment: A review on what we need. *Build Environ*. 2016;108:263-272. doi:10.1016/j.buildenv.2016.08.035

125. Wehrens SMT, Christou S, Isherwood C, et al. Meal Timing Regulates the Human Circadian System. *Curr Biol*. 2017;27(12):1768-1775.e3. doi:10.1016/j.cub.2017.04.059

126. Burke TM, Markwald RR, Mchill AW, et al. Effects of caffeine on the human circadian clock in vivo and in vitro. *Sci Transl Med*. 2015;7(305). doi:10.1126/scitranslmed.aac5125.Effects

127. Youngstedt SD, Elliott JA, Kripke DF. Human circadian phase–response curves for exercise. *J Physiol*. 2019;597(8):2253-2268. doi:10.1113/JP276943

128. Viola A, James L, Schlangen L, Dijk D-J. Blue-enriched white light in the workplace improves self-reported alertness, performance and sleep quality. *Scand J Work Env Heal*. 2008;34(4):297-306. doi:10.5271/sjweh.1268

129. Persson D, Erlandsson L-K, Eklund M, Iwarsson S. Value Dimensions, Meaning, and Complexity in Human Occupation-A Tentative Structure for Analysis. *Scand J Occup Ther*. 2001;8(1):7-18. doi:10.1080/11038120119727

Chapter 6: Study C - Mixed methods expert opinion study to support intervention design

This chapter presents a mixed methods study examining expert opinion regarding the most appropriate intervention to improve sleep in people with SzSD, conducted to support intervention development.

Aim:

- To examine and explore expert opinions regarding the appropriate components, format, length and other attributes of an intervention to improve sleep in people with schizophrenia spectrum disorders, for delivery by a mental health occupational therapist.

From the outset of the programme of research it was already stated that the intervention would be behavioural, and most likely utilise elements of CBTi, and would address daytime activity and light exposure. The results of the systematic reviews above supported retaining this plan. There were still many possible options regarding other components to include, and the manner in which to address those components already listed for inclusion. To inform these choices, we completed a study of expert opinion. Below is presented additional details on the aims and methods.

6.1. Supplementary detail on aims and objectives:

We sought recommendations regarding the utility and acceptability of:

- Modifications to existing sleep timing guidance.
- The nature of the input regarding daytime occupation.
- Other components that may be, or must be, included.
- The manner in which behavioural feedback should be integrated within the intervention.
- The format and level of flexibility in delivery of the intervention.
- The order in which components are given, and any flexibility in this.

We were also interested in:

- Differences in views between different expert groups, including people with personal experience.
- Views regarding for whom the intervention might be suitable, and regarding contra-indications or sub-groups for whom the intervention would be unsuitable.
- Views regarding what knowledge and training would be required for a non-sleep-specialist mental health occupational therapist to deliver the intervention.
- Barriers to implementation within existing services.
- Perspectives of potential referrers.

6.2. Selection of methods

Delphi methods were developed as a means of forecasting, to draw on expertise where other means of predicting outcomes are limited (Rowe and Wright, 1999). Delphi methods have been adapted for other situations where decisions or recommendations are required to solve complex problems (Vandelanotte et al., 2010), and have been successfully utilised to develop frameworks, protocols and recommendations for a range of complex interventions (Engels and Andries, 2007; Kelly et al., 2009, 2010; Saxena et al., 2012).

During planning, nominal group technique and Delphi methodology were considered (Murphy et al., 1998) (discussed in Chapter 3). A mixed methods approach based on Delphi methodology was chosen due to the requirement for time to analyse responses between rounds before the next rounds questions can fully be formulated. In some cases it is possible to identify potential components or options upfront from existing literature (Kelly et al., 2010), meaning voting on usefulness / appropriateness / importance can begin from Round 1.

In this case it was felt that there was insufficient directly relevant evidence and that a qualitative round was needed, as we did not have a full set of pre-determined 'options' to present for rating. In this respect the approach used resembles a modified Delphi technique (Saxena et al., 2012). In contrast to many versions of modified Delphi technique however, qualitative elements were also included in later rounds. It was anticipated that consensus would narrow during rounds 1 to 3, but it

was not anticipated that consensus will be achieved on all points. The number of rounds can be set in advance or determined based on when consensus is reached. As we were not focused on achieving consensus, we decided on three rounds; some have concluded three rounds is optimal (Trevelyan and Robinson, 2015).

Sampling used elements of a purposive strategy, as specific relevant individuals were approached, but representativeness was also sought by utilising quota sampling within each group (for instance, clinicians and researchers, those with expertise in different areas such as insomnia, circadian rhythm, mental health, or occupational therapy) (Robinson, 2014). Later stages of recruitment then specifically targeted gaps (Teddlie and Yu 2007). For instance, within the patients and carers group a target of 10 ethnic minority (out of a total of 30) participants was sought by targeting recruitment from relevant organisations, if needed, to attempt to achieve similar diversity service user population in the Trust. This was roughly achieved, as we recruited 24% who selected an ethnic minority (65% White British 65%, 12% prefer not to say). It is acknowledged that to an extent this was a volunteer sample, which must be embraced, as motivation of participants in expert opinion studies is key (Saxena et al. 2012).

It was initially planned for Round 1 to take place in-person, or using group teleconferences, as face-to-face contact can increase participant commitment and later response rates (Keeney et al., 2006). This plan was later revised with consideration of logistical issues recruiting senior clinicians and academics, some of whom were in different time-zones, and many of whom would be difficult to schedule to meet at once. The removal of group meetings from the design also enabled full anonymity of participants from each other. As a compromise, to increase the interpersonal element, the recruitment process involved a short phone-call to explain the project if desired, email invitations were individual not generic / templated, and the study introduction included a video welcome message from the study lead. There was an option to complete an interview, so those who took up this option were of course spoken to one to one.

We wanted to include and consider the views of people with relevant personal experience, in addition to our ongoing PPI. We wanted advice from those with personal experience, particularly regarding acceptability, perceived barriers, and preferences regarding intervention format. Initially we considered including these

participants in the same survey rounds as professional experts, but the type of expertise, and, therefore, the questions we wanted to ask these participants, differed from those we wanted to ask professional experts. It is acknowledged that simply adding people with personal experience to an expert panel and expecting them to deal with technical information and possess the same knowledge as professional panel members may not add validity (Baker et al., 2006). We therefore determined to address these participants separately, enabling us to present information differently to this group, and to focus our questions on acceptability. Following the expert / professional survey rounds we used a modified version of Nominal Group Technique (Murphy et al., 1998) involving as serial stages: private voting and commenting on information and ideas presented, focus group discussions in smaller groups of 4-6 participants, presentation back of ideas and comments, and then further private voting and written comments.

6.3. Rationale for pre-specified aspects of the intervention and mixed methods expert opinion questions

Building on existing work in CBTi, and based on the two process model (discussed earlier), it was intended that the intervention would include attention toward regularising sleep times (for circadian rhythm) and reducing excessive time in bed (for sleep pressure). Beyond that, it was not pre-determined that any particular elements of CBTi would be included.

It was planned that a component to address daytime occupation would be included to improve environmental zeitgeber exposure, and to make modifications meaningful and consistent with participants' priorities and their life circumstances. We had not predetermined in what way daytime activity would be addressed or how exactly this should fit with other elements.

We assumed environmental modifications (particularly in the sleeping environment) would be likely to be included as they are often suggested. Following on from the conclusions of the systematic reviews on light exposure intervention, the idea of altering light-dark exposure patterns was strongly considered, and was explored with a view to probable inclusion unless contra-indicated through expert opinion.

With the view to maximising the ease of future roll-out, it was planned that opportunities to utilise the existing skill set of mental health occupational therapists

would be utilised. We planned to use the qualitative findings from the expert opinion study to frame the intervention in terms and language which would be acceptable and meaningful for future participants; and which would be understood, accepted, and readily integrated within the existing knowledge, theory and professional values of occupational therapists. It is recognised that therapists do not learn theories in isolation, but that they integrate these within their existing theoretical understanding (Paterson et al., 2006).

We had pre-specified that the aim was to develop an intervention deliverable by an experienced mental health occupational therapist without a pre-existing sleep specialism, after a brief training course. Linked to this, it was specified that the intervention should not necessitate any advanced psychotherapeutic or talking therapy skills not already common amongst experienced mental health occupational therapists or teachable within a brief training course.

We specified that the intervention should remain 'brief' (although brief was not objectively defined), and we specified that it would be behavioural. This was with a view to improving the potential for future roll-out, and attempting to follow a stepped-care model (Mack and Rybarczyk, 2011). As sleep problems are common in SzSD, we were aiming to design a first line intervention.

We had pre-specified before the work was funded that the intervention would be focused on sleep in people with schizophrenia spectrum disorders (although this was challenged by participants, and thus was explored further in Round 3 as described in the paper).

We suggested that the intervention could utilise behavioural feedback using wearable technology for sleep and activity tracking to facilitate self-monitoring. This allowed us to ask views about this possibility; the inclusion of this component was then subject to the findings from this study and the identification of a suitable device.

The inclusion of technology within the provision of mental health intervention is in line with the NHS's Five Year Forward View plan which suggests increasing the use of digital and blended interventions, and optimising the use of digital technology (NHS England, 2016). We were aware there are a number of commercially available activity and sleep tracking devices available which have been utilised in research within this population (Kerz et al., 2016), and we assumed it was likely we might use

a commercial device, but we were open to suggestions of using a research device if this would be practical and economical.

6.4. PPI

Throughout the analysis of the expert opinion study, and the design and conduct of the feasibility study, PPI input was crucial in directing and guiding proceedings. PPI included regular meetings with the core group of patient contributors who remained involved throughout the study, and ad hoc consultations with an external pre-existing PPI group (Psychosis Research Unit's Service User Reference Group) at key points within the project.

6.4.1. Aims of PPI within the mixed methods expert opinion study:

PPI input was focused around the following core aims:

- Ensuring the aims and design of the questions considered the perspectives of those with personal experience.
- Ensuring the analysis considered the views of those with personal experience.
- Ensuring the lead researcher was regularly framing project progress, ideas and dilemmas for discussion, for those with personal experience, as well as for senior researchers.
- Enabling input on application and use of the expert opinion study findings to create the materials and intervention components to best suit the (diverse) target audience (see Chapter 7: Synthesis).

6.4.2. Approach to PPI within the mixed methods expert opinion study

PPI contributors were consulted during the design of the expert opinion study, and between rounds. Due to the iterative design of the questionnaire rounds there was scope for PPI comments and suggestions to influence prioritisation of questions for subsequent rounds, and what questions were considered closed, or requiring or further investigation. At the end of each round I met with the regular PPI contributors to give a summary of findings from that round and showed graphs of responses. Provisional questions for the next round were discussed, contributors suggested areas to probe, and they commented on phrasing of questions. I then drafted the questions for the next round and sent these draft questions for the next

round to contributors for further comment before finalising these and opening the next round to participants.

PPI input was utilised when preparing for the nominal group technique session with service users and carers. This followed the last survey round with professionals. Presentations for service user and carer audiences were piloted with PPI contributors, question sheets were tested, and the format and hosting of the day was discussed (for instance, group sizes for discussions, and whether to have focus groups with service users and carers mixed or separate). These conversations extended to practical aspects such as location, catering, time of day and duration, promotional materials, and recruitment.

6.5. Paper 4, study C: "A mixed methods expert opinion study on the optimal content and format for an occupational therapy intervention to improve sleep in schizophrenia spectrum disorders"

Paper number: 4

Page of thesis: 215

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Supplements to this paper are in Appendix 5 of this thesis.

Author contributions:

The study was designed by SF with supervisory / advisory input from RD, MO and PB. Data collection was conducted by SF, with support of those listed in the acknowledgements, including RD. Data analysis was conducted by SF with input and advice from RD, MO, MG and PB. The manuscript was drafted by SF, with input from RD, MO, MG and PB regarding structure, content, and style.

Full title: **A mixed methods expert opinion study on the optimal content and format for an occupational therapy intervention to improve sleep in schizophrenia spectrum disorders.**

Short title: **Expert opinion on optimal occupational therapy intervention for sleep in schizophrenia**

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Abstract:

Introduction:

People with schizophrenia spectrum disorder diagnoses commonly have poor sleep, which predicts various negative outcomes. The problems are diverse, including substantial circadian dysregulation, sleep-wake timing issues, hypersomnia (excessive sleep), and more classic insomnia.

Methods:

This paper reports on a mixed methods expert opinion study based on the principles of Delphi methodology. The study examines and explores opinion on the optimal contents and format for an occupational therapy intervention to improve poor sleep in this population. Views of clinical and academic topic experts (n=56), were elicited, examined and explored in three rounds, views from previous rounds being presented back to participants in subsequent rounds. Participants with relevant personal experience (n=26) then rated and commented on suggestions, with a focus on acceptability. Descriptive statistics and graphs of ratings were triangulated with qualitative content analysis of free-text.

Results:

Participants emphasised the central importance of intervention personalisation, although the manner and extent of personalisation suggested varied. Many components and domains were acknowledged as important, with the challenge being how to keep such an intervention simple, brief, and feasible for end-users, for sustainable implementation. The strongest consensus was to address evening routine, daytime activity, and environmental interventions. Relaxation, mindfulness, thermoregulation, sensory factors, and cognitive or psychological approaches were rated as less important. There was disagreement on whether to include time in bed restriction, and how to address napping, as well as how far to address medication

timing. Clinicians and researchers advocated some version of stimulus control, but participants with personal experience reported low levels of acceptability for this, describing entirely negative experiences using ‘the 15-minute rule’ (part of stimulus control).

Conclusion:

These results are informative for clinicians treating sleep problems in people with schizophrenia and related conditions, as well as for decision makers considering the potential contribution of the profession of occupational therapy toward sleep treatment.

Introduction:

People with schizophrenia spectrum diagnoses (SzSD) often have chronic sleep problems which persist outside of relapse [1,2]. Poor sleep is associated with, and may cause, negative physical and mental health outcomes in this population, including, but not limited to, the exacerbation of psychotic symptoms [3], poorer cardiometabolic health [4], compromised cognition [5] and functioning [6].

The type of sleep problems experienced by people with SzSD are diverse [7], and often differ from those in the general population, or in insomnia without comorbidity (previously described as 'primary insomnia' or 'psychophysiological insomnia'). Whilst many adults with SzSD do experience classic insomnia symptoms such as short sleep duration, difficulty with sleep onset and maintenance and early awakening, phenomenologically different problems also occur. Insomnia with normal sleep length, and insomnia with hypersomnia are also common (37.8%, 17.6% respectively) [8]. Circadian dysregulation problems (often identified via sleep timing abnormalities) are also prevalent, including free-running (non-24-hour) rhythms [9–11], which are usually considered rare in individuals without visual impairment [12]. Of note, many studies of sleep problems in SzSD do not distinguish between insomnia and circadian dysregulation, and typically describe all sleep problems as insomnia.

Some authors advocate the use of hypnotics and sedative antipsychotics to improve sleep in SzSD, and summarise positive effects [13,14]. However, there is no good evidence of long term sleep improvement, and there is evidence of long term harms associated with hypnotics [15]. Melatonin or melatonin agonists show promise in this group but there has been as yet only pilot work [16,17] except in antipsychotic naïve or treatment withdrawn patients [18]. People with SzSD tend to see drug

treatments for sleep problems as less acceptable [19,20], and value the opportunity to learn skills to manage their sleep non-pharmacologically [6].

There is clear evidence that cognitive behavioural therapy for insomnia (CBTi) can be effective in people with insomnia with and without comorbidity [21–24], and should be used in preference of drug treatments for sleep because of its lower adverse effects [25,26]. However, CBTi may not effectively target circadian rhythm sleep problems. CBTi in combination with morning light therapy has shown positive effects on sleep in young people with delayed sleep-wake phase disorder [27,28], but benefit might have been attributable to light therapy alone, as addition of CBTi showed no evidence of additional benefit [28]. For sleep problems more related to circadian dysregulation than insomnia processes, light therapy with sleep-wake scheduling has good theoretical backing, and support from basic research [29,30]. Light therapy has shown promising results in meta-analysis of clinical trials, despite some issues identified with sub-optimal treatment protocols [31,32], and light therapy in combination with CBTi has been successfully trialled in inpatients with psychotic and bipolar disorders [33].

Through having been designed to target insomnia rather than circadian abnormality, CBTi may target some sleep problems in SzSD more effectively than others, as this group experiences a mixture of both insomnia and circadian dysregulation. Chiu et al (2018) show that the greater benefits of CBTi may be observed in those with classic severe insomnia, with short sleep duration and low sleep efficiency, than in those with poor sleep with normal or excessive sleep duration [8].

Researchers recommend sleep as an important treatment target in people with SzSD [3,5,34], but attention to sleep in secondary care mental health services is limited. Staff often lack the knowledge and confidence to intervene [35–37]. Adapted CBTi

for people with schizophrenia and related disorders delivered by clinical psychologists has shown positive results, with significantly better sleep outcomes than treatment as usual [8,33,38–40]. However, clinical psychology and psychological therapies are scarce and costly resources within secondary care mental health services [41,42]. Furthermore, there are many other well evidenced therapies, such as CBT for psychosis [43], family intervention [41,44], and cognitive behavioural treatments for people who self-harm [45], which compete for the time of psychologists and psychological therapists. It has been suggested by many authors that the skills of occupational therapists (OTs) align well with the treatment of sleep problems via behavioural, educational and environmental interventions [35,46–48]. Occupational therapists focus already on activities, routines, and meaningful occupation [49–51], environmental adaptation [52], holistic assessments and consideration of complex systems [49,53,54], and work around personal motivations (volition) [55,56]. Although there is a good argument for this type of intervention delivered by OTs, the optimal approach and its feasibility has not been empirically evaluated.

There is an argument for evaluating acceptability and efficacy of one of the adapted CBTi protocols referenced above, when delivered by OTs. We have focused here instead on developing a novel intervention for delivery predominantly by an individual OT for two reasons: 1. because a formal expert opinion process has not previously been applied to the development of this type of intervention, 2. to generate a therapy which makes best use of the pre-existing skills of OTs.

It is increasingly recognised as important to incorporate the views of those who could receive the intervention during the intervention design process [57]. This study sought to explore opinions of experts and people with personal experience, on the most appropriate content, format and delivery methods for an intervention to be

delivered by mental health OTs, to improve sleep in SzSD. Through this process we aimed to co-design an acceptable and feasible intervention, tailored to the needs of people with SzSD, and to delivery by mental health OTs. We believe this to be the first study to explore and examine expert opinion to develop a treatment for poor sleep in SzSD, and the first to examine expert opinion to direct the treatment of sleep by OTs.

Methods:

The study received a favourable ethical opinion from South East Scotland Research Ethics Committee 02, 18/SS/0122. Written informed consent was obtained for in-person participation, audio recorded consent for interviews, and implied consent for survey responses.

Our methods were based on the principles of Delphi methodology, including recruitment of relevant experts, iteration between rounds, and presentation of responses from earlier rounds back to participants [58–60]. We did not aim to reach or force consensus [61], placing equal value on identifying where views diverged. The three online survey rounds with professionals, were followed by an in-person modified nominal group technique [62] session with service users and carers with relevant personal experience.

Sample:

We recruited two separate samples, 55 clinical and academic topic-specialists (56 recruited), and 30 people with relevant personal experience (service users and carers); eighty-five participants in total (see Tables 1 and 2).

We were aware that it would not be possible to recruit a large enough sample of occupational therapists with strong expertise in improving sleep in people with schizophrenia spectrum disorders, because this is as yet an underdeveloped area for the profession. As a result, we chose to recruit a range of expert groups each with one or more relevant angles to contribute (*occupational therapy*, *sleep and circadian rhythm*, and / or *mental health and schizophrenia*) (see also Fig 1 in Results). The large target sample accounted for heterogeneity of participants with diverse types of relevant experience [63].

Sampling was purposive, seeking representation of views and expertise from different groups through quota sampling [66], later stages of recruitment then specifically targeted any gaps [67]. Our expert group included clinicians and researchers specialising in insomnia, circadian rhythms, mental health, and occupational therapy (and in many cases multiple of these topics). We included clinicians and researchers, to ensure both performative and epistemological knowledge were considered [69].

We selected 15 as a target sample size for most professional sub-groups as many sources suggest a minimum sample of 12 in a homogenous group may produce adequate saturation [64,65], and that 8-15 is adequate for Delphi studies conducted in homogenous professional groups [63].

We set minimum criteria for each category, and then began by compiling lists of those we thought were most qualified to comment, then sent invitations individually by email. People with personal experience were recruited via clinical services and through publicly displayed posters and leaflets. We had less control over purposive sampling of people with personal experience, although we did ask recruiters to focus on less represented groups as recruitment progressed (e.g., female service users).

Clinicians and researchers were sought with the following targets:

- Sleep experts (15)
- Occupational therapists with expertise in sleep (10) (smaller target due to smaller total population)
- Mental health occupational therapy experts (15)
- Mental health experts and other senior mental health stakeholders (15)

Service user and carer participants were sought with the following relevant personal experience:

- Self-reported or referrer reported diagnosis of a schizophrenia spectrum disorder

  AND

- Experience of sleep problems (current or past)

  OR

- Carer of / close supportive contact of someone meeting the above criteria

Data collection:

Data collection instruments were designed in collaboration with patient contributors and were developed iteratively based on the results from previous rounds, as well as the wider evidence base and study aims. Rounds 1-3 were with clinicians and researchers, and a separate final stage sought views from participants with relevant personal experience.

Round 1 focused predominantly on eliciting participants' pre-existing views on what elements should be included in the intervention and how. Round 2 focused on rating and ranking of possibilities and suggestions, and Round 3 included further rating and further qualitative exploration of remaining controversial questions. The final stage of a service users and carers modified nominal group technique again asked about optimal content and format, but with more focus on intervention acceptability. Later rounds included graphs, and para-phrased quotes from the previous rounds, please see supplements S2-4 for the surveys.

Round 1: Clinicians and researchers. Online survey #1.

After a brief introductory video, written information was delivered to meet the differing needs of each group (for instance, background re: the role of the occupational therapist (OT) was provided to sleep experts, and background re: sleep and circadian rhythm was provided to mental health OT experts). Open questions were used, with free-text responses, beginning broad and soliciting participants' suggestions, then only later providing more specific prompts to consider, and options to rate and comment on certain areas.

Round 2: Clinicians and researchers. Online survey #2.

Where there appeared to be a strong consensus already in Round 1 this information was presented as 'agreed'. Summaries of content from Round 1 were presented back to participants through qualitative paraphrased comments, and graphed rating results, with summarised rationales given for competing suggestions. Items were rated on a 5-point scale (very important, important, neutral, not important, better NOT to include). Participants were also asked about optimum order of delivery (early, middle, late, doesn't matter when), and about which elements should be 'core' (given to all service users) or 'optional' (given when needed) or 'do not use' (categorical options) (an item being important to have available to use, was not the same as saying it should be used with all service users). Participants were able to add free-text comments justifying opinions or elaborating.

Round 3: Clinicians and researchers. Online survey #3.

Views from previous rounds were presented, including differences in views between different participant groups. Remaining areas of controversy were further examined, and feedback was given where consensus had occurred, with the opportunity to comment further. Finally, participant views were sought on some implementation issues raised in earlier rounds.

Rounds 1-3 launched in October 2018, November 2018 and January 2019. We allowed around a month to obtain responses to each email survey round, keeping gaps between rounds to less than a month. We sent up to a maximum of 5 reminders for Round 2 and Round 3. We also offered a thank you gesture of a £20 voucher claimed at the end of Round 3 (final round).

Individual interviews: optional, during rounds 1-3, with existing professional participants

All Round 1 participants were invited to arrange an interview if interested, 16 were able to be scheduled and conducted, those providing interviews were quite evenly spread across expert groups. Interviews explored the same overall research aims, except focusing more on whichever dimension of the intervention that participant had experience and views on. Participants were asked to elaborate on or clarify their answers to earlier rounds where relevant, and sometimes were presented with competing viewpoints to their own to respond to (without making other participants identifiable). This served to provide additional qualitative depth and explanation of rationales for proposed approaches.

Final stage: Modified Nominal Group Technique: Service users and carers with relevant personal experience.

We presented results from rounds 1-3 to participants for discussion and voting. We used graphs, images and verbal explanations. We presented both areas on which a provisional consensus has been reached, and areas where multiple options and approaches were still under consideration. There was a focus on acceptability of potential aspects of the intervention, format and presentation, expectations of effectiveness, and barriers and facilitators to engagement. There was anonymous voting (on paper) regarding various intervention components presented, focus groups

discussions (in five smaller groups), presentation back of points and views from these groups, and then further anonymous voting. The focus groups were between 4-6 participants each, and were chaired in tandem by the first author, and the co-facilitators named in the acknowledgements (some facilitators chaired in pairs). All are mental health researchers or clinical academics. For the topic guide see supplement S5 Topic Guide. We opted to group carers together on investigator and public patient involvement (PPI) suggestion.

This took place in-person and participants were reimbursed £50 for their time and provided travel expenses and lunch.

Analysis

The progression from the qualitative exploratory aspects of round one, to rating of resulting ideas from round 2 onwards can be characterised as a form of mixed methods exploratory sequential analysis [70]. Analysis of free-text data was using qualitative content analysis [71], including counting [72]. Descriptive statistics and graphs were used to present and analyse Likert scale ratings.

Free-text data was managed in Nvivo (version?), each 'case' was coded by participant attributes and participant group and sub-group (e.g., sleep, mental health, OT). Data was coded using both inductive and deductive codes [73]. Deductive coding was using a predetermined framework of codes relating to topics asked about and those expected based on literature (e.g., "Bed or sleeping surface"). Inductive codes were arrived at in response to the data, prompted by the data (not predetermined).

In some cases, statements were classifiable into specific sentiments or suggestions, and content within that topic was coded for each 'statement' (e.g., "Advocating Sleep Restriction Therapy (SRT)", "Be cautious with SRT", "SRT could trigger mania / psychosis", "Do not use SRT", "Use sleep compression instead of SRT"). This allowed use of counting to corroborate or contradict the impression of relative popularity and importance of each theme or sentiment, and prompt further analysis [71]. Data was searched for counterexamples before 'many', 'most' or 'all' statements were made. Caution was applied in over-interpretation of 'counts', as they do not show the strength and clarity of expression of a given statement, and they are not equivalent to ratings on the standard items. Similar codes were merged or linked, and related codes were grouped hierarchically to form themes. Contradictory or incompatible ideas were identified as candidates for further analysis, or for questions in later rounds.

Our two, lead PPI contributors who wished to be involved in analysis were shown anonymised data excerpts, the codes and themes being developed, and graphs of the Likert scale responses, and contributed toward decisions on questions for subsequent rounds, and descriptions of the overall findings.

Assessing consensus:

Consensus was assessed via a combination of similarity of qualitative content between participants from different groups, and relative levels of agreement in Likert ratings of items for appropriateness and importance to include. In determining what items to include, we considered not just likely effectiveness, but also affordability, practicability, and cost- effectiveness (APEASE criteria for designing and evaluating interventions or intervention ideas) [74]. The 'cost' of delivering an item, in this case, includes for example, time to train therapists to deliver, time to deliver, and time to assess with each participant whether it is relevant to deliver. As part of practicability, we considered compatibility of potential components for delivery together.

We had originally planned to assess extent of consensus by calculating median and interquartile range of Likert responses [75], seeking an interquartile range of 2 points or less. In practice this proved unhelpful as by this criterion there was a high level of consensus to include almost all items rated, whilst at the same time, many participant views suggested keeping the intervention as simple as possible (see sub-theme 'keep it simple'). Seventy-five percent is often considered an acceptable level of consensus [61]. Few items included with under 75% endorsing either 'appropriate' or 'very appropriate' and many had much more (e.g., 90-100%). Where lower percentages of professional participants endorsed an item, we focused on examining differences in views between participant groups (e.g., CBTi therapists VS mental health clinicians),

and what qualitative rationales were given. Although re-rating was completed for some Round 2 items in Round 3, on other occasions we instead opted to request ratings of more granular items, or new suggestions not rated in the prior round (see S1 Supporting Information, and S4 Survey. Round 3 survey questions).

Whilst we were able to examine consensus via multiple-choice ratings for larger domains (e.g., addressing light exposure), it was unrealistic to ask participants to rate all potential intervention protocol sub-components at the most granular level (e.g., if sleep is delayed encourage a morning walk). Some key suggestions on specifics were brought to later rounds for rating where we judged more views were needed; others were assessed based on congruence and compatibility of the free-text responses with each other and with relevant literature.

Results:

Participants

Table 1: Demographic data for professional participants

Total professional participants		56
Clinical role type*, **:	Senior specialist sleep OT	19
	Senior mental health OT	14
	Consultant psychiatrist	7
	Clinical psychologist	5
	Consultant (medical, other)	1
Academic role type*, **:	Doctoral (final year)	6
	Post-doctoral	7
	Lecturer / professor	9
	Head of lab / department	3
Participant selected for expertise in**:	Sleep and circadian rhythm	39
	Mental health	32
	Occupational therapy	31
Country of residence and work:	UK	36
	Elsewhere in Europe	5
	USA	8
	Canada	3
	Australia	3
	Asia	1

*=at time of participation, **=multiple may apply, OT = occupational therapist

We were able to exceed all our sub-group targets for all clinical and academic professional groups except mental health occupational therapists (target =15, recruited=14). Many participants fit into more than one subgroup, and we achieved a balance of clinical and academic expertise, as shown in Fig 1.

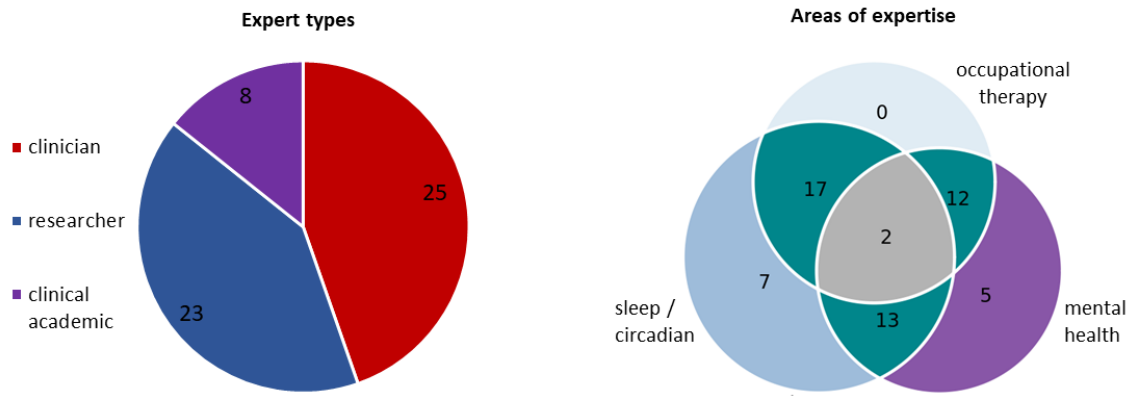

Fig 1: Types of expertise in professional participants.

Uptake from initial email invitation for Round 1 was good (66% of those invited participated). We overshot our target by one participant, as it was not possible technically to lock the survey to prevent further participation without also preventing part-completed responses from being finished. Retention through Round 2 (98% partially, 94% total completion) and Round 3 (96% partial, 95% total completion) was good. We allowed participation in Round 3 if Round 2 was missed. Although we anticipated relatively short free-text responses in the survey rounds, many participants entered rich multiple-sentence responses. Sixteen participants provided individual interviews between rounds 1 and 3.

As our Modified Nominal Group Technique with participants with personal experience was completed on a single day it was not possible to recruit further to replace participants who had to cancel at short notice or who did not arrive on the day. The participants were relatively diverse, although the low proportion of female participants should be noted, which appears to be at least somewhat in excess of any differences in gender balance of schizophrenia (Ochoa et al., 2012). Problems getting to sleep and staying asleep were more common in our sample (69%, 62%) than irregular, reversed, unrefreshing or excessive sleep (27%, 35%, 15% respectively) (see Table 2).

Table 2: Demographic data for participants with personal experience

Total participants with personal experience		26
Source of personal experience	Service user Carer / significant other	20 (77%) 6 (23%)
Age	Mean: 46.12 (SD= 15.68) range: 19-80	
Gender	Female Male Prefer not to say	8 (31%) 17 (65%) 1 (4%)
Ethnicity	White British Other Prefer not to say	17 (65%) 6 (24%) 3 (12%)
Diagnosis (service users only)	Schizophrenia Schizoaffective disorder Delusional disorder Psychosis not otherwise specified	11 (42%) 2 (8%) 1 (4%) 6 (23%)
Types of sleep problems experienced by you or the person you care for: problems with …	Getting to sleep Staying asleep Unrefreshing sleep Sleep timing Sleeping for too long Difficulty waking Nightmares Sleep-disordered breathing / Obstructive Sleep Apnoea (OSA) Restless Legs Syndrome (RLS)	18 (69%) 16 (62%) 7 (27%) 9 (35%) 4 (15%) 9 (35%) 9 (35%) 1 (4%) 4 (15%)
Advice previously received from… (could select 1 and 2)	Mental health care professionals Other HCPs Neither	15 (58%) 7 (27%) 5 (19%)
Intervention previously received…	CBTi (computerised or in-person)* Specific hypnotic Other prescription sedatives (e.g., Antidepressant, antihistamine) Continuous Positive Airway Pressure (CPAP)	1 (4%) 9 (35%) 3 (12%) 0 (0%)

*Although one participant reported receiving CBTi this participant did not describe anything relating to this in written answers or during focus group discussion, it is possible this participant received another type of CBT.

Results

The full findings are presented in S1 Supporting Information, for qualitative data excerpts and graphed results of all multiple choice and Likert responses the below summary may be read alongside this supplement. Findings are summarised here in

Table 3, as themes (1-7) and sub-themes. Themes 1-3 concern the content of the intervention (see also Table 4): 1. Intervention targets and scope (what problems to treat and in whom), 2. The assessment, and 3. Intervention domains (what broad areas to address, using what specific components). Themes 4-7 concern the manner of intervention delivery: 4. Personalisation, 5. Format, Structure and Pragmatic considerations, 6. Therapeutic Approach and therapist factors, 7. Implementation considerations.

Table 3: Summary of content themes and sub-themes within data

Broad topic area	Sub-topic / sub-theme	Specific suggestion or issue raised
INTERVENTION TARGETS AND SCOPE	Sleep problems and sleep interferers	Sleep effort and frustration
		Worry, rumination, stress and anxiety
		Psychotic symptoms
		Fear of the dark
		Fear of silence
		Fear of the bed
		Fear of sleep
		Long sleep
		Difficulty rising & sleep inertia
		Physical illness / physical symptoms
	How far to address 'other' sleep disorders	Screen for sleep-disordered breathing (SDB) and parasomnias
		Nightmares
		Assess nightmares
		Directly address nightmares specifically
		Nightmares may improve through treating sleep
		Refer on regarding nightmares
	Stability to intervene	How well or stable would clients need to be to benefit?
		Stability of social situation important
		Stability of medication important
		Concerns about exclusions
	Transdiagnostic intervention? (applied across diagnostic groups)	The intervention should be applied transdiagnostically
		The intervention should focus exclusively on people with a schizophrenia spectrum diagnosis within this study as they are harder to reach
THE ASSESSMENT	Format & manner of assessment	Use an interview
		Use checklists and / or standardised questionnaires
		Rapport in assessment
	Prioritisation of areas to assess	-
	Longitudinal self-report of sleep & activity (activity & sleep diary)	Sleep diary
		Activity diary
		Diary burden & difficulties
		Completing diaries as an intervention
		Format options, prompts and support
		Possibility of using an app

Broad topic area	Sub-topic / sub-theme	Specific suggestion or issue raised
	Passive monitoring within the assessment	Self-report and passive monitoring results will differ (useful to compare / need both)
		Passive monitoring as an intervention
	Measurement of light exposure	Measurement or self-reporting of light exposure at baseline and during the intervention
INTERVENTION DOMAINS	Sleep schedule	Address sleep schedule regularity
		Regular rise time
		Regular bedtime
		Allowable flexibility in sleep schedule
		Need to fit sleep in with life
		It might be OK to be nocturnal
		Gradual approach to sleep timing changes
		Stabilise timing first before changing times
		Support to change sleep times
	Time in Bed restriction	Advocating Sleep Restriction Therapy (SRT)
		Be cautious with SRT
		SRT could trigger mania / psychosis
		Do not use SRT
		Use sleep compression instead of SRT
		Not keen to try reducing time in bed
		Already reduce time in bed, & advocate it
	Napping	Allow napping
		Avoid napping
		Evaluate naps
		Nap duration
		Nap timing
		Replace naps with activities
		Schedule naps
	Stimulus control, and managing awakenings	Avoid non-sleep activities in bed / bedroom
		Use ‘the 15-minute rule’ or similar
		Bad experience using ‘the 15-minute rule’ as self-help advice
		Address activities to do if awakening in the night
		Provide education on awakenings being normal
	Morning routine	Address type of activities
		Use of alarms
		Dawn simulator alarms

Broad topic area	Sub-topic / sub-theme	Specific suggestion or issue raised
		Education on sleep inertia
		Experience of struggle with waking
	Evening routine	Evening wind-down activities, lower stimulus
		Preparation for bed before wind-down
		Prepare for the next day - if relevant
		Support to find suitable activities
		Get ready for bed alarm
	Daytime activity	Increasing amount of activity
		Address activity type
		Address activity timing
		Scheduling activities
		Routines and habit formation
		Meaning, satisfaction and enjoyment
		Support to find and plan activities
	Addressing medications	Consider side effects
		Addressing timing of prescribed medications
3. INTERVENTION DOMAINS (continued)	Addressing food and drink	Consider food and drink timing
		Address avoiding late eating
		Address skills and / or routines around meals
		Night eating
		Consider food and drink content
	Addressing substance use	Substance use
		Alcohol
		Caffeine
		Nicotine
	Light Exposure	Modifying light exposure
		Timing of modifications to light
		Morning light exposure
		Daytime light exposure
		Increasing evening light
		Reducing evening light exposure
		Reducing light at night
		Method to modify light
		Light box
		Light visor
		Blue-blockers
		Modifying light in the home & bedroom
		Using outdoor light / natural light
		Season is important
		Embedding light in activity / occupation
		Education regarding light, circadian rhythm and mood

Broad topic area	Sub-topic / sub-theme	Specific suggestion or issue raised
		Low expectation of efficacy regarding light
		Acute alerting effects of light
	Environmental assessment and intervention	Home environment
		Bed or sleeping surface
		Bedroom / bed not for non-sleep activities
		Having other useable rooms
		Noise in the bedroom
		Temperature in the bedroom
		Air quality
		Sensory factors
		Pets in the bedroom
		Home environment intervention
		Feeling safe in the home
		Social environment & context
		Social environment in the home
		Support from friends, family and carers
		Social commitments
		Peer support
		Loneliness
		Cultural factors
	Relaxation and / or mindfulness	Relaxation technique
		Breathing techniques
		Mindfulness meditation
3. INTERVENTION DOMAINS (continued)	Thermoregulation	-
	Addressing sensory factors	-
	Cognitive or psychological approaches	Cognitive or psychological approaches
		Psychological approaches better dealt with by psychological therapist
4. PERSONALISATION	-	The goals of the intervention should be individually determined
		The methods of intervention should be personalised
		Limits to personalisation
FORMAT, STRUCTURE AND PRAGMATIC CONSIDERATIONS	Personalisation and complexity vs simplicity to deliver	Personalisation
		Keep it simple
	Format of intervention and assessment materials	Format options & literacy
		Use of technology in delivery of the intervention
	Core vs optional components	-

Broad topic area	Sub-topic / sub-theme	Specific suggestion or issue raised
	Order of delivery	-
	Follow-up and ending of therapy	Maintenance plan
		Follow-up / tapering of ending
THERAPEUTIC APPROACH AND THERAPIST FACTORS	Therapeutic approach, therapist attitude & manner	An educational approach
		Education re: normal sleep
		Normalising
		Experimentation
		Benefits of change, motivational interviewing approach
		Therapeutic rapport & listening
		Rapport required before home assessment
	Therapist knowledge, skills & confidence	Therapist confidence in delivering the intervention
		Relationship to OT role & skills
		Generic working barrier to OT interventions
IMPLEMENTATION CONSIDERATIONS	Reaching referrals	-
	MDT approach	MDT knowledge & attitude
		MDT approach to intervention
		MDT approach to medication
		MDT approach to maintenance

1. Intervention targets and scope

From the outset participants were told the intention was to develop an intervention to improve poor sleep, including insomnia and circadian dysregulation. All participants appeared to assume that sleep onset, maintenance and timing were valid targets. People with personal experience rated ‘feeling more alert’, ‘sleeping at night, not in the day’, ‘waking less often’, and ‘falling asleep without getting stressed’ as the most important targets.

Sleep-related distress

Participants identified problems to be targeted: frustration when trying to sleep (intense sleep effort), non-sleep-related worry preventing sleep, the impact of psychotic symptoms, sleep-related fears, and the social and functional impact of long sleep and difficulty rising.

How far to address 'other' sleep disorders

Some participants suggested screening for sleep-disordered breathing and common parasomnias, and referring to sleep services. Others did not mention these conditions.

All who commented on it, agreed to assess nightmares. There was disagreement about how far the intervention should address nightmares; professionals often noted specialist psychological therapies are contingent on therapist training. It was noted that some non-specific approaches, e.g., stabilising and consolidating the sleep period, might improve nightmares, without requiring psychological therapy skills training.

Stability

There was some consensus that a behavioural sleep treatment was unlikely to be effective either during acute psychiatric crisis, or during environmental instability, such as homelessness, and ratings agreed (66% in round 2 rising to 71% in round 3). Some participants suggested that addressing sleep problems in acutely unwell patients, for example, hospital inpatients, needed a different intervention.

Transdiagnostic intervention?

Although it had not been our aim to explore this, many participants suggested the intervention could be suitable irrespective of diagnosis, or said the study should not be diagnostically focused. Once we asked in round 3, 62% endorsed this in some form. A large minority, however, suggested retaining the diagnostic focus because those with SzSD may be harder to reach and less likely to be offered non-drug interventions.

2. The initial assessment

Format and manner of assessment

Professional participants emphasised establishing rapport, whilst also finding out a potentially large amount of information on many areas. An interview format was recommended, incorporating structured elements. Some people with personal experience felt a home assessment requires developing trust and so should be done later, and for some a home assessment was not acceptable.

Prioritisation of areas to assess

Very many assessment areas were suggested by professionals, and were highly endorsed in ratings, however, it was acknowledged that covering everything in full depth would be laborious. We asked about areas to prioritise, some were acceptable to explore in-depth only if necessary.

Longitudinal self-reported assessment of sleep and activity

Although both professionals and people with personal experience described completing a sleep and daytime activity diary as burdensome, they also felt the data this would produce would be very valuable to guide intervention. Many professionals felt the process of completing this might have some direct beneficial effect. Participants recommended seeking an easy-to-use format, possibly offering format options, and endorsed reminders to complete (65% = 'important' or 'very important', personal experience).

Passive monitoring within the assessment

Professionals varied in their prioritisation of subjective or objective measures, but participants agreed that both combined provided valuable insight. The process of comparison was noted as potentially useful in itself, by both professionals and those with personal experience. Participants with personal experience were mostly willing to wear an activity monitoring watch (42%=definitely, 25%=probably,

12%=possibly, 21%=not really), and suggested a longer period of wear for assessment before beginning the intervention than did professionals on average (3 or 4 weeks versus 2 weeks).

Some suggested varying the length of the baseline passive monitoring period depending on the type of sleep problem being assessed (circadian rhythm problems potentially taking longer to capture than classic insomnia), others felt this complicated matters.

3. Intervention domains

Consensus, controversy and dilemmas around which domains to address are discussed, see Table 4 for a summary.

Table 4: Summary of findings regarding intervention domains to address and how

Domain	**Consensus to include***	**Congruence and compatibility of suggestions on *how* to address (if included)**	
	Strength	Rating	Brief description
Sleep schedule	Very strong	Mostly congruent	Some disagreement re: level of rigidity of regular rise time required.
Time in Bed restriction	Weak - conflicted	Somewhat congruent	Strong feelings for and against. Some variability in level / manner of restriction.
Addressing napping	Strong	Conflicted	Consensus to evaluate napping, conflict regarding extent to reduce / allow naps.
Stimulus control, and managing awakenings	Strong	Congruent / conflicted	Consensus re: non-sleep activities away from bed, views differ re: 15 min rule.
Morning Routine	Strong	Mostly congruent	General agreement re: creating morning routine, some variation re: alarms
Evening Routine	Very strong	Congruent	Strong agreement re: setting similar calming evening routine.
Daytime activity	Very strong	Very congruent	Compatible suggestions from all participant groups.
Addressing medications	Moderate	Somewhat congruent	Views vary on far to address and with how much prescriber input
Addressing food and drink	Moderate	Congruent	Consensus re: late eating, less re: food timing, least consensus re: food content
Addressing substance misuse	Moderate	Congruent	Disagreement only re: how personalised or flexible to be re: caffeine reduction
Light exposure	Strong	Somewhat congruent	Agreement to address, some variance on priority level, and means to modify light
Environmental intervention	Strong	Very congruent	Similar suggestions on all aspects except re: reducing / blocking noise at night.
Relaxation and / or mindfulness**	Weak - less priority	Somewhat conflicted	Raised often (together), not often highly prioritised, incongruent re: best approach
Thermoregulation	Weak - less priority	Congruent / conflicted	Agreement re: bedroom temp & bedding, disagreement re: socks & baths
Addressing sensory factors	Weak - less priority	Congruent	Argument against inclusion to prioritise other areas, but brief to address.

Cognitive or psychological approaches	Weak - less priority & conflicted	Somewhat congruent	A little conflict re: whether in scope of OT, also less prioritised than other areas.

*There were no domains with a consensus *not* to address. **We acknowledge these are not equivalent, but they were usually discussed together and form one domain in these findings.

Sleep schedule

Suggestions were largely consistent to increase regularity of sleep timing, with some variation around the level and timing of any allowable flexibility. There was more support for occasional flexibility to accommodate life events once a routine is established, than for flexibility to recover sleep debt, although a minority did advocate the latter.

Although two participants with personal experience suggested it might be OK to be nocturnal / reversed, they described this as merely better than getting no sleep, rather than a preference, and the goal of 'sleeping at night, not in the day' was one of the most highly rated by this group. Suggestions were consistent regarding changes to sleep timing being made in small increments, and two professional participants suggested first stabilising timing, then moving the sleep window, if practical.

Time in Bed restriction

Time in bed restriction was controversial, and views diverged further as rounds progressed. Qualitatively, strong views were expressed on both sides. Participants emphasised the efficacy and evidence base for sleep restriction therapy, and others emphasised the potential risk of adverse effects such as triggering mania or psychosis. Some felt this meant it should not be used, whilst others suggested it should be used with caution, regular monitoring, and adequate therapists training and supervision. Sleep compression was suggested as a gentler alternative approach (reducing the sleep window gradually rather than in one step), and this was then endorsed by 56% (28% neutral, 6% disagree, 0% strongly disagree).

Participants with personal experience expressed some reluctance toward the idea of time in bed restriction and avoidance of napping, which may have been driven by their lack of belief that this approach would work (ratings of feeling it would be likely to work: 35%=not really, 44%=somewhat, 20%=mostly, 4%=completely). This was quite in contrast to professionals who felt it was likely to work, but difficult to adhere to or might have adverse effects. Participants with personal experience rated this as the area of which they had second-lowest prior awareness, after light exposure.

Napping

Professionals endorsed addressing napping, and agreed strongly to evaluate the role of naps, but were divided between 'avoid napping', 'allow napping' and 'encourage a regular planned nap'. Some said it depended on the individual's mental health and co-morbidities, whilst others felt avoiding or reducing napping was always preferable. Keeping naps short and not too late in the day (if taken) was suggested and was uncontroversial, as was a safety nap if driving and sleepy (or, do not drive). In participants with personal experience, some thought avoiding napping might be useful whilst, some already did not nap, and some would not be willing to try this. Qualitatively some expressed they felt one should 'get sleep whenever you can'.

Stimulus control, and managing awakenings

Professionals and people with personal experience alike agreed on making the bedroom, or at least the bed, for sleep and sex only (if other rooms are available). Rising if not asleep was mostly uncontroversial with professionals, who varied more on after how long to get up, or whether this depended on how you were feeling (e.g., sleepy, or irritable and alert). Much discussion explored how best to support clients to find suitable activities to engage in during the night if they wake.

By contrast, many people with personal experience had tried ‘the 15-minute rule’ or similar, as part of self-help advice, and in 4 out of 5 of the focus group discussions participants independently raised problems with this approach. People described getting less sleep, feeling worse in the daytime, waking up even more, and becoming engrossed in activities so not going back to bed. It was not clear how long participants had persevered, although we know these were not experiences as part of structured CBTi as participants had not had CBTi (see Table 2). No-one replied to describe any good experiences when attempting to use the 15-minute rule.

Morning Routine

Morning routine was rated as very appropriate to address in round 1 (>80%), and suggestions were consistent regarding how to address this. These focused around energising activity, and some emphasised light exposure soon after waking, planning activities to improve motivation to get up, and use of alarms. ‘Support to set alarms’, and ‘dawn simulation alarms’ were rated highly by professionals. Dawn simulator alarms were also popular when discussed by participants with personal experience, none had tried them, but many felt they might help.

The use of multiple alarms set away from the bed was rated highly by professionals. Participants with personal experience emphasised the real struggle to wake, and many emphasised that harsh approaches were probably necessary and acceptable if they can be woken. Some already asked friends to phone to wake them up or arranged activities they would have to get up for. We note the daytime nature of the discussion group may have meant those with ongoing delayed or reversed sleep were underrepresented (discussed in limitations).

Evening Routine

Evening routine was discussed very frequently, and almost all the specific suggestions rated, were rated as very important to include. Participants with and without personal experience suggested similar types of activities for therapists to suggest or encourage within the evening routine. The exception being watching TV, which some strongly advised against, whilst others felt it was not a major problem. There was varied emphasis on having a *similar routine each night* during the wind-down period in the qualitative content, but this was rated highly by professionals when asked. Many participants with mental health expertise suggested it might be necessary to support participants to identify and plan suitable activities, describing using lists of ideas, or providing materials. Two professionals and one person with personal experience recommended the option of setting an alarm to cue initiating the getting ready for bed routine.

Daytime activity

Daytime activity was rated in round 1 as one of the more important areas to address, perhaps influenced by knowledge that it will be OTs delivering the intervention. The types of interventions to address daytime activity were very consistent between participants, and involved promoting occupational balance in routines, identifying interests, scheduling activities, and setting goals (resembling common mental health OT approaches). Participants with personal experience concurred regarding the barriers, and the approach needed: describing too few satisfying productive activities, the need to increase activity and exercise, and to make very concrete and specific plans to increase follow-through. This specific scheduling fits well with the suggestion 'continue with activities planned irrespective of sleep' (akin to behavioural activation), which had been well endorsed in round 2 ratings by professionals.

Addressing medications

Some participants suggested addressing the exact timings of oral medications, particularly those which are sedating and taken at night, levels of confidence to discuss medication timing varied (even within the 'nocte' prescriber instruction). Many suggested liaising with the prescriber or a pharmacist. Mental health clinicians and researchers were more likely to think this was important to address. Participants with personal experience were more focused on addressing or considering side effects of medications. Sometimes professionals mentioned addressing medication dosages in liaison with the prescriber.

Addressing food and drink

Meal timing was rated as important, but less so than other areas, and type of food and drink was only rated as important by a few participants. Some linked daytime meal timing to circadian rhythm and daytime routine, others only focused on late eating causing sleep interference. To avoid late night eating, some participants (mostly but not exclusively OTs) noted it might be necessary to address food preparation and shopping skills and routines elsewhere in the day. The same was said about night eating, although more tentatively. Participants varied a lot in how common they thought night eating might be in this group and this did not seem to relate to amount of experience with people with SzSD. One person admitted not asking about night eating as much as they thought they should. Religious and cultural considerations were noted (e.g., Ramadan).

Addressing substance misuse

Participants in round 1 commonly and consistently suggested addressing illicit substance misuse as far as possible and as far as the client is willing. They also

noted though some levels of substance abuse that would preclude useful participation in the intervention such as regular amphetamine use.

Education regarding the impact of alcohol on sleep was emphasised. Late caffeine or high levels of caffeine was recommended to address, however, participants varied in how strict or how personalised rules should be. The impact of smoking was acknowledged; some professionals said 'reduce smoking' or 'avoid late at night', but professionals and people with personal experience noted reducing smoking was hard to do.

Light exposure

Increasing morning or daytime light exposure was regularly emphasised in qualitative data, more so than reducing evening light. Professionals, including circadian rhythm researchers, varied in how strong they felt the evidence was for reducing evening light exposure. Whilst no professionals described altering light exposure as harmful, a minority felt it was relatively unimportant or not worth the effort / burden. Professionals spoke of circadian effects, a small number spoke specifically about the acute alerting effects of light (4 professionals, one person with personal experience). Some said the importance of light will vary between individuals. Views among those with personal experience varied regarding light.

Using natural light was by far the most endorsed method to modify light exposure, partly for accompanying benefits of social contact and physical activity. A few participants, mostly those with mental health expertise, spoke about embedding light exposure within activity / occupation. People with personal experience were reasonably willing to go outside for natural light, more than to use a light box, although many also expressed difficulties and concerns around going out. Some described needing a lot of support to work toward going out, as more of a long-term

goal. Modifying light exposure to improve sleep was rated as difficult to stick to (65% rated 'somewhat difficult', 'difficult' or 'very difficult').

Season was noted as influential, with both professionals and people with personal experience describing potential for sleep patterns depending on season, and some noting light boxes were more needed in winter than summer, as well as weather affects going out.

Reducing light at night during the sleep period was very often mentioned and advocated by professionals. Among people with personal experience, some felt darkness improved sleep, others experienced fear of the dark. Participants mentioned blackout curtains, eye-masks, and avoiding screens and bright lights during awakenings (but light enough to prevent falls).

Giving education regarding the effects of light was often discussed as important by professionals. In-keeping with this; people with personal experience demonstrated often quite poor understanding of the effects of light especially on circadian rhythm (understandably), and many had low expectations of efficacy from changing light exposure.

Environmental assessment and intervention

There was a strong consensus to address bedroom environment, and to a slightly lesser extent home environment generally. The specific suggestions which we requested rating of, were highly endorsed, especially addressing window coverings, and moving belongings to support stimulus control (bed only for sleep). There were many areas identified as potentially helpful to address but where financial constraints might limit options, such as poor-quality bed or bedding, or air quality related to mould and damp. Noise disruption at night was similarly 'worth being aware of'; but might be beyond control, except by using white noise generators or earplugs - views

on these were mixed. Improving the ability to return to sleep after disruptions, or reducing sleep-related anxiety, could help with noise. Sense of security in the home would affect sleep, and might be modifiable via practical measures or discussions, or might be hard to change, depending on the basis of these fears. It was acknowledged that clients might not sleep in the bed for a range of reasons including trauma.

The social environment, both in the home and more broadly was noted as potentially a barrier or facilitator of successful sleep improvement. Either busy homes, or loneliness in those who live alone, could cause problems. Social commitments could facilitate regularity, or it might be unconducive to regular sleep schedules (e.g., work and family responsibilities might conflict with desired sleep pattern). Cultural factors must also be taken account of, for example, religious observances, and varied cultural norms relating to sleep. Professionals and people with personal experience cited support from family, friends or carers as a facilitator should be utilised when present, although some lack informal support. Some professionals suggested using peer support (e.g., groups) within the intervention, while this was not mentioned by those with personal experience.

Relaxation and / or mindfulness

In round 1 many participants suggested inclusion of either mindfulness or relaxation. Ratings of breathing techniques, progressive muscle relaxation, guided imagery, and mindfulness meditation, endorsement and consensus were higher in round 2 then reduced by round 3. Some commented that relaxation or mindfulness were not enough of a priority to include in limited time, others felt it was a priority, and some strongly felt relaxation was *counterproductive* for sleep, particularly if practiced in bed with the intention of inducing sleep (induces sleep effort).

Although many treated mindfulness and relaxation as interchangeable or at least closely related in the context of a sleep intervention, some noted that mindfulness is not intended to produce relaxation.

Of those who advocated use of relaxation, there were suggestions to practice this in the daytime (although some did suggest practicing in bed), and to select a physically based strategy over for instance, visualisation. Many suggested individual responses vary, and some thus suggested offering different options for clients to try, but then some pointed out the high cost in training, skills and time (of client and therapist) to try out multiple options.

Thermoregulation

Thermoregulation could be addressed in terms of the temperature of the bedroom, bedding and nightclothes, warming the extremities prior to bed (slippers, bed socks, hot water bottles), and pre-bed baths or showers. There was agreement regarding addressing appropriate bedroom temperature (cool-ish) and that optimum temperature varies individually.

Beyond bedroom temperature there was little agreement, readings of the evidence varied between professionals, as did practice-based experiences. Some felt warming the feet or bathing prior to bed were neither harmful nor effective, others felt pre-bed bathing / showering might add to a calming evening routine, others felt direct thermoregulatory effects were important in aiding sleep onset (drop in body temperature and vasodilation of extremities). Participants mostly agreed that these strategies did not take much time to address for therapist or client and were low risk; may help some, and could be tried at low 'cost'. No one with personal experience expressed any strong views relating to temperature, some felt these interventions can be, or might be, helpful.

Addressing sensory factors

Although sensory factors were mentioned in some way by 52% of professionals, they were not given a lot of emphasis by many and were rated as relatively less important. They related mostly to the bedroom environment (colour, clutter), but also nightclothes. Many noted that sensory preferences are individual and can be identified by the client. More endorsed this as 'optional' than 'core'.

Cognitive or psychological approaches

Addressing sleep interfering beliefs was rated as relatively important in round 1, some suggested this should be using cognitive or psychological approaches, although some suggested these might be better delivered by a psychological therapist. Some stated sleep interfering beliefs or cognitive processes would often be modified by behavioural approaches, and cognitive techniques not required. It was not possible to fully explore all the many therapeutic modalities and techniques mentioned. Overall views suggested some patients may benefit from use of some cognitive approaches if it is feasible to equip the therapist with relevant skills to use when needed, or if therapists already have some skills.

4. Personalisation

Professionals suggested personalisation of the *goals of the intervention* to suit clients' priorities, to varying degrees. Similarly, people with personal experience rated very highly 'find the best sleep times to fit your schedule'. Personalisation of the *methods of intervention* for different sleep phenotypes, or patient choice and preferences, was also suggested by both professionals and people with personal experience (personalisation of various components is discussed in their respective sections). Limits of personalisation were acknowledged, in the form of increased complexity and skill demand upon the therapist.

5. Format, Structure and Pragmatic Considerations

A tension was identified by some participants between the desire to personalise, and the need to keep the protocol and the process simple, for both the client and the therapist. Increased personalisation options (content and delivery order) were noted to potentially increase the training requirements, whilst simplicity could improve therapist confidence, which was also important (discussed below).

Having options in the format of materials and around use of technology vs paper was described as straightforward, and was advocated. People with personal experience were positive about the use of technology, apart from those who were not confident using devices.

Most suggested some components would be optional, whilst a few recommended to cover everything. There was some consensus regarding some components which were 'core' (vs 'optional'), especially: evening routine, psychoeducation regarding normal sleep, activity and occupation, and morning routine (85%-98% = 'core'). There was weaker consensus regarding: modifying light exposure, sleep schedule and home environment being core components (all 70% = 'core'). For other components views varied more. Rationales given for some items being optional were around personalisation to phenotypes, to preferences, or where sleep might be improved by an earlier 'core' component, making other items unnecessary.

Views were divided regarding pre-determined versus variable order of component delivery. Where it came to which domains should be addressed first, overall, more items were suggested for delivery early or middle, whilst less were suggested to be delivered later or 'it doesn't matter when'. Evening routine and psychoeducation regarding normal sleep were recommended to be delivered early (90%, 88%), and to

a slightly lesser extent morning routine (73%), whilst views were more divided for other components. Often those which were rated as 'optional' elements were suggested to deliver middle, later, or doesn't matter when (food and drink, thermoregulation, sensory factors, cognitive approaches to worry), with those rated as 'core' also most rated as 'use early'. Exceptions included addressing medication (optional, use early), and activity and occupation (core, use middle).

There were suggestions around how to maintain gains: many suggested a follow-up or booster session, or a tapered ending to therapy. Participants suggested producing a maintenance plan for the client and their care team to keep and refer to (choice of format to suit the client).

6. Therapeutic approach and therapist factors

An educational approach was promoted, and education on normal sleep, sleep pressure, and circadian rhythm was suggested often. This was very compatible with suggestions of a 'normalising' approach. Some spoke about promoting learning using experimentation / behavioural experiments, using motivational interviewing techniques to increase readiness for change, and the need to establish rapport. People with personal experience touched on rapport specifically regarding the home assessment, which some felt could otherwise be invasive - some participants feared judgement.

As well as an empowering approach, and establishing rapport, some professionals described the importance of the therapist being confident in their delivery, thus inspiring confidence in the client. Areas of the intervention where common OT skills would be well utilised were mentioned, including problem solving, teaching, listening, and exploring routines and activities with clients. Barriers to the delivery of this type of intervention by OTs were discussed, including lack of talking therapy

skills / the need for training in this area. Three UK OTs independently raised the issue of generic working in community mental health teams, with some UK OTs becoming unable to deliver OT interventions as their roles had become focused on case management (care coordination).

7. Implementation considerations

Team perceptions were identified as a potential implementation barrier, as staff may not see sleep as the role of OT. Limited staff awareness of sleep might prevent identification of sleep problems, or staff might not be in the habit of asking clients about sleep as they feel they have nothing to offer. A potential facilitator of reaching the clients, was that clients were very willing to discuss sleep, and wanted support. Also, some who were not interested in talking therapy might be interested in a more behaviourally based and educational approach (comments from professionals and people with personal experience). Similarly, people with personal experience rated intervention 'using elements of CBTi' as relatively unappealing, despite that few (possibly none) had had CBTi.

A multi-disciplinary team (MDT) approach to the intervention was advocated, particularly around medication advice, and maintenance of gains after therapy is complete. Some described benefits of involvement of multiple professions, each with sleep specialism, directly in intervention delivery, whilst others framed MDT collaboration more as the individual sleep OT liaising and delivering information or training to those non-sleep specialist MDT members involved in the client's ongoing care.

Discussion:

This paper has evaluated the views and recommendations of relevant experts regarding the appropriate contents and format for a mental health OT intervention to improve poor sleep, in people with SzSD. Although a clear consensus was not reached on several issues, the results were informative and provided a basis for the development of an intervention. Due to the diverse experiential and theoretical participant perspectives drawn upon, we anticipated that consensus may not be reached on some items. The results instead describe the arguments for certain approaches, and how views and approaches vary within and between groups. We hope these results may also prove informative for others making decisions about treatment of poor sleep in SzSD, and sleep treatment by mental health occupational therapists.

The findings emphasised the importance of personalisation within an OT-delivered intervention for poor sleep in SzSD, although the optimal manner and extent of personalisation described varied. Professionals agreed on what to assess, and agreed on a few domains to address with all clients. There was consensus regarding the importance of addressing evening routine, education regarding sleep processes, morning routine, and input regarding daytime activity, as core elements, and suggestions on how to address these domains were aligned.

Findings suggested many domains were better to address early. This may suggest a design of intervention with more input weighted toward the front. The time required for behaviour change and circadian rhythm change, equally suggests allowing time for clients to put new knowledge into practice. Emphasis on supportive therapeutic relationships, suggests some ongoing check-ins with the therapist for troubleshooting and support.

Interventions recommended appeared to be influenced by professional roles and accepted theoretical or moral stances, for instance, in views around approaches to napping, time in bed restriction, and regularity of rise time. Participants who were CBTi practitioners emphasised these elements and suggested less flexibility here, and focused on homeostatic sleep drive and behavioural associations, which are core elements within CBTi theory [77]. Mental health experts, and particularly mental health OTs, emphasised personalisation and patient choice over various areas of the intervention (often including napping), perhaps in line with the predominant professional culture around client-centred practice [78,79] and shifts toward shared decision making in mental health [80]. The formulation and presentation of the intervention should take account of the predominant professional culture of both those who will deliver the intervention, as well as other groups in the wider healthcare system.

Views diverged between professionals and those with personal experience regarding the ’15-minute rule’ aspect of stimulus control therapy, although some professionals acknowledged some of the potential difficulty of this rule, others described it as fairly benign. It is indeed often included in self-help advice [81–84]. These negative experiences emphasise that how a component is delivered and received (interpretation and intention) is crucial to its effect. This finding may raise the possibility that this component could be differently received in people with SzSD than other groups, perhaps due to difficulties in regulation of arousal [85]. It would be interesting to know how and by whom this advice was delivered, and for how long and in what context the person tried it (e.g., during an acute exacerbation of sleep and mental health, or under more stable circumstances). These may be questions to address in future research focused on this component alone. We suggest

that this aspect of stimulus control advice may not be useful as stand-alone self-help advice in this group.

Views on the appropriate contents of the intervention can be interpreted in terms of differing emphasis regarding which key mechanisms to focus on; some professionals emphasised sleep pressure and behavioural associations (more so recommending time in bed restriction and stimulus control), whilst others emphasised modulation of arousal (more so recommending relaxation and anxiety reduction), and still others emphasised circadian rhythm (more so recommending timed light exposure and other cues). These differing emphases reveal participant's working hypotheses regarding the predominant factors which interfere with sleep in clients with SzSD. These different hypotheses are each supported by empirical evidence. Meta-analysis of passive monitoring studies shows high prevalence of hypersomnia in SzSD [2], and authors propose a role of maladaptive time in bed extension [86,87]. A role of hyperarousal and of night-time worry in interfering with sleep has been supported in this group [88] and in general [89,90], and both observational and basic science studies support a role of altered or reduced circadian response in SzSD [34,91]. Thus, is it reasonable and not surprising that a number of distinct mechanisms might be targeted.

Readings of the evidence for light-based intervention varied widely among professionals, with some feeling there was very good evidence whilst others felt there was very little. This may relate to partial or incomplete awareness of the evidence, but our impression was that this was more due to differing epistemological perspectives regarding the evidence hierarchy [92]. Perhaps also different standards of proof were being sought, by some as though to recommend in policy, and by others only to be a good candidate for testing.

Another area where diverging views highlight a lack of directly relevant evidence was time in bed restriction in clients with SzSD, arguments for and against its safety and appropriateness were based on theoretical considerations or application of evidence from other groups. This points to a need for more studies of time in bed restriction in SzSD which assess or monitor safety ('single component' and 'multi-component' formulations may both be informative).

Which factor(s) to focus on first, or most, can potentially be completely determined in response to each client's individual problems and presentation, and some advocated this. However, there was a potential trade-off identified between the extent of personalisation and increasing complexity. The amount of therapist procedural knowledge required (when-then rules) may be increased by such personalisation, which each require repetition to become automatic. Prior to this procedural knowledge being easily accessed, interpersonal skills are adversely affected [93]. Thus it is a consideration that therapist capacity for listening, use of self, and fostering alliance [94,95], could actually be adversely affected by a protocol that allows too much personalisation.

Furthermore, presenting options and choices to clients is not always experienced as positive, and can be debilitating, leading to excessive delay of decisions, avoidance of regret, and a feeling of forced responsibility - clients want information, and the choice of a practitioner they trust, but vary in their preferences for role and control within clinical decisions [80]. A particular area where the prioritisation of presenting a clear message versus offering choice is pertinent is time in bed restriction; by its nature time in bed restriction is challenging [96], but through its rigorous application can reduce sleep effort, dysfunctional sleep beliefs, and insomnia [97]. Our findings described the view that time in bed restriction must be delivered confidently to be

effective, but we also found many participants are concerned about the risks of time in bed restriction.

This poses a potential challenge. If therapists attempt to deliver time in bed restriction, but do so too deliberatively and cautiously, this may increase rather than reduce sleep effort and excessive concern about sleep; as therapist anxiety can interact with that of the patient [98]. This phenomenon has been found in exposure therapy; where therapists who were too cautious, allowing safety behaviours, offering many options, and terminating tasks too soon, produced poorer treatment effects, and even increased fear sensitisation [99]. Similarly, in relation to daytime activity plans, participants with personal experience, emphasised they didn't want things to be too vague to give them the opportunity to talk themselves out of things. This highlights that responsiveness to the patient should not mean changing course at the first sign of difficulty, or at any expression of resistance or reluctance.

There are a number of ways an intervention can be responsive to the individual. Personalisation may be driven solely by individual choice (as with 'personalisation of care' with individual budgets), or by identification of biomarkers or phenotypes which respond differently to different treatments. Both types of personalisation were discussed in these results. The former taken too far can be criticised for abdication of responsibility to individuals [100], whilst the latter alone might be too solely biological and neglect human factors [101].

Personalisation can be via an adaptive protocol with different plans for different scenarios, or personalisation can involve more free-form clinical reasoning of the individual therapist. The latter is described in some occupational therapy literature as a feature of client-centred practice, with authors describing the 'artistry' of clinical judgement, involving creativity and intuition, and very much a non-standardised

approach [78,79]. Personalisation advocated within these results includes the biologically driven, such as to account for interindividual variability in phase-delaying response to evening light [102], and also the less biological, involving intuitive crafting of some aspects of the intervention plan to suit the individual's unique circumstances and priorities. It is our challenge to accommodate both; they can be compatible. If occupational therapy is aligned with romanticism rather than empiricism [98] this might suggest a difficulty of implementing a protocol based therapy, involving biological mechanisms, as well as personal and contextual client factors. Occupational therapists have, however, also expressed alignment with empiricism [103], and have specifically described the desire for more research and scientific evidence based techniques to use in relation to sleep [35]. Further, many of the strongest advocates for a protocol-based approach within this study were sleep OTs.

Another approach to personalisation beyond the scope of current work but which could usefully be studied in future would be personalisation of sleep intervention by selection of a different therapy protocol / pathway and lead professional, based on screening or clinical assessment. Our findings suggest which areas are best suited to delivery by an OT (for instance, routine and activity), some better address by a clinical psychologist or psychological therapist (such as nightmares and trauma) and some which required medical input (such as medication). We have developed a stand-alone intervention deliverable by a single OT with access to supervision, partly for ease of testing and implementation against a background of limited current sleep expertise in services. However, we would equally be keen to see the development of an adaptive MDT delivered therapy protocol embedded in a rigorous process of co-design with clinician and stakeholder input.

Limitations:

We have not deemed it ethical to separately report on the views of participants who personally deliver adapted CBTi to participants with SzSD due to this being a very limited pool of experts internationally. Whilst it might have been interesting and informative to examine these views separately, our duty not to make individuals potentially identifiable over-rode this.

Typically health-related expert opinion Delphi studies recruit a smaller sample, all with similar expertise [63] and do not attempt to triangulate between groups. The diverse experience within this study is both a strength, as it addresses this topic in which various groups meet, and a limitation as it made the variation in responses more complex to analyse and interpret. Similarly, we included service users and carers together in the final stage of data collection, and largely analysed these views together, as they were sought to answer the same aims with carers giving proxy reports. Separate analysis appeared to further fragment the data and did not suggest any important differences, but we acknowledge that service user and carer views are not equivalent.

The rating of daytime activity as 'core', may of course have been influenced by the lead researcher and interviewer being an OT, thus those who felt activity and occupation were less relevant, or that OTs were an inappropriate profession to deliver sleep interventions might not have volunteered to participate, or may have increased their endorsement of the importance of occupation and activity through social acceptability bias [104,105]. This is a potential limitation, although efforts were made to reduce bias through encouraging honest responses, and through use of an online survey which is associated with less bias than in-person survey or interview [104].

It is acknowledged that the possibility of bias in selection of experts [68] cannot be completely removed, however, the diverse views represented hopefully gives some reassurance that participant selection was not biased by any desired outcome other than seeking relevant knowledge to inform intervention development.

We did not obtain any views from mental health nurses, who represent a large part of the workforce and include many individuals with relevant expertise. With hindsight, some of our mental health clinician and researcher experts should have been drawn from mental health nursing and had we set a sub-group target this would clearly have been achievable. We acknowledge limited representation of views from professionals with Asian and African residence, and our inability to include non-English speaking participants limits transferability.

Although we were able to recruit 24% non-White-British participants with personal experience, representation of reversed or very delayed sleep and hypersomnia may have been limited by the daytime nature of the group (10:30am-3pm). Previous work offering individual interviews in a location of participant choice included many more participants with these difficulties [20]. The group setting is also less likely to attract participants who are reluctant to disclose a psychosis related diagnosis, thus excluding those who experience most diagnosis related stigma or self-stigma [106]. Although we hoped to include by-proxy the views of service users who may struggle to attend by inclusion of carers, in hindsight adding options for remote or delayed participation could have improved inclusiveness.

Finally, it is a limitation that we stopped after a predetermined number of survey rounds (three), when there was more we could usefully have asked; but at the same time, we assume it would have negatively impacted our ability to recruit and retain the desired volume and quality of participants if length was not pre-determined.

Conclusion:

Participants felt intervention by mental health occupational therapists to improve sleep in people with SzSD was potentially feasible and worthwhile, and they were exceptionally willing to contribute time and energy to the development of such an intervention. They almost entirely agreed on the inclusion of a few core elements within this intervention, whilst views were mixed on other elements, and on the most appropriate emphasis within the intervention. There was no consensus on the *extent* of personalisation to accommodate, or on and *what aspects* of the intervention to personalise in response to individual circumstances and needs. Similarly, views varied on how and where to offer patient choice on therapy approach and format. It was agreed though that the intervention must personalise, whilst avoiding excess complexity.

Suggestions regarding how to address activity, routines and environment were very congruent within and between groups, and the approaches described were very compatible with the existing approaches of mental health occupational therapists. Occupational therapists have previously suggested that some of their core skills can effectively be repurposed to deliver behavioural sleep interventions, and our findings, based on a far wider group of stakeholders, tend to confirm that view.

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References:

1. Chan MS, Chung KF, Yung KP, Yeung WF. Sleep in schizophrenia: A systematic review and meta-analysis of polysomnographic findings in case-control studies. Sleep Med Rev. 2017;32: 69–84. doi:10.1016/j.smrv.2016.03.001

2. Meyer N, Faulkner SM, Mccutcheon RA, Pillinger T, Dijk D, Maccabe JH. Sleep and Circadian Rhythm Disturbance in Remitted Schizophrenia and Bipolar Disorder: A Systematic Review and Meta-analysis. Schizophr Bull. 2020. doi:10.1093/schbul/sbaa024

3. Waite F, Sheaves B, Isham L, Reeve S, Freeman D. Sleep and schizophrenia: From epiphenomenon to treatable causal target. Schizophr Res. 2020;221: 44–56. doi:10.1016/j.schres.2019.11.014

4. Robillard R, Rogers NL, Whitwell BG, Lambert T. Are cardiometabolic and endocrine abnormalities linked to sleep difficulties in schizophrenia? A hypothesis driven review. Clin Psychopharmacol Neurosci. 2012;10: 1–12. doi:10.9758/cpn.2012.10.1.1

5. Wulff K, Joyce E. Circadian rhythms and cognition in schizophrenia. Br J Psychiatry. 2011;198: 250–252. doi:10.1016/B978-0-444-53702-7.00008-7

6. Waite F, Evans N, Myers E, Startup H, Lister R, Harvey AG, et al. The patient experience of sleep problems and their treatment in the context of current delusions and hallucinations. Psychol Psychother Theory, Res Pract. 2015;89: 181–193. doi:10.1111/papt.12073

7. Wulff K, Porcheret K, Cussans E, Foster RG. Sleep and circadian rhythm disturbances: multiple genes and multiple phenotypes. Curr Opin Genet Dev. 2009;19: 237–46. doi:10.1016/j.gde.2009.03.007

8. Chiu VW, Ree M, Janca A, Iyyalol R, Dragovic M, Waters F. Sleep profiles and CBT-I response in schizophrenia and related psychoses. Psychiatry Res. 2018;268: 279–287. doi:10.1016/j.psychres.2018.07.027

9. Wulff K, Dijk D-J, Middleton B, Foster RG, Joyce EM. Sleep and circadian rhythm disruption in schizophrenia. Br J Psychiatry. 2012;200: 308–16. doi:10.1192/bjp.bp.111.096321

10. Wulff K, Joyce E, Middleton B, Dijk D-JJ, Foster RG, Foster G, et al. The suitability of actigraphy, diary data, and urinary melatonin profiles for quantitative assessment

of sleep disturbances in schizophrenia: A case report. Chronobiol Int. 2006;23: 485–495. doi:10.1080/07420520500545987

11. Meyer N, Joyce DW, Karr C, Hees VT van, Vos M de, Dijk D-J, et al. P029 Sleep and circadian rhythm disturbances and relapse in schizophrenia: a digital phenotyping study. Conference: BSS Scientific Conference Abstract Book, Birmingham, England. BMJ Open Respiratory Research; pp. 6(Suppl 1):A17.2-A18. Available: 10.1136/bmjresp-2019-bssconf.29

12. Mishima K. Pathophysiology and strategic treatment of sighted non-24-h sleep–wake rhythm disorders. Sleep Biol Rhythms. 2017;15: 11–20. doi:10.1007/s41105-016-0076-4

13. Oliveira P, Coroa M, Madeira N. Treatment Options for Insomnia in Schizophrenia: A Systematic Review. Pharmacopsychiatry. 2019;52: 165–169. doi:10.1055/a-0658-1645

14. Monti JM, Torterolo P, Pandi Perumal SR. The effects of second generation antipsychotic drugs on sleep variables in healthy subjects and patients with schizophrenia. Sleep Med Rev. 2016. doi:10.1016/j.smrv.2016.05.002

15. Kripke DF. Mortality Risk of Hypnotics: Strengths and Limits of Evidence. Drug Saf. 2016;39: 93–107. doi:10.1007/s40264-015-0362-0

16. Shamir E, Laudon M, Barak Y, Anis Y, Rotenberg V, Elizur A, et al. Melatonin Inproves Sleep Quality of Patients With Chronic Schizophrenia. J Clin Psychiatry. 2000;61: 373–377.

17. Kumar PNS, Andrade C, Bhakta SG, Singh NM. Melatonin in schizophrenic outpatients with insomnia: A double-blind, placebo-controlled study. J Clin Psychiatry. 2007;68: 237–241. Available: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc5&NEWS=N&AN=2007-07426-008

18. Mishra A, Maiti R, Ranjan B, Jena M, Nath S, Sahu P. Effect of add-on ramelteon therapy on sleep and circadian rhythm disruption in patients with schizophrenia : A randomized controlled trial. Eur Neuropsychopharmacol. 2020;31: 109–118. doi:10.1016/j.euroneuro.2019.11.008

19. Waters F, Chiu VW, Janca A, Atkinson A, Ree M. Preferences for different insomnia treatment options in people with schizophrenia and related psychoses: a qualitative study. Front Psychol. 2015;6: 1–10. doi:10.3389/fpsyg.2015.00990

20. Faulkner S, Bee P. Experiences, perspectives and priorities of people with schizophrenia spectrum disorders regarding sleep disturbance and its treatment: A qualitative study. BMC Psychiatry. 2017;17. doi:10.1186/s12888-017-1329-8

21. Wu JQ, Appleman ER, Salazar RD, Ong JC. Cognitive Behavioral Therapy for Insomnia Comorbid With Psychiatric and Medical Conditions. JAMA Intern Med. 2015;175: 1461–72. doi:10.1001/jamainternmed.2015.3006

22. Geiger-Brown JM, Rogers VE, Liu W, Ludeman EM, Downton KD, Diaz-Abad M. Cognitive behavioral therapy in persons with comorbid insomnia: A meta-analysis. Sleep Med Rev. 2015;23: 54–67. doi:10.1016/j.smrv.2014.11.007

23. Sweetman A, McEvoy RD, Smith S, Catcheside PG, Antic NA, Chai-Coetzer CL, et al. The effect of cognitive and behavioral therapy for insomnia on week-to-week changes in sleepiness and sleep parameters in patients with comorbid insomnia and sleep apnea: a randomized controlled trial. Sleep. 2020; 1–13. doi:10.1093/sleep/zsaa002

24. van Straten A, van der Zweerde T, Kleiboer A, Cuijpers P, Morin CM, Lancee J. Cognitive and behavioral therapies in the treatment of insomnia: A meta-analysis. Sleep Med Rev. 2018;38: 3–16. doi:10.1016/j.smrv.2017.02.001

25. Brandt J, Leong C. Benzodiazepines and Z-Drugs: An Updated Review of Major Adverse Outcomes Reported on in Epidemiologic Research. Drugs R D. 2017;17: 493–507. doi:10.1007/s40268-017-0207-7

26. Varma S. Benzodiazepines and hypnotics. Med (United Kingdom). 2016;44: 764–767. doi:10.1016/j.mpmed.2016.09.019

27. Gradisar M, Dohnt H, Gardner G, Paine S, Starkey K, Menne A, et al. A Randomized Controlled Trial of Cognitive-Behavior Therapy Plus Bright Light.pdf. Sleep. 2011;34: 1671–1680. Available: http://dx.doi.org/10.5665/sleep.1432

28. Danielsson K, Jansson-Fröjmark M, Broman JE, Markström A. Cognitive Behavioral Therapy as an Adjunct Treatment to Light Therapy for Delayed Sleep Phase Disorder in Young Adults: A Randomized Controlled Feasibility Study. Behav Sleep Med. 2016;14: 212–232. doi:10.1080/15402002.2014.981817

29. Gooley JJ. Treatment of circadian rhythm sleep disorders with light. Ann Acad Med Singapore. 2008;37: 669–676.

30. Munch M, Bromundt V. Light and chronobiology: Implications for health and disease. Dialogues Clin Neurosci. 2012;14: 448–453. doi:10.3109/07420528.2012.754448

31. Faulkner SM, Bee PE, Meyer N, Dijk DJ, Drake RJ. Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: A systematic review and meta-analysis. Sleep Med Rev. 2019;46: 108–123. doi:10.1016/j.smrv.2019.04.012

32. Faulkner SM, Dijk DJ, Drake RJ, Bee PE. Adherence and acceptability of light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuropsychiatric illness: a systematic review. Sleep Heal. 2020. doi:10.1016/j.sleh.2020.01.014

33. Sheaves B, Freeman D, Isham L, McInerney J, Nickless A, Yu LM, et al. Stabilising sleep for patients admitted at acute crisis to a psychiatric hospital (OWLS): An assessor-blind pilot randomised controlled trial. Psychol Med. 2018;48: 1694–1704. doi:10.1017/S0033291717003191

34. Jagannath A, Peirson SN, Foster RG. Sleep and circadian rhythm disruption in neuropsychiatric illness. Curr Opin Neurobiol. 2013;23: 888–894. doi:10.1016/j.conb.2013.03.008

35. Faulkner S, Mairs H. An exploration of the role of the occupational therapist in relation to sleep problems in mental health settings. Br J Occup Ther. 2015;78: 516–524. doi:10.1177/0308022614564771

36. Rehman A, Waite F, Sheaves B, Biello S, Freeman D, Gumley A. Clinician perceptions of sleep problems, and their treatment, in patients with non-affective psychosis. Psychosis. 2017;9: 129–139. doi:10.1080/17522439.2016.1206955

37. Barrett EA, Aminoff SR, Simonsen C, Romm KL. Opening the curtains for better sleep in psychotic disorders - considerations for improving sleep treatment. Compr Psychiatry. 2020;103. doi:10.1016/j.comppsych.2020.152207

38. Freeman D, Waite F, Startup H, Myers E, Lister R, McInerney J, et al. Efficacy of cognitive behavioural therapy for sleep improvement in patients with persistent delusions and hallucinations (BEST): a prospective, assessor-blind, randomised

controlled pilot trial. Lancet Psychiatry. 2015;2: 975–983. doi:10.1016/S2215-0366(15)00314-4

39. Bradley J, Freeman D, Chadwick E, Harvey AG, Mullins B, Johns L, et al. Treating Sleep Problems in Young People at Ultra-High Risk of Psychosis: A Feasibility Case Series. Behav Cogn Psychother. 2018;46: 276–291. doi:10.1017/S1352465817000601

40. Hwang D, Nam M, Lee YG. The effect of cognitive behavioral therapy for insomnia in schizophrenia patients with sleep Disturbance : A non-randomized , assessor-blind trial. Psychiatry Res. 2019;274: 182–188. doi:10.1016/j.psychres.2019.02.002

41. Prytys M, Garety PA, Jolley S, Onwumere J, Craig T. Implementing the NICE guideline for schizophrenia recommendations for psychological therapies: A qualitative analysis of the attitudes of CMHT staff. Clin Psychol Psychother. 2011;18: 48–59. doi:10.1002/cpp.691

42. Fiddick L, Neale E, Nathwani F, Bennert K, Gregory J. Referring to psychological therapy services in secondary NHS mental health services – how do mental health care professionals decide? Ment Heal Rev J. 2020;25: 185–196. doi:10.1108/MHRJ-04-2019-0013

43. Jolley S, Garety P, Peters E, Fornells-Ambrojo M, Onwumere J, Harris V, et al. Opportunities and challenges in Improving Access to Psychological Therapies for people with Severe Mental Illness (IAPT-SMI): Evaluating the first operational year of the South London and Maudsley (SLaM) demonstration site for psychosis. Behav Res Ther. 2015;64: 24–30. doi:10.1016/j.brat.2014.11.006

44. Bird V, Premkumar P, Kendall T, Whittington C, Mitchell J, Kuipers E. Early intervention services, cognitive-behavioural therapy and family intervention in early psychosis: Systematic review. Br J Psychiatry. 2010;197: 350–356. doi:10.1192/bjp.bp.109.074526

45. Hawton K, Witt KG, Salisbury TLT, Arensman E, Gunnell D, Hazell P, et al. Psychosocial interventions following self-harm in adults: a systematic review and meta-analysis. The Lancet Psychiatry. 2016;3: 740–750. doi:10.1016/S2215-0366(16)30070-0

46. Fung C, Wiseman-Hakes C, Stergiou-Kita M, Nguyen M, Colantonio A. Time to wake up: bridging the gap between theory and practice for sleep in occupational

therapy. Br J Occup Ther. 2013;76: 384–386. doi:10.4276/030802213X13757040168432

47. Solet JM. Sleep and rest. 12th ed. In: Schell BA, Gillen G, Scaffa M, Cohn ES, editors. Willard and Spackman's Occupational Therapy. 12th ed. Philadelphia: Wolters Kluwer - Lippincott Williams and Wilkins; 2014. pp. 714–730.

48. Green A, Brown C. An Occupational Therapist's Guide to Sleep and Sleep Problems. London: Jessica Kingsley Publishers; 2015.

49. Hardaker L, Halcomb EJ, Griffiths R, Bolzan N, Hardaker L, Halcomb EJ, et al. The role of the occupational therapist in adolescent mental health: A critical review of the literature. Aust e-Journal Adv Ment Heal. 2007;6: 194–203. doi:10.5172/jamh.6.3.194

50. Kinn LG, Aas RW. Occupational therapists ' perception of their practice : A phenomenological study. Aust Occup Ther J. 2009;56: 112–121. doi:10.1111/j.1440-1630.2007.00714.x

51. Creek J, Ilott I, Cook S, Munday C. Valuing Occupational Therapy as a Complex Intervention. Br J Occup Ther. 2005;68: 281–284.

52. Pentland D, Kantartzis S, Clausen MG, Witemyre K. Occupational therapy and complexity : defining and describing practice. London; 2018.

53. Kielhofner G. Model of human occupation: Theory and application. Philadelphia: Lippincott Williams & Wilkins.; 2008.

54. Roley SS, DeLany J V., Barrows CJ, Brownrigg S, Honaker D, Sava DI, et al. Occupational Therapy Practice Framework: Domain & Process 2nd Edition. Am J Ocupational Ther. 2008.

55. Chern J, Kielhofner G, Heras G De, Magalhaes LC. The Volitional Questionnaire: Psychometric Development and Practical Use. Am J Occup Ther. 1995;50: 516–525.

56. Smith NR, Kielhofner G, Watts JH. The relationships between volition, activity pattern, and life satisfaction in the elderly. Am J Occup Ther. 1986;40: 278–283. doi:10.5014/ajot.40.4.278

57. Berry N, Lobban F, Bucci S. A qualitative exploration of service user views about using digital health interventions for self-management in severe mental health problems. BMC Psychiatry. 2019;19: 1–13. doi:10.1186/s12888-018-1979-1

58. Hsu C, Ohio T. The Delphi Technique : 2007;12.

59. Keeney S, Hasson F, McKenna H. Consulting the oracle: Ten lessons from using the Delphi technique in nursing research. J Adv Nurs. 2006;53: 205–212. doi:10.1111/j.1365-2648.2006.03716.x

60. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs. 2000;32: 1008–1015. doi:10.1046/j.1365-2648.2000.t01-1-01567.x

61. Diamond IR, Grant RC, Feldman BM, Pencharz PB, Ling SC, Moore AM, et al. Defining consensus : A systematic review recommends methodologic criteria for reporting of Delphi studies. J Clin Epidemiol. 2014;67: 401–409. doi:10.1016/j.jclinepi.2013.12.002

62. Murphy M, Black N, Lamping D, McKee CM, Sanderson C, Askham J, et al. Consensus development methods, and their use in clinical guideline development. Health Technol Assess. 1998;2: i–iv, 1–88. doi:10.3310/hta2030

63. Trevelyan EG, Robinson N. Delphi methodology in health research: How to do it? Eur J Integr Med. 2015;7: 423–428. doi:10.1016/j.eujim.2015.07.002

64. Sim J, Saunders B, Waterfield J, Kingstone T. Can sample size in qualitative research be determined a priori? Int J Soc Res Methodol. 2018;21: 619–634. doi:10.1080/13645579.2018.1454643

65. Boddy CR. Sample size for qualitative research. Qual Mark Res. 2016;19: 426–432. doi:10.1108/QMR-06-2016-0053

66. Robinson OC. Sampling in Interview-Based Qualitative Research: A Theoretical and Practical Guide. Qual Res Psychol. 2014;11: 25–41. doi:10.1080/14780887.2013.801543

67. Teddlie C, Yu F. Mixed Methods Sampling: A Typology With Examples. J Mix Methods Res. 2007;1: 77–100. doi:10.1177/2345678906292430

68. Keeney S, Hasson F, McKenna HP. A critical review of the Delphi technique as a research methodology for nursing. Int J Nurs Stud. 2001;38: 195–200. doi:10.1016/S0020-7489(00)00044-4

69. Weinstein BD. W H A T IS A N E X P E R T ? BRUCE D. WEINSTEIN The Center for Health Ethics and Law, West Virginia University, 1354 Health Sciences North, Morgantown, WV 26506, USA. 1993; 57–73.

70. Ozawa S, Pongpirul K. 10 Best Resources on.. Mixed Methods Research in Health Systems. Health Policy Plan. 2014;29: 323–327. doi:10.1093/heapol/czt019

71. Morgan DL. Qualitative Content Analysis: A Guide to Paths Not Taken. Qual Health Res. 1993;3: 112–121.

72. Migiro SO, Magangi BA. Mixed methods : A review of literature and the future of the new research paradigm. African J Bus Manag. 2011;5: 3757–3764. doi:10.5897/AJBM09.082

73. Elo S, Kääriäinen M, Kanste O, Pölkki T, Utriainen K, Kyngäs H. Qualitative Content Analysis. SAGE Open. 2014;4: 215824401452263. doi:10.1177/2158244014522633

74. Michie S, Stralen MM van, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6. doi:doi:10.1186/1748-5908-6-42

75. Vandelanotte C, Dwyer T, Van Itallie A, Hanley C, Mummery WK. The development of an internet-based outpatient cardiac rehabilitation intervention: a Delphi study. BMC Cardiovasc Disord. 2010;10: 27. doi:10.1186/1471-2261-10-27

76. Ochoa S, Usall J, Cobo J, Labad X, Kulkarni J. Gender Differences in Schizophrenia and First-Episode Psychosis: A Comprehensive Literature Review. Schizophr Res Treatment. 2012;2012: 1–9. doi:10.1155/2012/916198

77. Manber R, Carney CC, Erdinger J, Dana E, Freisman L, Haynes PL, et al. Dissemination of |CBTi to the non-sleep specialist: protocol Development and Training issues. J Clin sleep Med. 2012;8: 209–18.

78. Paterson M, Higgs J, Wilcox S. The artistry of judgement: A model for occupational therapy practice. Br J Occup Ther. 2005;68: 409–417. doi:10.1177/030802260506800905

79. Tickle-Degnen L. Client-Centered Practice, Therapeutic Relationship, and the Use of Research Evidence. Am J Ocupational Ther. 2002;56: 589–593.

80. Adams JR, Drake RE. Shared decision-making and evidence-based practice. Community Ment Health J. 2006;42: 87–105. doi:10.1007/s10597-005-9005-8

81. Ramos J. How To Sleep Better. In: www.helpguide.org/ [Internet]. 2018 [cited 16 Oct 2020]. doi:10.31988/scitrends.8002

82. Jacobson S. Are You Suffering From A Sleep Disorder? Top Tips For Insomnia. In: Harley Therapy Counselling Blog [Internet]. 2011 [cited 16 Oct 2020]. Available: https://www.harleytherapy.co.uk/counselling/sleep-disorder-tips-insomnia.htm

83. Sheaves B, Espie C. Having trouble with your sleep? Try following these 10 top tips for better sleep, Sleep and Circadian Neuroscience Institute (SCNi): University of Oxford. [cited 16 Oct 2020]. Available: https://www.ndcn.ox.ac.uk/research/sleep-circadian-neuroscience-institute/training-and-dissemination/having-trouble-with-your-sleep/sleep-tips_041214.pdf

84. National Centre for Mental Health. Sleep problems and how to manage them: Information for individuals, partners and families. 2019. Available: https://www.ncmh.info/wp-content/uploads/2019/05/Sleep-booklet-A5-leaflet-WEB.pdf

85. Nakamura M, Matsushima E, Ohta K, Ando K, Kojima T. Relationship between attention and arousal level in schizophrenia. Psychiatry Clin Neurosci. 2003;57: 472–477. doi:10.1046/j.1440-1819.2003.01150.x

86. Waite F, Myers E, Harvey AG, Espie C a., Startup H, Sheaves B, et al. Treating Sleep Problems in Patients with Schizophrenia. Behav Cogn Psychother. 2015; 1–15. doi:10.1017/S1352465815000430

87. Poulin J, Chouinard S, Pampoulova T, Lecomte Y, Stip E, Godbout R. Sleep habits in middle-aged, non-hospitalized men and women with schizophrenia: a comparison with healthy controls. Psychiatry Res. 2010;179: 274–278. Available: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med5&NEWS=N&AN=20493544

88. Chiu VW, Hons B, Harvey RH, Sloan NB, Ree M, Lin A, et al. Cognitive and Behavioral Factors Associated With Insomnia in Inpatients With Schizophrenia and Related Psychoses. J Nerv Ment Dis. 2015;203: 1–6. doi:10.1097/NMD.0000000000000370

89. Morin CM, Rodrigue S, Ivers H. Role of stress, arousal, and coping skills in primary insomnia. Psychosom Med. 2003;65: 259–267. doi:10.1097/01.PSY.0000030391.09558.A3

90. Lemyre A, Belzile F, Landry M, Bastien CH, Beaudoin LP. Pre-sleep cognitive activity in adults: A systematic review. Sleep Med Rev. 2020;50: 1–13. doi:10.1016/j.smrv.2019.101253

91. Pritchett D, Wulff K, Oliver PL, Bannerman DM, Davies KE, Harrison PJ, et al. Evaluating the links between schizophrenia and sleep and circadian rhythm disruption. J Neural Transm. 2012;119: 1061–1075. doi:10.1007/s00702-012-0817-8

92. Hutchison KJ, Rogers WA. Challenging the epistemological foundations of EBM: What kind of knowledge does clinical practice require? J Eval Clin Pract. 2012;18: 984–991. doi:10.1111/j.1365-2753.2012.01905.x

93. Bennett-Levy J. Therapist skills: A cognitive model of their acquisition and refinement. Behav Cogn Psychother. 2006;34: 57–78. doi:10.1017/S1352465805002420

94. Zilcha-Mano S, Muran JC, Eubanks CF, Safran JD, Winston A. Not Just a Non-specific Factor: Moderators of the Effect of Within- and Between-Clients Alliance on Outcome in CBT. Cognit Ther Res. 2018;42: 146–158. doi:10.1007/s10608-017-9866-5

95. Birken M, Henderson C, Slade M. The development of an occupational therapy intervention for adults with a diagnosed psychotic disorder following discharge from hospital. Pilot Feasibility Stud. 2018;4.

96. Kyle SD, Morgan K, Spiegelhalder K, Espie C a. No pain, no gain: an exploratory within-subjects mixed-methods evaluation of the patient experience of sleep restriction therapy (SRT) for insomnia. Sleep Med. 2011;12: 735–47. doi:10.1016/j.sleep.2011.03.016

97. Maurer LF, Espie CA, Omlin X, Reid MJ, Sharman R, Gavriloff D, et al. Isolating the role of time in bed restriction in the treatment of insomnia: a randomised, controlled, dismantling trial comparing sleep restriction therapy with time in bed regularisation. Sleep. 2020; 1–12. doi:10.1093/sleep/zsaa096

98. Waller G, Turner H. Therapist drift redux: Why well-meaning clinicians fail to deliver evidence-based therapy, and how to get back on track. Behav Res Ther. 2016;77: 129–137. doi:10.1016/j.brat.2015.12.005

99. Farrell NR, Deacon BJ, Dixon LJ, Lickel JJ. Theory-based training strategies for modifying practitioner concerns about exposure therapy. J Anxiety Disord. 2013;27: 781–787. doi:10.1016/j.janxdis.2013.09.003

100. Williams I, Dickinson H. Going It Alone or Playing to the Crowd? A Critique of Individual Budgets and the Personalisation of Health Care in the English National

Health Service. Aust J Public Adm. 2016;75: 149–158. doi:10.1111/1467-8500.12155

101. Louis R, Roche N. Personalised medicine: Are we ready? Eur Respir Rev. 2017;26: 1–4. doi:10.1183/16000617.0088-2017

102. Phillips AJK, Vidafar P, Burns AC, McGlashan EM, Anderson C, Rajaratnam SMW, et al. High sensitivity and interindividual variability in the response of the human circadian system to evening light. Proc Natl Acad Sci U S A. 2019;116: 12019–12024. doi:10.1073/pnas.1901824116

103. Taylor RR, Kielhofner G, Baker NA. Occupational Therapy as an Evidence-Based Practice Profession. 2nd ed. In: Taylor ReR, editor. Kielhofner's Research in Occupational Therapy: Methods of Inquiry for Enhancing Practice. 2nd ed. Philadelphia: F.A. Davis Company; 2017. pp. 1–10.

104. Krumpal I. Determinants of social desirability bias in sensitive surveys: A literature review. Qual Quant. 2013;47: 2025–2047. doi:10.1007/s11135-011-9640-9

105. Dahlgren GH, Hansen H. I'd rather be nice than honest: An experimental examination of social desirability bias in tourism surveys. J Vacat Mark. 2015;21: 318–325. doi:10.1177/1356766715577503

106. Wood L, Byrne R, Enache G, Morrison AP. A brief cognitive therapy intervention for internalised stigma in acute inpatients who experience psychosis: A feasibility randomised controlled trial. Psychiatry Res. 2018;262: 303–310. doi:10.1016/j.psychres.2017.12.030

Supporting information captions (see Appendix 6 of this thesis):

S1 Supporting Information. Data to support findings presented. Qualitative data excerpts and graphed results of multiple choice and Likert responses, organised by topics and themes

S2 Survey. Round 1 survey questions

S3 Survey. Round 2 survey questions

S4 Survey. Round 3 survey questions

S5 Topic Guide. Topic guide for focus groups. Used in stage 4 with participants with relevant personal experience

Chapter 7: Synthesis, development of intervention and design of study protocol

Earlier chapters have presented background literature, evidence synthesis and primary research, conducted to support the design of a novel intervention, and the development of a feasibility study protocol through which to initially test it. This chapter describes the synthesis of these results, and provides rationales for intervention and study design decisions made in response.

7.1. Overview of findings of Studies A-C

Study A found that existing studies suggest light treatment causes some improvement in sleep disturbance in groups prone to circadian dysregulation, although studies and effects are heterogenous. Study B found that the acceptability of, and adherence to, these interventions appears to be good, although measurement and reporting of feasibility related outcomes is limited. There were exceptions, but as a general rule, existing studies of light treatment included limited personalisation such as consideration of fitting the intervention to the participant's individual sleep problem or life context.

Study C examined expert opinions regarding the most appropriate content and manner of delivery for an intervention to improve poor sleep in SzSD. There was a strong consensus regarding inclusion of a limited number of core components, and views supported a high level of personalisation. Overall, there were many potentially appropriate or important aspects to consider, arguably more than could feasibly be covered within a brief intervention. See Table 17 for a summary of the studies conducted to inform intervention design, and the remaining questions, which the process of synthesis described in this chapter aims to address.

Table 17: Main finings and key questions remaining

	Chapter 4: Study A	**Chapter 5: Study B**	**Chapter 6: Study C**
Method	Meta-analysis with meta-regression	Systematic review with narrative synthesis	Mixed methods expert opinion study
Topic	Light / dark therapy in groups prone to ~CRSWD	Light / dark therapy in groups prone to ~CRSWD	Intervention to improve sleep in SzSD by occupational therapists
Question type	Effectiveness and effect moderators.	Acceptability, adherence and adverse effects.	Most recommended content and format.
Main Findings	Light / dark therapy compared to control condition showed: ■ increased sleep continuity ■ reduced self-reported sleep disturbance on composite measures ■ advance of sleep timing in DSWPD ■ evening light avoidance was associated with larger effects on TST in meta-regression.	Poor measurement and reporting of feasibility outcomes, but suggests: ■ good acceptability / satisfaction ■ good recruitment, low attrition, possibly good adherence ■ few, mostly minor adverse effects Interventions typically showed limited personalisation and many resembled lab protocols.	Strongest consensus re: ■ evening routine ■ activity and occupation interventions ■ home environment interventions ■ personalisation. ■ Disagreement over how to address some areas. ■ Conflict between ‘keeping it simple’, and many optional components.
Key questions and gaps remaining	■ More and better evidence required. ■ Effect moderator questions remain. ■ No studies specifically in SzSD.	■ What factors enhance adherence? ■ More and better acceptability data needed. ■ What is the impact of considering baseline light exposure and personalising?	■ What is the optimal, internally consistent, brief intervention informed by these recommendations? ■ What exact materials and equipment are needed to deliver this?

7.1.1. Synthesis of findings and background evidence, for design of the intervention

During intervention development, findings from the PhD studies and PPI views were considered. Background evidence was considered, including the evidence synthesised within the systematic reviews, the wider evidence base, such as that summarised in the background chapter, and my relevant previous work (see Figure 13). Findings are discussed in relation to the resulting intervention manual sections, those elements *not* included are also discussed. Sometimes evidence and findings clearly suggested a specific approach (marked "*uncontroversial*" below), whilst in other cases there appeared to be multiple justifiable responses to the data, and decisions required more discussion (marked *"debated").* In acknowledgement that there is nothing absolute about any specific level of agreement or endorsement of particular elements, mixed methods expert opinion study results informed, but did not completely dictate, intervention content. We did not automatically insert all elements with over a specific level of endorsement without consideration of other evidence and compatibility with other components. Decision making processes involved academics and PPI contributors from within the research team and more broadly. These processes, and the resulting decisions, are outlined below.

Published evidence was considered when making decisions, particularly in any cases where there was a scientific consensus regarding a topic. Evidence from meta-analysis of RCTs was prioritised, followed by individual RCTs, then theoretical and observational work. For some components (particularly sleep schedule components), evidence came from the inclusion of a component within CBTi. An element being part of CBTi was taken as a point in its favour, because of the good evidence base for CBTi, but this alone was not considered as reason enough to include that element. There was no planned commitment to include all CBTi elements.

Whilst the final components of the developed intervention are presented separately and consecutively, they were not designed serially. Conclusions regarding each component affected the others, and intervention development was iterative. For example, decisions regarding activity tracking, and practicalities of how activity data could be presented, affected how recommendations addressing daytime activity could be implemented. Thus, discussions moved back and forth between elements until each element solidified.

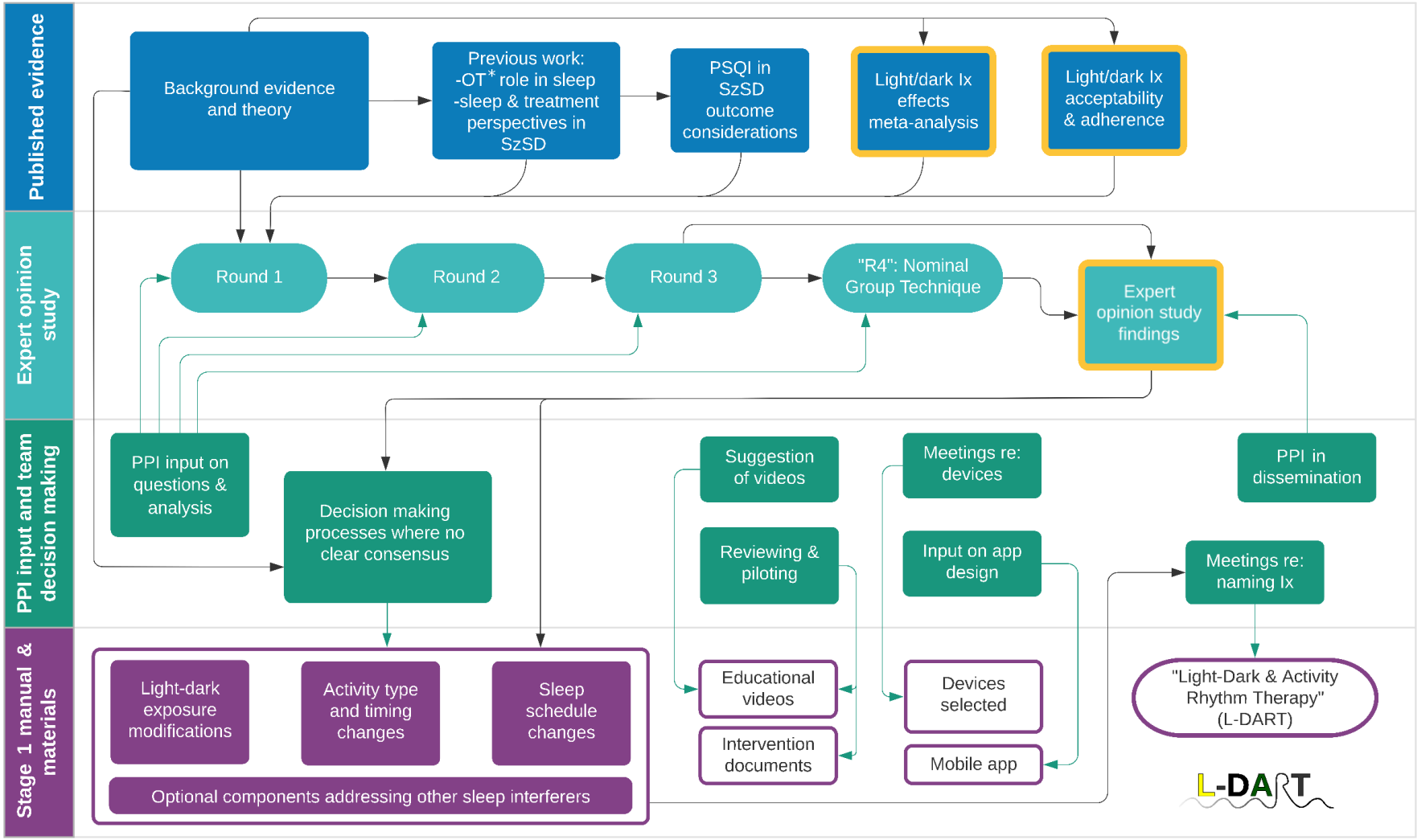

Figure 13: Development of L-DART

*OT = occupational therapist

Framing the problem to develop the intervention

Previous work by myself and other researchers describes modifiable behavioural and environmental factors contributing to sleep disturbance in people with SzSD. The mixed methods expert opinion study findings corroborated, and provided more information and formulation around these problems. For instance, problems which impact on sleep that are cited as more prevalent in this group include: limited daytime activity, social avoidance and / or exclusion, sleeping to escape (including daytime sleeping), inappropriate window coverings which cannot easily be opened in the daytime, and other poor environmental conditions.

Before designing a behavioural intervention, it is important to define the problem in behavioural terms, and to select the behaviours to target for change. A means of changing behaviour ('intervention function') should then be selected, and the specific behaviour change technique(s) (BCT) to be used can then be specified (Michie et al., 2014). This process of selecting a target behaviour and a BCT, from within those in an intervention protocol (if there are options), is also undertaken by the therapist at the individual level, when personalising the intervention.

This thesis does not assert that sleep problems in SzSD can be explained entirely in behavioural terms, but it does work on the assumption that behaviours can contribute to, or maintain, difficulties; see Table 18 (second row) for examples. These will not apply to all individuals. As can be seen, if the intervention development process stopped at stage 4, merely telling the person to make certain changes (e.g., 'increase your daytime activity'), this would constitute little more than self-help advice. Whilst occasionally simple instruction is sufficient for an individual to change their behaviour, very often simply telling a person what needs to change, will not alter their behaviour. The examples in Table 14 will be revisited later when discussing the selection of intervention functions, BCTs, and format of delivery.

Table 18: Behavioural intervention development, Stage 1: Understand the behaviour

Behaviour change intervention design stage (Michie et al., 2014)	**Example 1** Problem: Poor circadian entrainment.	**Example 2** Problem: Poor distinction between day and night, activities, provides few 'cues' regarding time.	**Example 3** Problem: Too little sleep pressure at night due to daytime napping.
1. Define the problem in behavioural terms	A routine involving limited daytime light exposure and excess light at night.	Limited daytime activity, inappropriate timing of activities, or both.	Napping in the daytime, in response to poor sleep at night, or to avoid distress.
2 and 3. Select and specify target behaviour (options)	1. Not opening curtains in morning. 2. Staying in the house / going out infrequently. 3. Using bright artificial lights at night. 4. Light-emitting screen use at night.	1. Too much sitting or lying down in the daytime. 2. Doing active or stressful activities late at night.	1. Napping (intentionally). 2. Falling asleep by accident. Specify time of day, location, duration, reasons or prompts for napping.
4. Identify what needs to change (options)	1. Open curtains routinely after waking. 2. Go out more often, for longer and / or earlier in the day. 3. Use brighter artificial light during day. 4. Switch to dim lamps in the evening. 5. Reduce evening screen use, and / or use dimming filters.	1. Increase daytime activity. 2. Do more active activities in daytime and more restful activities at night (wind-down)	1. Reduce duration, change timing, or avoid naps completely. 2. Identify times when accidental sleep occurs and modify typical routines. 3. Do something else, or move, if noticing falling asleep.

From synthesis of recommendations, to specific, observable, replicable therapist actions

It was not a given that the synthesis of findings and background evidence would result in items specific enough to constitute a manual against which fidelity could be assessed. Recommendations resulting from such synthesis sometimes relate to the target behaviour of the client (above: 'what needs to change'), rather than concrete therapist actions to promote this. Instructions to 'open curtains in the morning', or even, 'encourage opening curtains in the morning', are not specific enough. Rather,

this may be developed within a manual to ‘provide education, set and review goals, use reminders’). In a manual, observable, replicable actions, should be specified.

7.2. Core components

The components which became ‘core’ (to always address) were:

- light-dark exposure changes
- intervention regarding activity (type, timing, and balance)
- sleep schedule modifications

These are discussed below, and are reflected in the naming of the intervention, discussed at the end of this section.

7.2.1. Light-dark exposure changes

This topic was addressed by the systematic reviews and the mixed methods expert opinion study. See Table 19 for findings and background on each sub-topic and how each is addressed in the intervention. Deliberated decisions are then discussed below.

Table 19: Synthesis of evidence and findings informing light-dark exposure changes

Topic	Background evidence	Findings from Systematic Reviews	Expert opinion study findings	Approach in L-DART?
Light exposure modification	Human circadian rhythm is entrained predominantly by light exposure, thus alterations in light may affect sleep.	▪ Can improve some aspects of sleep but there has not been much research. ▪ Better effects in people with severe mental illnesses and with CRSWD than with dementia. ▪ No studies focused on SzSD. ▪ Appears feasible and acceptable, but issues with measurement and reporting of feasibility and acceptability. ▪ Existing studies delivered mostly short-term light box use with limited / no personalisation.	▪ Strong consensus to address. (91%=very appropriate / appropriate, 9%=neutral / don't know, 0%=inappropriate). ▪ Some variation regarding recommendations on how to address. ▪ Less confidence in expected effects voiced by people with personal experience. Low awareness and understanding reported.	<u>Included (core component)</u> *uncontroversial* ▪ Provide education ▪ The manner of addressing light exposure should be personalised in relation to problem, context, and the participant's goals. ▪ Emphasise more if sleep phase or regularity problems, but included for all.
Increasing morning light exposure	▪ Phase advances circadian rhythm. ▪ Acutely alerting. ▪ Evidence of effects on depression (Geoffroy et al., 2019).	▪ Phase advanced sleep in people with DSWPD. ▪ Adverse effects may be caused by sudden earlier wake time for light.	▪ Endorsed generally for improved circadian entrainment, or for sleep phase advance. ▪ Endorsed for helping to wake up in the morning.	<u>Included (optional)</u> *uncontroversial* ▪ Emphasise if: delayed sleep, sleep inertia, or difficulty waking, or if irregular or free-running (~Non24). ▪ Do not emphasise *morning* light if advanced sleep.

Topic	Background evidence	Findings from Systematic Reviews	Expert opinion study findings	Approach in L-DART?
Increasing daytime light exposure	▪ May help maintain entrainment. ▪ More daytime light exposure may reduce effect of evening light.	Studies which increased overall daytime light exposure were mostly in dementia - effects or acceptability in severe mental illnesses and CRSWD are unknown.	Endorsed by professionals and people with personal experience.	Included (core) *uncontroversial* ▪ Emphasise more if daytime light exposure is low at baseline.
Increasing evening light exposure	▪ Phase delays circadian rhythm. ▪ Acutely alerting.	Lack of evidence for improved sleep or delay of phase in ASWPD, few studies.	Rarely suggested (only 2 professions mentioned, 4%).	Not included *uncontroversial* ▪ If advanced sleep, advocate increasing afternoon light, but not to increase late evening light (assuming using only normal household lights in the evening). ▪ If advanced sleep, no encouragement to reduce evening light.

Topic	Background evidence	Findings from Systematic Reviews	Expert opinion study findings	Approach in L-DART?
Use of environmental light (e.g., natural light, changing room lights)	▪ Natural light is still a powerful zeitgeber, even on an overcast day (Woelders et al., 2018). ▪ Direct sunlight can cause sunburn. ▪ Increased light in work environments has been found to improve sleep and mood (Figueiro et al., 2017).	▪ 29% of studies used this. ▪ Sub-group analysis was not appropriate (confounding). ▪ Commonly applied in dementia. ▪ Was not applied in CRSWD. ▪ Environmental light modification did not require 'adherence management' approaches.	▪ Endorsed. Raised often by professionals. ▪ Using outdoor light (if possible) rated as important / very important (98%) ▪ Challenges with going outdoors for natural light identified (professionals and service users). Behaviour change requires support. ▪ Addressing window coverings rated as important / very important (97%). ▪ Altering artificial lighting in the home, rated as important but less than the above (72%=important / very, 18%=neutral, 10%=not important)	<u>Included (core)</u> *debated* ▪ Encourage going outdoors more. ▪ Activity scheduling. ▪ Involve social support where present. ▪ Advise regarding sun-cream use and hats if sunny, especially for pale skinned people. ▪ Advise on sitting in a different place indoors. ▪ Address opening curtains. ▪ Change bulbs, use lamps. ▪ Provide lace / nets if needed. ▪ Provide blackout curtains if not already in place.

Topic	Background evidence	Findings from Systematic Reviews	Expert opinion study findings	Approach in L-DART?
Use of light boxes	▪ Much research done on the effects of light on sleep and circadian rhythm has been using light boxes. ▪ Modern light boxes filter UV light (so do not cause sunburn). ▪ Light boxes have a low side effect profile (Terman and Terman, 2005). ▪ Photosensitivity is more likely from natural light as natural light is much brighter and unfiltered (Drucker and Rosen, 2011).	▪ 45% / 57% of studies used (ch3 and 4 respectively). ▪ A drawback was time required to receive light, but time could be experienced positively depending on the environment.	▪ Endorsed particularly if unable to get outdoors, and especially in winter (dark mornings). ▪ Important / very =80%, neutral=16%, not important=2%, better NOT to use=2%) ▪ Acceptability to service users varied, some very keen some not willing to use.	<u>Included (optional)</u> *debated* ▪ Offer to all participants, can be declined (participants do not have to be initially willing to use a light box to be recruited). ▪ Emphasise more if natural light cannot be obtained (e.g., poor weather, limited mobility, agoraphobia). ▪ Personalise instructions for use depending on sleep timing.
Use of light visors	Light visors deliver light directly in a portable format.	Used in 10% / 6% of studies. Some reports of discomfort from glasses.	Mentioned only once: “use of light mask?”, not investigated further.	<u>Not included</u> *uncontroversial*
Use of dawn simulator alarms	Dawn simulation, similarly to other light therapy, was linked to improvement of seasonal and non-seasonal depression (Golden et al., 2005).	▪ Was used occasionally in DSWPD and SAD. ▪ Potential adverse effect: can wake bed-partner up early. ▪ Low burden and easy to adhere to (comes on automatically on timer).	Rated highly by professionals, and commented positively upon by professional and people with personal experience.	<u>Included (core)</u> *debated* ▪ Provide dawn simulator alarm to all participants. ▪ Can be supplemented by another alarm clock.

Topic	Background evidence	Findings from Systematic Reviews	Expert opinion study findings	Approach in L-DART?
Reducing evening light exposure	Less evening light may reduce circadian phase delay, and reduced evening screen use is associated with better sleep (Carter et al., 2016), however, interindividual effects of evening light vary (Phillips et al., 2019).	▪ Often neglected in light therapy studies reviewed. ▪ Insufficient evidence to conclude regarding whether reducing evening light alone can improve sleep quality of timing. ▪ Interventions including reducing evening light was associated with greater increase in total sleep time.	▪ Views varied regarding evening light's importance. ▪ Some discussed individual variability in light sensitivity. ▪ Reducing screen use at night was not popular with service user participants, but using dim evening lights was more popular.	<u>Included (optional emphasis)</u> *uncontroversial* ▪ Mention evening light reduction to all participants. ▪ Emphasise more if problems with sleep onset and short total sleep time. ▪ Encourage use of dim lamps, and to modify type and timing of activities to reduce evening light.
Reducing light at night	Light at night is considered a potential causal mechanism for increased cancer in shift-workers (Touitou et al., 2017), and is associated with obesity (McFadden et al., 2014).	Reducing light at night was studied alongside other measures (e.g., reducing evening light, increasing morning or daytime light).	▪ Endorsed by professionals. ▪ Addressing window coverings was highly rated (96% important or very important). ▪ Despite some discussion of fear of the dark, having the bedroom dark was the highest rated specific light measure by people with personal experience (regarding how willing to do).	<u>Included (core)</u> *uncontroversial* ▪ Encourage sleeping with lights off ▪ Use sunset function to avoid sudden darkness if this induces fear. ▪ Install blackout curtains if required *(see discussion).*

Topic	Background evidence	Findings from Systematic Reviews	Expert opinion study findings	Approach in L-DART?
Use of amber glasses	▪ Light at the blue end of the spectrum has been shown to affect circadian rhythm more (Gooley et al., 2010). ▪ The impact of spectral qualities on circadian response is complex, not yet well understood, and light from elsewhere in the visible spectrum contributes (Lucas et al., 2014; Woelders et al., 2018).	▪ Only two randomised studies used amber glasses. ▪ Ideally offer different models for comfort.	▪ Less endorsed than other light modification approaches, views varied. ▪ Acceptability for service users varied (service user and professionals reported). ▪ Rated more willing to do than avoid screens, but less than having dim evening lights.	Not Included *debated*

Whilst some recommendations from synthesis of evidence and findings are already in the form of specific BCTs, (e.g., Provide education), others are in the form of desired resulting behaviours (e.g., 'Encourage sleeping with lights off'). Table 16 gives an example of how some desired behaviour changes which might be targeted in relation to light exposure are addressed using BCTs.

Table 20: Development from 'what needs to change', to BCTs in a manualised intervention

<table>
<tr><td>Intervention design stage</td><td colspan="3">Example 1
<u>Problem</u>: Poor circadian entrainment.</td></tr>
<tr><td>4. Identify what needs to change (options)</td><td colspan="3">1. Open curtains routinely after waking.
2. Go out more often, for longer and / or earlier in the day.
3. Use brighter artificial light during the day.
4. Switch to dim lamps in the evening.
5. Reduce evening screen use, and / or use dimming filters.</td></tr>
<tr><td rowspan="2">Areas of capability, opportunity and motivation to address</td><td>Capability</td><td>Opportunity</td><td>Motivation</td></tr>
<tr><td>▪ Skills and practice may be required to go outside.
▪ Ability to resist screen use and identify other tasks could be developed.</td><td>▪ Environmental resources (lights, curtains etc).
▪ Environmental prompts (e.g., screens in / out of bedroom, materials or ideas for non-screen activities).</td><td>▪ Lack of awareness of any effect of light on sleep.
▪ No habit of opening curtains.
▪ Habit of high evening screen use.</td></tr>
<tr><td>5. Identify intervention functions</td><td>▪ Enablement (behavioural support)
▪ Persuasion
▪ Environmental structuring</td><td>▪ Environmental structuring
▪ Enablement (behavioural support)</td><td>▪ Education
▪ Persuasion</td></tr>
<tr><td>(6. Policy category)</td><td colspan="3">It was predetermined that the intervention would be 'service provision' (e.g., not a public health communication approach, or a legislative approach to behaviour change)</td></tr>
<tr><td rowspan="4">7. Behaviour change techniques (BCTs)</td><td colspan="2">BCT</td><td>Intervention function</td></tr>
<tr><td colspan="2">▪ Provide lace / nets if needed.
▪ Provide blackout curtains.
▪ Provide light box and dawn simulator</td><td>Environmental structuring.</td></tr>
<tr><td colspan="2">Provision of educational videos, encourage to watch and discuss.</td><td>Education, persuasion.</td></tr>
<tr><td colspan="2">Goal setting, encouragement, discussion, barrier identification, problem solving, planning activities involving light exposure.</td><td>Enablement (behavioural support).</td></tr>
<tr><td colspan="2">Behavioural experiments.</td><td>Persuasion.</td></tr>
</table>

Natural light exposure and light boxes (both included):

Background evidence and findings from Studies A and B support use of natural outdoor light. Other benefits were described to this source of light over light boxes (e.g., exercise, social integration through going outdoors). In terms of availability, natural light is free, although less available in winter. The major limitation to the use of outdoor light was that some participants might have significant psychological and / or practical barriers to going out. This was particularly highlighted with accessing morning light which required certain steps (getting up and getting ready) before going outside. Conversations with PPI and academic team members focused around the degree to which outdoor light should be supplemented with light box use if at all, and how this might fit with personalisation. Advantages and disadvantages were identified in discussions, with the eventual decision being to offer lightboxes to all, but with varying levels of use within the individual's treatment plan (see Table 21).

Table 21: Options evaluation for light delivery methods

Option:	**Advantages**	**Disadvantages**
Focus only on natural light	▪ Outdoor light is brighter. ▪ Clearer message, less complex to explain. ▪ No equipment cost.	▪ More difficult to adhere to for some. ▪ Affected by season and weather. ▪ Less transferable to higher latitude locations. ▪ Requires more behaviour change before light exposure is altered.
Offer lightbox to some	▪ Keeps equipment cost lower than offering to all. ▪ Can offer where clear need (e.g., mobility issues, agoraphobia)	▪ Difficult to determine at what point to make decision of whether to offer. ▪ Participants could feel it was unfair.
Offer lightbox to all - this option was selected	▪ Likely to be seen as fair. ▪ Participants can try the lightbox in order to help decide whether and how it fits into their long term plan. ▪ Light box is available even if only used occasionally, e.g., heavy rain.	▪ Unused lightboxes could form clutter. ▪ Some equipment cost may be wasted. ▪ Could distract from message re: outdoor light being superior.

PPI comments suggested checking the cost of electricity to run light boxes, and considering compensating participants depending on the cost. Costs turned out to be negligible and contributors agreed compensation was not needed.

Lumie offered to sponsor the study through provision of light boxes. We compared these to devices from other manufacturers and concluded that their specifications were similar, so we then selected between options from Lumie. Lumie Light box options were physically examined in meetings with PPI and academic team members, evaluating four options. These were weighed up, and two devices were ruled out (Lumie Desklamp and Lumie Brazil), the other two both offered different advantages (portability vs brightness). We decided to offer these two options, allowing for participants with more space and / or where sleep timing was more of an issue to opt for the brighter Lumie Arabica, whilst those with more limited space might opt for Lumie Vitamin L (see Table 22).

Table 22: Selection of a light box

Feature:	**Lumie Vitamin L** - selected	**Lumie Desklamp**	**Lumie Arabica** - selected	**Lumie Brazil**
viewing distance for 10,000 lux	16cms	11cms (diffuser) 20cms (without diffuser)	25cm	35cms
Brightness at 50cm	1,800 lux	~1,300-1,500 lux (diffuser) 3,800 lux (no diffuser)	4,000 lux	5,000 lux
Power use	22W	12W	48W	100W
Cost to run 7 hrs / week	2.1p per week	1.1p per week	5.0p per week	10.5p per week
Device cost	£75	£120	£100	£150
	Team member comments (academic and PPI):			
Appearance	-Attractive appearance, like an i-pad.	-Socially normal appearance (good). -Many don't use a desk (not good). -Not suited for on the kitchen table.	-Utilitarian. -OK. -No issues.	-Looks a bit scary. -Might attract comment in your home.
Practicality	-Portable.	-Difficult to turn on and off.	-Not too big, unless space very limited.	-Would be too big for a lot of people.
Impressions / opinions on brightness.	-Could be brighter, but portability allows good positioning.	-Not bright enough with diffuser. -Unpleasant without diffuser.	-Bright enough.	-Very bright. -Some might find too bright.

Dawn simulation (included):

Dawn simulation whilst having limited evidence (few studies), was highly endorsed in out expert consensus work. Devices we found on the market were much less bright than light boxes or daytime natural light, so on this basis we did not consider for dawn simulation to replace other light exposure modifications. It was discussed whether to offer dawn simulation to all participants, or only participants meeting some criteria (e.g., difficulty rising). It was concluded to offer this component to all, as there was not enough evidential basis to determine who would benefit more, (potential benefits even for early risers had been highlighted in data, such as less jarring wake-up experience). This was also seen as fairer.

We were sent 3 samples of dawn simulation devices by Phillips and Lumie to try. The core group of PPI contributors as well, and I, took turns trying different devices at home for a few nights, in order to use the settings and see the devices working in dim-light conditions (rather than daytime in the office). We made notes on ease of use and experience and reported back. Taking into account mixed methods expert opinion study findings, we concluded that the features to prioritise were: 1) a choice of sounds including natural sounds (e.g., birdsong), and 2) dim light function for use in the night if waking up, and a 'sunset' option (useful if afraid of the dark). Fear of the dark had been raised in our expert opinion study but not linked to dawn-simulation. The features we identified as a priority were common to the Phillips Somneo HF3650/01 and Lumie Bodyclock glow. We selected the Phillips Somneo HF3650/01 because it was brighter (and adjustable, so being too bright was not a concern).

Use of amber glasses / blue-blockers (not included):

Amber glasses can block blue light in the evening with the aim of prevent phase delay of the circadian pacemaker and promoting sleep onset. Discussions deliberated between using amber glasses as an optional component, or not issuing amber glasses at all. Advantages were the relatively low cost, but disadvantages included increased intervention complexity; many objects and equipment were already included (with stronger consensus). The decision not to include amber glasses was made to simplify the intervention by excluding components with weaker endorsement. Removing this component was seen as worthwhile to reduce intervention delivery time as having multiple models of amber glasses available for participants to try on would take time. It

was difficult to reach a decision, and there remains an argument for testing of amber glasses in this group.

7.2.2. Occupational intervention / intervention regarding activity (type, timing and balance)

In the acceptability and adherence systematic review, we highlighted the potential interaction of occupational routines with light exposure intervention effects and acceptability, and thus, the importance of considering occupational routines. The systematic review did not present findings on the specifics of how to address occupation however. Table 23 presents mixed methods expert opinion study findings, background evidence, and the selected approach within the intervention. Overall, this area created less controversy, perhaps because of it being so closely linked to the core role of occupational therapists.

Table 23: Synthesis of evidence and findings informing occupational intervention

Topic	Background evidence	Mixed methods expert opinion study findings	Approach in L-DART
Amount of activity.	Occupational participation is linked to improved quality of life (Loh et al., 2020), and social integration (Papageorgiou et al., 2016).	Both professionals and people with personal experience emphasised the importance of increasing activity levels.	Included (optional) *uncontroversial* ■ Address if low activity at baseline. ■ Use interests checklist if required (included in intervention materials) ■ Set graded collaborative goals.
Type, timing and balance of activities.	■ Physical activity can improve sleep and mental health. ■ There is a significant theoretical literature on occupational balance.	Professionals and service users described the importance of: ■ occupational balance. ■ physical activity. ■ timing of activities which are stimulating or calming. ■ scheduling which is concrete. ■ Completing an activity diary was seen as useful but burdensome.	Included (core) *uncontroversial* ■ Assess occupational balance via self-rating, and by activity diary recording for some days. ■ Schedule activities using diaries or calendars. ■ Ensure inclusion of non-exercise physical activity, or exercise, within routines. ■ Assess and monitor timing and level of physical activity via L-DART app.
Morning activity.	A 'rise-up routine' was utilised in SzSD by Freeman et al. The therapy was effective and rated high for client satisfaction (Freeman et al., 2015; Waite, Myers, et al., 2015).	Professionals advocated: ■ encouraging energising activity soon after waking. ■ planning activities for motivation to get up. ■ involving social contact if possible.	Included (optional emphasis) *uncontroversial* ■ Determine emphasis depending on how appropriate morning routine is at baseline. ■ Support to identify and plan activities. ■ Scheduling (see below). ■ Self-monitor via the L-DART app (described below).

Topic	Background evidence	Mixed methods expert opinion study findings	Approach in L-DART
Evening activity.	▪ CBTi suggests avoiding stimulating activities near bedtime. ▪ Theories of behavioural association suggest doing similar activities each night will create sleep cues.	▪ Professionals and service users advocated identifying low stimulus evening wind-down activities. ▪ Professionals strongly endorsed having a similar routine each evening, and support to find suitable relaxing activities (both 98% important / very important). ▪ Endorsed, but less strongly, to start bed-preparation at the same time each day.	<u>Included (core)</u> *uncontroversial* ▪ Discuss in detail with all participants. ▪ Identify activities using prompts, existing interests, and interests checklist if needed. ▪ Discuss where bed preparation activities (e.g., self-care) fit in with wind-down. ▪ Determine individually what time wind-down should ideally begin.
Activity within the sleep period	▪ CBTi includes instructions to go to another room and do something else if not asleep.	▪ Findings emphasised the importance of having a plan, in advance, re: activities to engage in if waking in the night. ▪ Views varied somewhat, but most suggested calming activities. ▪ See below for findings re: "the 15-minute rule".	<u>Included (core)</u> *uncontroversial* ▪ Prepare plans of activities to engage in if getting out of bed during the night. ▪ Activity ideas should be generated and chosen as above, and materials should be ready. ▪ Where possible, an area will be set up in advance to go if waking in the night.

In the case of modifying activity routines, many recommendations resulting from synthesis of background evidence and the expert opinion study were already in the form of BCTs. These required less development to form protocol elements than did the light exposure recommendations. Table 20 describes how these BCTs act upon determinants of behaviour (capability, opportunity or motivation) (Michie et al., 2014). Paper materials were then developed to support this process (see below).

Table 24: BCTs intended effect on daytime activity behaviours

<table>
<tr><td>Behaviour change intervention design stage</td><td colspan="3">Example 2
<u>Problem</u>: No distinction between day and night, activities give few ‘cues’ regarding time.</td></tr>
<tr><td>4. Identify what needs to change (options)</td><td colspan="3">1. Increase daytime activity.
2. More active activities in daytime and more restful activities at night (wind-down)</td></tr>
<tr><td rowspan="2">Areas of capability, opportunity and motivation to address</td><td>Capability</td><td>Opportunity</td><td>Motivation</td></tr>
<tr><td>▪ Unused to setting regular times for activities.
▪ Lacking diary use skills.
▪ Setting goals that are too easy or too difficult.</td><td>Lack of knowledge, ideas or resources for a balanced occupational routine of activities.</td><td>▪ Lack of awareness of effect of activities on level of alertness and arousal.
▪ Lack of confidence to do some activities.
▪ Lack of confidence in planning own routine (e.g., after institutionalisation).</td></tr>
<tr><td>5. Identify intervention functions</td><td>▪ Education
▪ Training
▪ Enablement (behavioural support)
▪ Environmental structuring</td><td>▪ Environmental structuring
▪ Enablement (behavioural support)</td><td>▪ Education
▪ Training
▪ Persuasion
▪ Enablement (behavioural support)</td></tr>
<tr><td>(6. Policy category)</td><td colspan="3">Service provision</td></tr>
<tr><td rowspan="6">7. Behaviour change techniques (BCTs)</td><td>BCT</td><td colspan="2">Intervention function</td></tr>
<tr><td>Use of interests checklist (see below)</td><td colspan="2">Education, enablement (behavioural support)</td></tr>
<tr><td>Identifying priorities and goal setting (using worksheets, see below)</td><td colspan="2">Enablement (behavioural support), persuasion</td></tr>
<tr><td>Completion of an activity and sleep diary to better understand current routine</td><td colspan="2">Education, environmental restructuring</td></tr>
<tr><td>Activity scheduling</td><td colspan="2">Environmental restructuring, enablement (behavioural support)</td></tr>
<tr><td>Grading</td><td colspan="2">Training</td></tr>
</table>

Development of materials:

The overall approach to this element followed readily from findings and background evidence. Specifics of how this should be implemented were discussed and further solidified during the development of the written materials and templates described below.

Interests checklist: A number of existing interests checklists were reviewed (these are commonly used by occupational therapists), but none fitted with requirements and some are now quite historical and pre-date the era of widespread internet use. An interests checklist was drafted based on areas and categories often covered within occupational therapy assessments. We included options to select in-person vs remote / online versions of activities, options to select 'alone' vs 'with others', and some updated interests options. This was sent to a selection of mental health occupational therapists for comment (including expert opinion study participants), was revised, and was reviewed by PPI contributors who added and re-phrased some response options.

Morning routine, evening routine, and daytime activity worksheets: Three separate worksheets were made, but not necessarily with the intention of using all of these with each participant. Drafts were examined and modified in meetings with PPI contributors, particularly around the examples and tips for identifying good morning and evening activities. The intention with these sheets was to provide a structure within which to record progress in discussions about plans, and leave homework to consider plans further and / or implement changes. Expert opinion study findings and PPI suggestions alike suggested homework should always be written down unless the participant has too poor literacy, in which case homework should be recorded in another way (e.g., audio recorded).

Activity and sleep diary template: Findings had suggested that this would be worthwhile, despite the burden of completing an activity diary. Few suggested a whole week of daytime activity recording was needed. PPI discussions focused on how many days of activity recording to request, and what format this should be in (e.g., length of time slots, days per page, electronic or paper). We concluded that a paper template was needed, although if the participant uses another form of diary already, this can be used instead (and populated not just with plans, but also with a record of what was done). PPI contributors also felt this was an area for personalisation, so the number of days to

be completed could be discussed and agreed between the therapist and client. Contributors suggested 2 days as a minimum to aim for, but emphasised that the intervention must be able to go on if self-reports are incomplete. We concluded activity tracking and recall could be used instead if needed. PPI contributor's comments helped to simplify instructions for diary completion, but agreed that instructions should be on the sheet itself, so they cannot become separated from it.

How sleep recording is addressed on this sheet is discussed in the following section. We concluded in discussions to keep sleep and activity recording on one sheet together, to encourage looking at the two holistically over the whole period of the day, and also to give fewer sheets.

Activity scheduling template: Activity scheduling will be completed using whatever diary or calendar the participant already uses, if this is suitable (electronic, book-type, wall planner), as long as there is space to record timed planned events or tasks. For if more space is needed, or if the participant has no diary or planner at all, a weekly activity scheduling template has been produced.

7.2.3. Sleep schedule interventions

Although the systematic reviews were not specifically focused on sleep schedule interventions, light therapy sometimes included altering sleep schedules, thus some findings relate to sleep schedules. See Table 25 for mixed methods expert opinion study findings (and some review findings), and how these were taken into account in the intervention design. There was much controversy regarding time in bed restriction, and differences in views between professionals and service users regarding the 15-minute rule.

Table 25: Synthesis of evidence and findings informing sleep schedule components

Topic	**Background evidence**	**Expert opinion study findings** *(and review findings)*	**Approach in L-DART**
Regularising sleep timing	▪ Is a core part of CBTi. ▪ Circadian rhythm encourages sleep at the same time each day, and regular sleep consolidates circadian rhythm.	▪ Strongly endorsed by professionals, and mostly endorsed by people with personal experience. ▪ More important to have a regular rise-time than regular bedtime. ▪ Some variability in professional views re: allowable flexibility once a routine is established. ▪ Use of alarms was endorsed by most.	Included (core) *uncontroversial* ▪ Participant to determine optimum regular rise time. ▪ Use alarms as required. ▪ Utilise support from social network if available and appropriate. ▪ Educational content explains how regularity affects sleep quality.
Gradually moving sleep period	Circadian rhythm can only move so fast	▪ Suggested by professionals, and no-one suggested the opposite. ▪ Systematic review finding: Some studies linked sudden change in sleep timing to adverse effects.	Included (optional) *uncontroversial* ▪ Explain rationale to client. ▪ Move sleep timing by increments agreed with client - no faster than 30 min per day.
Time in bed reduction	▪ Excessive sleep is linked to worse morbidity and mortality. ▪ People with SzSD are often not happy with long sleep. ▪ Extending sleep to escape rather than due to sleep need has been identified by clients (Waite, Evans, et al., 2015; Faulkner and Bee, 2017). ▪ Sleep extension can result in more broken sleep as sleep pressure is reduced.	▪ Professionals felt reducing time in bed in hypersomnia was important or neutral (not important if not client priority). ▪ Professionals felt importance varied depending on functional impact, client experience, and impact on sleep quality.	Included (optional) *uncontroversial* ▪ Include if client has long sleep and is unhappy with this. ▪ Include if a long sleep-window is affecting sleep maintenance or quality. ▪ Educational content addresses how extended sleeping can reduce sleep continuity.

Topic	**Background evidence**	**Expert opinion study findings** *(and review findings)*	**Approach in L-DART**
Time in bed restriction	▪ Sleep restriction therapy (SRT) has a strong evidence base within CBTi and alone. ▪ Some suggest SRT should not be used in people who experience psychosis. ▪ Clients report using total sleep deprivation on themselves in order to attempt to control sleep (Faulkner and Bee, 2017). ▪ There is less research on sleep compression, but the principle of increasing sleep pressure is similar. As sleep compression is more gradual, adverse effects monitoring may be easier.	▪ Strongly advocated by many. ▪ Many emphasise caution to restrict time in bed in psychosis. ▪ Some suggest 'do not use'. ▪ Views varied on appropriate degree of modification, including minimum sleep window. ▪ Sleep compression was suggested, then rated positively in next round.	<u>Included (optional)</u> *debated* ▪ Use sleep compression if needed. ▪ Complete after addressing evening routine, morning routine, daytime activity and light exposure (from 4th or 5th intervention session). ▪ Educational content explains sleep pressure, supporting the rationale for sleep compression.
Napping	▪ In CBTi avoiding naps is strongly suggested, to build sleep pressure. ▪ Napping if sleepy and needing to drive is recommended. ▪ Although napping is associated with negative health outcomes causality is unclear (Léger et al., 2019), napping may benefit some groups such as older people or those with particular conditions.	▪ 97% agreed 'evaluate the role of naps'. ▪ Views fairly split between avoid or allow napping, or encourage planned nap. ▪ Replacing naps with activities was either endorsed or neutral. ▪ Views were split between calming or active and energising activities. ▪ Low expectations of success in avoiding napping in people with personal experience.	<u>Included (core)</u> *uncontroversial* ▪ Assess the role of naps. ▪ Provide education on sleep pressure. ▪ Determine priorities and if / how napping fits with these. ▪ Support to identify plans and activities to help avoid napping. ▪ If continuing to nap - consider duration and timing, to reduce negative impact of naps on night-time sleep. ▪ Safety naps if sleepy and need to drive are always recommended.

Topic	**Background evidence**	**Expert opinion study findings** *(and review findings)*	**Approach in L-DART**
"Stimulus control" (Bed / bedroom only for sleep) (15-minute rule / get up if not asleep)	▪ Included as a standard part of CBTi. ▪ Reduces behavioural association of bed with wakefulness. ▪ Included in adapted CBTi in SzSD and acute mental health (Freeman et al., 2015; Sheaves et al., 2017). ▪ Following this rule will restrict time in bed if the person is waking up.	▪ Avoiding non-sleep activities in the bedroom if possible was strongly endorsed by professionals and service users. ▪ Professionals suggested getting out of bed if not asleep, and focused on what activities to do if waking. ▪ Service users had overwhelmingly negative experiences of following the 15-minute rule.	<u>Included (optional)</u> *debated* ▪ Suggest avoiding non-sleep activities in bed, giving stimulus control rationale. ▪ Discuss the rationale for the 15-minute rule, and develop a personalised plan incorporating the participant's preferences (e.g., using a longer period than 15 minutes, or get out of bed 'if you are frustrated').

As can be seen in the example of addressing napping (above), findings included some BCTs suggested by expert opinion study participants. Discussion within the study team weighed up different suggestions around how far to personalise the approach to napping, how strict the approach should be, and how much to prioritise this amongst other elements. Table 22 below gives further detail of BCTs and their intervention functions, for in a case where reducing napping is selected as a target behaviour.

Table 26: BCTs intended impact on sleep pressure

<table>
<tr><td>Behaviour change intervention design stage</td><td colspan="3">Example 3
<u>Problem</u>: Too little sleep pressure at night due to daytime napping. Napping in the daytime in response to poor sleep at night or avoid distress.</td></tr>
<tr><td>4. Identify what needs to change (options)</td><td colspan="3">1. Reduce duration, change timing, or avoid completely.
2. Identify times when accidental sleep occurs and modify typical routines.
3. Do something else, or move, if noticing falling asleep.</td></tr>
<tr><td rowspan="2">Areas of Capability, opportunity and motivation to address</td><td>Capability</td><td>Opportunity</td><td>Motivation</td></tr>
<tr><td>▪ Skills and habits around planning activities for times when accidental sleep occurs.
▪ Awareness of strategies to avoid napping.</td><td>Environment promotes daytime sleep (e.g., watching TV in bed, or sleep on couch).</td><td>▪ Lack of awareness of sleep pressure and impact of naps.
▪ Belief in needing longer sleep due to illness.
▪ Lack of activities (reason not to nap).</td></tr>
<tr><td>5. Identify intervention functions</td><td>▪ Enablement (behavioural support)
▪ Training</td><td>▪ Environmental structuring</td><td>▪ Education
▪ Persuasion
▪ Enablement (behavioural support)</td></tr>
<tr><td>(6. Policy category)</td><td colspan="3">Service provision.</td></tr>
<tr><td rowspan="7">7. Behaviour change techniques (BCTs)</td><td colspan="2">BCT</td><td>Intervention function</td></tr>
<tr><td colspan="2">Education on sleep pressure</td><td>Education, persuasion</td></tr>
<tr><td colspan="2">Practice and support to schedule activities</td><td>Training, enablement (behavioural support)</td></tr>
<tr><td colspan="2">Modify where items and tasks are located at home</td><td>Environmental structuring</td></tr>
<tr><td colspan="2">Explore reasons for napping, addressing beliefs or worries</td><td>Education, persuasion</td></tr>
<tr><td colspan="2">Use behavioural experiments</td><td>Persuasion</td></tr>
<tr><td colspan="2">Planning ‘if, then’</td><td>Enablement (behavioural support)</td></tr>
</table>

Time in bed restriction:

Whether, and in what situation, to include time in bed restriction was discussed at length with both PPI and academic team members. The decision to include a version of time in bed restriction was taken in acknowledgement that although there are risks associated with any intervention which can temporarily shorten sleep, my previous work shows these risks are in many cases already present if clients are frustrated with their inability to sleep, as many may be taking extreme measures in their attempts at self-help. These could include totally sleep depriving themself for a full night to re-establish sleep timing, using illicit substances, or taking more than their prescribed medication dosage to induce sleep. We want to provide access to the most effective components, in a safely monitored situation, if the other, potentially easier and safer components, have not improved sleep enough yet. To reduce the potential for negative effects we will address other sleep interferers first, before significantly restricting time in bed. We will also use sleep compression (more gradual reduction) to avoid the initial shock of sleep restriction therapy. We have taken on board professional participants' suggestions that stimulus control alone will already restrict time in bed, so stimulus control even without sleep compression requires monitoring. The use of sleep compression rather than sleep restriction, and the inclusion of time in bed restriction whenever relevant (when time in bed is not already restricted) as a core rather than optional component, is one major area where L-DART differs from TranS-C (Harvey and Buysse, 2018).

Stimulus control:

Based on the theoretical foundation of the behavioural association of bed with non-sleep activities, we were keen to retain some version of stimulus control, however, service user views were very negative regarding its effectiveness. Both PPI and academic team members viewed it as important for wakefulness in bed to be reduced if possible, but PPI contributors especially felt a standardised rule was not helpful (this was also implied by many professional participants having adapted rules). This dilemma prompted more reading regarding how stimulus control is delivered, and reflection on the importance of the intention, and the client's expectation, not just the behavioural instruction, on the experience and effect of following such a rule.

7.2.4. Home environment assessment and interventions

Environmental interventions relate to light / dark exposure, occupational intervention, and sleep schedule modifications, which have already been described in the tables above. Expert opinion study findings were largely consistent regarding the specific interventions to be suggested, with the only consideration being that a large minority of service users said they would not wish for a home visit, or would prefer this to be later within the intervention, once more rapport and trust was built. We discussed in PPI meetings how to balance some clients' reluctance for a home visit, with perceived benefits of home assessment and intervention; environmental interventions would in some cases provide some immediate improvement with limited participant effort. We concluded that the timing of the home assessment should be modifiable, earlier if possible, and later if needed, and if a visit were not possible, for home environment to be discussed instead.

PPI discussions also focused on social factors in the home environment, such as busy households, disruptive routines of others, and loneliness in those living alone. Many of these factors were not readily modifiable, so this did not result in specific protocol elements, but instead was noted for the therapist to take account of. These discussions contributed to the home environment questions in the initial assessment, including checking if participants regularly stay elsewhere.

7.3. Optional components

Some components were included for use as required: substance use (caffeine, alcohol, illicit drugs, over the counter), addressing prescribed medications, napping, meal timing, nightmares (see Table 23).

Table 27: Synthesis of evidence and findings informing optional components included

Topic	Background evidence	Expert opinion study findings	Approach in L-DART
Substance use (caffeine, alcohol, illicit drugs, over the counter)	There is much evidence of the effect of numerous substances on sleep, although changing substance use behaviour can be a difficult, and is a specialist field in itself.	▪ Providing education was uncontroversial. ▪ Views of how personalised or directive this should be varied somewhat. ▪ Many mentioned motivational interviewing as a relevant approach for use by mental health occupational therapists, both to address sleep behaviours and for substance use specifically.	Included (optional) *uncontroversial* ▪ If relevant then address early. ▪ Provide educational content on the effect of caffeine, alcohol or nicotine. ▪ Set collaborative goals and use a motivational interviewing approach. ▪ Use behavioural experiments altering timing of use or reducing use. ▪ Liaise with substance use services if relevant.
Prescribed medications	It is known that some medications, including many antipsychotics, have a sedating effect.	▪ Addressing timing of sedating medication within the evening was advocated by professionals and by those with personal experience. ▪ Some occupational therapists had reservations about addressing medication, feeling it was beyond the scope of their role. ▪ Mostly rated as important / very important. ▪ Highly rated by participants with mental health expertise.	Included (optional) *debated* ▪ If relevant then address early. ▪ Liaise with the prescriber. ▪ Modify only within ‘evening’ / ‘morning’ instructions (e.g., 10pm to 9pm, or making timing more regular, not changing from morning to evening without prescriber advice). ▪ Further modifications (e.g., divided doses, changes to dosages) only to be made by prescriber.

Topic	Background evidence	Expert opinion study findings	Approach in L-DART
Meal timing	Timing of food intake may act as a weak zeitgeber, but light has much more effect on circadian rhythm.	▪ Many mentioned considering the timing of food and drink. ▪ Views of importance varied; overall seen as less important than some other areas, but may be a significant issue for some patients.	Included (optional) *uncontroversial* ▪ Address later if needed. ▪ Avoid having one large late large meal, and work on routines earlier in the day to enable earlier eating if this is an issue. ▪ If night eating is a problem, then address whether this is due to poor daytime eating habits or other factors.
Nightmares	▪ Nightmares are common in SzSD, and are linked to worse symptoms and distress (Sheaves et al., 2015). ▪ Imagery focused therapy for nightmares has a developing evidence base in SzSD (Waite et al., 2020).	▪ There was agreement to assess nightmares. ▪ Approaches advocated included directly addressing these using psychological approaches, providing education, and referring on. ▪ Other aspects of intervention may help indirectly. ▪ Whether it can be the role of this therapy and of the occupational therapist to deliver specialist nightmare therapy would depend on their training.	Included (optional) *debated* ▪ Specialist psychological intervention not included, refer if needed. ▪ Address later if needed. ▪ Provide education and normalise if appropriate. ▪ Address how to calm down if waking with a nightmare.

7.3.1. Prescribed medication

Reservations of some occupational therapist participants about their scope of role regarding medication was discussed with PPI and academic team members (one of whom is a prescriber). PPI contributors thought patients would often self-determine the exact time to take medication within 'evening' instructions, and that discussing this in relation to routine and sleep timing would be helpful. Clinical team members (SF and RD) note from experience that some care co-ordinators would advise patients on exact timing without seeking prescriber advice, whilst others would seek advice, similar to the varied views of our participants. We determined that this component should be used, with discussion with prescribers regarding individual cases as relevant.

7.3.2. Nightmares

Although it would be desirable to have an optional component of imagery rehearsal therapy to use when relevant, this was deemed beyond the scope of this work and this study. The limited manner in which nightmares are addressed in this intervention was selected as it could safely be delivered by occupational therapists with minimal additional training, and would be enough to reduce nightmares for some people. Those who need more specialised psychological therapy for nightmares could be referred.

7.4. Components not included

In order to keep the intervention brief, some components were not included. When considering components which had less consensus and less background evidence, we favoured excluding those which would take longer to implement or longer to train a mental health occupational therapist to deliver. Table 28 presents these components, for which there were positive but mixed opinions, and describes in some cases a limited manner in which these elements might be partly included when relevant.

Table 28: Synthesis of evidence and findings informing components not included

Topic	Background evidence	Expert opinion study findings	Approach in L-DART
Relaxation	▪ Evidence is mixed, the contribution of relaxation within CBTi is not completely clear. ▪ Some CBTi protocols include relaxation and others do not. ▪ Types of relaxation and instructions for its use to improve sleep vary (e.g., in the daytime, in bed).	▪ Views varied re: whether this should be core, optional or best avoided. ▪ Trying various options of different types of relaxation was suggested. ▪ Noted that relaxation must be practiced a lot before benefit is felt. ▪ Some felt it can be counterproductive by promoting sleep effort. ▪ Relaxing activities, as opposed to formal relaxation, were less controversial.	Not included *debated* ▪ Discuss including relaxing activities within evening routine. ▪ Relaxation is mentioned on the interests checklist; and can be explored as an interest if the person enjoys or values it.
Mindfulness	▪ There is evidence that mindfulness improves sleep. ▪ To teach mindfulness requires significant training, including personal practice (Mace, 2007).	▪ The consensus to include was high in round 2 but reduced by round 3. ▪ Some felt it was low priority. ▪ Some felt it should not be used as part of a sleep intervention.	Not included *debated* ▪ Meditation is mentioned on the interests checklist; and can be explored as an interest.
Thermoregulation	▪ Thermoregulation and sleep regulation are linked (Krauchi and Deboer, 2010). ▪ There is evidence passive body warming improves sleep, the optimum timing requires further research (Haghayegh et al., 2019).	▪ There was a consensus regarding considering bedroom temperature (also part of CBTi). ▪ Views varied regarding warming feet or pre-bed bathing to promote sleep. ▪ Was rated less important.	Not included *debated* ▪ Address bedroom temperature and bedding if relevant. ▪ Advise when relevant regarding a pre-bed shower or bath, only as part of wind-down routine, not with specific thermoregulation related instructions. ▪ Advise warm socks before bed if the person complains of cold feet, but not promoted to all.

Topic	Background evidence	Expert opinion study findings	Approach in L-DART
Sensory factors	▪ Sensory processing issues are associated with poor sleep (Engel-Yeger and Shochat, 2012). ▪ There is limited evidence for specific sensory interventions (Case-Smith et al., 2015).	▪ Mentioned by many, but not emphasised by many. ▪ Was rated as less important. ▪ Some sensory interventions are easy and low burden, with little harm in using: e.g., bedroom clutter / colour, trying different pyjamas.	<u>Not included</u> *debated* ▪ Offer basic interventions around bedroom environment, but no specific sensory interventions (e.g weighted blanket) ▪ Not specifically using a sensory framework, no sensory training needed for therapists.
Other cognitive or psychological approaches (some elements included, most not included)	▪ The cognitive components used in CBTi are very varied and evidence of their contribution is limited. ▪ Paradoxical intention may be effective. ▪ Thought suppression may be harmful.	▪ Was rated less highly than other components. ▪ Some felt these were better addressed by a psychologist or psychological therapist. ▪ Some noted sleep beliefs might be changed via behaviour. ▪ Suggested to use if therapists can be taught the skills or already have skills.	<u>Not fully included</u> *debated* ▪ Sleep interfering beliefs can be challenged through education and behavioural experiments. ▪ If night-time worry or distress remains a problem later in the intervention, worry postponement can be tried (using the 'Managing worry, distress and symptoms' worksheet).

7.4.1. Mindfulness

Mindfulness was excluded due to the training requirements for the therapist (not achievable through a brief training course), however, if a participant practices mindfulness already, then the timing of this can be discussed, as with any other activity.

7.4.2. Relaxation

Relaxation was discussed at more length, some felt the therapist did not have to be able to personally deliver relaxation, but could use pre-recorded audio material. PPI suggestions encouraged use of relaxation audio already available to download, and suggested offering many options to try. This remained a possible component until the week-by-week protocol was being drawn together, the assessment created, and the volume of content and topics included was clear. At this point it was agreed that the volume of content needed to be limited to avoid patients being overwhelmed, and relaxation was not included for this reason.

7.4.3. Thermoregulation and sensory intervention

Thermoregulation and sensory factors were debated due to being rated as relatively less important, but also described as an easy and low burden intervention which for some would provide improvement. PPI contributors felt it would be silly not to address cold feet if this was raised, and we agreed it would not require additional therapist training. It was concluded that so long as limited time was spent assessing these factors, they should be addressed in a brief and practical way if they arise.

7.4.4. Cognitive and psychological approaches

Cognitive and psychological approaches were included in a limited way, behavioural experiments are often used by mental health occupational therapists and could be used without significant training, however, many other specific CBTi cognitive techniques were not included. This was partly owing to a lack of agreement regarding which were most important, partly to limit training requirements, and partly as these were described by many CBTi therapist participants as to be used later, only if still needed by then. There had been a suggestion from participants with personal experience that there should be something done to address anxiety or distress directly if this was desired by the participant, so we included one component ‘worry postponement’ which can be delivered as guided self-help (Verkuil et al., 2011) with limited training. It is suitable to be delivered as a single component, and can be explained with relatively limited time

(McGowan and Behar, 2013). It is also potentially beneficial that worry postponement can be tried by clients in the daytime, and remains an appropriate approach to apply at night. This was seen as more appropriate than more active approaches to worry, such as rationalising; because motivated goal directed cognitive activity (involved in rationalising) interferes with sleep onset (Sotelo et al., 2020).

7.5. Incorporation of activity tracking feedback

7.5.1. Selection of a wearable device

During refinement of the intervention we faced the challenge of selecting a suitable commercial device and a user-facing app for self-monitoring of activity patterns. Apps present data to participants in varied formats, and we were conscious of the possibility that any device and app chosen had the potential to modify our intervention in unintended ways, or to cause harm. It has been shown that actigraphic feedback on sleep quality can improve, or worsen, perceived sleep quality and daytime functioning (Tang and Harvey, 2006; Gavriloff et al., 2018), and some device algorithms may underestimate sleep (Mantua et al., 2016). We therefore took seriously the potential for harm from a device and app which might underestimate sleep. We were also conscious that as the technological landscape is changing very rapidly, any chosen device could become unavailable (as with the BasisPeak used by Sheaves *et al.*, (2017)), and that native app features may change or be removed (BBC News, 2017).

The device was intended to be worn for prolonged periods, used for on-going self-monitoring, and could be damaged or lost, so we sought a relatively cheap, readily available device, with a socially normal appearance (ideally with options regarding appearance). There were options both from the consumer wearables market, and some of the cheaper research actigraphy and accelerometery devices were considered. The priorities of people with personal experience in the expert opinion study did not prioritise appearance, but instead prioritised accurate data, comfort, and having instant access to the data (see Figure 14). Qualitative comments from both topic experts and those with personal experience also spoke a lot about the benefits of looking at one's own data as an important part of the intervention, to become more aware of one's own patterns, and to monitor progress when making changes.

Figure 14: Views of participants with personal experience regarding most important features of a wearable for use in the intervention

Relatively equal prioritisation of accurate data and instant access presented a challenge, because of the devices giving the most accurate data (research devices), none gave instant access to the data for participants, whilst consumer devices give instant access, but with concerns regarding accuracy.

We borrowed a number of different devices from University stocks for examination, testing, and discussion with PPI contributors, however, there was no single device which met all our requirements. Overall, research devices had similar attributes to each other, as did consumer devices, and those that offered instant access to data did not offer access to raw data (data was pre-processed with proprietary algorithms) (see Table 29).

Table 29: Features of actigraphy versus consumer wearables considered

Feature	Research actigraphy / accelerometery devices	Consumer wearables
Cost / availability	££-£££, institutions may loan	£-††
Comfort	Varies, some are uncomfortable	Usually comfortable, often different strap options available
Appearance	Size varies, usually look like research devices	Small / streamline, normal appearance
Also tells the time	No	Sometimes
Waterproof	Usually	Usually
Battery life	Days to a month	Months to 1 year +
Instant access to data	No	Yes
Accuracy of data	Accurate	Concerns re: accuracy
Access to raw data	Yes	No

We wanted instant access to data in order to use this within the intervention to monitor overall rest-activity patterns, and to monitor changes in these. For this purpose we felt the timing and number of steps provided by consumer wearables would be adequate. The accurate approximation of sleep was not required to support the therapy itself, but was predominantly desired as a secondary research outcome, thus we opted to use a consumer wearable throughout, and additionally use an actigraphy device just at the baseline, endpoint and follow-up points.

The concern with the accuracy of consumer wearables data shown to participants was around whether the algorithm correctly identified sleep, rather than incorrect identification of active vs inactive periods. For instance, a device might fail to detect any sleep if sleep maintenance is poor, or fail to detect daytime naps. It was not possible to 'turn off' sleep tracking on any of the available consumer device's apps, and they all included their own health advice and 'goals' - potentially confusing the intervention. Thus, we concluded that we could not rely on any available commercial wearable device and app due to the way the data was presented back to participants, and that actigraphy was also not an option due to the lack of real-time access to data.

We looked into the possibility of developing an app to re-display wearables data, and once it was confirmed this was possible, we selected the Withings Move watch. This was selected as it has a long battery life, normal appearance, colour choices, and because Withings offered integration with custom mobile applications via an application program interface (API).

7.5.2. Development of the L-DART app

The specifications for the L-DART app were that it should pull steps and sleep data from the Withings server, and display this in a graphical form to participants. This would remove the distinction made by the Withings algorithm between sleep and inactivity, such that participants could keep track of their rest-activity patterns without focusing on the Withings assessment of sleep, which may be inaccurate. It can however be relied on, that when steps are being detected, the person is not asleep. The key difference in display format we wanted was for the time of day to line up visually so that patterns and changes in timing could be seen (e.g., change in rise time). Drawings were shown to PPI contributors, who favoured the second option (right) (see Figure 15).

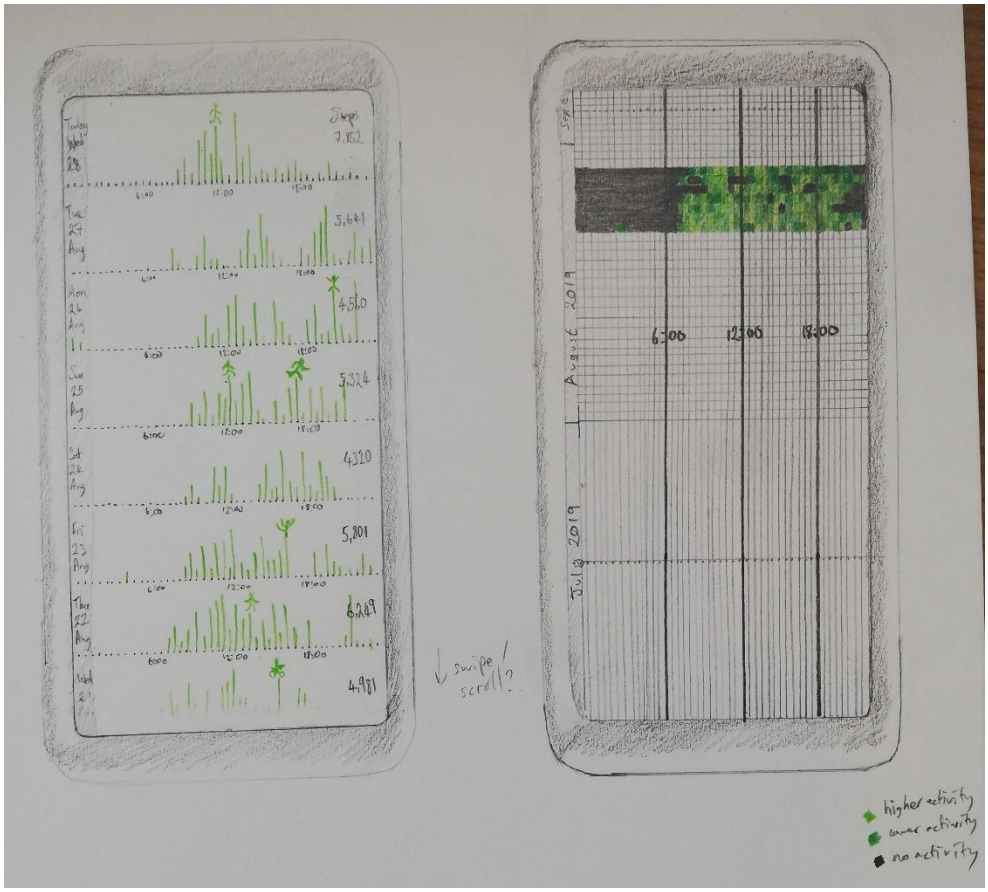

Figure 15: Initial designs for the L-DART app

Drawings and specifications were provided to the app developer, who wrote the code. User testing was then completed by myself and two other volunteers who already used Withings watches. Testing involved logging in, linking the L-DART app to your Withings HealthMate account, reviewing rest-activity pattern plots, and performing

specific operations as instructed by the developers (such as minimising the app, zooming, and scrolling).

Users of the L-DART app only need to log in once, and can then refresh their data with a single action. Users can scroll and zoom in on their rest activity pattern plot, to look more closely at a particular period or time of day (see Figure 16). There is also a daily step count displayed (although increasing daily steps would not necessarily be the goal for all participants). Users must still have the Withings HealthMate app installed for the Withing Move watch to synch, however, they do not have to interact with the HealthMate app, unless they need to manually prompt their watch to synch. Participants could, therefore, be instructed that there is no need to use the HealthMate app, and would be informed that the sleep tracking may be inaccurate. In a future version of the intervention, this technical limitation of still requiring the commercial app installed, could be overcome.

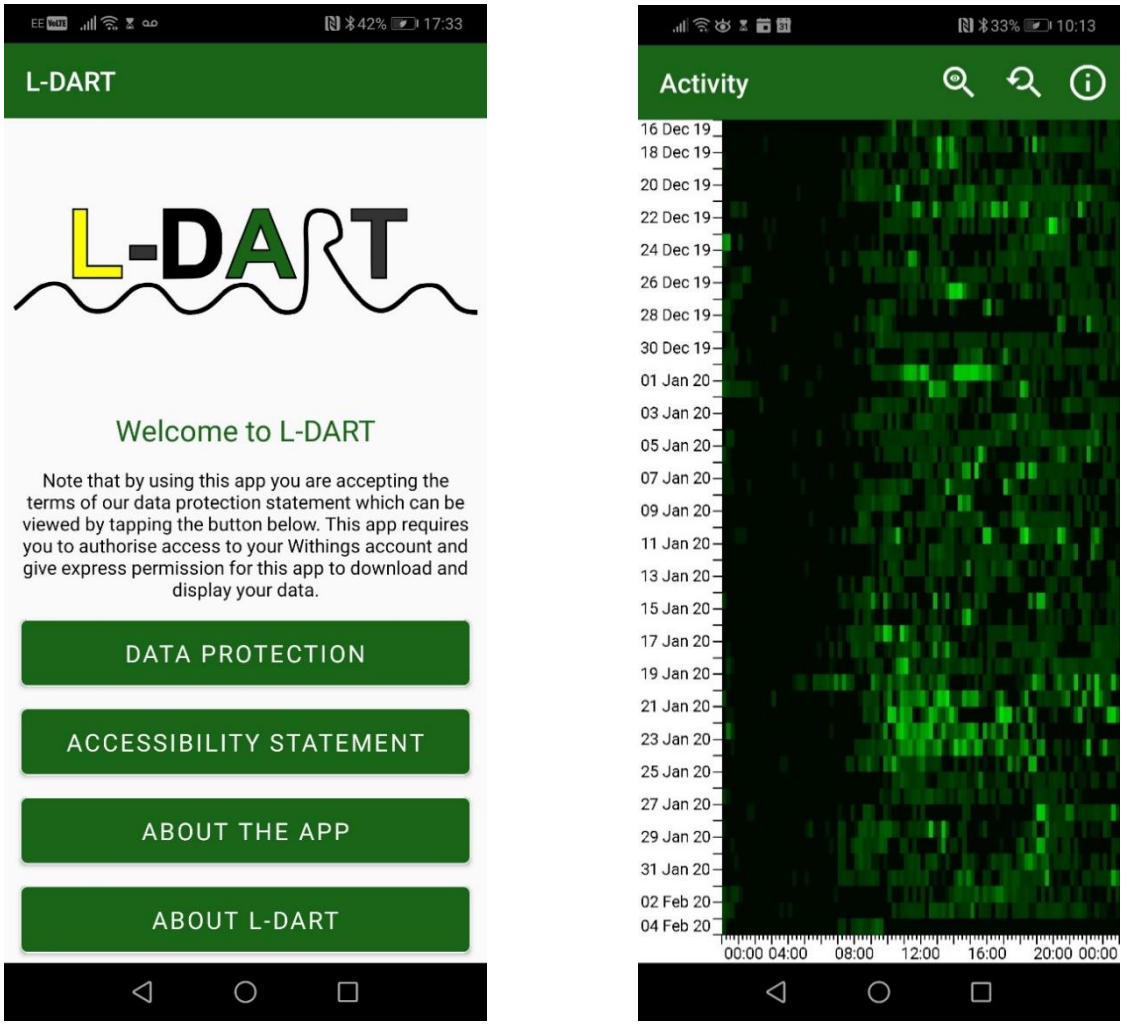

Figure 16: Screenshots from the L-DART app

7.6. Structure and format of delivery

A collaborative approach has been planned, from beginning the initial assessment by asking the person's top sleep priorities, to deciding the content of the maintenance plan together. The structure and order for delivery of content has been made flexible, but not completely unstructured, in response to suggestions from expert opinion study participants. This structure aims to balance personalisation with ease of delivery, and thus support therapist confidence. There are some elements which should come earlier, the chief of which is educational content, without which the rationale for changes suggested later will not make sense. For week-by-week content and options see Figure 17, this is also described in the study protocol in Chapter 9.

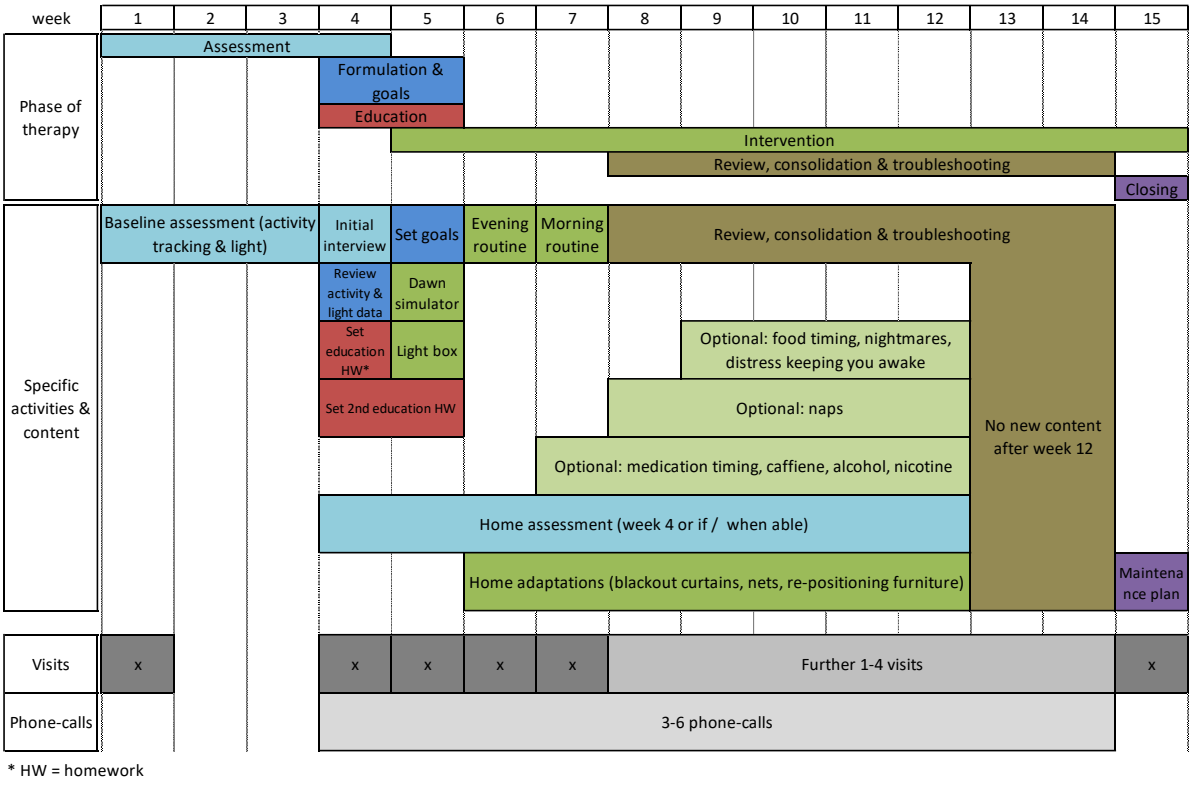

Figure 17: Intervention content by week of study

The order of delivery was informed by the expected mechanisms of change. This was considered on two levels: how behaviour changes may improve sleep, and also, how BCTs may affect behaviour. Anticipated causal pathways are depicted in Figure 18. It is recommended to describe and illustrate the supposed intervention mechanisms and expected interactions during intervention design, and to inform plans for the evaluation

of complex interventions (Moore et al., 2015). This visualisation informed order of delivery, presentation of content together or separately, and when in-person versus phone sessions might be most appropriate. Supposed mechanisms of change also informed plans for what aspects of 'adherence' to measure in the feasibility study protocol.

The components of L-DART are in some cases similar to those in TranS-C, for example 'evening routine' / 'learning a wind-down routine', and in some cases in L-DART component are named according to what they contain (e.g. 'light box'), whilst in TranS-C some components are named after the targeted change (e.g. 'improving sleep efficiency') (Harvey and Buysse, 2018).

Figure 18 shows many behaviour changes which may be targeted in this intervention. It is expected that not everyone will implement everything completely and immediately. However, it is also anticipated that if some changes are implemented, then benefits may be felt, without perfect adherence. Once some benefits are felt, this may be motivating, or improve wellbeing, enhancing adherence further. So although there are many potential target behaviours, changes can be undertaken step-by-step, targeting easy-wins first, and in the way best suiting that individual's situation.

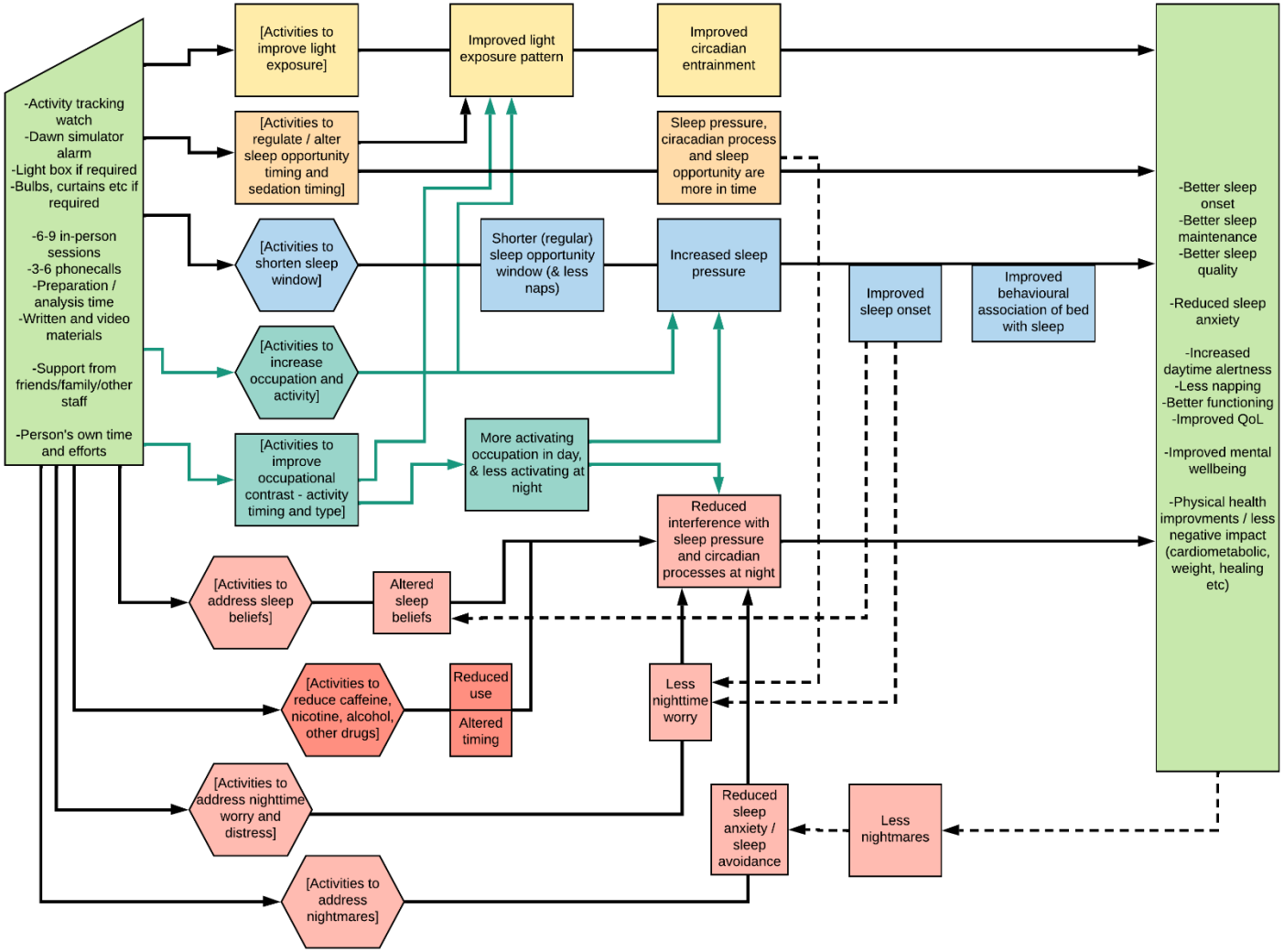

Figure 18: Logic model of supposed mechanisms of all intervention components

The final consideration around how to apply BCTs is the mode of delivery, this was discussed under 'format' in the expert opinion study. Depending on the intervention functions selected, an intervention might be able to be delivered via a self-help booklet, by a website or app, by phone, or might lend itself best to in-person sessions. Overall, the main intervention functions common across the intervention components are: education, persuasion, training, enablement (behavioural support), and environmental structuring.

Table 30 returns to some example BCTs from above and gives step 8, mode of delivery. The presence of environmental re-structuring, and use of equipment and an app dictated that if possible in-person visits should be offered, and the emphasis on education encouraged creation of video content for viewing between sessions.

Table 30: BCTs, and format of delivery

	Example 1	**Example 2**	**Example 3**
7. Example behaviour change techniques (BCTs)	Provide: ▪ lace / nets if needed ▪ blackout curtains if needed ▪ light box ▪ dawn simulator.	▪ Use of interests checklist. ▪ Identifying priorities and goal setting. using worksheets. ▪ Completion of an activity and sleep diary to understand current routine.	▪ Modify where items and tasks are located at home. ▪ Explore reasons for napping and address beliefs or worries.
BCTs common between examples 1-3	Education, goal setting, barrier identification and problem solving, behavioural experiments, activity scheduling, grading, planning - 'if, then'.		
8. Mode of delivery	▪ 6-9 in-person sessions (remote if necessary, with items delivered). ▪ 3-6 phone-calls. ▪ Video educational content. ▪ Written worksheets for use between sessions. ▪ Text reminders (move to setting own reminders by end of therapy). ▪ Using the L-DART app and activity tracking wearable for self-monitoring.		

7.7. Naming the intervention and branding

Although the intervention shares some features in common with CBTi, and was influenced by CBTi, we deemed it insufficiently similar to CBTi to accurately be described as an adaptation of CBTi. Furthermore, the process of intervention development did not take CBTi specifically as a starting point, as might be implied by the description 'adapted CBTi'. Using the same name for distinct therapeutic agents can cause confusion and imprecision in clinical communication (King and Voruganti, 2002). Language and branding can influence perceptions of interventions (McPherson et al., 2020), and design quality and 'packaging' can influence implementation success (Damschroder et al., 2009), and naming is important and often neglected (King and Voruganti, 2002). The associations carried by words vary between groups (Buckton et al., 2015); thus the naming of the intervention was a key area for PPI consultation.

I generated a range of name options and word options, in informal discussion with colleagues and people with personal experience. These options were then taken to the regular PPI contributors within the project, and to the Service User Reference Group (SURG) attached to Psychosis Research Unit (PRU), at GMMH. At this meeting the intervention was described, and novel suggestions for words and names were gathered from the group. Comments and votes were collected for the different words, and intervention names. The intervention was eventually named using words which were highly rated. These meetings suggested use of the word 'therapy' over 'intervention', 'activity' over 'occupation' / 'occupational', and also positively rated the word 'light', both because it had positive connotations and as it accurately conveyed intervention content. All the top voted intervention names started with the word 'light'. Contributors voted for 'Light and Activity focused Sleep Therapy' (LAST), from the options brought and generated on that day, however, contributors were not totally happy with any of the options. One downside was that this name did not convey anything regarding the importance of the *timing* of rest and activity.

Contributors thought the acronym was important, desirable features of the acronym were that it should be short, pronounceable, and that the letters should stand for first letters of the words making up the therapy name (not letters within words). Also, contributors noted that if the acronym sounds like a word, it should have positive associations. Potential acronyms were searched for online in order to rule out any

with unwanted connotations, meanings in other languages, or which could easily be confused with another intervention if searched online.

Once the name Light-Dark and Activity Rhythm Therapy (L-DART) was selected, I generated logo designs and sent these to team members for comments. Criteria were that it should be simple enough to work as an app thumbnail icon, should not include the full title of the intervention, and should work when printed in black and white. PPI contributors were keen on inclusion of visual elements to represent rhythm, light, or dark being included (see Figure 19 below). Attempting to represent glowing light in the 'L' was abandoned due to poor reproduction in small versions. The bottom-right option was selected as the final design.

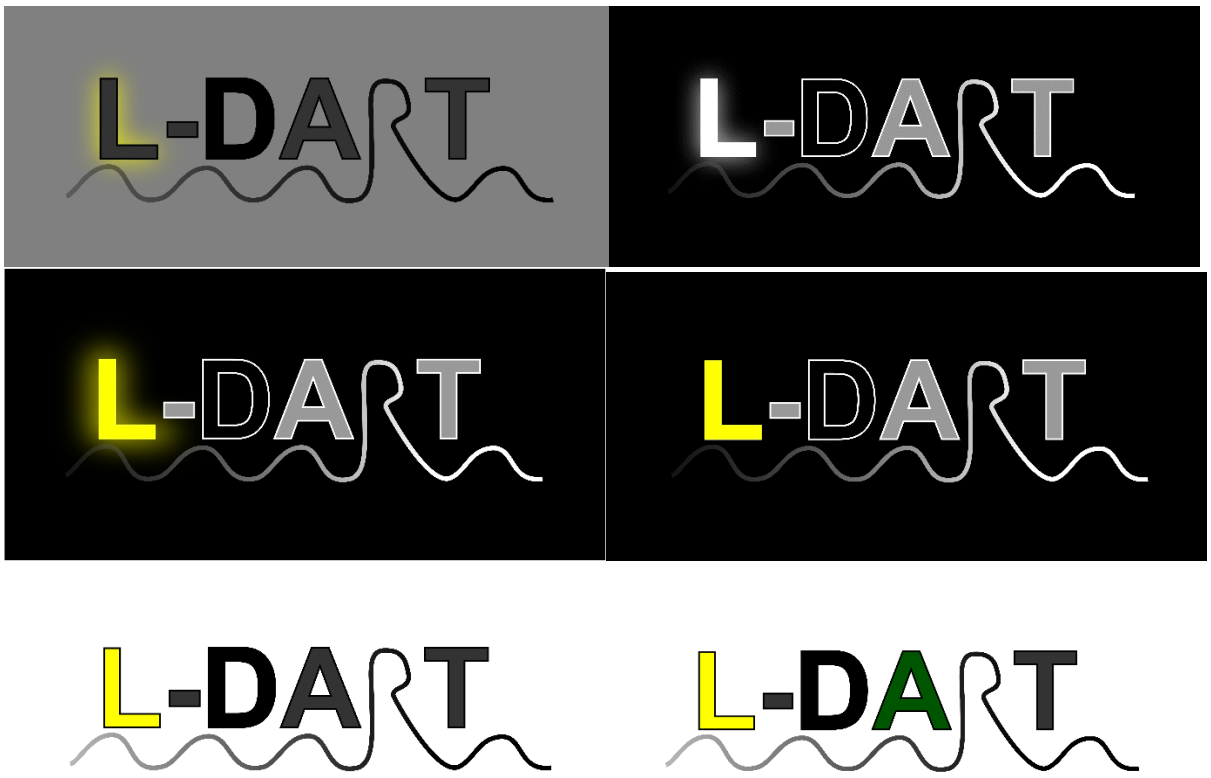

Figure 19: Colourways considered for the L-DART logo

7.8. Influence of findings and evidence on the design of the feasibility study protocol and on the staff and service user surveys

Synthesis of previous work evaluating light interventions informed our study protocol development decisions. Although the mixed methods expert opinion study was originally intended to focus on study design, participants were aware that the intervention was destined for testing, not immediate implementation, and they made suggestions and raised issues relevant to study design.

7.8.1. Sample inclusion criteria

At the stage of the funding application for this PhD fellowship, the intention was to develop and evaluate an intervention for use in SzSD. However, as discussed in the mixed methods expert opinion study paper, some participants spontaneously suggested transdiagnostic use. These views were further explored. We considered changing the plan, based on these responses, background evidence, and the results of evidence synthesis regarding light exposure (summarised in Table 31).

Issues around diagnostically-led inclusion criteria were discussed at various PPI meetings, with regular and one-off contributors throughout the award. On several separate occasions contributors expressed that diagnosis was a somewhat arbitrary means of including people, as diagnoses might be inaccurate or might be contested by the service user. At the same time those consulted felt that people with SzSD sometimes missed out on being offered non-pharmacological treatments, compared to, for instance, people with mood disorders or personality disorders. Contributors worried that if the study was open to people with other diagnoses, that referrers might not refer many people with SzSD, and professionals in the expert opinion study had expressed similar views. Weighing this up, we eventually decided to remain with the original proposal, to focus the current feasibility study exclusively on people with SzSD, to ensure their inclusion.

7.8.2. Assessing acceptability

Study B summarised how acceptability has been assessed in previous studies of light therapy and the results of these measurements. This, along with background theory (Sekhon et al., 2018) and PPI input, influenced the approach to measuring acceptability in the feasibility study (see Table 32).

7.8.3. Assessing adherence

Adherence management approaches are part of the intervention, and assessing adherence is part of this; the therapist asking about adherence can both measure and influences adherence. The approach taken will prioritise reducing burden on participants, it was influenced by the systematic review findings (see Table 33).

7.8.4. Monitoring safety and adverse effects

Although the systematic review did not result in any firm suggestions regarding how is best to monitor for adverse effects, a list was able to be generated of all those effects reported from light treatment. These were then covered in the checklist to be used in the feasibility study (see Table 34).

Table 31: Synthesis of evidence and findings informing diagnostic inclusion criteria

Background evidence	Findings from Systematic Reviews	Expert opinion study findings	Approach in feasibility study protocol and surveys
▪ There are few studies of sleep interventions specifically in SzSD. ▪ People with SzSD have a high prevalence of sleep problems even compared to other groups with severe mental illnesses. ▪ Many theories emphasise the transdiagnostic nature of sleep problems. ▪ Previous work highlights that some barriers to referral and treatment may be more prevalent in SzSD.	▪ There were no studies of light therapy to improve sleep in SzSD specifically (mixed mental health groups only). ▪ Findings in related populations were promising regarding effects and acceptability.	▪ Points were raised in favour of testing the intervention transdiagnostically, it was felt to be relevant. ▪ Diagnosis based inclusion was less popular than sleep problem / presentation-based inclusion with clinicians and service users. ▪ A more focused study in SzSD was recommended by researchers, due to the small sample size. ▪ Participants raised gatekeeper and patient barriers to recruitment of people with SzSD, and suggested this group may be harder to reach.	▪ Feasibility study inclusion criteria requires SzSD. ▪ Staff and service user surveys to evaluate extent, and type of problems, and willingness for treatment / to refer, across all diagnostic groups.

Table 32: Synthesis of evidence and findings informing assessing acceptability

Background evidence	Findings from Systematic Review	Approach taken in the feasibility study protocol and surveys
▪ MRC guidance describes how the early assessment of acceptability of interventions is important. ▪ The theoretical framework of acceptability (TFA) suggests examining the following domains: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness, self-efficacy.	▪ Factors which might affect burden varied widely among light interventions, but burden was rarely assessed or asked about. ▪ Expectations of efficacy were sometimes asked about, but never expectations of ability to adhere to intervention or expectations of acceptability. ▪ Four studies used satisfaction questionnaires (not specifying whether anonymous). Two studies qualitatively explored satisfaction.	▪ Interview with topic guide covering relevant domains from the TFA. ▪ <5 min pre-intervention interview to identify shifts in perspective (e.g., self-efficacy to adhere before versus after). ▪ Satisfaction 3 item Likert scale. Not anonymous, but participants complete online between sessions, or fold in half to return (not seen by the therapist-researcher until later). ▪ Acceptability of, or desire for, different sleep treatment approaches, and reasons to not want to be referred for L-DART or similar, will be assessed in the service user survey. This can later be compared with feasibility study intervention recipients. ▪ Reasons for declining referral collected when given.

Table 33: Synthesis of evidence and findings informing adherence monitoring / measurement

Background evidence	Findings from Systematic Review	Approach taken in the feasibility study protocol
▪ Adherence to CBTi is poorly measured and reported in literature (Matthews et al., 2013). ▪ Session attendance is often reported in therapies, but active engagement in the therapy also influences outcomes as well as mere attendance (e.g., homework completion) (Glenn et al., 2013; Decker et al., 2016).	▪ Adherence was often discussed but was rarely reported in concrete terms. ▪ When reported, this may be % sessions, % minutes, or % of participants 'adherent', and may be from self-report, or via light monitors. ▪ Reasons / barriers to adherence would have been informative, but when reported the means of gathering this information was unclear and may have been ad hoc.	▪ Record session attendance within therapy window. ▪ Record homework completion compared to agreed plans (recorded by therapist). ▪ Evaluate adherence to planned sleep schedule, activity and light exposure plans via self-report, light measurements, and activity monitoring devices. ▪ Barriers and facilitators of adherence to be explored through qualitative interviews.

Table 34: Synthesis of evidence and findings informing safety and adverse effects monitoring

Background evidence	Findings from Systematic Reviews	Expert opinion study findings	Approach in feasibility study protocol and surveys
▪ Theory and opinion pieces suggest hypomania or psychosis could be induced by light therapy or by reducing sleep opportunity. ▪ Adverse effects and safety monitoring during clinical trials is important and expected.	▪ Many studies reported but without clear information on how adverse effects were monitored. ▪ A list of all the adverse effects of light therapy reported was collated.	▪ Professional participants emphasised the importance of safety monitoring with time in bed restriction, and were less concerned re: light therapy safety. ▪ Checklists were recommended.	▪ Clinical assessment during sessions regarding mental state. ▪ Checklist for adverse effects. ▪ Adverse events reporting and assessment procedure in place.

Chapter 8: Study D - Surveys on potential future implementation issues

This chapter presents a cross-sectional survey study exploring potential implementation considerations, conducted to inform future larger scale intervention testing, intervention refinement, promotion, and implementation. The rationale for the broad methodological choices made was presented in Chapter 3. Below is presented a rationale for some of the particular questions asked, based on my earlier work and on the expert opinion study results. This is in addition to methods detail included in the paper.

8.1. Service user survey

In previous qualitative work (Faulkner and Bee, 2017) service users described feeling it was impossible to improve their sleep, we wanted to find out how widely endorsed this belief was, so we asked how far participants endorsed "I don't think it is possible to improve my sleep". In the expert opinion study some participants felt negatively about the idea of 'therapy', but 'professional support' was more acceptable, therefore we separated the selectable options "help from a professional" and "a therapy". The following barriers to engaging in sleep interventions were raised in the expert opinion study, and we therefore asked about relevance of these barriers in the survey: medication side effects, excessive worry or repetitive thoughts, using illicit drugs, and symptoms of psychosis (such as hearing voices or having unusual thoughts). In order to facilitate direct comparison of the sleep problem ratings of survey participants and feasibility study participants, we asked the following question, which would also be used in the feasibility study (identically worded) "Thinking of the sleep issues you ticked above, how much of a problem are they for you? On a scale of 1-5 where 5 is a really big problem".

8.2. Staff survey

We were aware from previous research (Faulkner and Mairs, 2015; Rehman et al., 2017) that awareness of sleep problems might be very different from confidence addressing sleep problems so we ensured we asked separately about confidence to identify, and to address, sleep problems. My previous study in occupational

therapists identified a lot of sleep knowledge from mainstream media and ‘general awareness’, which participants viewed as not of a very high standard, so we asked about this source of knowledge in this survey. Informal communications and expert opinion study results suggested few professions receive much training in sleep covered as part of their professional training, so we asked about this in this larger survey sample.

8.3. Paper 5, study D: “Sleep problems and referral intentions in mental health services: service user self-report and staff proxy report surveys.”

Paper number: 5

Page of thesis: 333

Prepared for submission to Psychiatric Services.

Supplements to this paper are in Appendix 6 of this thesis.

Author contributions:

The study was designed by SF with supervisory input from PB and RD. Data collection was conducted by SF. Data analysis was conducted by SF, with input and advice from RD, PB and Emily Eisner (EE). The manuscript was drafted by SF, with input from RD, PB and EE regarding structure, content, and style.

Title:

Sleep problems and referral intentions in mental health services: service user self-report and staff proxy report surveys.

Disclosures:

The authors have no conflicts of interest to declare.

Acknowledgements:

Thanks to our PPI contributors who proof-read and tested the service user survey.

Grant support:

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Word count: 2998

Highlights:

- Self-reported or staff reported sleep problems are common in mental health service users.
- Staff are less aware of sleep disordered breathing and parasomnias than are service users.
- There is demand for non-pharmacological sleep interventions and wish to refer / be referred.
- Staff have had limited training regarding sleep, but more training is associated with greater confidence to assess and address sleep.

This content has not been previously presented elsewhere, but will be presented in the lead author's PhD thesis which will remain embargoed

Abstract:

Background:

Sleep problems are common in mental health service users, but few non-pharmacological therapies are offered. Therapies are being developed and tested, but there may be barriers to these therapies reaching those who need them.

Methods:

Light-Dark and Activity Rhythm Therapy (L-DART), is a new sleep therapy delivered by an occupational therapist, which is being feasibility tested in people with schizophrenia spectrum disorders. This paper presents two surveys, conducted with service users and mental health staff, on sleep problems, treatment wishes; and barriers and facilitators to uptake of L-DART or similar therapies. Descriptive statistics, single-level and multi-level ordinal logistic regression were used to examine factors associated with sleep problems and referral intentions.

Findings:

Sleep problems were commonly identified by service users and staff, and there was demand for non-pharmacological intervention across diagnostic and demographic categories. Staff and service user reports differed in awareness of sleep disordered breathing and parasomnias, and wish for referral. Staff were more confident identifying sleep problems than addressing them, but more training was associated with greater confidence concerning both assessment and treatment.

Conclusions:

A range of sleep problems are prevalent and recognised in mental health service users, and there is an unmet need for non-pharmacological sleep interventions. Staff and service users report a high readiness to refer or be referred, despite some variability between different groups. Staff training to improve identification of sleep problems, and differentiation between types of sleep problems, would support access to the most appropriate treatments.

Background

Sleep problems are common in people who use specialist mental health services (1), but mental health professionals express limited knowledge and confidence to address them (2–4). Research suggests improving sleep in people experiencing psychosis could reduce symptoms and improve functioning (5), but individuals may not always seek and / or access sleep treatment. Service-users sometimes accept sleep problems as an inevitable part of their condition (6,7), don't see sleep as a concern of mental health professionals (7), or feel 'talking' would have limited effect on their sleep (8).

Occupational therapists are an appropriate staff group to address sleep problems in mental health service users, utilising their relevant core skills (9–11), although this has not traditionally been a focus for the profession (11). The authors have developed an occupational therapy intervention to improve sleep in people with schizophrenia spectrum disorders, called Light-Dark and Activity Rhythm Therapy (L-DART). Although developed with a focus on schizophrenia spectrum disorders, participants in the intervention development study suggested L-DART may be relevant transdiagnostically (12). Feasibility testing is underway at the time of writing (13).

The MRC framework for complex interventions recommends advance consideration and investigation of issues which may affect larger scale testing, and suggests planning for potential barriers to implementation (14,15). Implementation theories suggest identifying what may prevent, or would facilitate, the desired behaviour from stakeholders (16). Critical factors which can affect intervention uptake include the intervention source, and the perceived relative importance of the targeted problem (17). Some clinicians and academics suggested that poor understanding of the role of occupational therapists (18–20) could cause reluctance to refer, and some suggested service users and staff might find it difficult to identify or seek help for sleep issues.

We present two cross-sectional surveys of staff and service users, evaluating presence of and awareness of different types of sleep problems, readiness to refer or be referred, and staff and service user factors influencing these.

Methods

Aims

The study aimed to:

1. examine staff confidence and knowledge to identify and address sleep problems
2. examine the presence of and awareness of different types of sleep problems
3. examine readiness to refer or be referred to an intervention like L-DART
4. explore factors influencing help-seeking, and service user treatment preferences

A favourable ethical opinion was obtained from Research Ethics Committee Reference 20/NW/0059.

Participants

Staff and service users were recruited from two large mental health NHS Trusts in the North of England. Participation was anonymous.

Inclusion, exclusion and recruitment

All clinical staff were eligible, and there were no exclusions. Quotas were used to attempt to balance staff groups included (21), and purposive sampling targeted remaining gaps later

in recruitment by appealing for required staff groups. Posters, internal emails, social media, and presentations at meetings or trainings were used.

Any service user from a participating NHS Trusts could participate. There were no further inclusion or exclusion criteria, except not inviting anyone who involved staff felt would find completing the survey confusing or distressing. Recruitment was via meetings, leaflets / posters, phone-call / text, and in-person from specific services (e.g., depot clinic, clozapine clinic, residential and inpatient settings).

Survey Development

Surveys questions covered factors that might influence service users' sleep problems or readiness to be referred, such as age, gender, diagnosis, and sleep-related beliefs endorsed in prior research (Waite, Evans, et al., 2015; Faulkner and Bee, 2016; Faulkner and Bee, 2017).

The staff and service user surveys were piloted, commented on and timed by four clinical colleagues, and three patient public contributors respectively, and revised accordingly.

Survey structure and questions

The surveys are available in Appendix A. Service users were asked about their sleep problems (if any), their self-identified treatment needs, readiness and preferences, and demographic questions.

Staff were asked their profession, service, duration of experience, and knowledge and confidence to identify and address sleep problems. Staff were then asked to give a proxy report of sleep problems (if any), and readiness to refer, for the last 5 service users on their caseload with whom they had had contact. No personally identifying information was collected.

Data collection

Both surveys were online, and service users were offered alternatives (paper, in-person, or over the phone) to minimise sampling bias (26).

Data analysis

Statistical analyses were conducted in Stata (version 14.0) and considered statistically significant at two-tailed $p<0.05$. Multiple-choice responses were examined using descriptive statistics. Categories containing few participants were collapsed for analysis where appropriate. Severity, frequency and impact of sleep disruption were highly correlated with each other, and were consolidated into ordinal 'sleep problem' variables, consisting of the sum of severity, frequency and impact, for use in all subsequent analyses.

Ordinal logistic regression was used to examine which variables from the service user survey predicted more severe self-reported sleep problems, and which variables predicted desire for referral to a behavioural sleep intervention (27). Multilevel ordinal logistic regression was used to examine the equivalent research questions in the staff survey, to account for the clustered nature of this data (as each staff participant reported on five service users) (28). Free-text questions were analysed using a framework approach (29), coded by one researcher, in Nvivo software (version 12).

Results

Sample

We recruited 147 staff and 190 service users, meeting targets for all staff sub-groups except psychiatry trainee doctors (target=3, recruited=0). Staff participants reported on 619 anonymous service users. See Table 1 for demographics of both samples.

To evaluate indications of bias the demographics of service user survey participants were compared to service users of Trust #1 using summary information available from Business Intelligence. Both trusts have somewhat similar demographics. Ethnicity, gender and age were comparable, except for underrepresentation of people aged 71 years and over. See Appendix B.

Table 1: Demographics of service user and staff participants, and service users proxy reported on by staff

Service user participants	Total: 190	**Staff participants**	Total: 147	**Service users via staff proxy**	Total: 619
Primary diagnosis:		**Profession**		**Primary diagnosis**	
schizophrenia	83 (43.7%)	NHS support staff (clinical)	21 (14.4%)	schizophrenia spectrum disorder	199 (32.2%)
schizoaffective disorder	10 (5.3%)	clinical psychologist	12 (8.2%)		
bipolar affective disorder	14 (7.4%)	clinical psychology trainee	1 (0.7%)	bipolar affective disorder	53 (8.6%)
depression / anxiety	22 (11.6%)	mental health nurse	55 (38.7%)	depression / anxiety	102 (16.5%)
other psychosis diagnosis	16 (8.4%)	occupational therapist	12 (8.2%)	psychosis not otherwise specified	74 (12.0%)
personality disorder	13 (6.8%)	other AHP**	3 (2.1%)	personality disorder	77 (12.4%)
other, none of the above	7 (3.7%)	other junior doctors***	3 (2.1%)	substance misuse disorder	56 (9.1%)
I don't have a diagnosis	10 (5.3%)	psychiatry consultant	15 (10.3%)	none of the above	58 (9.4%)
I don't know / can't remember	6 (3.2%)	psychiatry / other trainee	0 (0.0%)	**How often seen?**	
no response	9 (4.7%)	social worker	21 (14.4%)	more than weekly	146 (23.6%)
Ethnicity:*		student (other)	3 (8.3%)	weekly	89 (14.4%)
White British	140 (77.3%)	third sector (non-NHS)	0 (0.0%)	fortnightly	124 (20.0%)
Mixed	13 (7.2%)	**Experience:**	mean, (SD)	3 weekly	53 (8.6%)
Asian	10 (5.5%)	Years in current profession	11.30 (10.2)	monthly	97 (15.7%)
Black / African / Caribbean	5 (2.8%)	Years in mental health	13.17 (10.0)	2 - 6 monthly	62 (10.0%)
Other white	4 (2.2%)	**Service:**	n= (%)	7 monthly - yearly	21 (3.4%)
Any other ethnic group	3 (1.7%)	CMHT****	66 (44.9%)	**How long known?**	
I prefer not to say	6 (3.3%)	Early Intervention in Psychosis	16 (10.9%)	less than 1 month	90 (14.5%)
Gender:		Rehabilitation	9 (6.1%)	1-3 months	120 (19.4%)
female	89 (48.9%)	Acute Inpatients	28 (19.0%)	>3 months <6 months	97 (15.7%)
male	86 (47.2%)	Crisis Team	2 (1.4%)	6 months - 1 year	116 (18.7%)
other*	5 (2.8%)	Other specialist service	20 (13.6%)	over 1 year	176 (28.4%)
I prefer not to say	2 (1.1%)	None of the above	6 (4.1%)		
Age		**Organisation:**	n= (%)		
18-24	11 (6.0%)	NHS Trust #1	82 (55.8%)		
25-30	19 (10.4%)	NHS Trust #2	63 (42.9%)		
31-40	39 (21.4%)	Neither of the above	1 (0.7%)		
41-50	52 (28.6%)	Prefer not to say	1 (0.7%)		
51-60	42 (23.1%)				
61-70	16 (8.8%)				
71+	3 (1.7%)				

* non-binary / gender fluid / genderqueer / other / I prefer to self-describe ** (includes speech and language, dietician, physiotherapist, art / music / drama therapists) *** (staff grade, locum etc) **** Community Mental Health Team

Prevalence and severity of sleep problems

Most service users reported sleep problems (70.4%), staff proxy-report was similar (69.6%), a large proportion reported significant or severe problems (service users 41.8%, staff proxy-report 43.39%). Service users endorsed 'severe' sleep problems slightly more often than staff (see Table 2).

Ordinal logistic regression of service user self-reports in a model including only diagnostic predictor variables suggested schizophrenia was associated with less severe sleep problems (4.8% severe, OR 0.383, p=0.003). Personality disorder (38.5% severe, odds ratio (OR) 5.432, p=0.001) or bipolar (35.7% severe, OR 3.475, p=0.007) diagnoses were associated with worse sleep.

Goodness of fit statistics indicated that a model in which age, gender and NHS Trust were included as covariates provided a better fit then diagnostic variables alone, and explained more variance in sleep problems (with age gender and Trust: AIC 693, BIC 771, McFadden's pseudo-R^2 0.119) (diagnostic variables only: AIC 773, BIC 839, pseudo-R^2 0.095). Once age, gender, and NHS Trust were added to the model, only diagnoses of bipolar (OR 2.741, p=0.033) and personality disorder (OR 4.970, p=0.004) remained statistically significant, now schizophrenia did not predict better sleep; instead being from NHS Trust #2 predicted better sleep (OR 0.352, p=0.003). Of note, proportionately more service user participants with schizophrenia were recruited from NHS Trust #2 (66.7% vs 22.7%%, see Appendix C) and these were largely recruited from clozapine clinics in NHS Trust #2.

Staff reported only 25.63% of their service users with schizophrenia spectrum disorders to be good sleepers, compared to >40% in self-report responses above. Multilevel ordinal logistic regression of staff proxy reports found no significant associations between service user diagnosis and sleep problems, but certain professional groups were more likely to report sleep problems in their service users (clinical psychologists OR 3.239, p= 0.007, consultant psychiatrists OR 2.842, p=0.009, occupational therapists OR 2.092, p= 0.045, and other allied health professionals OR 8.715, p=0.034).

Types of sleep problems

The most common type of sleep problems reported by either group were 'difficulty getting to sleep' and 'difficulty staying asleep / waking in the night', with service users and staff reporting similar levels of these. Service users reported more daytime sleepiness, difficulty waking up, or having too much sleep, than staff. Service users also reported more night-eating, sleepwalking, restless legs syndrome, and sleep apnoea than staff (see Table 2).

Table 2: Severity and types of sleep problems reported (select all that apply)

Severity of sleep problems	**Service user self-report**	**Staff proxy report**	**z test of difference of 2 proportions**	
			z=	p=
no, I am a good sleeper	54 (28.6%)	144 (23.3%)	1.350	0.177
mild sleep problems	54 (28.6%)	172 (27.8%)	0.078	0.94
significant sleep problems	47 (24.9%)	194 (31.3%)	-1.650	0.099
severe sleep problems	32 (16.9%)	65 (10.5%)	2.247	0.025
I'm unsure	2 (1.1%)	44 (7.1%)	-3.153	0.002
Total sample	190 (100%)	619 (100%)		
Type of sleep problem				
difficulty getting to sleep	84 (44.2%)	231 (37.3%)	1.604	0.109
difficulty staying asleep / waking in the night	78 (41.1%)	217 (35.1%)	1.401	0.161
poor sleep quality	74 (39.0%)	182 (29.4%)	2.372	0.018
sleeping at the wrong times	45 (23.7%)	147 (23.8%)	0.000	1.000
daytime sleepiness	68 (35.8%)	152 (24.6%)	2.938	0.003
difficulty waking up	42 (22.1%)	51 (8.2%)	5.103	<0.000
having too little sleep	59 (31.1%)	130 (21.0%)	2.755	<0.006
having too much sleep	43 (22.6%)	78 (12.6%)	3.266	0.001
nightmares	53 (27.9%)	67 (10.8%)	5.664	<0.000
sleepwalking	7 (3.7%)	7 (1.1%)	2.039	0.041
restless legs syndrome	35 (18.4%)	27 (4.4%)	6.209	<0.000
night eating	29 (15.3%)	9 (1.5%)	7.666	<0.000
other sleep-related movement disorder	2 (1.1%)	0 (0.0%)	cannot calculate	
suspected / diagnosed obstructive sleep apnoea / sleep disordered breathing	14 (7.4%)	7 (1.1%)	4.464	<0.000

Staff training, confidence and knowledge

Levels of self-reported staff sleep training were low, and knowledge from informal sources was more common than formal training. Most staff were relatively confident in their ability to identify sleep problems, but less confident in intervening (see Table 3). Staff were understandably more often 'unsure' of service user's sleep problems, than service users were themselves (see Table 2), this included being unsure when the service user was seen often or known for years (see Appendix C).

Greater staff confidence in identifying sleep problems was significantly associated with having had more sleep training (OR 2.011, p=0.006). Lower confidence identifying sleep problems was associated with working in an 'other specialist service' (OR 0.198, p=0.027), or being a psychiatry consultant doctor (OR 0.131, p=0.017). Greater confidence to address

or improve sleep problems was also significantly associated with having more sleep training (OR 2.093, p=0.002), whereas lower confidence was associated with being a psychiatry consultant doctor (OR 0.196, p=0.033), working in an acute inpatient setting (OR 0.306, p=0.025), and working in rehabilitation (OR 0.110, p=0.016).

Table 3: Staff confidence and knowledge regarding identification and treatment of sleep problems

Statement	**not confident at all**	**not very confident**	**reasonably confident**	**very confident**
How confident do you feel in your ability to identify sleep problems?	0 (0%)	16 (10.9%)	102 (69.4%)	29 (19.7%)
How confident do you feel in your ability to address or improve sleep problems?	4 (2.7%)	56 (38.1%)	77 (52.4%)	10 (6.8%)
	none	**hardly any**	**some**	**a lot**
How much training have you had regarding sleep?	47 (32.0%)	48 (32.7%)	49 (33.3%)	2 (1.4%)
Please select the main sources of your knowledge (select all that apply)				
I have a sleep-related qualification	0 (0%)			
my own research	108 (73.5%)			
general awareness and mainstream media	73 (49.7%)			
content covered as part of my professional training (pre-qualification)	55 (37.4%)			
a university / college course about sleep	7 (5.0%)			
Trust delivered training about sleep	19 (12.9%)			
a course from another provider	11 (7.5%)			

Seeking treatment

Both surveys briefly described the L-DART intervention ("a non-drug sleep intervention involving changes to sleep schedule, light exposure and daytime occupation / activity […] from a mental health occupational therapist") and asked participants hypothetically, whether they would refer or be referred to such an intervention. For service users with any sleep problem (mild, significant, or severe), most staff said they would 'definitely' or 'probably' refer (62.9%), and 46.5% of such service users said they would want to be referred (see Table 4).

Table 4: Staff and service user referral intentions (if mild, significant or severe sleep problems), and service user treatment beliefs and preferences.

Would you refer / want to be referred?	**Service user referral intent**	**Staff referral intent**	**z test of difference of 2 proportions**	
			z=	p=
total asked (asked sleep problems mild- severe)	134	429		
definitely	45 (33.8%)	136 (31.7%)	-0.301	0.763
probably	24 (12.6%)	134 (31.2%)	2.638	0.004
maybe	23 (17.3%)	61 (14.2%)	-0.696	0.486
probably not	14 (10.5%)	57 (13.3%)	0.715	0.475
no / highly unlikely	27 (20.3%)	41 (9.6%)	-3.133	0.002

Are any of these statements true for you? (service-user responses)	(select all that apply) n (%)
I don't want to improve my sleep	42 (22.1%)
I don't think it's possible to improve my sleep	47 (24.7%)
I would like to improve my sleep on my own	41 (21.6%)
I would like self-help advice	37 (19.5%)
I would like help from a professional to improve my sleep	61 (32.1%)
I would like a therapy to help improve my sleep	53 (27.9%)

Statement (service user responses)	**Strongly agree**	**Agree**	**Neither agree nor disagree**	**Disagree**	**Strongly disagree**
I would like to be prescribed a drug for my sleep	15.6%	18.0%	18.8%	17.2%	30.5%
I am already taking a drug for my sleep	18.1%	16.5%	9.5%	14.2%	41.7%
I would like to have a talking-based therapy for my sleep	13.4%	27.6%	13.4%	21.3%	24.4%
I would like to have an activity-based therapy for my sleep	15.1%	33.3%	13.5%	15.9%	22.2%
I would like to have a sleep treatment involving changing my light exposure	21.9%	23.4%	16.4%	20.3%	18.0%
I would have any type of sleep therapy if it will work	27.8%	27.8%	14.3%	15.9%	14.3%
I would like to be referred to an intervention like L-DART*	33.8%	18.1%	17.3%	10.5%	20.3%

Service users were asked to rate or select interest in individual components of sleep interventions, and treatment related preferences and beliefs. Being prescribed a drug for sleep was least popular, and 'I will have any type of sleep therapy if it will work' was most endorsed (see Table 4).

Ordinal logistic regression found no demographic / diagnostic variables were associated with service users wanting to be referred. Unsurprisingly, service users with worse sleep problems were significantly more likely to want a referral (OR 1.319, p=0.002).

Similarly, multi-level ordinal logistic regression of staff survey responses found that staff had more intention to refer service users with worse sleep problems (OR 1.660, p=<0.000). Intention to refer was lower in NHS Trust #2 (OR 0.301, p=0.011), if the service user had a primary diagnosis of substance misuse (OR 0.203, p=0.019), schizophrenia spectrum disorder (OR 0.324, p=0.012) or diagnosis 'none of the above' (OR 0.116, p=0.001).

Qualitative comments

Free text comments were entered by a minority of respondents. These expressed some common sentiments, including:

- medication aids sleep, so sleep therapy is unnecessary (n=5 service users);
- sleep problems might resolve without therapy (n=2 staff);
- therapy will not work (n=4 service users);
- the service user does not engage enough with services (n=5 staff);
- noting current barriers to the service user making the required changes (n=6 staff, n=3 service users), e.g., stimulants, bereavement, homelessness, mental state, and lifestyle / too busy to take on recommendations.

Full content summary and illustrative quotes are provided in Appendix C.

Discussion

Summary

Staff were aware of service user's having sleep problems, reporting these with a similarly high prevalence to service users, but lacking detailed awareness of problem types. Staff were more confident to identify sleep problems than to intervene, and confidence was particularly low among psychiatrists, and inpatient and rehabilitation staff. Reassuringly, more training regarding sleep and sleep problems was associated with higher confidence to identify and address sleep.

Overall, respondents with significant or severe sleep problems were moderately likely to want referral to an intervention like L-DART, and staff were similarly likely to want to refer. Service users' desire for referral was mostly influenced by their level of sleep problems, whilst staff readiness to refer was also influenced by factors such as profession, service, and schizophrenia spectrum diagnosis. Barriers to referral and engagement raised were reported to affect only a minority, and many were temporary or situational.

Need for non-pharmacological sleep interventions

Some service users reported being good sleepers and some commented that medication helped with sleep. However, sleep medication was rated negatively compared to other

approaches. Medication effects and timing were also endorsed as factors to address to improve sleep. Overall, this suggests medication is a good solution for some but not all cases, with potential for benefit or harm.

Among the 809 service users responding or reported upon, 241 selected 'significant sleep problems', and 97 'severe…', 339 selected 'probably' or 'definitely' wanting referral to L-DART or similar (42%). Whilst sampling biases may have inflated the percentage of service users wanting referral, even half this amount (21%) would be substantial demand. This agrees with previous qualitative studies where participants described behavioural sleep treatments as acceptable, and preferable to drug-based approaches (6,24). Improving sleep amongst service users of mental health trusts could bring many benefits; including better cardiometabolic health (30), quality of life (31), and reduced relapse in psychosis (5,32,33), bi-polar (34) and depression (35,36).

Need for sleep education among staff

Staff reported limited training and confidence regarding sleep, agreeing with previous research (2–4). More training predicted higher confidence to identify and address sleep problems. Although staff mostly reported some awareness of service users' sleep problems, mental health staff reportedly mostly assess sleep informally and unsystematically (2,4); this may explain limited staff awareness of sleep apnoea, night eating, or parasomnias. Prevalence studies found 12.3% (37) or 22.4% (38) of mental health outpatients had night eating syndrome, suggesting our service user self-reports were more accurate (15.3%) than staff reports (1.5%). Restless legs is similarly more prevalent (14.8%) (39) than staff reports noted (4.4%). A review of Obstructive Sleep Apnoea (OSA) prevalence research suggests OSA is present in 11%-42% of patients with severe mental illness (40). Both our service user self-report (7.4%), and especially staff report (1.4%), underestimate OSA. This suggests a lack of awareness in staff, not over-reporting by service users.

It is possible those staff reporting least confidence to intervene in sleep problems (psychiatrists, rehab and inpatient staff) may not have worse skills, but more awareness of skill gaps. Psychiatrists have a particular responsibility for considering differential diagnosis, and are approached regarding hypnotic prescription or cessation. Rehabilitation and inpatient staff may be confronted by unresolved sleep problems at night. These groups may therefore particularly embrace sleep education.

Barriers and facilitators to referral and engagement in an intervention like L-DART

Lifestyle a nd illness-related barriers were similar to those reported by staff and service users elsewhere (2,12). Many were potentially temporary. Attitudes such as 'I don't think it's possible to improve my sleep' may be amenable to change. More evidence of effectiveness, presented accessibly with examples, may help. Motivational interviewing appears promising for enhancing engagement and uptake in other therapies (41), and may help with uptake of sleep therapies. Sometimes antidepressant treatment of low mood might improve motivation (42) enough to enable better utilisation of behavioural sleep treatment.

Less staff readiness to refer those using alcohol or illicit drugs is perhaps reasonable, as the intervention did not describe a means to first address substance use. Less readiness to refer service users with a schizophrenia spectrum diagnosis might be due to prescription of more sedative antipsychotics, which could be seen as already addressing sleep. However, sedating people at night without addressing circadian rhythm can leave unresolved daytime

sleepiness. Other research found staff considered sleep treatment too demanding in people with psychosis (4). Promoting evidence for effectiveness in this group will therefore be critical.

Service users endorsed "I would have any type of sleep therapy if it will work". This underlines how far expected efficacy might predict engagement. Albeit how far participants persist must also be studied in practice. One hundred and two potentially eligible people said they would want referral if L-DART were available in clinical services, but presented with the option most did not refer to the feasibility study of L-DART (n=29 referrals, still sufficient for this study recruit well ahead of target). This could be through lack of evidence for a trial intervention, distrust of researchers (19), lack of time to refer, or people may just be less willing to refer than they say. Of course, it is problematic for generalisability that different people participate during trials than accept therapies once offered in services.

Limitations

Selection bias may have influenced the study findings. Studies of non-respondents showed differences between participants and those declining, including worse drug use (43), and lower socio-economic status (44). Even with high response rates, participants may differ systematically from others, based on who the study title or promotional material appeal to (45).

This study was ostensibly about sleep so may have attracted participants interested in sleep. The service user sample may overrepresent those who were easier to engage by phone and / or less acutely unwell, although we aimed to reduce this by recruiting from inpatient wards, clozapine clinics and depot clinics. We did not record medication, which was likely a significant residual confounder in the service user sample: service users from the Trust which recruited most patients from clozapine clinic reported less severe problems. Dose and type of medication may easily affect sleep problem ratings. Similarly, we did not rate severity of ongoing psychiatric symptoms, which could have affected sleep problem scores.

Service users with poor sleep are less likely to be systematically over-represented in the staff proxy reports, since staff were instructed to report on their five most recently seen service users. Although these reports may over-represent those with higher service use, who may have worse sleep due to being more ill.

Conclusions

Our findings suggest there is an unmet need for effective behavioural and psychological sleep interventions among mental health service users, and that staff are aware of this need, despite lacking detailed knowledge, or confidence to help. Findings suggest more training would help, and may be enthusiastically received. Service user barriers to referral or engagement reported were not widespread or insurmountable. The main barrier remains the lack of availability of well evidenced sleep interventions for people with severe mental illnesses, such interventions may have great unexploited potential to improve lives, reduce morbidity and mortality, and should be a priority.

References:

1. O'Sullivan M, Rahim M, Hall C. The prevalence and management of poor sleep quality in a secondary care mental health population. J Clin Sleep Med. 2015;11(2):111–6.

2. Rehman A, Waite F, Sheaves B, Biello S, Freeman D, Gumley A. Clinician perceptions of sleep problems, and their treatment, in patients with non-affective psychosis. Psychosis. 2017;9(2):129–39.

3. Faulkner S, Mairs H. An exploration of the role of the occupational therapist in relation to sleep problems in mental health settings. Br J Occup Ther [Internet]. 2015;78(8):516–24. Available from: http://bjo.sagepub.com/lookup/doi/10.1177/0308022614564771

4. Barrett EA, Aminoff SR, Simonsen C, Romm KL. Opening the curtains for better sleep in psychotic disorders - considerations for improving sleep treatment. Compr Psychiatry. 2020;103.

5. Waite F, Sheaves B, Isham L, Reeve S, Freeman D. Sleep and schizophrenia: From epiphenomenon to treatable causal target. Schizophr Res. 2020;221:44–56.

6. Chiu VW, Ree M, Janca A, Waters F. Sleep in Schizophrenia: Exploring Subjective Experiences of Sleep Problems, and Implications for Treatment. Psychiatr Q. 2016;87(4):633–48.

7. Faulkner S, Bee P. Experiences, perspectives and priorities of people with schizophrenia spectrum disorders regarding sleep disturbance and its treatment: A qualitative study. BMC Psychiatry. 2017;17(1).

8. Waters F, Chiu VW, Janca A, Atkinson A, Ree M. Preferences for different insomnia treatment options in people with schizophrenia and related psychoses: a qualitative study. Front Psychol [Internet]. 2015;6:1–10. Available from: http://journal.frontiersin.org/article/10.3389/fpsyg.2015.00990

9. Fung C, Wiseman-Hakes C, Stergiou-Kita M, Nguyen M, Colantonio A. Time to wake up: bridging the gap between theory and practice for sleep in occupational therapy. Br J Occup Ther [Internet]. 2013;76(8):384–6. Available from: http://openurl.ingenta.com/content/xref?genre=article&issn=0308-0226&volume=76&issue=8&spage=384

10. Solet JM. Sleep and rest. In: Schell BA, Gillen G, Scaffa M, Cohn ES, editors. Willard and Spackman's Occupational Therapy. 12th ed. Philadelphia: Wolters Kluwer - Lippincott Williams and Wilkins; 2014. p. 714–30.

11. Green A. Sleep and Occupation. In: An Occupational Therapist's Guide to Sleep and Sleep Problems. London: Jessica Kingsley Publishers; 2015.

12. Faulkner S, Bee P, Eisner E, Drake R. A mixed methods expert opinion study on the optimal content and format for an occupational therapy intervention to improve sleep in schizophrenia spectrum disorders.

13. www.RE-AIM.org [Internet]. 2019 [cited 2019 Jun 17]. Available from: www.re-aim.org

14. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: update [Internet]. 2019. Available from: www.mrc.ac.uk/complexinterventionsguidance

15. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: new guidance. MRC. 2008;

16. Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide to Designing Interventions. The Behavior Change Wheel: Book Launch Event. 2014. 1–46 p.

17. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. Implement Sci. 2009;4(1):1–15.

18. Buckland N, Mackenzie L. Exploring the role of occupational therapy in caring for cancer survivors in Australia: A cross sectional study. Aust Occup Ther J. 2017;64(5):358–68.

19. Simpson A, Bowers L, Alexander J, Ridley C, Warren J. Occupational therapy and multidisciplinary working on acute psychiatric wards: The Tompkins acute ward study. Br J Occup Ther. 2005;68(12):545–52.

20. Cook S, Birrell M. Defining an occupational therapy intervention for people with psychosis. Br J Occup Ther [Internet]. 2007;70(3):96–106. Available from: http://search.ebscohost.com/login.aspx?direct=true&db=psyh&AN=2007-05700-001&lang=ja&site=ehost-live%5Cns.p.cook@shu.ac.uk

21. Vehovar V, Toepoel V, Steinmetz S. Non-probability Sampling In: The SAGE Handbook of Survey Methodology. In: The SAGE Handbook of Survey Methodology [Internet]. 2016. p. 329–45. Available from: https://dx.doi.org/10.4135/9781473957893

22. Faulkner S, Bee P. Perspectives on Sleep, Sleep Problems, and Their Treatment, in People with Serious Mental Illnesses: A Systematic Review. PLoS One [Internet]. 2016;11(9):e0163486. Available from: doi.org/10.1371/journal.pone.0163486

23. Faulkner S, Bee P. Experiences, perspectives and priorities of people with schizophrenia spectrum disorders regarding sleep disturbance and its treatment: a qualitative study. BMC Psychiatry [Internet]. 2017;17(1):158. Available from: DOI 10.1186/s12888-017-1329-8

24. Waite F, Evans N, Myers E, Startup H, Lister R, Harvey AG, et al. The patient experience of sleep problems and their treatment in the context of current delusions and hallucinations. Psychol Psychother Theory, Res Pract [Internet]. 2015;89:181–193. Available from: http://doi.wiley.com/10.1111/papt.12073

25. Cowles, E., & Nelson E. Introduction to Survey Research. Cowles, E., & Nelson E, editor. Business Expert Press; 2015.

26. Pierce M, McManus S, Jessop C, John A, Hotopf M, Ford T, et al. Says who? The significance of sampling in mental health surveys during COVID-19. The Lancet Psychiatry [Internet]. 2020;7(7):567–8. Available from: http://dx.doi.org/10.1016/S2215-0366(20)30237-6

27. Liu X, Koirala H. Fitting proportional odds models to educational data with complex sampling designs in ordinal logistic regression. J Mod Appl Stat Methods. 2013;12(1):235–48.

28. Sommet N, Morselli D. Keep calm and learn multilevel logistic modeling: A simplified three-step procedure using stata, R, Mplus, and SPSS. Int Rev Soc Psychol. 2017;30(1):203–18.

29. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol [Internet]. 2013;13(117). Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3848812&tool=pmcentrez&rendertype=abstract

30. Medic G, Wille M, Hemels MEH. Short- and long-term health consequences of sleep disruption. Nat Sci Sleep. 2017;9:151–61.

31. Hofstetter JR, Lysaker PH, Mayeda AR. Quality of sleep in patients with schizophrenia is associated with quality of life and coping. BMC Psychiatry [Internet]. 2005 [cited 2014 Nov 4];5(13). Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=554780&tool=pmcentrez&rendertype=abstract

32. Meyer N, Kerz M, Folarin A, Joyce DW, Jackson R, Karr C, et al. Capturing rest-activity profiles in schizophrenia using wearable and mobile technologies: Development, implementation, feasibility, and acceptability of a remote monitoring platform. JMIR mHealth uHealth. 2018;6(10).

33. Reeve S, Sheaves B, Freeman D. The role of sleep dysfunction in the occurrence of delusions and hallucinations : A systematic review. Clin Psychol Rev [Internet]. 2015;42:96–115. Available from: http://dx.doi.org/10.1016/j.cpr.2015.09.001

34. Harvey AG, Kaplan KA, Soehner AM. Interventions for sleep disturbance in bipolar disorder. Sleep Med Clin. 2015;10(1):101–5.

35. Hayley AC, Williams LJ, Venugopal K, Kennedy GA, Berk M, Pasco JA, et al. The relationships between insomnia, sleep apnoea and depression: findings from the American National Health and Nutrition Examination Survey, 2005-2008. Aust N Z J Psychiatry [Internet]. 2015;49(2):156–70. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=prem&NEWS=N&AN=25128225

36. Baglioni C, Battagliese G, Feige B, Spiegelhalder K, Nissen C, Voderholzer U, et al. Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies. J Affect Disord [Internet]. 2011 Dec [cited 2014 Oct 3];135(1–3):10–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21300408

37. Lundgren JD, Rempfer M V., Brown CE, Goetz J, Hamera E. The prevalence of night eating syndrome and binge eating disorder among overweight and obese individuals with serious mental illness. Psychiatry Res [Internet]. 2010;175(3):233–6. Available from: http://dx.doi.org/10.1016/j.psychres.2008.10.027

38. Saraçli Ö, Atasoy N, Akdemir A, Güriz O, Konuk N, Sevinçer GM, et al. The prevalence and clinical features of the night eating syndrome in psychiatric out-patient population. Compr Psychiatry. 2015;57:79–84.

39. Hombali A, Seow E, Yuan Q, Chang SHS, Satghare P, Kumar S, et al. Prevalence and correlates of sleep disorder symptoms in psychiatric disorders. Psychiatry Res [Internet]. 2019;279(February 2018):116–22. Available from: https://doi.org/10.1016/j.psychres.2018.07.009

40. Szaulińska K, Pływaczewski R, Sikorska O, Holka-Pokorska J, Wierzbicka A, Wichniak A, et al. Obstructive sleep apnea in severe mental disorders. Psychiatr Pol. 2015;49(5):883–95.

41. Simpson HB, Zuckoff A. Using Motivational Interviewing to Enhance Treatment Outcome in People With Obsessive-Compulsive Disorder. Cogn Behav Pract. 2011;18(1):28–37.

42. Gorwood P, Vaiva G, Corruble E, Llorca PM, Baylé FJ, Courtet P. The ability of early changes in motivation to predict later antidepressant treatment response. Neuropsychiatr Dis Treat. 2015;11:2875–82.

43. Sofuoglu M, Dudish-Poulsen S, Nicodemus KK, Babb DA, Hatsukami DK. Characteristics of research volunteers for inpatient cocaine studies: Focus on selection bias. Addict Behav. 2000;25(5):785–90.

44. Bros L, Leeuw E de, Hox J, Kurvers G. Nonrespondents in a Mail Survey: Who Are They? In: Laaksonen S, editor. International Perspectives on Nonresponse, Proceedings of the Sixth International Workshop on Household Survey Nonresponse 25-27 October 1995. Helsinki: Statistics Finland; 1996. p. 23–9.

45. Johnson TP, Wislar JS. Response rates and nonresponse errors in surveys. JAMA - J Am Med Assoc. 2012;307(17):1805–6.

Chapter 9: Feasibility study protocol

The influence of the findings of studies A-C on this protocol is described at the end of Chapter 7. This study was designed and submitted for ethical approval together with the surveys presented in Chapter 8, but was not able to commence data-collection until later due to pandemic restrictions.

This study has now completed recruitment. Half of the participants have completed participation, and the second half are in follow-up at the time of writing. An update on progress of this study is included in Appendix 7.

9.1. Paper 6: “Protocol for Light-Dark and Activity Rhythm Therapy for sleep: Feasibility and acceptability in Schizophrenia spectrum disorders (L-DART FitSz)”

Paper number: 6

Page of thesis: 352

Prepared for submission to Pilot and Feasibility Studies.

An update on this study, which is ongoing at the time of writing, is included in Appendix 7.

Author contributions:
The study was designed by SF with supervisory input from PB and RD. The manuscript was drafted by SF, with input from RD and PB on structure, content, and style.

Abstract

Background: Sleep problems are common in people with diagnoses of schizophrenia spectrum disorders (>50%), even during periods of relative stability of psychotic symptoms. Evidence suggests that people living with schizophrenia spectrum disorders are often keen to improve their sleep, but few non-pharmacological sleep treatments are available to patients in specialist mental health services. It has been proposed that occupational therapists may have the relevant skills for the delivery of behavioural sleep interventions. This mixed method, proof-of-concept study aims to assess the feasibility and acceptability of a new intervention, Light-Dark and Activity Rhythm Therapy (L-DART), to improve sleep in people with schizophrenia spectrum disorder diagnoses.

Methods: A single group of 10-12 service users with schizophrenia spectrum diagnoses and self-reported problems with sleep onset, maintenance, timing or quality will be offered L-DART. L-DART will be delivered over 6-9 in-person sessions and 3-6 phone-calls by an occupational therapist. Feasibility measures will comprise recruitment and retention logs, fidelity based on session records, adverse effects, and study attrition. Intervention uptake, engagement and adherence will be measured, and barriers to adherence explored. Acceptability will be assessed though quantitative satisfaction ratings and qualitative interviews. Activity patterns and dynamic light exposure will be measured, as well as self-reported sleep, wellbeing and functioning, to inform outcome selection in a larger trial.

Discussion: The findings will inform any necessary modifications to the intervention and its materials, enabling the development of a stage 2 manual and a therapist training package. The results will support the design of a randomised multi-therapist feasibility trial.

Trial registration: ISRCTN11998005, assigned registration on 17.02.2020

Background

Sleep problems are common in people with schizophrenia spectrum disorders (schizophrenia, schizoaffective disorder and delusional disorder) (Wulff et al., 2012), and cause, or are linked to, significant problems with physical and mental health (Spiegel et al., 2005; Krystal et al., 2008; Meerlo et al., 2008; Haus and Smolensky, 2013). Sleep problems have been linked to poorer medication adherence (Afonso, Brissos, et al., 2014), and circadian rhythm (body clock) problems are thought to be responsible for some of the cognitive impairment associated with schizophrenia (Wulff and Joyce, 2011).

People with psychotic illnesses see sleep as important and want to sleep better (Auslander and Jeste, 2002); participants with schizophrenia have reported that poor sleep impacts on their functioning and mental health and feel that poor sleep should be better treated (Waite, Evans, et al., 2015). Participants describe the impact of sleep problems on their self-image, on their ability to keep social arrangements and their ability to obtain paid or voluntary work (Faulkner and Bee, 2017). Experts identify quality of sleep as a modifiable factor and an important treatment target in schizophrenia (Wulff and Joyce, 2011; Jagannath et al., 2013), yet sleep treatment is rarely offered to those under specialist mental health services. Staff often lack knowledge and confidence to intervene (Faulkner and Mairs, 2015; O'Sullivan et al., 2015).

People with schizophrenia have somewhat different sleep problems than those in the general population and those with common mental health problems, in whom psychophysiological insomnia is common. People with schizophrenia experience more circadian dysregulation (less regular day-night rhythms) (Bersani et al., 2012), often resulting in reduced daytime activity, and increased night-time activity, irregular or changeable rest-activity rhythms, or non-24-hour (free-running) patterns (Eklund et al., 2010; Wulff et al., 2012). 50% have been found to have significantly delayed, or free running rest-activity patterns. People with schizophrenia described that broken sleep, or sleep which was not experienced as 'deep', was a very high priority to improve (Faulkner and Bee, 2017). Broken or shallow sleep is also a very common experience by both subjective accounts and objective measurement (Afonso, Figueira, et al., 2014; Ilanković et al., 2014; Faulkner and Bee, 2017; S. Faulkner et al., 2019).

Qualitative research suggests patients prefer non-drug to drug interventions for sleep difficulties, despite the effort they acknowledge is required to successfully engage in these (Waite, Evans, et al., 2015; Faulkner and Bee, 2016; Faulkner and Bee, 2017). Patient and public involvement completed whilst designing this programme of research has corroborated this stance.

Current theories of sleep regulation suggest reducing excessive time in bed, reducing napping, and increasing daytime activity (thereby increasing 'sleep pressure' and tiredness at bedtime) are all strategies likely to improve sleep maintenance (Kyle et al., 2015). Cognitive Behavioural Therapy for Insomnia (CBTi) includes elements to manipulate sleep pressure, to increase behavioural associations of bed with sleep, as well as sleep hygiene advice (Matthews et al., 2013; Miller et al., 2014). Many protocols also include strategies to reduce arousal or address night-time worry, such as relaxation or cognitive therapy elements (Matthews et al., 2013).

Increasing daytime activity can improve timing of exposure to environmental and behavioural cues (zeitgebers), including light, which help to entrain circadian rhythms and keep bodily sleep-wake rhythms aligned with day-night cycles (Pauley, 2004; Jagannath et al., 2013). This study will evaluate an intervention which includes increased focus on these environmental zeitgebers, compared to traditional CBTi, delivered by an occupational therapist.

Authors have described the relevance of the occupational therapist's existing skill set to sleep interventions, including: activity analysis, activity scheduling, graded behaviour change interventions, and environmental assessment and adaptation (Creek, 2003; Fung et al., 2013; Solet, 2014; Faulkner and Mairs, 2015). Sleep is increasingly becoming recognised as a legitimate concern for occupational therapists, and it is receiving increased coverage in literature (Green and Brown, 2015), and therapist training (Brown, 2016). However, a scoping search of completed or ongoing occupational therapy trials in schizophrenia found none related to sleep. This study is the first we are aware of to develop an occupational therapy intervention to address sleep in this group.

Light-Dark and Activity Rhythm Therapy for sleep: Development of the L-DART intervention

A mixed methods expert opinion study was conducted by the study authors (October 2018 - March 2019) to systematically identify and integrate the views and expertise of clinical and academic experts and people with personal experience (service users and carers). The findings of this study were used to develop the intervention which will be tested in this study.

L-DART incorporates some elements of cognitive behavioural therapy for insomnia: sleep scheduling, avoiding or reducing naps and increasing association of bed with sleep through 'stimulus control'. L-DART also utilises current knowledge of circadian rhythm, changing light exposure patterns to phase advance or phase delay, and stabilising circadian rhythm and rest-activity patterns. L-DART frames and personalises light and activity level and timing modifications in the context of meaningful and balanced activity routines (meaningful occupation), utilising the core skills of occupational therapists.

The intervention addresses the following core areas:

- modifications to light exposure patterns across the day including environmental adaptation
- nature, balance and timing of activities
- sleep schedule modifications

Previous research, and the expert opinion study in Chapter 6, suggest a high level of personalisation is required to treat sleep in this client group, more so due to the diversity of sleep disturbance phenotypes. These include delayed / advanced sleep, non-24-hour rhythms, irregular sleep timing, psychophysiological insomnia, insomnia due to poor sleep hygiene, and 'hypersomnia' with poor sleep quality. There are thus different approaches depending on the problem, and optional components to address specific sleep disrupting influences which may be present for some but not all participants.

Aims of the present study:

This study aims to recruit 10 participants, who will all receive the intervention. Our aim is to assess and explore acceptability and feasibility, this will be approached using mixed methods. We will also measure potential clinical outcomes around sleep and quality of life, which would be measured in a larger future study.

Methods

Aim:

To explore the feasibility and acceptability of delivering and testing L-DART within a larger scale trial.

Outcomes contributing toward this aim:

To evaluate or provide:

- To what extent participants find the intervention acceptable
- Qualitative exploration of acceptability
- Whether participants are willing and able to adhere to different aspects of the intervention.
- Initial exploration of the proposed mechanisms of action, and problem types and combinations for which different elements of the intervention are more or less applicable.
- Mixed methods evaluation of adherence and barriers to adherence.
- Feasibility of recruitment and resources required to recruit.
- A rough estimate of rates of attrition likely in a larger study (although confidence intervals for this estimate are likely to be wide (Hertzog 2008)).
- Initial indications of effect size
- Suitability of outcome measures and passive data monitoring (activity and light measurement devices):
    - Their ability to capture factors participants deemed important (via comparison with qualitative data).

    - Acceptability of measures, participant burden, face validity and perceived relevance.
    - Levels of completion on measures.
    - Initial indications of variance on selected measures (would require supplementation with further cross-sectional work) (Thabane et al. 2010).
- Relationships and comparability of data from self-report measures and passive data channels to inform which are most useful in a larger future study.
- To contribute toward estimates of the number of potentially eligible participants.

Sample:

Target sample = 10

Sample size is not based around efficacy or estimation of effects, but seeks to balance feasibility of study delivery within the available timescale and resources, whilst recruiting a sufficient number of participants to represent a range of different types of sleep problem s and circumstances. A purposive approach (Teddlie and Yu, 2007) will be used if some problem types are becoming under-represented by mid-study; by requesting certain types of referrals from gatekeepers, but participants will not be denied participation in order to purposively sample.

Inclusion criteria:

1. Diagnosis of non-affective psychosis: Schizophrenia, Schizotypal disorder, Delusional disorder, Schizoaffective disorder (ICD-10 F20, F21, F22, F25, F28 / DSM 295.*, 297.1).
2. Open to secondary care mental health services in Greater Manchester Mental Health and NHS Foundation Trust (GMMH) or Pennine Care NHS Foundation Trust (Pennine Care).
3. Over 18.
4. Expresses dissatisfaction with their sleep (length of time to fall asleep, amount of sleep, subjective sleep quality, broken sleep, unrefreshing sleep, difficulty waking up, unsatisfactory timing of sleep).
5. Interested in receiving the intervention.

Exclusion criteria:

Stability or acuity:

1a. Change of medication within the last 1 month.
1b. Discharged from hospital within the last 1 month.
1c. Current inpatient or acuity of illness requiring home treatment team.
1d. Actively suicidal (expressing suicidal plans or intent).
1e. Risk to others prevents lone visiting.

Due to wrong sleep disorder:

2a. Known untreated significant sleep apnoea (Apnoea Hypopnoea Index (AHI) Index >20, or symptomatic)
2b. Primary complaint is of sleep apnoea, sleep-related movement disorder or parasomnia.
2c. Diagnosis of narcolepsy or Rapid Eye Movement (REM) sleep behaviour disorder.

1. Co-morbid learning disability, dementia, or moderate to severe neurological impairment.
2. Alcohol or substance dependent (unsuitable if using heavily every day and / or not able to be sober for sessions).
3. No fixed abode.
4. Does not have capacity to give informed consent.

Recruitment:

Service user participants will be recruited via clinical gatekeepers who will be approached at team meetings, one to one in teams, and via other Trust research promotion (e.g., internal email, 'splash-screen' adverts). Leaflets can be passed on by gatekeepers. Service user participants will be approached by members of the research delivery team at GMMH or Pennine where local policies permit this. The researcher will attend client and service user meetings by arrangement or invitation

to present information about the study. Posters and leaflets will be placed in patient areas so that potential participants can self-refer. The referral form will be used by research delivery staff, clinical staff or the chief investigator to record / pass on the details of potential participants who have verbally consented to be contacted by the chief investigator.

Participants who withdraw consent [or lose capacity to consent]:
Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected.

If a participant loses the capacity to consent during the study (for instance, due to acute physical or mental illness), we will retain the data already contributed, but not collect any new data. When (or if) he participant regains capacity to consent we will ask if they want to continue to participate further.

Data collection:

Routine therapy data:

- Initial assessment proforma
- Self-reported activities (diary)
- Self-reported sleep (diary)
- Homework log (plan, progress and feedback)
- Therapy notes, correspondence and documents (emails, letters, therapy summary and maintenance plan)
- Adverse effects monitoring (checklist)

Custom measures and case report forms:

- Therapy satisfaction 3 item Likert
- Qualitative pre-intervention questions regarding - prospective acceptability (~5 minutes)
- Qualitative post-intervention interview – retrospective acceptability (~60 minutes)
- End point assessment questions

- Demographic information form
- Therapy component delivery and fidelity log
- Attendance log and adherence log
- Recruitment log

Standardised outcome measures:

- Insomnia Severity Index (ISI) (Bastien et al., 2001; Morin et al., 2011)
- PROMIS-SD 8a (Sleep Disturbance) (Buysse et al., 2010; Yu et al., 2011)
- PROMIS-SRI 8a (Sleep-Related Impairment) (Buysse et al., 2010; Yu et al., 2011)
- Warwick–Edinburgh Mental Wellbeing Scale (WEMWBS) (Tennant et al., 2007)
- EQ 5D-5L (5-level EQ-5D version, EuroQol) (Janssen et al., 2013)
- PROMIS-AP 8a (Ability to Participate in social roles and activities) (Hahn et al., 2010)
- Clinical Global Impression-Schizophrenia (CGI- SCH) (Haro et al., 2003)

Passive data / objective data:

- Withings Move activity watch data -
    - Walking and running: Steps and pace (we will not collect any Global Positioning System (GPS) data, distance and elevation using GPS will only be collected by HealthMate if the person has chosen to turn on connected GPS, which we are not asking people to do)
    - Swimming: Session duration
    - Automatic detection of: walking, running, cycling, tennis, table tennis, squash, badminton, weights, basketball, soccer, volleyball, dance, boxing (time and duration)
    - Sleep: Deep and light sleep phases, sleep interruptions
- CamnTech MotionWatch 8 accelerometry and light exposure recording (wrist worn, dynamic outdoor light - coat / bag mounted, environmental light – mounted in the home)
- Therapy session audio recordings (additional consent, not essential to participation)

Custom measures and case report forms (details):

Therapy satisfaction 3 item Likert:

Custom measure to be used during and after intervention, give 5-point ratings on 3 questions relating to affective attitude toward the intervention - liking, satisfaction, readiness to recommend.

Pre-intervention questions – prospective acceptability:

There will be a brief (~5 minutes) qualitative exploration of prospective perceived effectiveness, and self-efficacy completed by the chief investigator pre-intervention (see qualitative topic guide).

Qualitative post-intervention interview:

The post-intervention interview will be conducted by an experienced qualitative researcher with personal experience of psychosis and of receipt of mental health services. The interview will explore various dimensions of acceptability of the therapy as a whole and of its various components (see qualitative topic guide).

End point assessment questions:

Repetition of the quantitatively rated and self-reported objective questions from the initial assessment proforma, used to quantify change.

Demographic information form:

Record of demographic information used to describe the sample and to inform the therapy. Information collected after consent to participation but prior to the start of therapy from clinical notes or from referrer. Items included to describe sample: diagnosis, gender, age at day 1 of study, ethnicity, religious / spiritual orientation. Items also used within initial assessment: height, weight, BMI (to inform screening for sleep disordered breathing), medications, doses, timing and frequency.

Therapy component delivery and fidelity log:

Record of which components have been delivered and when to each participant, and any changes or protocol deviations which occurred (and why), completed by the therapist after the session.

Attendance and adherence

Records of sessions attended within the therapy window, and of homework completion between sessions by participants, completed by the therapist at and after sessions.

Recruitment log

Record of referrals with consent to contact received, sources of referrals, and reasons for ineligibility or reasons for declining participation (where reasons were given).

See Figure 1 for the research participation timeline per participant, and Table 1 for an overview of which measures are used at each time point.

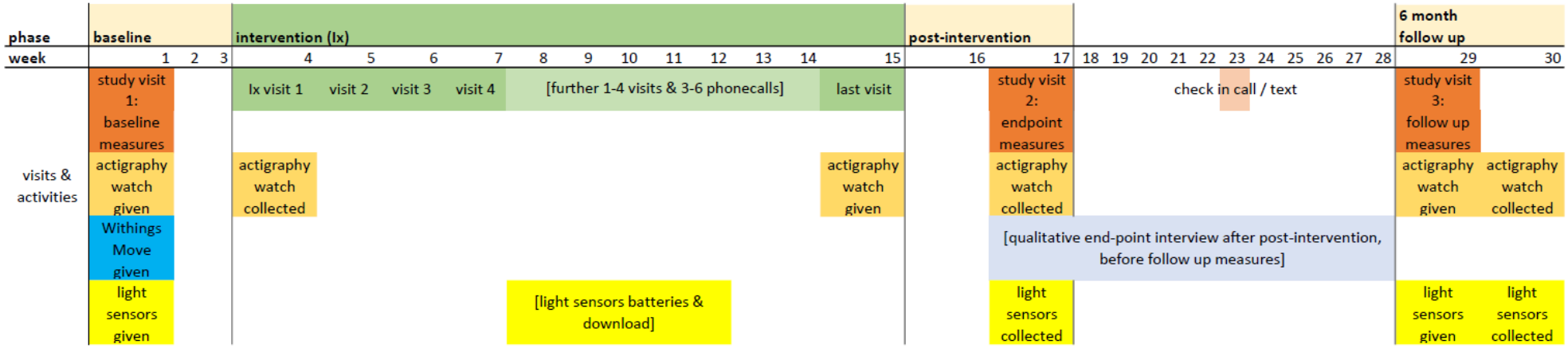


Figure 1: Research participation timeline

Table 1: Data collection per week of participation

	week	1	4	5	6	7	8	9	10	11	12	13	14	15	17	29	30
	measure \ period	B	therapy window												P	FU	
Standardised	ISI	x													x	x	
	PROMIS-SD 8a	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
	PROMIS-SRI 8a	x													x	x	
	WEMWBS	x													x	x	
	EQ 5D-5L	x													x	x	
	PROMIS-AP 8a	x													x	x	
	CGI-SCH	x													x	x	
	MotionWatch 8 accelerometry	[------]												[------]		[------]	
	Withings Move activity watch	[----------															]
	Therapy session audio		x	x	x	x	x	?	x	?	x	?	?	x			
	Dynamic outdoor light	[----------													]	[------]	
	Environmental light [1]	[----------													]	[------]	
Routine data	Initial assessment		x														
	Self-reported activities	----------as required----------															
	Self-reported sleep	----------as required----------															
	Homework log			x	x	x	x	x	x	?	x	?	?	x			
	Therapy notes		x	x	x	x	x	x	x	?	x	?	?	x			
	Adverse effects			----------as required----------													
Custom measures and forms	Demographic information	x															
	Therapy satisfaction Likert		x	x	x	x	x	x	x	x	x	x	x	x			
	End point assessment														x	x	
	Qualitative pre-therapy questions		x														
	Qualitative post-therapy interview														--x--		
	Therapy delivery and fidelity log		x	x	x	x	x	x	x	x	x	x	x	x			
	Attendance and adherence records		x	x	x	x	x	x	x	x	x	x	x	x			
	Recruitment log	n/a, data collected prior to recruitment															

B=baseline, P=post-intervention, FU=follow-up, ?=dependent on occurrence of session / phone-call (optional), [1] At week 1 or at first home visit, prior to modification to home environment and following modification to home environment or at end of intervention.

Intervention:

The study is a single group design, all participants will be offered L-DART.

L-DART will be delivered by the Chief Investigator (CI) who is an experienced mental health occupational therapist, it will be given in 6-9 sessions plus 3-6 phone-calls as needed.

The intervention addresses the following core areas:

5. modifications to light exposure patterns across the day
6. nature, balance and timing of activities
7. sleep schedule modifications

Optional components to be used when relevant include:

- reducing or changing the timing of use of substance use including: caffeine, alcohol, illicit drugs, over the counter medications
- altering or regulating the timing of sleep-inducing prescribed medications
- addressing meal timing
- addressing nightmares
- methods to reduce or avoid daytime naps

See Figure 2 for an overview of core and optional components and when used.

1) Modifications to light exposure

Modern light exposure patterns differ from those in which humans evolved, due to time spent indoors and exposure to artificial light at night. These light patterns are more difficult for the circadian system to entrain to, and due to individual differences some are affected more than others (Skeldon et al., 2017). L-DART will aim to return light exposure patterns closer to those which naturally occur on earth (i.e. light in the daytime and dark at night), by increasing daytime and morning light exposure, and reducing artificial light at night and in the late evening.

For those with a late-shifted rhythm there will be more emphasis on increasing morning light and avoiding evening light, to bring the rhythm earlier. For those with an early-shifted rhythm (less common) there will be more emphasis on daytime and afternoon light exposure, and less emphasis on reducing evening light. We will not increase evening light to attempt to delay sleep patterns, as meta-analysis has not shown evidence for this (S. M. Faulkner et al., 2019), and as light exposure is acutely alerting evening light exposure may interfere with sleep (Cajochen, 2007; Xu and Lang, 2018). For those with an irregular sleep rhythm, true circadian timing (e.g., timing of melatonin rhythm) cannot easily be ascertained without more invasive procedures than we plan to use, so daytime light and late-evening and night-time light avoidance will be emphasised, as this should be beneficial irrespective of circadian timing at baseline.

What is useful to address will vary depending on the baseline light exposure patterns of each individual, for instance, some participants will already have plenty of daytime light and so might only need to reduce evening light. Typical changes will include:

Behavioural changes, such as:

- Going outdoors more.
- Sitting in a different place indoors where there is more natural light.
- Travelling by a different means to get more daylight, e.g., walking rather than driving
- Reducing use of light emitting screens in the evening and at night.
- Switching from main lights to dim lamps in the evening.

Environmental modification and provision of equipment:

- Provision of blackout curtains in the bedroom to reduce night-time light from street lights.
- Provision of lace / net curtains to allow curtains to be opened in the daytime without compromising privacy (windows overlooked by neighbours and passers-by).
- Moving furniture to enable sitting / working in areas with more natural light where possible.

- Fitting dim bulbs in lamps in order to allow switching to lower light in the evening.
- Provision of a sunrise alarm.
- Provision of a light box with instructions for use when natural light cannot be obtained (e.g., poor weather, limited mobility, symptoms of illness which make it difficult to go out). Use will be in accordance with manufacturers' guidelines and will supplement natural and environmental light exposure where required.

2) Nature, balance and timing of activities

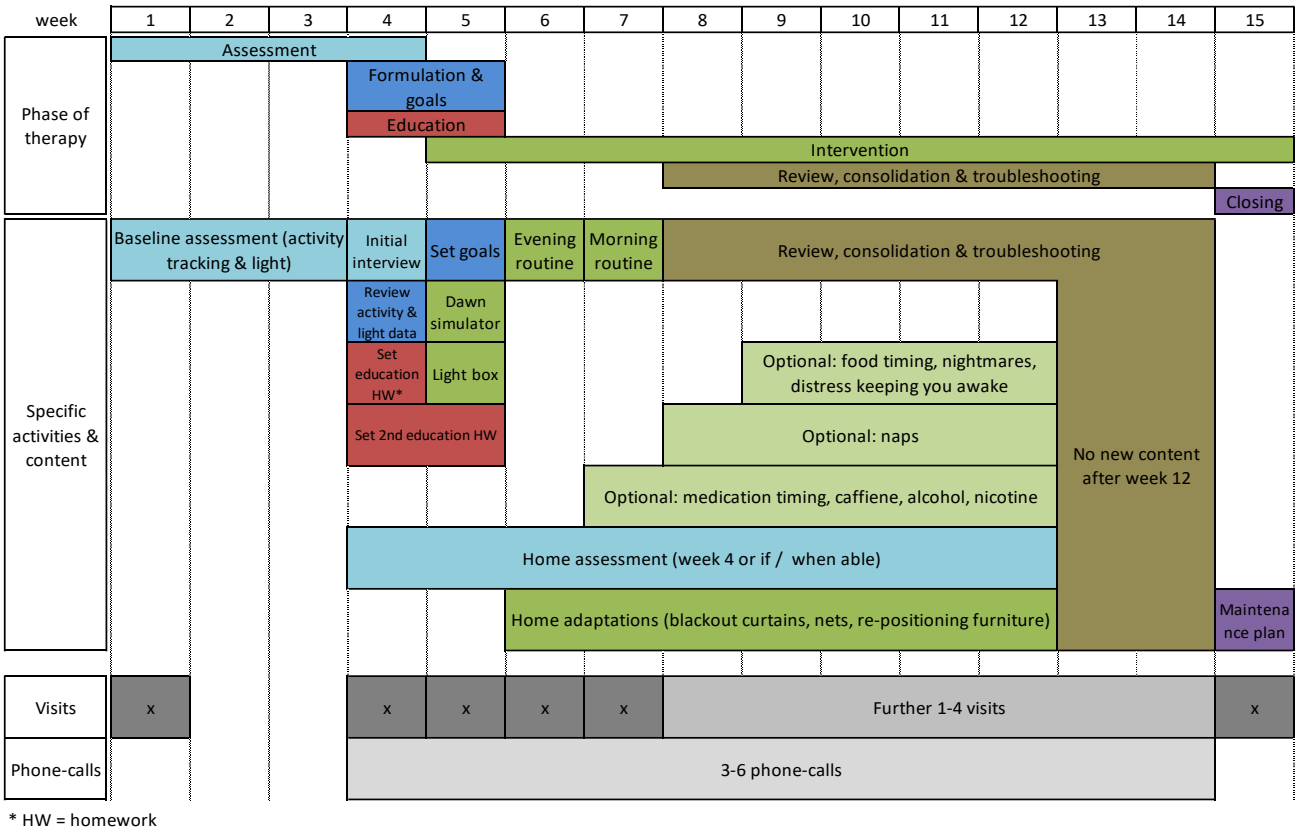
Depending on each participant's occupational routine at baseline we will address occupational imbalance, occupational deprivation, timing of occupations, and light exposure achieved during occupations. This is assessed in the initial assessment, and through wearable activity and light data. Depending on the situation this might involve changing the timing of existing activities, changing locations activities are done, introducing new activities, and potentially reducing engagement in some activities. An interests checklist will be used where participants would benefit from input to identify activities they might enjoy. Participants' values, preferences, interests and goals will be taken into account, as well as their desired changes to their sleep-wake pattern. Collaborative graded goals will be set, activity scheduling will be used, and progress monitored through self-report and output from activity and light sensors. Participants will be encouraged to monitor their own progress with physical activity and activity timing goals through the L-DART app, which will show them their activity from the Withings Move.

3) Sleep schedule modifications

The sleep opportunity window (time in bed) will be modified if needed to improve its regularity, length, and timing in relation to social and personal requirements. For some this will involve shortening the length of time in bed if it is overly long, for some this will involve increasing regularity of timing, and for some this will involve making a gradual shift in timing - if sleep timing is regular, but too early or too late. For those whose timing and length of time in bed is already appropriate, but who are unable to get to sleep and sleep through, a temporary and gradually titrated

shortening of the sleep window will be used (sleep compression), in order to increase sleep pressure and improve sleep onset and maintenance, and associations of bed with sleep. The '15-minute rule' (get out of bed if you have been awake for 15 minutes) or variants of this (using a longer period than 15 minutes, get out of bed 'if you are frustrated', or 'if you don't feel at all sleepy') will be discussed, and plans made will depend on the participant's preferences and presentation. The instruction to 'go to bed only when feeling sleepy' will be added only after evening wind-down routine has been addressed, if still needed.

Figure 2: Therapy content and progression per week of study



Research and therapy devices:

Movement sensing, light sensing, and light emitting devices will be used within the research study and the intervention. All devices have been tested by the manufacturers prior to being made available on the market, and all are available for individual consumers to purchase on the open market without prescription.

The light boxes are used outside of their CE marked purpose, and this study is not designed or powered to support any additional CE marking of these light boxes. However, the light boxes are not the subject of the study, but are used as tools (amongst others) within the therapy to modify light exposure (see Table 2).

Devices will be issued directly to participants by the research therapist.

Table 2: Devices used within the study

Device type	**Device brand and model**	**Classification and certified use of device**	**Use within this study**
Light box (medium size)	Lumie Arabica	Class 11a Medical Device, CE marked to improve energy circadian rhythm and mood in winter depression (seasonal affective disorder).	Use as per manufacturer instructions, but outside of CE mark in schizophrenia spectrum disorder. Two size options for practicality.
Light box (small size)	Lumie Vitamin L		
Wake up light	Phillips Somneo	Class 1 Medical device, CE marked for use to provide a more gradual wake up and better morning alertness.	Use as per manufacturer instructions and CE mark.
Activity tracking watch (consumer wearable)	Withings Move	Not classified as a medical device, classified as a wellbeing wearable.	For participants to self-monitor their activity patterns when making changes as part of the intervention.
Actigraphy watch (research device)	CamnTech Motionwatch 8	Class 1 Medical device, CE marked for use to measure activity, sleep and light within research.	Used as a research outcome measure. Light exposure measurements used as part of initial assessment.

Analysis:

Feasibility of therapist delivery of, and participant adherence to, the intervention:

Therapy component delivery and fidelity logs will be summarised regarding therapist's protocol non-adherence using descriptive statistics. Reasons recorded for non-adherence, and components in which non-adherence occurred, will be examined.

Although there is some flexibility in order of delivery and optional components, therapist fidelity issues could include: failure to deliver the core content, delivery of components in some way differently to the protocol, delivery content outside of its allowed time range, or significant time spent not delivering intervention content at all (for instance, this can occur if managing immediate risk, where no intervention content might be delivered that session).

Attendance at sessions will be summarised using descriptive statistics, as will reasons for missed sessions (e.g., client cancelled / postponed in advance, client did not attend, session not arranged (client unavailable), session not arranged (therapist unavailable).) Completion of the minimum number of sessions will be summarised.

Rates of completion of delivery of the core components of the intervention will be recorded, and time and sessions taken to deliver these. Contact time to deliver the intervention in total will be calculated.

Participant adherence to different elements of the homework will be summarised, including:

- watching / reading educational content.
- making self-report recordings.
- making behavioural changes / completing agreed goals (sub-categories relating to area of change, e.g., sleep timing, caffeine, screen use, daytime activities).

Qualitative reports regarding barriers and facilitators of adherence will be explored within the qualitative interviews.

Qualitative data will be compared within and between participants regarding aspects or components of the intervention which were better or worse adhered to, and these will be examined in relation to acceptability (for instance, did some participants not adhere to a certain component because it conflicted with their values, or because they did not see it as important?).

We will calculate what modifications in activity levels, light exposure patterns, and other 'intermediate' outcomes have occurred during the therapy, by comparing data from the activity tracking devices, light sensors, and self-report measures before and

after intervention. Where appropriate, comparisons to baseline values will use statistical tests for paired data.

We will make preliminary examinations of whether in individual cases and across cases, the mechanisms of change may be as proposed by background theory and expert opinion - as represented in the logic model. For instance, if the end outcome occurs, but the intermediate outcomes we supposed were responsible for causing that outcome never occurred for any participants, then this will prompt discussion and potentially revision of the logic model, and could prompt design of further exploratory or mechanism based research.

Acceptability of the intervention:

Likert ratings of satisfaction will be summarised using descriptive statistics and graphed for each participant and will accompany the qualitative acceptability data and week-by-week therapy component delivery log. We will examine whether there are any particular therapy components whose delivery are associated with higher or lower ratings of satisfaction by examining satisfaction average ratings on weeks during and after these are given, and by triangulating with qualitative data.

Semi-structured qualitative interviews will be analysed using a framework approach in Nvivo software. Transcripts will be separately analysed by the qualitative interviewer researcher and by the CI. An a-priori coding frame will be developed containing descriptive codes, and further analytic codes will be developed during analysis.

Feasibility of larger scale testing of the intervention, and future implementation:

Rates of eligible participants will be summarised, as will number of declines, with reasons given (or no reason given). Recruitment rates per month and by the end of the study will be summarised. Attrition from the study will be summarised both during the intervention and from follow-up.

Problem subtypes, problem clusters or phenotypes for which the intervention is more or less adhered to or more or less effective will be examined by reference to qualitative data predominantly, as quantitative data will be underpowered to detect differences between groups. Instead quantitative data will be examined alongside the qualitative data.

Pre-post change and variance will be calculated for each measure in order to begin to inform future sample size calculations. Outcome measures (both content and change captured) will be compared to the quantitative data regarding factors participants deemed important, in order to inform selection of measures and selection of a primary outcome for a future larger study. Acceptability of measures, face validity and perceived relevance, will be ascertained through analysis of the qualitative interview. Participant burden of measures will be ascertained from the qualitative interview and also through timing completion. Levels of completion on measures will be calculated, and any particular items or measures with higher rates of non-completion will be noted (with reasons if these can be ascertained from researcher notes or the qualitative interviews).

Self-report and passive data channels will be examined in order to inform which are most practical and useful in a larger future study, and for use within the intervention.

Time taken to deliver components, and to deliver the intervention overall, will be examined in case efficiencies or problems can be identified. Recruitment logs will be examined regarding reasons for ineligibility and therapy related reasons for declines (when reason given), as these could affect future implementation in clinical practice as well as larger scale testing (www.RE-AIM.org, 2019).

Safety considerations and adverse events:

It is not anticipated that any aspect of L-DART poses a high risk of harming participants, however, the potential risks include:

- Eye strain / discomfort
- Headache
- Migraine (in those who experience migraine)
- Sunburn (going outdoors)

- Risk of falls (reducing evening illumination)
- Distress when discussing sleep or something related to sleep
- High or low energy and mood

Eye-strain, or a headache, should go away if the person stops using the light box. Some people get used to the light box so that it no longer causes them discomfort, or sit farther away to reduce the brightness.

Light therapy boxes don't cause sunburn, but increasing time outdoors could. We will talk to participants about how to avoid sunburn when we talk about going outside more.

Reducing evening illumination and installation of blackout curtains poses the potential to increase risk of falls. This will be reduced by advising participants on how to ensure sufficient light to safely move around at night (for instance, using the 'midnight light' mode on the Phillips Somneo wake-up light for night-time bathroom trips), and by encouraging clear thoroughfares without trip hazards.

With an increase in light exposure comes a potential risk of hypomania or agitation, however, light therapy using light boxes has been used in patients with bipolar without this causing mania (Sit et al., 2017; Sheaves, Freeman, et al., 2018). Participants with schizoaffective disorder will be gradually and cautiously introduced to light exposure. Participants mental state and functioning will be monitored when time in bed is being shortened. Participants will be advised not to drive or operate heavy machinery if they feel sleepy.

Adverse effects monitoring and recording:

Participants will be asked about any adverse effects they might have experienced from any aspect of the intervention at each session by the therapist, and these will be recorded on the adverse effects checklist, including notes regarding to what the effect is attributed (e.g., from use of the light box, from sleep schedule changes).

Adverse Events monitoring and reporting:

Adverse effects and adverse events will be monitored and recorded. These will be discussed routinely at intervals with the therapist researcher's clinical academic supervisor Professor Richard Drake. More serious adverse events (whether intervention related or not) will be reported and discussed with Richard Drake as soon as practicably possible. Decisions and categorisations will be made regarding

severity and potential intervention relatedness, and where ambiguity or uncertainty exists, cases will be discussed with an independent expert (Professor Bill Deakin). Serious Adverse Events (SAEs) will be reported to the Research Ethics Committee if they are intervention related and unexpected.

Discussion and Conclusions:

Sleep problems in people with diagnosis of schizophrenia spectrum disorder require treatment as part of routine care. If a relatively brief and cost-effective sleep treatment can be evidenced, recommended and implemented, this has the potential to improve quality of life and functional outcomes for this group. Cost savings elsewhere in services due to reduced relapse are also a real possibility. The findings of this study will form the first stage in this process, by informing any necessary modifications to the intervention and its materials, enabling the development of a stage 2 manual, and a therapist training package. If feasible, the results will support design of a larger scale multi-therapist feasibility study. Findings of this study will be disseminated via a peer reviewed journal, and to study participants and referrers in a more accessible format.

References:

1. Wulff K, Dijk D-J, Middleton B, Foster RG, Joyce EM. Sleep and circadian rhythm disruption in schizophrenia. Br J Psychiatry [Internet]. 2012 Apr [cited 2014 Oct 20];200(4):308–16. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3317037&tool=pmcentrez&rendertype=abstract

2. Krystal AD, Thakur M, Roth T. Sleep Disturbance in Psychiatric Disoders: Effects on Function and Quality of Life in Mood Disorders, Alcoholism, and Schizophrenia. Ann Clin Psychiatry. 2008;20(1):39–46.

3. Spiegel K, Knutson K, Leproult R, Tasali E, Van Cauter E. Sleep loss: a novel risk factor for insulin resistance and Type 2 diabetes. J Appl Physiol [Internet].

2005 Nov [cited 2014 Nov 4];99(5):2008–19. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16227462

4. Meerlo P, Sgoifo A, Suchecki D. Restricted and disrupted sleep: effects on autonomic function, neuroendocrine stress systems and stress responsivity. Sleep Med Rev [Internet]. 2008 Jun [cited 2014 Sep 16];12(3):197–210. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18222099

5. Haus EL, Smolensky MH. Shift work and cancer risk: potential mechanistic roles of circadian disruption, light at night, and sleep deprivation. Sleep Med Rev [Internet]. 2013 Aug [cited 2014 Oct 25];17(4):273–84. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23137527

6. Afonso P, Brissos S, Cañas F, Bobes J, Bernardo-Fernandez I. Treatment adherence and quality of sleep in schizophrenia outpatients. Int J Psychiatry Clin Pract [Internet]. 2014 Jan [cited 2014 Oct 20];18(1):70–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24047426

7. Wulff K, Joyce E. Circadian rhythms and cognition in schizophrenia. Br J Psychiatry. 2011;198(4):250–2.

8. Auslander LA, Jeste D V. Perceptions of problems and needs for service among middle-aged and elderly outpatients with schizophrenia and related psychotic disorders. Community Ment Health J [Internet]. 2002;38(5):391–402. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed5&NEWS=N&AN=2004163305

9. Waite F, Evans N, Myers E, Startup H, Lister R, Harvey AG, et al. The patient experience of sleep problems and their treatment in the context of current delusions and hallucinations. Psychol Psychother Theory, Res Pract [Internet]. 2015;89:181–193. Available from: http://doi.wiley.com/10.1111/papt.12073

10. Faulkner S, Bee P. Experiences, perspectives and priorities of people with schizophrenia spectrum disorders regarding sleep disturbance and its treatment: a qualitative study. BMC Psychiatry [Internet]. 2017;17(1):158. Available from: DOI 10.1186/s12888-017-1329-8

11. Jagannath A, Peirson SN, Foster RG. Sleep and circadian rhythm disruption in neuropsychiatric illness. Curr Opin Neurobiol [Internet]. 2013 [cited 2014 Nov 4];23(5):888–94. Available from: http://dx.doi.org/10.1016/j.conb.2013.03.008

12. O'Sullivan M, Rahim M, Hall C. The prevalence and management of poor sleep quality in a secondary care mental health population. J Clin Sleep Med. 2015;11(2):111–6.

13. Faulkner S, Mairs H. An exploration of the role of the occupational therapist in relation to sleep problems in mental health settings. Br J Occup Ther [Internet]. 2015;78(8):516–24. Available from: http://bjo.sagepub.com/lookup/doi/10.1177/0308022614564771

14. Bersani FS, Iannitelli A, Pacitti F, Bersani G. Sleep and biorythm disturbances in schizophrenia, mood and anxiety disorders: A review. Riv Psichiatr. 2012;47(5):365–75.

15. Eklund M, Erlandsson L, Leufstadius C. Time use in relation to valued and satisfying occupations among people with persistent mental illness: Exploring occupational balance. J Occup Sci. 2010;17(4):231–8.

16. Ilanković A, Damjanović A, Ilanković V, Filipović B, Janković S, Ilanković N. Polysomnographic sleep patterns in depressive, schizophrenic and healthy subjects. Psychiatr Danub. 2014;26(1):20–6.

17. Afonso P, Figueira ML, Paiva T. Sleep-wake patterns in schizophrenia patients compared to healthy controls. world J Biol psychiatry [Internet]. 2014;15:517–24. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23316764

18. Faulkner S, Drake R, Dijk D-J, Bee P. Development of an occupational therapy intervention to improve sleep in people with schizophrenia spectrum disorders. IRAS ID 228454. Unpubl Rep. 2019;

19. Faulkner S, Bee P. Perspectives on Sleep, Sleep Problems, and Their Treatment, in People with Serious Mental Illnesses: A Systematic Review. PLoS One [Internet]. 2016;11(9):e0163486. Available from: doi.org/10.1371/journal.pone.0163486

20. Kyle SD, Aquino MRJ, Miller CB, Henry AL, Crawford MR, Espie CA, et al. Towards standardisation and improved understanding of sleep restriction therapy for insomnia disorder: A systematic examination of CBT-I trial content. Sleep Med Rev. 2015;23:83–8.

21. Miller CB, Espie CA, Epstein DR, Friedman L, Morin CM, Pigeon WR, et al. The evidence base of sleep restriction therapy for treating insomnia disorder. Sleep Med Rev. 2014;18(5):415–24.

22. Matthews EE, Arnedt JT, McCarthy MS, Cuddihy LJ, Aloia MS. Adherence to cognitive behavioral therapy for insomnia: A systematic review. Sleep Med Rev [Internet]. 2013;17(6):453–64. Available from: http://dx.doi.org/10.1016/j.smrv.2013.01.001

23. Pauley SM. Lighting for the human circadian clock: recent research indicates that lighting has become a public health issue. Med Hypotheses [Internet]. 2004 Jan [cited 2014 Nov 4];63(4):588–96. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15325001

24. Fung C, Wiseman-Hakes C, Stergiou-Kita M, Nguyen M, Colantonio A. Time to wake up: bridging the gap between theory and practice for sleep in occupational therapy. Br J Occup Ther [Internet]. 2013;76(8):384–6. Available from: http://openurl.ingenta.com/content/xref?genre=article&issn=0308-0226&volume=76&issue=8&spage=384

25. Solet JM. Sleep and rest. In: Schell BA, Gillen G, Scaffa M, Cohn ES, editors. Willard and Spackman's Occupational Therapy. 12th ed. Philadelphia: Wolters Kluwer - Lippincott Williams and Wilkins; 2014. p. 714–30.

26. Creek J. Occupational therapy defined as a complex intervention. London: College of Occupational Therapists; 2003.

27. Green A, Brown C. An Occupational Therapist's Guide to Sleep and Sleep Problems. London: Jessica Kingsley Publishers; 2015.

28. Brown C. Pre-Conference Workshop: The Occupation of Sleep [Internet]. 2016 [cited 2016 May 2]. Available from: http://www.caot.ca/default.asp?pageid=3984

29. Teddlie C, Yu F. Mixed Methods Sampling: A Typology With Examples. J Mix Methods Res. 2007;1(1):77–100.

30. Bastien C, Valliers A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Med. 2001;2:297–307.

31. Morin CM, Belleville G, Bélanger L, Ivers H. The insomnia severity index: Psychometric indicators to detect insomnia cases and evaluate treatment response. Sleep. 2011;34(5):601–8.

32. Yu L, Buysse DJ, Germain A, Moul DE, Stover A, Dodds NE, et al. Development of Short Forms From the PROMISTM Sleep Disturbance and Sleep-Related Impairment Item Banks. Behav Sleep Med. 2011;10(1):6–24.

33. Buysse DJ, Yu L, Moul DE, Germain A, Stover A, Dodds NE, et al. Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments. Sleep [Internet]. 2010;33(6):781–92. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2880437/

34. Tennant R, Hiller L, Fishwick R, Platt S, Joseph S, Weich S, et al. The Warwick-Edinburgh mental well-being scale (WEMWBS): Development and UK validation. Health Qual Life Outcomes. 2007;5:1–13.

35. Janssen MF, Pickard AS, Golicki D, Gudex C, Niewada M, Scalone L, et al. Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: A multi-country study. Qual Life Res. 2013;22(7):1717–27.

36. Hahn EA, DeVellis RF, Bode RK, Garcia SF, Castel LD, Eisen S V., et al. Measuring social health in the patient-reported outcomes measurement information system (PROMIS): Item bank development and testing. Qual Life Res. 2010;19(7):1035–44.

37. Haro JM, Kamath SA, Ochoa S, Novick D, Rele K, Fargas A, et al. The Clinical Global Impression-Schizophrenia scale: A simple instrument to measure the diversity of symptoms present in schizophrenia. Acta Psychiatr Scand Suppl. 2003;107(416):16–23.

38. Skeldon AC, Phillips AJK, Dijk D-J. The effects of self-selected light-dark cycles and social constraints on human sleep and circadian timing: a modeling approach. Sci Rep [Internet]. 2017;7(45158). Available from: http://www.nature.com/articles/srep45158

39. Faulkner SM, Bee PE, Meyer N, Dijk DJ, Drake RJ. Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: A systematic review and meta-analysis. Sleep Med Rev [Internet]. 2019;46:108–23. Available from: https://doi.org/10.1016/j.smrv.2019.04.012

40. Cajochen C. Alerting effects of light. Sleep Med Rev [Internet]. 2007 Dec [cited 2014 Nov 4];11(6):453–64. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17936041

41. Xu Q, Lang CP. Revisiting the alerting effect of light: A systematic review. Sleep Med Rev [Internet]. 2018;41:39–49. Available from: https://doi.org/10.1016/j.smrv.2017.12.001

42. www.RE-AIM.org [Internet]. 2019 [cited 2019 Jun 17]. Available from: www.re-aim.org

Chapter 10: Discussion

10.1. Overview of findings

This thesis first presented a meta-analysis of the effect of light treatment on sleep problems in mental illness, then a systematic review of the adherence to and acceptability of these treatments. There were too few studies confined to schizophrenia spectrum disorders (SzSD) to focus exclusively on these; however, results of studies in related populations with other severe mental illnesses appeared relevant. These reviews were followed by a mixed methods expert opinion study on the optimum content and delivery for a non-pharmacological sleep treatment in SzSD. These studies were then synthesised to inform the design of an intervention protocol. Surveys with potential referrers and potential intervention recipients were conducted to evaluate demand, and potential factors influencing intervention implementation and roll out. Finally, the protocol for the initial small-scale feasibility testing of an intervention, L-DART, was presented.

The MRC process for development and evaluation of complex interventions has been followed: reviewing evidence, exploring stakeholder views, and taking these sources into account in the design of an intervention, followed by development of a mixed methods feasibility study protocol. This should ensure that the intervention and study procedures are well developed before more substantial funds and participant time are devoted to a larger trial.

The findings and outputs of Chapters 4-9 are summarised in Table 35. The implications of Studies A-C for the development of L-DART were described in the synthesis chapter (Chapter 7). This discussion will now address broader implications of this work, and incorporate the findings of Study D.

Table 35: Main findings and outputs of chapters 4-9

	Chapter 4: Study A	**Chapter 5: Study B**	**Chapter 6: Study C**	**Chapter 7: Synthesis**	**Chapter 8: Study D**	**Chapter 9: Protocol**
Topic	Light / dark therapy in groups prone to ~CRSWD		Intervention to improve sleep in SzSD by occupational therapists			
Method	Meta-analysis with meta-regression.	Systematic review with narrative synthesis.	Mixed methods expert opinion study.	Synthesis of earlier findings.	Cross-sectional surveys.	Protocol paper for a mixed methods feasibility study.
Aims / Purpose	Effectiveness. Effect moderators.	Acceptability, adherence and adverse effects.	Intervention development.		Examination of implementation issues.	Intervention feasibility testing.
Main Findings / Outputs	Light / dark therapy compared to control condition showed: ▪ increased sleep continuity ▪ reduced self-reported sleep disturbance on composite measures ▪ advance of sleep timing in DSWPD. ▪ Evening light avoidance was associated with larger effects on TST in meta-regression.	Poor measurement and reporting of feasibility outcomes, but suggests: ▪ good acceptability / satisfaction ▪ good recruitment, low attrition, possibly good adherence ▪ few, mostly minor adverse effects. ▪ Interventions typically showed limited personalisation and many resembled lab protocols.	Strongest consensus re: ▪ evening routine ▪ activity and occupation interventions ▪ home environment interventions ▪ personalisation. ▪ Disagreement over some areas. ▪ Conflict between 'keeping it simple', and many optional components. **Outputs**: L-DART initial manual, and associated materials.		▪ Staff and service users commonly identify sleep problems and want a therapy like L-DART. ▪ More training is associated with better staff confidence re sleep ▪ Staff were less likely to refer service users with primary substance misuse, with no diagnosis, or with SzSD. ▪ Service from which recruited was a confounder of diagnosis and sleep problem.	**Outputs**: ▪ Protocol. ▪ Ethics obtained. ▪ Study set-up.

10.2. Strengths and limitations of this thesis

10.2.1. Strengths and limitations of the systematic reviews

The systematic reviews were conducted and reported according to established standards (Smith and Egger, 2008; Moher et al., 2009), using a systematic search and screening strategy. This enabled them to highlight credibly where more research is needed, as well as the current state of empirical evidence relevant to light therapy for sleep problems in SzSD.

The systematic reviews chose to focus on a single intervention component (altering light exposure patterns) in order that study results could meaningfully be synthesised. This necessitated that there were other sleep intervention components for which this thesis includes less evidence synthesis. This included time in bed restriction, stimulus control and relaxation. Separate reviews on these topics would have strengthened the development of the intervention but this was not feasible within time and the resources available; these topics received narrative review in the background section, and decisions were then shaped by expert opinion findings and PPI. The focus on circadian factors for systematic evidence synthesis does not imply that circadian factors are *more* important in SzSD than other sleep disrupting factors such as insomnia processes, only that circadian factors had received comparatively less attention, and thus this work attempts to redress this. Other intervention components were reviewed using narrative synthesis of primary evidence gathered through searches conducted using systematic principles and reading of existing evidence syntheses (presented in the background [Chapter 1] and Synthesis [Chapter 7]).

10.2.2. Strengths and limitations of the mixed methods expert opinion study and stakeholder surveys

The primary research studies presented have incorporated service user perspectives, in the mixed methods expert opinion study (Study C) and in surveys (Study D). These views have been triangulated with health professionals' views using the same methods. Patient public involvement (PPI) contributors worked within the research team and guided the aims and phrasing of the questions for both service user and staff participants. Both studies recruited a diverse range of professionals with a

variety of relevant service experience, and a diverse range of service users in terms of age, gender, ethnicity, and service involvement.

10.2.2.1. Mixed methods expert opinion study methods limitations

In this study professionals' opinions were sought in three survey rounds, and then service users' and carers' opinions were sought in an in-person modified nominal group technique session. Requesting service user and carer participants in the modified nominal group technique session to rank items on paper was unsuccessful. Without 1 to 1 researcher support many participants assigned the same ranking to multiple items even after careful explanation. Ranking items is more cognitively demanding and attempts to force participants to differentiate between things they may see as equivalent or not comparable (Nobarany et al., 2012). Data quality may have been enhanced by doing this electronically or using a template with cards or moveable stickers to arrange into an order.

In the paper, it was noted that adding the option for remote participation or delayed participation could have been helpful. Having the modified Nominal Group Technique session with participants with personal experience entirely face to face limited how long participants with personal experience had to complete written responses. This may have contributed toward receiving shorter responses from participants with personal experience than from topic experts (who were responding in their own time). Whilst perhaps some participants might have given short responses no matter what, others might have had more to say given more time or if content had been provided in advance.

It has been argued that asynchronous data collection (e.g., remote interviews conducted by email or message rather than 'live') can enable more in-depth responses and a more collaborative approach, by allowing more time for participants to think about their response (James, 2016; Spencer et al., 2021). We decided on an in-person event to avoid biasing our sample toward people with higher literacy and computer skills, but it would have been possible to follow a hybrid approach, allowing those who wished to comment further online or by post to do so within a set time period afterwards. This suggestion is partly inspired by the multi-modal and personalised approach to technology that the mixed methods expert opinion study suggested should be employed in the intervention, and appears equally relevant to research data collection.

10.2.2.2. Limitations and learning from the survey study

The survey enabled us to reach 147 staff and 190 service user participants, including many who might not have taken part in a study requiring more time commitment. Its main limitation was that it did not recruit a random sample. The apparent association of schizophrenia with better sleep, driven by participants from clozapine clinics in NHS Trust #2, underlines the importance of controlling for confounders. One approach that addresses the problems of confounding is to sample purposively by service or treatment, and to take steps to increase returns from under-represented groups in order to improve generalisability. However, such approaches rely on a relatively high uptake to reach targets. An alternative approach, needing fewer resources, may have been to have more detailed capture of the source of responses in anonymous participation surveys (e.g., 'where did you hear about this survey' options), enabling a fuller examination of potential confounders.

Given more resources, reimbursement may have increased response rates, allowing a different recruitment model with fewer, more focussed invitations; although, foregoing the altruistic ethos of the survey might have introduced its own biases. Similarly, a more demanding model where the same patients reported upon by staff were themselves surveyed could have generated paired data and allowed us to investigate the agreement between these sources.

With hindsight, the service user survey could have utilised a standardised measure of sleep disturbance, such as the ISI, or PROMIS-SD (6 or 8 item version). The approach was designed to mirror the staff survey, however as the service user survey was self-report, this opened the option to use one of various short, validated measures. This could have provided a better means of comparison with other research samples, and also provided a more accurate estimate of the levels of clinically relevant sleep problems, than using custom self-report items.

10.3. Findings regarding use of light-dark exposure modification interventions

The synthesis of the somewhat limited available evidence suggests light therapy may be beneficial for sleep problems, particularly for some types of sleep problems in some groups, despite possible suboptimal delivery in some protocols (Study A). Although evidence of efficacy for light could be stronger, it is relevant to consider

the limited side effect profile, and relatively good acceptability and adherence in intervention studies (Study B). Prospective views from service user participants in the intervention design study (Study C), and survey participants (Study D) paint a less enthusiastic picture, with light being one of the less endorsed components, or with participants having less confidence in it (Study C). Similar to discussion within the survey paper, this demonstrates how a different view is obtained depending on the type of study approach.

The burden of making alterations to one's pattern of light-dark exposure is highly variable, depending on the specific light exposure protocol, and the person's routine and sleep pattern at baseline (Study B). Some life events, mental health crises, or heavy substance use might prohibit behavioural sleep treatments generally (Study D). Professionals and clients acknowledge difficulties in undertaking the types of changes in behaviour required to alter light exposure patterns, and education on light and circadian rhythm may be an important factor in adherence (Study C). Provision of education has seldom been described in previous light treatment studies (Study B), but this was a key component endorsed by professional experts and service users alike (Study C).

These findings taken together suggest clinical use of light-dark alterations should sometimes be recommended, but in other cases the expected burden and difficulty of undertaking to make alterations to light exposure patterns would not be worthwhile on the basis of relatively weak evidence and modest average effects. These conclusions roughly concur with a previous review (van Maanen et al., 2016), and with the American Academy of Sleep Medicine Practice Guidelines for treatment of intrinsic CRSWD, which weakly recommended light therapy (for delayed, irregular, and advanced sleep phase disorders) or describe insufficient evidence (sighted Non-24) (Auger et al., 2015).

Our findings and interpretation differ from those of Auger et al, in that neither our meta-analysis, nor mixed methods expert opinion study recommended increased evening light exposure to correct (delay) advanced sleep timing. This was due to a lack of empirical results suggesting benefit, and theoretical concerns that because of its acute alerting effect, that bright evening light might impair sleep quality or increase sleep onset time.

If the client has a diagnosis, or probable diagnosis, of insomnia, and if the option for CBTi referral is available and acceptable, then CBTi should be recommended ahead of light treatment. CBTi has a strong evidence base for improvement of subjective sleep complaints (Zachariae et al., 2016; van Straten et al., 2018; Mitchell et al., 2019), including in co-morbid insomnia (Taylor and Pruiksma, 2014; Geiger-Brown et al., 2015). Of course CBTi and light-dark interventions can be, and have been, combined with good effect (Danielsson et al., 2016a; Sheaves, Isham, et al., 2018a; Janků et al., 2020), sometimes better than CBTi alone (Janků et al., 2020). Mixed methods expert opinion study participants who did not prioritise light exposure did so only in so far as it may take up time and distract from other aspects of the intervention such as sleep scheduling, time in bed restriction or stimulus control.

Examples of cases where light-dark interventions might be recommended ahead of CBTi include those where the sleep problem appear to be more circadian (e.g., delayed or non-24-hour pattern), with less rationale to recommend CBTi. At higher latitude in winter, light interventions would be likely to have more effect, because there is less natural light. This was supported by expert opinion (and theory) but meta-regression found no difference in effects, although the utility of this latter analysis was reduced by limited reporting of season of administration.

A significant motivator for recommendation of light-dark interventions for CRSWD or ~CRSWD is that, unlike with insomnia, there are few and poorly researched alternatives. The only other treatment which American Academy of Sleep Medicine has summarised as having weak positive evidence is timed oral melatonin / melatonin agonists (Auger et al., 2015). As summarised in the background, there is promising initial evidence for melatonin / melatonin agonists in SzSD (Shamir et al., 2000; Kumar et al., 2007; Mishra et al., 2020), but service users should ideally have a choice between pharmacological and behavioural options. In future, the timed use of such compounds could complement a non-pharmacological approach such as L-DART. An advantage of add-on melatonin is that there is limited additional time burden for patients, and if scheduling of light and sleep timing is already being addressed, then scheduling of melatonin administration does not add as much labour for the patient or staff. There could be a case for testing melatonin with and without such behavioural interventions.

Although this thesis has focused on treatment of poor sleep in SzSD, low mood, depression and feeling low in energy are also common in people with SzSD (Firth et al., 2016; Upthegrove et al., 2017; Vancampfort et al., 2017). Thus, in practice it is likely that clinicians may look toward light therapy to target a combination of mood, energy and sleep complaints, which may interact. Light therapy has a moderately strong evidence base for improving low mood in seasonal, non-seasonal and bi-polar depression (Cunningham et al., 2019; Geoffroy et al., 2019; Maruani and Geoffroy, 2019), although studies in schizophrenia and schizoaffective disorder are limited. The theoretical rationale for, and expert opinions supporting, light treatment for combined low mood, low energy and poor sleep in SzSD, suggest that such an intervention should be tested for this indication.

Although natural light, and even light boxes and other equipment, are relatively cheap and accessible, the challenge clinically comes from access to expertise within teams. It requires expertise both to prescribe appropriately personalised light exposure for the person's circumstance and problem, and to deliver this in a manner that best facilitates behaviour change. At present, sleep and circadian rhythm expertise are limited in mental health services in the UK. There are sleep specialist clinicians working in mental health, some of whom participated in our mixed methods expert opinion study (Study C), but most mental health services do not have such specialists. Mental health service staff report poor knowledge of, and confidence in, treating sleep problems (Faulkner and Mairs, 2015; Rehman et al., 2017; Barrett et al., 2020). This may be a little better in general practitioners (Hassed et al., 2012; Ashraf et al., 2016), particularly with reference to circadian dysregulation (Hassed et al., 2012). Light therapy is more commonly used by psychiatrists in clinical practice in parts of Europe and North America (personal communication, various, SLTBR Groningen 2019) but even there this is mostly to address seasonal, and to a lesser extent non-seasonal, depression. Light therapy is seldom applied to SzSD, and is used less often to target sleep than it is to target mood (Fischer et al., 2012; Oldham and Ciraulo, 2014b).

Light therapy adherence is poorly measured and reported in research; assessment of adherence in simple light box studies have been demonstrated by a few studies and it was proposed that these are more widely used (Study B). Light exposure modification interventions may be delivered in a flexible and bespoke manner but

customisation makes measurement and operationalisation of adherence difficult. Unobtrusive ambulatory light monitoring technologies may improve this in future, although algorithms may be needed to make this information simple enough to discuss within a clinical encounter, and to translate into specific advice capable of improving adherence.

10.4. Light and environmental design

A case where light exposure changes brings little or no burden is environmental alteration to improve light exposure patterns. Environmental changes were suggested and supported by professional experts and people with personal experience (Study C), some noting these were worth doing even if effects may only be small. Environmental interventions to improve sleep have rarely been studied outside of dementia (Studies A and B). Even though individual responses can vary, bringing a light exposure pattern closer to that of the natural day-night cycle, is generally thought to be beneficial; which for most people in industrialised countries means increasing daytime light and reducing light in the evening and at night (International Commission on Illumination (CIE), 2019). Traditional approaches to building lighting provide adequate light for vision, but this may not provide optimal circadian or acute alerting stimulus. Circadian researchers recommend increased consideration of these non-visual effects of light in architecture and lighting design (Lucas et al., 2014; International Commission on Illumination (CIE), 2016; Khademagha et al., 2016), including due consideration of how daylight is allowed into buildings, and use of 'dynamic lighting' which simulates outdoor light patterns (Sanders and Oberst, 2017).

L-DART can perhaps be criticised for not going far enough with environmental light modification, as this collaborative intervention relies on the service user to, (for example) draw the curtains, switch to a dim light in the evening, turn on the light box, or go outside. We considered adopting a more technologically automated approach by using dynamic lighting (e.g., the Philips Hue System) as used in some studies included in the reviews of Studies A and B. Automatic dimming of domestic lighting in the evening, and integrated dawn simulation, might provide value and would reduce intervention burden, as long as the recipient was happy to accept this environmental modification. The key barrier to using such a system in domestic settings is the requirement for the person to have home internet (needed for the

automated light scheduling to work). People with severe mental illnesses have less internet access than the general population (Spanakis et al., 2021), and may rely more on mobile data, as opposed to home broadband. Using a method requiring home internet would likely exclude a large proportion of potential participants.

Additionally, the maximum brightness obtained in the daytime from a domestic light bulb is much less (~150-300 lux) than outdoor light even on an overcast day (>1000 lux) (Duffy and Wright, 2005; Figueiro et al., 2015) 2005). It is also less than a light box used at appropriate distance (>1000 lux). Thus, to gain anticipated benefits of increasing daytime light exposure, additional daytime light supplementation would likely still be required. Sleep interventions on a ward might be more easily able to use technology to automate daily timed lighting changes. As discussed in Studies A and B, this has been trialled in dementia settings (Van Someren et al., 1999; Sloane et al., 2007), but not yet in SzSD or on mixed diagnosis mental health wards. There are also other environmental factors known to affect sleep which may be more pertinent or more amenable to change through intervention at a ward or unit level than in domestic settings. These include factors such as noise, temperature, institutional routines, and safety observations (Tamrat et al., 2014; Norton et al., 2015; Dubose and Hadi, 2016; Stiver et al., 2017). Future research could design and evaluate environmental changes aimed at improving sleep at an institutional level, potentially leading to cluster-randomised evaluation of environmental interventions.

An effective but expensive method to improve light-dark patterns indoors is through improved architectural design. Building orientation, shading by other buildings, wall to window ratio and room depth can all have a significant impact on the circadian lighting received indoors (Altenberg Vaz and Inanici, 2021; Potočnik and Košir, 2021). Access to recreational green spaces is associated with better health outcomes (Geneshka et al., 2021), including lower risk of developing schizophrenia (Chang et al., 2019). Researchers have examined green space and health in relation to physical activity; however, increased daytime light exposure when green space is more abundant may also play a role (Munch and Bromundt, 2012; Wright et al., 2013). Unfortunately, societal factors are difficult to modify for an individual therapist. L-DART has identified minor adaptions such as modifying window coverings, but the extent to which these changes can improve daily light exposure patterns will

require a robust feasibility study with valid measurement of ambulatory light to evaluate. It is likely that the alteration to light exposure patterns through these means will be modest compared to what could be achieved through architectural and city-planning changes. Behaviour changes in how people use available space may have more impact, as the location and orientation of the person in relation to existing windows has been shown to make a lot of difference to the circadian stimulus received (Konis, 2018; Altenberg Vaz and Inanici, 2021).

Prior light exposure has been shown to predict subsequent sleep, not just experimentally but also in the field (Wams et al., 2017). Economic deprivation is common in those with SzSD, and there are a number of reasons that people in more economically deprived groups may have poorer light exposure; including, increased shift work, smaller windows, less access to private outdoor space, and less ready access to public green spaces. Prolonged poor light exposure in economically deprived groups may contribute to worse health outcomes. Socio-economic health inequality is increasing, and the NHS Long Term Plan aims to reduce this (NHS, 2019). The physical and mental health impacts of light environments should be investigated in the future. This could establish a case for regulation and investment in this area, to improve the wellbeing of all. Equally, if it were shown that people with SzSD (and / or other groups) are more sensitive to the adverse effects of poor light exposure, there could even be a case for differential treatment when allocating housing. Depending on the extent of its impact, this environmental accommodation may be comparable to other disability adaptations currently accepted as fair and necessary under UK legislation (Housing Grants Construction and Regeneration Act 1996, 1996; Care Act 2014, 2014). Notably the Care Act describes a duty for provision of facilities and resources (e.g., equipment, adaptations, or support) to prevent, delay or reduce health needs arising, so this could be applied to reducing the risk of psychotic relapse.

10.5. Research implications regarding non-pharmacological sleep interventions in SzSD

Study B showed that it is possible to recruit well to light therapy studies and that attrition is low. Intervention adherence may be high but could be measured and described more thoroughly. Appendix 7 and Study D (surveys) suggest it may also be possible to recruit well to multi-component sleep interventions including light

among other components. Attrition and adherence to light exposure modification may be worse as part of multi-component interventions than in single component interventions. This is likely for two main reasons: 1) other components add more burden and may distract from the light exposure elements, 2) participants who are less interested or less persuaded of light therapy may enrol in a multi-component intervention study, and then be less keen to undertake the light exposure component. These people would presumably be less likely to enrol in a pure light therapy study, which may over-represent those who are keen for light therapy. Although initial feasibility testing could begin to address research attrition and intervention adherence, a larger scale study will be needed to estimate these effects accurately.

The mixed methods expert opinion study highlighted potential problems with acceptability, adherence, and effects of stimulus control in people with SzSD, particularly the importance of framing and delivering this advice. Stimulus control is a relatively simple, core component of CBTi (M. L. Perlis et al., 2010). The way stimulus control may remove unhelpful rumination in bed appears particularly relevant to people with SzSD, who are prone to excessive rumination, and to unhelpful strategies to respond to worry (Morrison and Wells, 2000), but our findings raised doubts regarding its acceptability and effects. It is possible that these very differences in how people with schizophrenia respond to worry might interact with attempts to utilise stimulus control, making it harder to apply successfully. Qualitative and mixed methods findings from the feasibility study, the protocol of which is presented in Chapter 9, should further clarify how stimulus control advice is received and perceived, and more focused study may be warranted.

10.6. Directions for further research

This thesis has developed an intervention based on the best existing evidence and opinions, answering questions about effectiveness and acceptability of light therapy, opinions on optimal contents and format for an occupational therapist delivered sleep intervention in SzSD, the need for such an intervention, and potential implementation issues (see Table 35). It has also highlighted many unanswered questions which may further inform the refinement of L-DART and similar therapies.

Background evidence and expert opinion alike highlighted that irregular, free-running, or abnormally timed rest-activity patterns are present in a large proportion

of people with SzSD (Wulff et al., 2012; Meyer et al., 2018). It has been suggested that these patterns might be influenced by genetic factors (Jagannath et al., 2013), and by abnormal environmental exposures such as less daylight exposure (Meyer, 2020). The development of L-DART has assumed that environment and routine play some role and that there is the possibility of change through behavioural intervention. Further cross-sectional work, and modelling the impact of changes in light exposure, may inform future intervention refinement (Skeldon et al., 2017; Meyer et al., 2019). Similarly, experimental work using different types of light exposure modifications, with tightly controlled adherence management and / or monitoring methods, could establish some useful parameters to guide intervention. Questions which could be asked which might be informative for L-DART and similar interventions are summarised in Table 36.

Table 36: Research questions to further inform L-DART and similar interventions

Question which could be addressed	**Potential methods which could be employed**	**How could this inform L-DART and similar interventions**
How long should be spent outdoors for optimal circadian stimulus and within what time range? At what point are there diminishing returns? How does this vary according to weather conditions? What is the impact of skipping a day? Is consistency or average amount more important?	Studies using ambulatory light monitoring and melatonin assay, or laboratory studies simulating different circadian stimuli based on real conditions.	Could optimise advice given, minimising burden, whilst maximising chances of effect and realistic expectations (e.g., "30 min per day minimum if sunny, no later than 2pm and ideally before 11am, 40 min if cloudy", times would likely be specified in relation to mid-sleep time not external time of day.)
How far does circadian stimulus required for entrainment vary between individuals and are there any reliable predictors?	Cross-sectional comparison studies using standardised circadian stimulus, and assessing effects in individuals with different potential predictors, such as chronotype, diagnosis, age, and ocular factors.	Could be used to develop a checklist or algorithm to personalise advice (e.g., patient predictors are entered into an algorithm and advice similar to above is generated, or therapist instructions for how far to address light)
What is the optimum level of low evening lighting, and spectral qualities, to allow for vision whilst reducing	Experimental study in domestic settings, including measurement of acceptability of different lighting	Could reduce burden by recommending only as much reduction in evening light levels as is useful, to allow for

Question which could be addressed	Potential methods which could be employed	How could this inform L-DART and similar interventions
phase delay? How far does this vary individually? What are the predictors of circadian response?	recommendations, subjective experience, and perception of visual impact. Measuring and controlling for predictors including diagnosis.	continued meaningful activity in the evenings whilst reducing unwanted phase delay.
If sleep timing is irregular, what is the best strategy to ascertain optimal light exposure time to attempt to entrain to a regular day-night sleep cycle?	Experimental study utilising different strategies, including with or without information from melatonin assay or other biological prediction methods.	Could inform relative merit of incorporating melatonin assay or other prediction methods, and better inform protocol for patients with irregular patterns.
What is the impact of commonly prescribed psychotropic (or other) medications upon circadian response?	Experimental study in healthy controls, followed by interventional study in patient participants with the relevant condition.	Could inform contraindications for specific medications in patients with particular sleep problems, personalisation of prescriber advice, or personalisation of behavioural intervention.
What is the impact of oral versus depot medication on circadian response, and on sleep propensity?	Experimental study in participants already on the medication, randomising administration method.	Could inform prescribing advice given, or inform sleep intervention given to patients on depot versus oral medication

Mixed methods expert opinion study findings demonstrated that expert stakeholders have drawn diverse conclusions regarding the likely safety and efficacy of sleep restriction in SzSD, as there is a lack of directly relevant evidence. The feasibility study will contribute only a small amount of evidence regarding sleep compression acceptability and adherence, and will not inform at all regarding effects, or comparison with other approaches. Protocols restricting time in bed in SzSD might merit study in their own right, perhaps particularly for those with hypersomnia. Time in bed restriction (or a multi-component protocol such as L-DART) could be trialled specifically in those with hypersomnia irrespective of medication, or in groups on particular medications associated with hypersomnia (such as clozapine), in case the effects are different depending on their cause.

The interaction between sleep problems and psychiatric medications suggests potential benefits to testing a multi-disciplinary intervention, incorporating L-DART with appropriate modifications to pharmacological treatment (e.g., alterations to dose, timing, or type of medication) or supplemental treatment (e.g., hypnotics, melatonin). At present L-DART is being tested as a single therapist intervention. Whilst it is possible for liaison with the prescriber to result in modifications to pharmacological treatment, this approach clearly differs from one with a dedicated pharmacological input from a sleep specialist. Such an approach may by synergistic and could be developed and tested in the future.

10.7. Sleep disturbance phenotypes and personalisation

L-DART has been developed to target a range of potentially overlapping sleep problems. These vary in their presentation (e.g., short sleep, long sleep onset latency, poor sleep maintenance), and their causes (e.g., anxiety, unhelpful sleep beliefs, poor circadian entrainment, excess caffeine, sedative medications). Thus, if different causes are at play, complete amelioration of problems would not be expected for all patients using any single intervention. To improve outcomes in a diverse group one can either: A) select more homogenous groups who require the same approach, or B) use a personalised approach with a heterogenous group. L-DART took the latter approach, partly due to the assumption that problems would often overlap, and partly due to expectations that referrers may not have made a systematic assessment of the contribution of insomnia and circadian processes to presenting problems.

If more targeted therapies are developed in future for specific problem types, or if in future it is found that L-DART or a similar intervention is effective for some types of problems but not others, then reliable and low resource methods to identify different sleep pattern types could become useful. The baseline period of rest-activity recording within L-DART intends to help distinguish between different types of problems. L-DART currently relies on the ability of the clinician to visually interpret the plot; however, there is potential for the use of predictive technologies such as machine learning in this area (Perez-Pozuelo et al., 2020). Even without the use of algorithms, longitudinal self-report or passive monitoring can remove recall bias and can reveal patterns that the person was not aware of through their recollection of experience (Shiffman et al., 2008).

Existing studies have been focused on sleep being absent where it is wanted, as we found in the outcomes selected by authors in our reviews. Excess sleep is not scored as a problem in the PSQI (Faulkner and Sidey-Gibbons, 2019). Sleep may, however, intrude during waking hours (long sleep, sleep inertia, daytime sleepiness). The neglect of sleep inertia and excessive or mistimed sleepiness in outcome measurement can lead to assumptions by researchers that this is not important. This work has tried to redress the balance by focusing equally on both rest and activity, sleep and wakefulness, and focusing on the whole day, not just the sleep period. Similarly getting enough sleep is often a focus, whilst sleep timing and regularity are often not considered, but achieving sleep at night rather than in the day might be a high priority for service users. L-DART has attempted to address both sleep amount and timing; however, we found a lack of measures which captured changes in sleep timing and regularity. The diversity of sleep-related aims between intervention recipients makes outcome measurement challenging.

There is an increasing drive toward personalised healthcare, and precision medicine, including phenotyping (Pokorska-Bocci et al., 2014), but personalisation brings complexity and challenges. Behaviour change interventions must personalise not just for differing sleep problem phenotypes, but also to account for differing goals, personal life context and environment. This can bring a substantial cognitive load for the therapist and also potentially for patients who may need to understand the rationale and make further adjustments if their circumstances change after therapy has ended. During future development and refining of the L-DART, it may be necessary to focus on clear and simple messages in how the intervention is delivered. For instance, whilst it may be more accurate to say that going outdoors 'most days' is enough for a good effect on circadian rhythm, a rule of 'every day for at least 30 minutes', might be more motivating to follow. It is possible that giving more choice, may at times be less helpful and may just "give people a chance to think and talk themselves out of doing it" (mixed methods expert opinion study participant with personal experience).

10.8. Implications for occupational therapy's contribution to sleep treatment

This project has developed, manualised and commenced evaluation of L-DART. L-DART is recognisable as an occupational therapy intervention through embodying

occupational therapy values and using approaches common to occupational therapy interventions, and through exploiting occupational therapy core skills to reduce therapist training requirements. Results of the mixed methods expert opinion study suggest that a range of stakeholders view the development of an occupational therapy intervention to improve sleep in SzSD as a worthwhile endeavour. If this intervention proves effective and successful in future this would no doubt increase interest and confidence in the use of occupational therapists to address sleep problems in other groups and settings.

10.8.1. Occupational therapy as a profession, not an intervention in itself

It is an important distinction to note that this project has not manualised and evaluated *'occupational therapy for sleep problems'*, nor is this any more sensible than the notion of evaluating 'psychiatry for sleep problems' or 'nursing for sleep problems'. Interventions require more specification than this for evaluation to be informative. There has been debate regarding whether occupational therapy in itself can be defined as a complex intervention (Creek, 2003; Lambert et al., 2007). This thesis has been formulated on the assumption that occupational therapy is not an intervention, but is a profession which provides various interventions to improve health and / or functioning. These will often (but not always) have common features. Very often occupational therapy interventions are complex and highly personalised. This can make manualisation challenging, but absolutely does not preclude it (Blanche et al., 2011; Hunt et al., 2017; Birken et al., 2018). If L-DART proves effective and acceptable in future, this should not be overgeneralised to assume that referring for generic 'occupational therapy' to improve sleep, will necessarily have similar results, as 'occupational therapy' includes a range of diverse approaches which cannot be exhaustively listed. L-DART is a specific intervention, with associated materials, equipment, therapist training, and importantly - a structured process of assessment. This is probably quite different to how sleep problems would be addressed by many occupational therapists or other mental health professionals, who report limited knowledge and a lack of structure and specificity to their approach (Faulkner and Mairs, 2015; O'Sullivan et al., 2015; Rehman et al., 2017; Barrett et al., 2020). Equally there are other specific occupational therapy interventions to improve sleep, which have their own distinct evidence base; these differ from L-DART, and include interventions ranging from group CBTi for veterans (Eakman et al., 2017), sleep hygiene, weighted blankets for mental health

inpatients (Champagne et al., 2015), and vibrating pillows for people with poor self-reported sleep (Gutman et al., 2017).

10.9. Implications for implementation of L-DART and similar interventions in mental health services

The mixed methods expert opinion study and surveys together suggest there is demand for an intervention like L-DART, and suggest that if delivered in practice, it would be utilised. The feasibility study has also recruited well ahead of target (see Appendix 7). However, it is problematic to infer too much from this until intervention acceptability and adherence data is fully collected and analysed (discussed below in 'Future work').

The mixed methods expert opinion study found that professional stakeholders perceived sleep treatment in SzSD to be potentially more challenging than in other groups, and that stakeholders thought referrers would show more readiness to refer people with conditions other than SzSD. The prospective staff survey then confirmed reduced intentions to refer people with SzSD than with other conditions to L-DART or a similar therapy. It is of course possible that different barriers or referral behaviours may be present during routine practice, so further evaluation of this would be beneficial. However, if such barriers are confirmed then it may be important to educate staff on the effectiveness of sleep treatment in people with SzSD. Pessimistic views of recovery have been expressed by mental health staff in relation to other psychological therapies (Prytys et al., 2011), and similar views may be at play here in relation to recovery from sleep problems. Whatever concerns motivate the lower inclination to refer, these may prove unwarranted as sleep interventions in psychosis (Sheaves, Isham, et al., 2018b) can show high completion rates when trialled in this group, as can psychological interventions in general (Jolley et al., 2015).

Another potential barrier to referral identified in the mixed methods expert opinion study was that sleep experts believe mental health staff are not knowledgeable regarding sleep. The staff survey corroborated this, as non-sleep specialist staff reported low levels of confidence and training. Findings of low levels of training and sleep expertise in mental health staff are reflected in other literature as cited earlier in this thesis (Faulkner and Mairs, 2015; Rehman et al., 2017; Barrett et al., 2020).

Improved levels of knowledge among non-sleep-specialist staff could help to address less severe problems without the need for specialist referral. Enhanced knowledge may be needed to improve problem identification, particularly as more therapies may become available to refer to, and / or as different pathways are offered to people with different sleep problem types, which will demand more of referrers in terms of triage.

It should be acknowledged that the intervention developed includes several devices: a light box, a dawn simulator, and a commercial activity tracker (and smartphone if not already present). The feasibility study additionally uses three light measuring actigraphy devices per participant. The cost of devices could potentially affect future scalability if device cost and functions remained static in future. However, noting the increasing affordability of activity trackers, and increasing smart phone ownership among people with severe mental illnesses, it seems likely that the cost of providing technology used in the intervention will continue to reduce, as it has so far. Future work could streamline technology and equipment used, and the evidence currently being collected in the feasibility study will inform this. Advances in technology may facilitate, for instance, having one device for both dawn simulation and to use as a light box, or, environmental pre-programable light-delivery solutions may become more readily accessible, as home wifi becomes more widely available, or cheaper to provide within the intervention when needed. Even assuming increased availability, functionality, and reduced cost, what devices are adding to the intervention, should be explicitly evaluated at various stages, to ascertain their value.

10.10. Future work

The next step is completion of the initial feasibility study of L-DART, as outlined in the protocol in Chapter 9. This work has already commenced. The data collection focuses on qualitative acceptability, and mixed methods evaluation of adherence to recommendations. This study should begin to answer questions regarding acceptability of various aspects of the intervention and the manner of its delivery, the feasibility of delivering the intervention with fidelity, in different specific circumstances, and its application to different types of sleep problems. Following this, adaptations may be indicated, these could include the specific components offered, the order of format of delivery, or aspects of the inclusion criteria for which L-DART is recommended. The feasibility study will also inform the design of a

larger scale multi-therapist feasibility trial, and then a fully powered randomised study to definitively evaluate intervention clinical and cost effectiveness.

L-DART was formulated as one personalisable intervention, to cover ~CRSWD and / or insomnia; however, there may be arguments for increased separation of these pathways. Our inclusion criteria were purposely broad and did not assume that referrers would necessarily have an accurate view of whether problems were driven by circadian factors, insomnia processes, or both. This assumption may have been justified based on findings of the mixed methods expert opinion study and surveys; however, in a larger future study it may be possible to offer education and training to referrers to enable more pre-identification of problem types, or to include more pre-consent screening as part of the trial process.

The meta-analysis suggested stratification of samples by sleep problem type, in order to offer different interventions to different problems, and / or to assess different outcomes depending on the problem at baseline.

The feasibility study protocol attempts to account for the different outcomes desired and required by different participants (e.g., longer or shorter sleep, earlier or later sleep) by using a broad self-rating measure and asking about change on the issues that are most important to that person. However, if future research were stratified or otherwise separated by sleep problem type at baseline, specific objective sleep characteristics might also be candidates as outcomes. These may benefit from less subjective evaluation of sleep driven by contextual or expectation based reasons (Adamson et al., 2004; Faulkner and Sidey-Gibbons, 2019), and so may be more sensitive to change.

Depending on how sleep therapy will eventually be delivered within services, different study designs might be appropriate to more closely reflect how the intervention would fit into existing elements of clinical care. The intervention could potentially be delivered by a person in each team, or by a smaller number of specialists who work full time, or several days per week, in this role. The former would provide advantages in terms of integration with other aspects of services, whilst the latter might allow for sustainability and for better practiced and more automatic therapist skills. The feasibility study which is currently ongoing more closely resembles a model where one specialist service in-reaches to all teams.

However, it would be possible to design future studies to resemble other models of delivery if relevant.

Another possibility for future development of L-DART, is to more formally incorporate multi-disciplinary inputs within the intervention. For instance, the version of L-DART currently being tested incorporates liaison with the prescriber, and supervisory input from a clinical academic psychiatrist, but it would be possible to incorporate a medication review or prescriber advice from a sleep specialist psychiatrist. Mixed methods expert opinion study participants suggested pharmacy, psychiatry, and psychology colleagues might have specific roles within a sleep intervention. Equally, it would be possible to extend the scope of the intervention to incorporate team-level changes or training, in relation to accessing referrals and providing lower intensity sleep intervention before referral, rather than the dyadic therapist-client model. Examining feasibility study findings as well as other evidence sources, will help to determine future options for evaluation.

10.11. Conclusion

This thesis has gathered, generated and evaluated evidence to support the development of an occupational therapy intervention to improve sleep in people with SzSD. Meta-analyses suggest that light therapy may be efficacious in improving sleep in people with intrinsic circadian rhythm disorders and neuropsychiatric illness, but that more research is needed in those with SzSD (Study A). Light therapy appears broadly acceptable in the few studies that measure its acceptability. Attrition in studies is low and adherence to therapy appears potentially good, but poorly measured (Study B). There is agreement among expert and personal experience stakeholders on some of the elements which should be included in a sleep intervention for SzSD: sleep scheduling, morning and evening routines, daytime activity, and environmental interventions. Restricting time in bed and stimulus control appear more controversial. Our surveys suggest that there is a lot of unmet need and demand for a behavioural sleep intervention for SzSD populations (Study D). Survey responses suggest that training may be needed to improve staff confidence in identifying, treating, and / or referring sleep problems, and that special attention may be required to address preconceptions about the potential efficacy (or inefficacy) of sleep treatment in people with SzSD.

Together, this evidence has enabled the development of an intervention. Review of the literature in the thesis background, Studies A and B, and the synthesis chapter confirms that this diverse group has a range of sleep initiation, maintenance, and timing problems, with varied biological and psychosocial contributing factors. A personalisable intervention has been developed, to identify and address circadian dysregulation, insomnia processes, environmental factors, and the contribution of occupational routines. Factors relevant to implementation and reach of such an intervention have been evaluated, which will inform the further development, testing and implementation of this and similar interventions in future. A feasibility study protocol has been developed. This aims to evaluate acceptability, adherence and fidelity of intervention delivery, and to inform any changes required before the development of therapist training, and larger scale feasibility testing.

References:

Adamson, J., Gooberman-Hill, R., Woolhead, G. and Donovan, J. (2004) '"Questerviews": using questionnaires in qualitative interviews as a method of integrating qualitative and quantitative health services research.' *Journal of health services research & policy*, 9(3) pp. 139–45.

Afonso, P., Brissos, S., Cañas, F., Bobes, J. and Bernardo-Fernandez, I. (2014) 'Treatment adherence and quality of sleep in schizophrenia outpatients.' *International journal of psychiatry in clinical practice*, 18(1) pp. 70–6.

Agravat, A. (2018) ''Z'-hypnotics versus benzodiazepines for the treatment of insomnia.' *Progress in Neurology and Psychiatry*, 22(2) pp. 26–29.

Aichhorn, W., Stelzig-Schoeler, R., Geretsegger, C., Stuppaeck, C. and Kemmler, G. (2007) 'Bright light therapy for negative symptoms in schizophrenia: A pilot study.' *Journal of Clinical Psychiatry*, 68(7) p. 1146.

Alston, M., Cain, S. W. and Rajaratnam, S. M. W. (2018) 'Advances of Melatonin-Based Therapies in the Treatment of Disturbed Sleep and Mood.' *In* Landolt, H.-P. and Dijk, D.-J. (eds) *Sleep-Wake Neurobiology and Pharmacology, Handbook of Experimental Pharmacology 253*. Springer International Publishing, pp. 305–3019.

Altenberg Vaz, N. and Inanici, M. (2021) 'Syncing with the Sky: Daylight-Driven Circadian Lighting Design.' *LEUKOS - Journal of Illuminating Engineering Society of North America*, 17(3) pp. 291–309.

American Academy of Sleep Medicine (2014) *International classification of Sleep Disorders, 3rd edition (ICSD-3)*. Darien: IL: American Academy of Sleep Medicine.

American Psychiatric Association (2013) *Diagnostic and statistical manual of mental disorders: DSM-5™*. 5th ed., Arlington, VA: American Psychiatric Publishing, Inc.

Andreou, C. and Moritz, S. (2016) 'Editorial: Non-pharmacological Interventions for Schizophrenia: How Much Can Be Achieved and How?' *Frontiers in Psychology*, 7(1289).

Angarita, G. A., Emadi, N., Hodges, S. and Morgan, P. T. (2016) 'Sleep abnormalities associated with alcohol, cannabis, cocaine, and opiate use: A comprehensive review.' *Addiction Science and Clinical Practice*. BioMed Central, 11(1) pp. 1–17.

Appleton, R. E., Jones, A. P., Gamble, C., Williamson, P. R., Wiggs, L., Montgomery, P., Sutcliffe, A., Barker, C. and Gringras, P. (2012) 'The use of melatonin in children with neurodevelopmental disorders and impaired sleep: A randomised, double-blind, placebo-controlled, parallel study (mends).' *Health Technology Assessment*, 16(40) pp. 1–239.

Arain, M., Campbell, M. J., Cooper, C. L. and Lancaster, G. a (2010) 'What is a pilot or feasibility study? A review of current practice and editorial policy.' *BMC Med Res Methodol*, 10(67) p. 67.

Aschbrenner, K. A., Naslund, J. A., Shevenell, M., Mueser, K. T. and Bartels, S. J. (2016) 'Feasibility of Behavioral Weight Loss Treatment Enhanced with Peer Support and Mobile Health Technology for Individuals with Serious Mental Illness.' *Psychiatric Quarterly*, 87(3) pp. 401–415.

Ashare, R. L., Lerman, C., Tyndale, R. F., Hawk, L. W., George, T. P., Cinciripini, P. and Schnoll, R. A. (2017) 'Sleep Disturbance during Smoking Cessation: Withdrawal or Side Effect of Treatment?' *Journal of Smoking Cessation*, 12(2) pp. 63–70.

Asher, C. J. and Gask, L. (2010) 'Reasons for illicit drug use in people with schizophrenia: Qualitative study.' *BMC Psychiatry*, 10.

Ashraf, I., Alam, M. K., Ashraf, S., Asif, J. A., Mohamad, N. and Baig, A. A. (2016) 'Knowledge and Attitudes Regarding Obstructive Sleep Apnea among Medical and Dental GP's.' *International Medical Journal*, 23(6) pp. 630–632.

Augedal, A. W., Hansen, K. S., Kronhaug, C. R., Harvey, A. G. and Pallesen, S. (2013) 'Randomized controlled trials of psychological and pharmacological treatments for nightmares: A meta-analysis.' *Sleep Medicine Reviews*, 17(2) pp. 143–152.

Auger, R. R., Burgess, H. J., Emens, J. S., Deriy, L. V, Thomas, S. M. and Sharkey, K. M. (2015) 'Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders.' *Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine (AASM)*, 11(10) pp. 1199–236.

Aurora, R. N., Kristo, D. A., Bista, S. R., Rowley, J. A., Zak, R. S., Casey, K. R., Lamm, C. I., Tracy, S. L. and Rosenberg, R. S. (2012) 'The Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder in Adults—An Update for 2012: Practice Parameters with an Evidence-Based Systematic Review and Meta-Analyses.' *Sleep*, 35(August).

Auslander, L. A. and Jeste, D. V (2002) 'Perceptions of problems and needs for service among middle-aged and elderly outpatients with schizophrenia and related psychotic disorders.' *Community Mental Health Journal*, 38(5) pp. 391–402.

Baandrup, L., Jennum, P., Lublin, H. and Glenthoj, B. (2013) 'Treatment options for residual insomnia in schizophrenia.' *Acta Psychiatrica Scandinavica*, 127 pp. 81–82.

Baglioni, C., Battagliese, G., Feige, B., Spiegelhalder, K., Nissen, C., Voderholzer, U., Lombardo, C. and Riemann, D. (2011) 'Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies.' *Journal of affective disorders*, 135(1–3) pp. 10–9.

Baglioni, C., Bostanova, Z., Bacaro, V., Benz, F., Hertenstein, E., Spiegelhalder, K., Rücker, G., Frase, L., Riemann, D. and Feige, B. (2020) 'A Systematic Review and Network Meta-Analysis of Randomized Controlled Trials Evaluating the Evidence Base of Melatonin, Light Exposure, Exercise, and Complementary and Alternative Medicine for Patients with Insomnia Disorder.' *Journal of Clinical Medicine*, 9(6) p. 1949.

Baker, J., Lovell, K. and Harris, N. (2006) ‘How expert are the experts? An exploration of the concept of “expert” within Delphi panel techniques.’ *Nurse researcher*, 14(1) pp. 59–70.

Barbini, B., Benedetti, F., Colombo, C., Dotoli, D., Bernasconi, A., Cigala-Fulgosi, M., Florita, M. and Smeraldi, E. (2005) ‘Dark therapy for mania: A pilot study.’ *Bipolar Disorders*, 7(1) pp. 98–101.

Baron, K. G., Duffecy, J., Berendsen, M. A., Cheung Mason, I., Lattie, E. G. and Manalo, N. C. (2018) ‘Feeling validated yet? A scoping review of the use of consumer-targeted wearable and mobile technology to measure and improve sleep.’ *Sleep Medicine Reviews*, 40 pp. 151–159.

Barrett, E. A., Aminoff, S. R., Simonsen, C. and Romm, K. L. (2020) ‘Opening the curtains for better sleep in psychotic disorders - considerations for improving sleep treatment.’ *Comprehensive Psychiatry*, 103.

Basner, M. and McGuire, S. (2018) ‘WHO environmental noise guidelines for the european region: A systematic review on environmental noise and effects on sleep.’ *International Journal of Environmental Research and Public Health*, 15(3).

BBC News (2017) *Nokia ‘regrets’ Withings health app backlash*. [Online] [Accessed on 6th October 2018] https://www.bbc.co.uk/news/technology-40555752.

Becker, S. P., Duraccio, K. M., Sidol, C. A., Fershtman, C. E. M., Byars, K. C. and Harvey, A. G. (2022) ‘Impact of a Behavioral Sleep Intervention in Adolescents With ADHD: Feasibility, Acceptability, and Preliminary Effectiveness From a Pilot Open Trial.’ Journal of Attention Disorders, 26(7) pp. 1051–1066.

Benjamins, J. S., Migliorati, F., Dekker, K., Wassing, R., Moens, S., Blanken, T. F., te Lindert, B. H. W., Sjauw Mook, J. and Van Someren, E. J. W. (2017) ‘Insomnia heterogeneity: Characteristics to consider for data-driven multivariate subtyping.’ *Sleep Medicine Reviews*, 36 pp. 71–81.

van den Berg, F., Verhagen, C. and Uitenbroek, D. (2014) ‘The relation between scores on noise annoyance and noise disturbed sleep in a public health survey.’ *International Journal of Environmental Research and Public Health*, 11(2) pp. 2314–2327.

Berger, L. (2012) ‘Evaluation of the efficacy of a new insomnia service providing cognitive behavioural therapy for insomnia (Clinical Update Sleep Abstracts).’ *Journal of Thoracic Disease*, 8(2).

Berk, M. (2009) ‘Sleep and depression - theory and practice.’ *Australian family physician*, 38(5) pp. 302–304.

Berry, A., Yung, A. R., Carr, M. J., Webb, R. T., Ashcroft, D. M., Firth, J. and Drake, R. J. (2021) ‘Prevalence of Major Cardiovascular Disease Events Among People Diagnosed With Schizophrenia Who Have Sleep Disturbance, Sedentary Behavior, or Muscular Weakness.’ *Schizophrenia Bulletin Open*, 2(1).

Bianchi, M. T. (2018) ‘Sleep devices: wearables and nearables, informational and interventional, consumer and clinical.’ *Metabolism: Clinical and Experimental*, 84

pp. 99–108.

Birken, M., Henderson, C. and Slade, M. (2018) ‘The development of an occupational therapy intervention for adults with a diagnosed psychotic disorder following discharge from hospital.’ *Pilot and Feasibility Studies*, 4(81).

Bishop, S. R., Lau, M., Shapiro, S., Carlson, L., Anderson, N. D., Carmody, J., Segal, Z. V., Abbey, S., Speca, M., Velting, D. and Devins, G. (2004) ‘Mindfulness: A proposed operational definition.’ *Clinical Psychology: Science and Practice*, 11(3) pp. 230–241.

Blanche, E. I., Fogelberg, D., Diaz, J., Carlson, M. and Clark, F. (2011) ‘Manualization of Occupational Therapy Interventions: Illustrations from the Pressure Ulcer Prevention Research Program.’ *American Journal of Occupational Therapy*, 65(6) pp. 711–719.

Blanken, T. F., Benjamins, J. S., Borsboom, D., Vermunt, J. K., Paquola, C., Ramautar, J., Dekker, K., Stoffers, D., Wassing, R., Wei, Y. and Van Someren, E. J. W. (2019) ‘Insomnia disorder subtypes derived from life history and traits of affect and personality.’ *The Lancet Psychiatry*, 6(2) pp. 151–163.

Böge, K., Karadza, A., Fuchs, L. M., Ehlen, F., Ta, T. M. T., Thomas, N., Bajbouj, M. and Hahn, E. (2020) ‘Mindfulness-Based Interventions for In-Patients With Schizophrenia Spectrum Disorders—A Qualitative Approach.’ *Frontiers in Psychiatry*, 11(June) pp. 1–15.

Bolla, K. I., Lesage, S. R., Gamaldo, C. E., Neubauer, D. N., Funderburk, F. R., Cadet, J. L., David, P. M., Verdejo-Garcia, A. and Benbrook, A. R. (2008) ‘Sleep disturbance in heavy marijuana users.’ *Sleep*, 31(6) pp. 901–908.

Bond Sutton, L., Erlen, J. A., Glad, J. A. M. and Siminoff, L. A. (2003) ‘Recruiting vulnerable populations for research: Revisiting the ethical issues.’ *Journal of Professional Nursing*, 19(2) pp. 106–112.

Bonnet, M. H. and Arand, D. L. (2003) ‘Clinical effects of sleep fragmentation versus sleep deprivation.’ *Sleep Medicine Reviews*, 7(4) pp. 297–310.

Boote, J., Telford, R. and Cooper, C. (2002) ‘Consumer involvement in health research: a review and research agenda.’ *Health Policy*, 61(2) pp. 213–236.

Bootzin, R. R. and Perlis, M. L. (2011) ‘Stimulus Control Therapy.’ *In* Perlis, M., Aloia, M., and Kuhn, B. (eds) *Behavioral Treatments for Sleep Disorders*. 1st ed., Amsterdam: Elsevier Inc., pp. 21–30.

Borbély, A. A., Daan, S., Wirz-Justice, A. and Deboer, T. (2016) ‘The two-process model of sleep regulation: A reappraisal.’ *Journal of Sleep Research*, 25(2) pp. 131–143.

Bradley, J., Freeman, D., Chadwick, E., Harvey, A. G., Mullins, B., Johns, L., Sheaves, B., Lennox, B., Broome, M. and Waite, F. (2018) ‘Treating Sleep Problems in Young People at Ultra-High Risk of Psychosis: A Feasibility Case Series.’ *Behavioural and Cognitive Psychotherapy*, 46(3) pp. 276–291.

Brickwood, K. J., Watson, G., O'Brien, J. and Williams, A. D. (2019) 'Consumer-based wearable activity trackers increase physical activity participation: Systematic review and meta-analysis.' *Journal of Medical Internet Research*, 21(4).

Broman, J. E., Mallon, L. and Hetta, J. (2008) 'Restless legs syndrome and its relationship with insomnia symptoms and daytime distress: Epidemiological survey in Sweden.' *Psychiatry and Clinical Neurosciences*, 62(4) pp. 472–475.

Brower, K. J. (2003) 'Insomnia, alcoholism and relapse.' *Sleep Medicine Reviews*, 7(6) pp. 523–539.

Brown, C. (2016) *Pre-Conference Workshop: The Occupation of Sleep*. [Online] [Accessed on 2nd May 2016] http://www.caot.ca/default.asp?pageid=3984.

Brown, L. F., Davis, L. W., Larocco, V. A. and Strasburger, A. (2010) 'Participant perspectives on mindfulness meditation training for anxiety in schizophrenia.' *American Journal of Psychiatric Rehabilitation*, 13(3) pp. 224–242.

Brown, T. M., Brainard, G. C., Cajochen, C., Czeisler, C. A., Hanifin, J. P., Lockley, S. W., Lucas, R. J., Münch, M., OHagan, J. B., Peirson, S. N., Price, L. L. A., Roenneberg, T., Schlangen, L. J. M., Skene, D. J., Spitschan, M., Vetter, C., Zee, P. C. and Wright, K. P. (2022) 'Recommendations for daytime, evening, and nighttime indoor light exposure to best support physiology, sleep, and wakefulness in healthy adults.' PLoS Biology, 20(3) pp. 1–24.

Bucci, S., Butcher, I., Hartley, S., Neil, S. T., Mulligan, J. and Haddock, G. (2015) 'Barriers and facilitators to recruitment in mental health services: Care coordinators' expectations and experience of referring to a psychosis research trial.' *Psychology and Psychotherapy: Theory, Research and Practice*, 88(3) pp. 335–350.

Buckton, C. H., Lean, M. E. J. and Combet, E. (2015) ''Language is the source of misunderstandings'-impact of terminology on public perceptions of health promotion messages Health behavior, health promotion and society.' *BMC Public Health*, 15(1) pp. 1–13.

Buijs, F. N., León-Mercado, L., Guzmán-Ruiz, M., Guerrero-Vargas, N. N., Romo-Nava, F. and Buijs, R. M. (2016) 'The circadian system: A regulatory feedback network of periphery and brain.' *Physiology*, 31(3) pp. 170–181.

Burke, T. M., Markwald, R. R., Mchill, A. W., Chinoy, E. D., Jesse, A., Bessman, S. C., Jung, C. M., Neill, J. S. O., Kenneth, P. and Jr, W. (2015) 'Effects of caffeine on the human circadian clock in vivo and in vitro.' *Science Translational Medicine*, 7(305).

Burton, N. W., Pakenham, K. I. and Brown, W. J. (2010) 'Feasibility and effectiveness of psychosocial resilience training: A pilot study of the READY program.' *Psychology, Health and Medicine*, 15(3) pp. 266–277.

Buysse, D. J., Reynolds, C. F. 3rd, Monk, T. H., Berman, S. R. and Kupfer, D. J. (1989) 'The Pittsburgh Sleep Quality Index: A New Instrument for Psychiatric Practice and Research.' *Psychiatry Res*, 28(2) pp. 193–213.

Buysse, D. J. and Tyagi, S. (2017) 'Clinical Pharmacology of Other Drugs Used as

Hypnotics.' *In* Kryger, M., Roth, T., and Dement, W. C. (eds) *Principles and Practice of Sleep Medicine*. 6th editio, Elsevier Inc., pp. 432–445.

Buysse, D. J., Yu, L., Moul, D. E., Germain, A., Stover, A., Dodds, N. E., Johnston, K. L., Shablesky-Cade, M. A. and Pilkonis, P. A. (2010) 'Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments.' *Sleep*, 33(6) pp. 781–792.

Caddick, Z. A., Gregory, K., Arsintescu, L. and Flynn-Evans, E. E. (2018) 'A review of the environmental parameters necessary for an optimal sleep environment.' *Building and Environment*, 132(January) pp. 11–20.

Cajochen, C. (2007) 'Alerting effects of light.' *Sleep medicine reviews*, 11(6) pp. 453–64.

Callesen, P. (2020) *ISRCTN85892563, Testing the effect of metacognitive therapy for insomnia*. ISRCTN. [Online] [Accessed on 4th September 2020] http://www.isrctn.com/ISRCTN85892563.

Care Act 2014 (2014) *Care Act 2014*.

Carney, C. E., Buysse, D. J., Ancoli-israel, S., Edinger, J. D., Krystal, A. D., Lichstein, K. L. and Morin, C. M. (2012) 'The Consensus Sleep Diary : Standardizing Prospective Sleep Self-Monitoring.' *SLEEP*, 35(2) pp. 287–302.

Carrico, A. W. and Antoni, M. H. (2008) 'Effects of psychological interventions on neuroendocrine hormone regulation and immune status in HIV-positive persons: A review of randomized controlled trials.' *Psychosomatic Medicine*, 70(5) pp. 575–584.

Carter, B., Rees, P., Hale, L., Bhattacharjee, D. and Paradkar, M. S. (2016) 'Association between portable screen-based media device access or use and sleep outcomes a systematic review and meta-analysis.' *JAMA Pediatrics*, 170(12) pp. 1202–1208.

Case-Smith, J., Weaver, L. L. and Fristad, M. A. (2015) 'A systematic review of sensory processing interventions for children with autism spectrum disorders.' *Autism*, 19(2) pp. 133–148.

Castelnovo, A., Ferri, R., Punjabi, N. M., Castronovo, V., Garbazza, C., Zucconi, M., Ferini-Strambi, L. and Manconi, M. (2019) 'The paradox of paradoxical insomnia: A theoretical review towards a unifying evidence-based definition.' *Sleep Medicine Reviews*, 44 pp. 70–82.

Champagne, T., Mullen, B., Dickson, D. and Krishnamurty, S. (2015) 'Evaluating the Safety and Effectiveness of the Weighted Blanket With Adults During an Inpatient Mental Health Hospitalization.' *Occupational Therapy in Mental Health*, 31(3) pp. 211–233.

Chan, M. S., Chung, K. F., Yung, K. P. and Yeung, W. F. (2017) 'Sleep in schizophrenia: A systematic review and meta-analysis of polysomnographic findings in case-control studies.' *Sleep Medicine Reviews*, 32 pp. 69–84.

Chang, A.-M., Santhi, N., St Hilaire, M., Gronfier, C., Bradstreet, D. S., Duffy, J. F., Lockley, S. W., Kronauer, R. E. and Czeisler, C. A. (2012) 'Human responses to bright light of different durations.' *The Journal of Physiology*, 590(13) pp. 3103–3112.

Chang, A. M., Scheer, F. A. J. L. and Czeisler, C. A. (2011) 'The human circadian system adapts to prior photic history.' *Journal of Physiology*, 589(5) pp. 1095–1102.

Chang, H. T., Wu, C. Da, Pan, W. C., Candice Lung, S. C. and Su, H. J. (2019) 'Association between surrounding greenness and schizophrenia: A taiwanese cohort study.' *International Journal of Environmental Research and Public Health*, 16(8).

Chaput, J. P., Dutil, C., Featherstone, R., Ross, R., Giangregorio, L., Saunders, T. J., Janssen, I., Poitras, V. J., Kho, M. E., Ross-White, A. and Carrier, J. (2020) 'Sleep duration and health in adults: an overview of systematic reviews.' *Applied physiology, nutrition, and metabolism = Physiologie appliquee, nutrition et metabolisme*, 45(10) pp. S218–S231.

Chellappa, S. L., Steiner, R., Oelhafen, P. and Cajochen, C. (2017) 'Sex differences in light sensitivity impact on brightness perception, vigilant attention and sleep in humans.' *Scientific Reports*, 7(1) pp. 1–9.

Chennaoui, M., Arnal, P. J., Sauvet, F. and Léger, D. (2015) 'Sleep and exercise: A reciprocal issue?' *Sleep Medicine Reviews*, 20 pp. 59–72.

Chiu, V. W., Hons, B., Harvey, R. H., Sloan, N. B., Ree, M., Lin, A., Janca, A. and Waters, F. (2015) 'Cognitive and Behavioral Factors Associated With Insomnia in Inpatients With Schizophrenia and Related Psychoses.' *Journal of Nervous & Mental Disease*, 203(10) pp. 1–6.

Chiu, V. W., Ree, M., Janca, A., Iyyalol, R., Dragovic, M. and Waters, F. (2018) 'Sleep profiles and CBT-I response in schizophrenia and related psychoses.' *Psychiatry Research*, 268(July) pp. 279–287.

Chiu, V. W., Ree, M., Janca, A. and Waters, F. (2016) 'Sleep in Schizophrenia: Exploring Subjective Experiences of Sleep Problems, and Implications for Treatment.' *Psychiatric Quarterly*, 87(4) pp. 633–648.

Cho, J. R., Joo, E. Y., Koo, D. L. and Hong, S. B. (2013) 'Let there be no light: The effect of bedside light on sleep quality and background electroencephalographic rhythms.' *Sleep Medicine*, 14(12) pp. 1422–1425.

Cho, Y. M., Ryu, S. H., Lee, B. R., Kim, K. H., Lee, E. and Choi, J. (2015) 'Effects of artificial light at night on human health: A literature review of observational and experimental studies applied to exposure assessment.' *Chronobiology International*, 32(9) pp. 1294–1310.

Chouinard, S., Poulin, J., Stip, E. and Godbout, R. (2004) 'Sleep in untreated patients with schizophrenia: a meta-analysis.' *Schizophrenia bulletin*, 30(4) pp. 957–967.

Chung, F., Subramanyam, R., Liao, P., Sasaki, E., Shapiro, C. and Sun, Y. (2018) *STOP-Bang Questionnaire*. STOPBang.ca, University Health Network, University of Toronto. Toronto: Toronto Western Hospital. [Online] [Accessed on 1st August

2018] http://www.stopbang.ca/osa/screening.php.

Chung, K. F., Lee, C. T., Yeung, W. F., Chan, M. S., Chung, E. W. Y. and Lin, W. L. (2018) 'Sleep hygiene education as a treatment of insomnia: A systematic review and meta-analysis.' *Family Practice*, 35(4) pp. 365–375.

Chung, K. F., Poon, Y. P. Y. P., Ng, T. K. and Kan, C. K. (2018) 'Correlates of sleep irregularity in schizophrenia.' *Psychiatry Research*, 270(February) pp. 705–714.

Cipriani, A. and Geddes, J. (2011) 'Comparison of systematic and narrative reviews: the example of the atypical antipsychotics.' *Epidemiologia e Psichiatria Sociale*, 12(3) pp. 146–153.

Clark, I. and Landolt, H. P. (2017) 'Coffee, caffeine, and sleep: A systematic review of epidemiological studies and randomized controlled trials.' *Sleep Medicine Reviews*, 31 pp. 70–78.

College of Occupational Therapists (2016) 'Entry level occupational therapy core knowledge and practice skills.' London: College of Occupational Therapists.

Cook, S. and Birrell, M. (2007) 'Defining an occupational therapy intervention for people with psychosis.' *The British Journal of Occupational Therapy*, 70(3) pp. 96–106.

Cooke, A. (2017) *Understanding psychosis and schizophrenia: Why people sometimes hear voices, believe things that others find strange, or appear out of touch with reality, and what can help (A report by the Division of Clinical Psychology: Revised Version)*. Leicester, England: British Psychological Society.

Costain, W. F. (2008) 'The effects of cannabis abuse on the symptoms of schizophrenia: Patient perspectives.' *International Journal of Mental Health Nursing*, 17(4) pp. 227–235.

Cowles, E., & Nelson, E. (2015) *Introduction to Survey Research*. Cowles, E., & Nelson, E. (ed.). Hampton, New Jersey: Business Expert Press.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. and Petticrew, M. (2008) 'Developing and evaluating complex interventions: new guidance.' *MRC*.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I. and Petticrew, M. (2019) *Developing and evaluating complex interventions: update*.

Crawford, M. J., Rutter, D., Manley, C., Weaver, T., Bhui, K., Fulop, N. and Tyrer, P. (2002) 'Systematic review of involving patients in the planning and development of health care.' *British medical journal*, 325(November) pp. 1–5.

Creek, J. (2003) *Occupational therapy defined as a complex intervention*. London: College of Occupational Therapists.

Creek, J., Ilott, I., Cook, S. and Munday, C. (2005) 'Valuing Occupational Therapy as a Complex Intervention.' *British Journal of Occupational Therapy*, 68(6) pp. 281–284.

Cui, R. and Fiske, A. (2020) ‘Predictors of treatment attendance and adherence to treatment recommendations among individuals receiving Cognitive Behavioral Therapy for Insomnia.’ *Cognitive Behaviour Therapy*, 49(2) pp. 113–119.

Cunningham, J. E. A., Stamp, J. A. and Shapiro, C. M. (2019) ‘Sleep and major depressive disorder: a review of non-pharmacological chronotherapeutic treatments for unipolar depression.’ *Sleep Medicine*, 61 pp. 6–18.

Czeisler, C. A., Duffy, J. F. and Shanahan, T. L. (1999) ‘Stability, precision, and near 24 hour period of the human circadian pacemaker.’ *Science*, 284(June) pp. 2177–2181.

Czosnek, L., Rankin, N., Zopf, E., Richards, J., Rosenbaum, S. and Cormie, P. (2020) ‘Implementing Exercise in Healthcare Settings: The Potential of Implementation Science.’ *Sports Medicine*, 50(1) pp. 1–14.

Dahlgren, G. H. and Hansen, H. (2015) ‘I’d rather be nice than honest: An experimental examination of social desirability bias in tourism surveys.’ *Journal of Vacation Marketing*, 21(4) pp. 318–325.

Dai Davies (2019) *Occupational Therapy Week 2019: The power of occupation changes lives*. RCOT website, news.

Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A. and Lowery, J. C. (2009) ‘Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science.’ *Implementation Science*, 4(1) pp. 1–15.

Danielsson, K., Jansson-Fröjmark, M., Broman, J. E. and Markström, A. (2016a) ‘Cognitive Behavioral Therapy as an Adjunct Treatment to Light Therapy for Delayed Sleep Phase Disorder in Young Adults: A Randomized Controlled Feasibility Study.’ *Behavioral Sleep Medicine*, 14(2) pp. 212–232.

Danielsson, K., Jansson-Fröjmark, M., Broman, J. E. and Markström, A. (2016b) ‘Light Therapy With Scheduled Rise Times in Young Adults With Delayed Sleep Phase Disorder: Therapeutic Outcomes and Possible Predictors.’ *Behavioral Sleep Medicine*, 16(4) pp. 325–336.

Davies, G., Haddock, G., Yung, A. R., Mulligan, L. D. and Kyle, S. D. (2017) ‘A systematic review of the nature and correlates of sleep disturbance in early psychosis.’ *Sleep Medicine Reviews*, 31 pp. 25–38.

Deboer, T. (2013) ‘Behavioral and Electrophysiological Correlates of Sleep and Sleep Homeostasis.’ *In* Meerlo, P., Benca, R., and Abel, T. (eds) *Sleep, Neuronal Plasticity and Brain Function. Current Topics in Behavioral Neurosciences, vol 25*. Berlin, Heidelberg.: Springer.

Decker, S. E., Kiluk, B. D., Frankforter, T., Babuscio, T., Nich, C. and Carroll, K. M. (2016) ‘Just showing up is not enough: Homework adherence and outcome in cognitive-behavioral therapy for cocaine dependence.’ *Journal of Consulting and Clinical Psychology*, 84(10) pp. 907–912.

Dijk, D. J. and Archer, S. N. (2010) ‘PERIOD3, circadian phenotypes, and sleep

homeostasis.' *Sleep Medicine Reviews*, 14(3) pp. 151–160.

Dijk DJ. and Landolt, H. (2019) 'Sleep Physiology, Circadian Rhythms, Waking Performance and the Development of Sleep-Wake Therapeutics.' *In* HP., L. and Dijk, D. (eds) *Sleep-Wake Neurobiology and Pharmacology. Handbook of Experimental Pharmacology, vol 253.* 1st ed., Switzerland AG 2019: Springer International Publishing.

Dixon-Woods, M. (2006) 'How can systematic reviews incorporate qualitative research? A critical perspective.' *Qualitative Research*, 6(1) pp. 27–44.

Dolsen, E. A., Dong, L. and Harvey, A. G. (2021) 'Transdiagnostic Sleep and Circadian Intervention for Adolescents Plus Text Messaging: Randomized Controlled Trial 12-month Follow-up.' Journal of Clinical Child and Adolescent Psychology. Routledge, 00(00) pp. 1–13.

Dongen, H. P. A. Van, Vitellaro, K. M. and Dinges, D. F. (2005) 'Individual Differences in Adult Human Sleep and Wakefulness : Leitmotif for a Research Agenda.' *Sleep*, 28(4) pp. 479–96.

Dowling, G. A., Burr, R. L., Van Someren, E. J. W., Hubbard, E. M., Luxenberg, J. S., Mastick, J. and Cooper, B. A. (2008) 'Melatonin and bright-light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease.' *Journal of the American Geriatrics Society*, 56(2) pp. 239–246.

Drucker, A. M. and Rosen, C. F. (2011) 'Drug-induced photosensitivity: Culprit drugs, management and prevention.' *In Drug Safety*, pp. 821–837.

Dubose, J. R. and Hadi, K. (2016) 'Improving inpatient environments to support patient sleep.' *International Journal for Quality in Health Care*, 28(5) pp. 540–553.

Duffy, J. F., Rimmer, D. W. and Czeisler, C. A. (2001) 'Association of Intrinsic Circadian Period With Morningness-Eveningness, Usual Wake Time, and Circadian Phase.' *Behavioural Neuroscience*, 115(4) pp. 895–899.

Duffy, J. F. and Wright, K. P. (2005) 'Entrainment of the human circadian system by light.' *Journal of Biological Rhythms*, 20(4) pp. 326–338.

Durmer, J. S. and Dinges, D. F. (2005) 'Neurocognitive Consequences of Sleep Deprivation.' *Seminars in neurology*, 25(1) pp. 117–129.

Eakman, A. M., Schmid, A. A., Henry, K. L., Rolle, N. R., Schelly, C., Pott, C. E. and Burns, J. E. (2017) 'Restoring effective sleep tranquility (REST): A feasibility and pilot study.' *British Journal of Occupational Therapy*, 80(6) pp. 350–360.

Edinger, J. D. and Wohlgemuth, W. K. (2001) 'Psychometric comparisons of the standard and abbreviated DBAS-10 versions of the dysfunctional beliefs and attitudes about sleep questionnaire.' *Sleep Medicine*, 2(6) pp. 493–500.

Edwards, C. J., Cella, M., Emsley, R., Tarrier, N. and Wykes, T. H. M. (2018) 'Exploring the relationship between the anticipation and experience of pleasure in people with schizophrenia: An experience sampling study.' *Schizophrenia Research*, 202 pp. 72–79.

Eisner, E., Barrowclough, C., Lobban, F. and Drake, R. (2014) ‘Qualitative investigation of targets for and barriers to interventions to prevent psychosis relapse.’ *BMC Psychiatry*, 14(1) pp. 1–14.

Eisner, E., Drake, R. and Barrowclough, C. (2013) ‘Assessing early signs of relapse in psychosis: Review and future directions.’ *Clinical Psychology Review*, 33(5) pp. 637–653.

Eitzel, M. V, Cappadonna, J. L., Santos-Lang, C., Duerr, R. E., Virapongse, A., West, S. E., Kyba, C. C. M., Bowser, A., Cooper, C. B., Sforzi, A., Metcalfe, A. N., Harris, E. S., Thiel, M., Haklay, M., Ponciano, L., Roche, J., Ceccaroni, L., Shilling, F. M., Dörler, D., Heigl, F., Kiessling, T., Davis, B. Y. and Jiang, Q. (2017) ‘Citizen Science Terminology Matters: Exploring Key Terms.’ *Citizen Science: Theory and Practice*, 2(1) p. 1.

Eklund, M., Erlandsson, L. and Leufstadius, C. (2010) ‘Time use in relation to valued and satisfying occupations among people with persistent mental illness: Exploring occupational balance.’ *Journal of Occupational Science*, 17(4) pp. 231–238.

Engel-Yeger, B. and Shochat, T. (2012) ‘The relationship between sensory processing patterns and sleep quality in healthy adults.’ *Canadian Journal of Occupational Therapy*, 79(3) pp. 134–141.

Engels, T. C. E. and Andries, C. (2007) ‘Developing a framework for a family-focused preventive intervention using the Delphi method.’ *International Journal of Child & Family Welfare*, 10 pp. 2–13.

Espie, C. A. and Kyle, S. D. (2009) ‘Primary Insomnia: An Overview of Practical Management Using Cognitive Behavioral Techniques.’ *Sleep Medicine Clinics*. Elsevier, 4(4) pp. 559–569.

Exelmans, L. and Van den Bulck, J. (2015) ‘Sleep quality is negatively related to video gaming volume in adults.’ *Journal of Sleep Research*, 24(2) pp. 189–196.

Eysenbach, G. and Wyatt, J. (2002) ‘Using the Internet for surveys and health research.’ *Journal of Medical Internet Research*, 4(2) pp. 76–94.

Fairholme, C. and Manber, R. (2014) ‘Safety behaviors and sleep effort predict sleep disturbance and fatigue in an outpatient sample with anxiety and depressive disorders.’ *Journal of psychosomatic research*, 76(3) pp. 233–236.

Faulkner, S. and Bee, P. (2016) ‘Perspectives on Sleep, Sleep Problems, and Their Treatment, in People with Serious Mental Illnesses: A Systematic Review.’ *PLoS ONE*, 11(9) p. e0163486.

Faulkner, S. and Bee, P. (2017) ‘Experiences, perspectives and priorities of people with schizophrenia spectrum disorders regarding sleep disturbance and its treatment: a qualitative study.’ *BMC Psychiatry*, 17(1) p. 158.

Faulkner, S. M., Bee, P. E., Meyer, N., Dijk, D. J. and Drake, R. J. (2019) ‘Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: A systematic review and meta-analysis.’ *Sleep Medicine Reviews*,

46 pp. 108–123.

Faulkner, S. and Mairs, H. (2015) ‘An exploration of the role of the occupational therapist in relation to sleep problems in mental health settings.’ *British Journal of Occupational Therapy*, 78(8) pp. 516–524.

Faulkner, S. and Sidey-Gibbons, C. (2019) ‘Use of the Pittsburgh Sleep quality index in people with schizophrenia spectrum disorders: A mixed methods study.’ *Frontiers in Psychiatry*, 10(May).

Ferini-Strambi, L., Fossati, A., Sforza, M. and Galbiati, A. (2019) ‘Subtyping insomnia disorder.’ *The Lancet Psychiatry*, 6(4) p. 284.

Fernandez, L. M. J. and Lüthi, A. (2020) ‘Sleep spindles: Mechanisms and functions.’ *Physiological Reviews*, 100(2) pp. 805–868.

Ferrara, M. and De Gennaro, L. (2001) ‘How much sleep do we need?’ *Sleep medicine reviews*, 5(2) pp. 155–179.

Figueiro, M. G., Hunter, C. M., Higgins, P. A., Hornick, T. R., Jones, G. E., Plitnick, B., Brons, J. and Rea, M. S. (2015) ‘Tailored lighting intervention for persons with dementia and caregivers living at home.’ *Sleep Health*, 1(4) pp. 322–330.

Figueiro, M. G., Steverson, B., Heerwagen, J., Kampschroer, K., Hunter, C. M., Gonzales, K., Plitnick, B. and Rea, M. S. (2017) ‘The impact of daytime light exposures on sleep and mood in office workers.’ *Sleep Health*, 3(3) pp. 204–215.

Firth, J., Rosenbaum, S., Stubbs, B., Gorczynski, P., Yung, A. R. and Vancampfort, D. (2016) ‘Motivating factors and barriers towards exercise in severe mental illness: A systematic review and meta-analysis.’ *Psychological Medicine*, 46(14) pp. 2869–2881.

Firth, J., Stubbs, B., Rosenbaum, S., Vancampfort, D., Malchow, B., Schuch, F., Elliott, R., Nuechterlein, K. H. and Yung, A. R. (2017) ‘Aerobic exercise improves cognitive functioning in people with schizophrenia: A systematic review and meta-analysis.’ *Schizophrenia Bulletin*, 43(3) pp. 546–556.

Fischer, R., Kasper, S., Pjrek, E. and Winkler, D. (2012) ‘On the application of light therapy in German-speaking countries.’ *European Archives of Psychiatry and Clinical Neuroscience*, 262(6) pp. 501–505.

Forbes, D., Blake, C. M., Thiessen, E. J., Peacock, S. and Hawranik, P. (2014) ‘Light therapy for improving cognition, activities of daily living, sleep, challenging behaviour, and psychiatric disturbances in dementia.’ *Cochrane Database of Systematic Reviews*, (2).

Freedman, R. and Papsdorf, J. D. (1976) ‘Biofeedback and progressive relaxation treatment of sleep-onset insomnia - A controlled, all-night investigation.’ *Biofeedback and Self-Regulation*, 1(3) pp. 253–271.

Freeman, D., Sheaves, B., Goodwin, G. M., Yu, L. M., Nickless, A., Harrison, P. J., Emsley, R., Luik, A. I., Foster, R. G., Wadekar, V., Hinds, C., Gumley, A., Jones, R., Lightman, S., Jones, S., Bentall, R., Kinderman, P., Rowse, G., Brugha, T., Blagrove,

M., Gregory, A. M., Fleming, L., Walklet, E., Glazebrook, C., Davies, E. B., Hollis, C., Haddock, G., John, B., Coulson, M., Fowler, D., Pugh, K., Cape, J., Moseley, P., Brown, G., Hughes, C., Obonsawin, M., Coker, S., Watkins, E., Schwannauer, M., MacMahon, K., Siriwardena, A. N. and Espie, C. A. (2017) 'The effects of improving sleep on mental health (OASIS): a randomised controlled trial with mediation analysis.' *The Lancet Psychiatry*, 4(10) pp. 749–758.

Freeman, D., Waite, F., Startup, H., Myers, E., Lister, R., McInerney, J., Harvey, A. G., Geddes, J., Zaiwalla, Z., Luengo-Fernandez, R., Foster, R. G., Clifton, L. and Yu, L.-M. (2015) 'Efficacy of cognitive behavioural therapy for sleep improvement in patients with persistent delusions and hallucinations (BEST): a prospective, assessor-blind, randomised controlled pilot trial.' *Lancet Psychiatry*, 2(11) pp. 975–983.

Fung, C., Wiseman-Hakes, C., Stergiou-Kita, M., Nguyen, M. and Colantonio, A. (2013) 'Time to wake up: bridging the gap between theory and practice for sleep in occupational therapy.' *The British Journal of Occupational Therapy*, 76(8) pp. 384–386.

Gabryelska, A., Feige, B., Riemann, D., Spiegelhalder, K., Johann, A., Białasiewicz, P. and Hertenstein, E. (2019) 'Can spectral power predict subjective sleep quality in healthy individuals?' *Journal of Sleep Research*, 28(6) pp. 1–6.

Gale, N. K., Heath, G., Cameron, E., Rashid, S. and Redwood, S. (2013) 'Using the framework method for the analysis of qualitative data in multi-disciplinary health research.' *BMC medical research methodology*, 13(117).

Garcia, A. N. and Salloum, I. M. (2015) 'Polysomnographic sleep disturbances in nicotine, caffeine, alcohol, cocaine, opioid, and cannabis use: A focused review.' *American Journal on Addictions*, 24(7) pp. 590–598.

Garland, S. N., Zhou, E. S., Gonzalez, B. D., Avenue, E. and Brunswick, N. (2016) 'The Quest for Mindful Sleep: A Critical Synthesis of the Impact of Mindfulness-Based Interventions for Insomnia.' *Current Sleep Medicine Reports*, 2(3) pp. 142–151.

Gates, P., Albertella, L. and Copeland, J. (2016) 'Cannabis withdrawal and sleep: A systematic review of human studies.' *Substance Abuse*, 37(1) pp. 255–269.

Gavriloff, D., Sheaves, B., Juss, A., Espie, C. A., Miller, C. B. and Kyle, S. D. (2018) 'Sham sleep feedback delivered via actigraphy biases daytime symptom reports in people with insomnia: Implications for insomnia disorder and wearable devices.' *Journal of Sleep Research*, (July) p. e12726.

Geiger-Brown, J. M., Rogers, V. E., Liu, W., Ludeman, E. M., Downton, K. D. and Diaz-Abad, M. (2015) 'Cognitive behavioral therapy in persons with comorbid insomnia: A meta-analysis.' *Sleep Medicine Reviews*, 23 pp. 54–67.

Geneshka, M., Coventry, P., Cruz, J. and Gilbody, S. (2021) 'Relationship between green and blue spaces with mental and physical health: A systematic review of longitudinal observational studies.' *International Journal of Environmental Research and Public Health*, 18(17).

Geoffroy, P. A., Schroder, C. M., Reynaud, E. and Bourgin, P. (2019) 'Efficacy of

light therapy versus antidepressant drugs, and of the combination versus monotherapy, in major depressive episodes: A systematic review and meta-analysis.' *Sleep Medicine Reviews*, 48.

Glasgow R E, Vogt T M and Boles S M (1999) 'Evaluating the public health impact of health promotion interventions: the RE-AIM framework.' *American Journal of Public Health*, 89(9) pp. 1322–1327.

Gleeson, J. F. M., Alvarez-Jimenez, M., Cotton, S. M., Parker, A. G. and Hetrick, S. (2010) 'A systematic review of relapse measurement in randomized controlled trials of relapse prevention in first-episode psychosis.' *Schizophrenia Research*. Elsevier B.V., 119(1–3) pp. 79–88.

Glenn, D., Golinelli, D., Rose, R. D., Roy-Byrne, P., Stein, M. B., Sullivan, G., Bystritksy, A., Sherbourne, C. and Craske, M. G. (2013) 'Who gets the most out of cognitive behavioral therapy for anxiety disorders? The role of treatment dose and patient engagement.' *Journal of Consulting and Clinical Psychology*, 81(4) pp. 639–649.

Golden, R. N., Gaynes, B. N., Ekstrom, R. D., Hamer, R. M., Jacobsen, F. M., Suppes, T., Wisner, K. L. and Nemeroff, C. B. (2005) 'The Efficacy of Light Therapy in the Treatment of Mood Disorders : A Review and Meta-Analysis of the Evidence.' *American Journal of Psychiatry*, 162(April) pp. 656–662.

Gomes, A. A., Tavares, J. and De Azevedo, M. H. P. (2011) 'Sleep and academic performance in undergraduates: A multi-measure, multi-predictor approach.' *Chronobiology International*, 28(9) pp. 786–801.

Gonçalves, B. S. B., Adamowicz, T., Louzada, F. M., Moreno, C. R. and Araujo, J. F. (2015) 'A fresh look at the use of nonparametric analysis in actimetry.' *Sleep Medicine Reviews*, 20 pp. 84–91.

Gooley, J. J. (2017) 'Chapter 14 Light Resetting and Entrainment of Human Circadian Rhythms.' *In* Kumar, V. (ed.) *Biological Timekeeping: Clocks, Rhythms and Behaviour*. Spinger (India) Pvt. Ltd, pp. 297–313.

Gooley, J. J., Rajaratnam, S. M. W., Brainard, G. C., Kronauer, R. E., Czeisler, C. A. and Lockley, S. W. (2010) 'Spectral responses of the human circadian system depend on the irradiance and duration of exposure to light.' *Science Translational Medicine*, 2(31).

Green, A. (2008) 'Sleep, Occupation and the Passage of Time.' *The British Journal of Occupational Therapy*, 71 pp. 339–347.

Green, A. (2015) 'Sleep and Occupation.' *In* Green, A. and Brown, C. (eds) *An Occupational Therapist's Guide to Sleep and Sleep Problems*. London: Jessica Kingsley Publishers.

di Gregorio, S. (2011) 'Using NVivo for Your Literature Review.' *In Strategies in qualitative research: Issues and results from analysis using QSR Nvivo and NUD*IST*, pp. 1–12.

Grundy, A. C. (2018) 'Patient and Public Invovlement (PPI) and the Research

Process.' *In* Penny Bee, Helen Brooks, Patrick Callaghan, and K. L. (ed.) *A research handbook for patient and public involvement researchers*. Manchester: Manchester University Press, pp. 9–24.

Grundy, A. C., Bee, P., Meade, O., Callaghan, P., Beatty, S., Olleveant, N. and Lovell, K. (2016) 'Bringing meaning to user involvement in mental health care planning: A qualitative exploration of service user perspectives.' *Journal of Psychiatric and Mental Health Nursing*, 23(1) pp. 12–21.

Guillemin, M., McDougall, R., Martin, D., Hallowell, N., Brookes, A. and Gillam, L. (2017) 'Primary care physicians' views about gatekeeping in clinical research recruitment: A qualitative study.' *AJOB Empirical Bioethics*, 8(2) pp. 99–105.

Guillodo, E., Lemey, C., Simonnet, M., Walter, M., Baca-García, E., Masetti, V., Moga, S., Larsen, M., Ropars, J. and Berrouiguet, S. (2020) 'Clinical applications of mobile health wearable–based sleep monitoring: Systematic review.' *JMIR mHealth and uHealth*, 8(4) pp. 1–10.

Gumley, A. I., Macbeth, A., Reilly, J. D., O'Grady, M., White, R. G., McLeod, H., Schwannauer, M. and Power, K. G. (2015) 'Fear of recurrence: Results of a randomized trial of relapse detection in schizophrenia.' *British Journal of Clinical Psychology*, 54(1) pp. 49–62.

Gumport, N. B., Yu, S. H., Mullin, A. C., Mirzadegan, I. A. and Harvey, A. G. (2020) 'The Validation of a Provider-Reported Fidelity Measure for the Transdiagnostic Sleep and Circadian Intervention in a Community Mental Health Setting.' *Behavior Therapy*, 51(5) pp. 800–813.

Gurpegui, M., Aguilar, M. C., Martínez-Ortega, J. M., Diaz, F. J. and De Leon, J. (2004) 'Caffeine intake in outpatients with schizophrenia.' *Schizophrenia Bulletin*, 30(4) pp. 935–945.

Gutman, S. A., Gregory, K. A., Sadlier-Brown, M. M., Schlissel, M. A., Schubert, A. M., Westover, L. A. and Miller, R. C. (2017) 'Comparative effectiveness of three occupational therapy sleep interventions: A randomized controlled study.' *OTJR Occupation, Participation and Health*, 37(1) pp. 5–13.

Haghayegh, S., Khoshnevis, S., Smolensky, M. H., Diller, K. R. and Castriotta, R. J. (2019) 'Before-bedtime passive body heating by warm shower or bath to improve sleep: A systematic review and meta-analysis.' *Sleep Medicine Reviews*, 46 pp. 124–135.

Hansen, B., Langsrud, K., Ruud, T., Morken, G., Stiles, T. C., Grawe, R. W., Kallestad, H., Hansen, B., Langsrud, K., Ruud, T., Morken, G., Stiles, T. C. and Gråwe, R. W. (2011) 'Differences between patients' and clinicians' report of sleep disturbance: a field study in mental health care in Norway.' *BMC psychiatry*, 11(186) p. 186.

Hardaker, L., Halcomb, E. J., Griffiths, R., Bolzan, N., Hardaker, L., Halcomb, E. J., Griffiths, R. and Bolzan, N. (2007) 'The role of the occupational therapist in adolescent mental health: A critical review of the literature.' *Australian e-Journal for the Advancement of Mental Health*, 6(3) pp. 194–203.

Harrison, E. G., Keating, J. L. and Morgan, P. E. (2019) 'Non-pharmacological interventions for restless legs syndrome: a systematic review of randomised controlled trials.' *Disability and Rehabilitation*, 41(17) pp. 2006–2014.

Harvey, A. G. and Buysse, D. J. (2018) Treating Sleep Problems: A Transdiagnostic Approach. Guildford: The Guildford Press.

Harvey, A. G., Dong, L., Hein, K., Yu, S. H., Martinez, A. J., Gumport, N. B., Smith, F. L., Chapman, A., Lisman, M., Mirzadegan, I. A., Mullin, A. C., Fine, E., Dolsen, M. R., Gasperetti, C. E., Bukosky, J., Alvarado-Martinez, C. G., Kilbourne, A. M., Rabe-Hesketh, S. and Buysse, D. J. (2021) 'A randomized controlled trial of the Transdiagnostic Intervention for Sleep and Circadian Dysfunction (TranS-C) to improve serious mental illness outcomes in a community setting.' Journal of Consulting and Clinical Psychology, 89(6) pp. 537–550.

Harvey, A. G., Kaplan, K. A. and Soehner, A. M. (2015) 'Interventions for sleep disturbance in bipolar disorder.' *Sleep Medicine Clinics*, 10(1) pp. 101–105.

Harvey, A. G., Murray, G., Chandler, R. A. and Soehner, A. (2011) 'Sleep Disturbance as Transdiagnostic: Consideration of Neurobiological Mechanisms.' *Clinical psychology review*, 31(2) pp. 225–235.

Harvey, A. G. and Tang, N. K. Y. (2012) '(Mis)perception of sleep in insomnia: a puzzle and a resolution.' *Psychological bulletin*, 138(1) pp. 77–101.Hassed, C., Antoniades, J., Jones, K., Rajaratnam, S., Kiropolous, L., Naughton, M. and Piterman, L. (2012) 'An examination of australian general practitioners' knowledge, attitudes and practices in relation to sleep disorders.' *Malaysian Family Physician*, 7(1) pp. 16–23.

Haus, E. L. and Smolensky, M. H. (2013) 'Shift work and cancer risk: potential mechanistic roles of circadian disruption, light at night, and sleep deprivation.' *Sleep medicine reviews*, 17(4) pp. 273–84.

Hayes, R. L. and Halford, W. K. (1996) 'Time use of unemployed and employed single male schizophrenia subjects.' *Schizophrenia Bulletin*, 22(4) pp. 659–669.

Haynes, S. N., Woodward, S., Moran, R. and Alexander, D. (1974) 'Relaxation treatment of insomnia.' *Behavior Therapy*, 5(4) pp. 555–558.

Hays, R. D., Martin, S. A., Sesti, A. M. and Spritzer, K. L. (2005) 'Psychometric properties of the Medical Outcomes Study Sleep measure.' *Sleep Medicine*, 6(1) pp. 41–44.

Heckers, S., Barch, D. M., Bustillo, J., Gaebel, W., Gur, R., Malaspina, D., Owen, M. J., Schultz, S., Tandon, R., Tsuang, M., Van Os, J. and Carpenter, W. (2013) 'Structure of the psychotic disorders classification in DSM-5.' *Schizophrenia Research*, 150(1) pp. 11–14.

Van der Helms & Walker, M. P. (2009) 'Overnight Therapy? The Role of Sleep in Emotional Brain Processing.' *Psychological bulletin*, 135(5) pp. 731–748.

Henriksen, T. E., Skrede, S., Fasmer, O. B., Schoeyen, H., Leskauskaite, I., Bjørke-Bertheussen, J., Assmus, J., Hamre, B., Grønli, J. and Lund, A. (2016) 'Blue-

blocking glasses as additive treatment for mania: A randomized placebo-controlled trial.' *Bipolar Disorders*, 18(3) pp. 221–232.

Henson, P., Barnett, I., Keshavan, M. and Torous, J. (2020) 'Towards clinically actionable digital phenotyping targets in schizophrenia.' *npj Schizophrenia*, 6(1) pp. 1–7.

Hodann-Caudevilla, R. M., Díaz-Silveira, C., Burgos-Julián, F. A. and Santed, M. A. (2020) 'Mindfulness-based interventions for people with schizophrenia: A systematic review and meta-analysis.' *International Journal of Environmental Research and Public Health*, 17(13) pp. 1–18.

Hofstetter, J. R., Lysaker, P. H. and Mayeda, A. R. (2005) 'Quality of sleep in patients with schizophrenia is associated with quality of life and coping.' *BMC psychiatry*, 5(13).

Hombali, A., Seow, E., Yuan, Q., Chang, S. H. S., Satghare, P., Kumar, S., Verma, S. K., Mok, Y. M., Chong, S. A. and Subramaniam, M. (2019) 'Prevalence and correlates of sleep disorder symptoms in psychiatric disorders.' *Psychiatry Research*, 279(February 2018) pp. 116–122.

Housing Grants Construction and Regeneration Act 1996 (1996) *Housing Grants Construction and Regeneration Act 1996*. UK Parliament.

Hoyer, D., Allen, A. and Jacobson, L. H. (2020) 'Hypnotics with novel modes of action.' *British Journal of Clinical Pharmacology*, 86(2) pp. 244–249.

Hsieh, H.-F. and Shannon, S. E. (2005) 'Three approaches to qualitative content analysis.' *Qualitative health research*, 15(9) pp. 1277–88.

Huang, Z. L., Zhang, Z. and Qu, W. M. (2014) 'Chapter 14: Roles of adenosine and its receptors in sleep-wake regulation.' *In* Mori, A. (ed.) *International Review of Neurobiology*. 1st ed., Amsterdam: Elsevier Inc., pp. 349–371.

Hughes, A. T. L. (2018) 'Locomotor exercise and circadian rhythms in mammals.' *Current Opinion in Physiology*, 5 pp. 51–57.

Hunt, G. E., Large, M. M., Cleary, M., Lai, H. M. X. and Saunders, J. B. (2018) 'Prevalence of comorbid substance use in schizophrenia spectrum disorders in community and clinical settings, 1990–2017: Systematic review and meta-analysis.' *Drug and Alcohol Dependence*, 191(July) pp. 234–258.

Hunt, J., Hooydonk, E. Van, Faller, P., Mailloux, Z. and Schaaf, R. (2017) 'Manualization of Occupational Therapy Using Ayres Sensory Integration ® for Autism.' *OTJR: Occupation, Participation and Health*, 37(3).

Hut, R. A., Kronfeld-Schor, N., van der Vinne, V. and De la Iglesia, H. (2012) *Chapter 17: In search of a temporal niche: Environmental factors*. Kalsbeek, A., Merrow, M., Roenneberg, T., and Foster, R. G. (eds) *Progress in Brain Research*. Amsterdam: Elsevier B.V.

Hwang, D., Nam, M. and Lee, Y. G. (2019) 'The effect of cognitive behavioral therapy for insomnia in schizophrenia patients with sleep Disturbance : A non-

randomized , assessor-blind trial.' *Psychiatry Research*, 274(February) pp. 182–188.

International Commission on Illumination (CIE) (2016) *TECHNICAL REPORT: Research Roadmap for Healthful Interior Lighting Applications*.

International Commission on Illumination (CIE) (2019) *CIE statement on non-visual effects of light: Recommending proper light at the proper time*.

INVOLVE (2012) *Briefing notes for researchers: public involvement in NHS , public health and social care research*.

Iranzo, A. (2018) 'Parasomnias and Sleep-Related Movement Disorders in Older Adults.' *Sleep Medicine Clinics*, 13(1) pp. 51–61.

Irish, L. A., Kline, C. E., Gunn, H. E., Buysse, D. J. and Hall, M. H. (2015) 'The role of sleep hygiene in promoting public health: A review of empirical evidence.' *Sleep medicine reviews*, 22 pp. 23–36.

Irish, L. A., Mead, M. P., Cao, L., Veronda, A. C. and Crosby, R. D. (2020) 'The effect of caffeine abstinence on sleep among habitual caffeine users with poor sleep.' *Journal of Sleep Research*, 00(November 2019) p. e13048.

Ives, J., Damery, S. and Redwod, S. (2013) 'PPI, paradoxes and Plato: Who's sailing the ship?' *Journal of Medical Ethics*, 39(3) pp. 181–185.

Iwama, M. (2015) 'Foreword.' *In* Green, A. and Brown, C. (eds) *An Occupational Therapist's Guide to Sleep and Sleep Problems*. London: Jessica Kingsley Publishers, pp. 9–10.

Jacobson, R. M., Adegbenro, A., Pankratz, V. S. and Poland, G. A. (2001) 'Adverse events and vaccination-the lack of power and predictability of infrequent events in pre-licensure study.' *Vaccine*, 19(17–19) pp. 2428–2433.

Jagannath, A., Peirson, S. N. and Foster, R. G. (2013) 'Sleep and circadian rhythm disruption in neuropsychiatric illness.' *Current Opinion in Neurobiology*, 23(5) pp. 888–894.

James Lind Alliance (n.d.) *James Lind Alliance*. James Lind Alliance, Priority Setting Partnerships. [Online] [Accessed on 13th November 2020] https://www.jla.nihr.ac.uk/.

James, N. (2016) 'Using email interviews in qualitative educational research: creating space to think and time to talk.' *International Journal of Qualitative Studies in Education*, 29(2) pp. 150–163.

Janků, K., Šmotek, M., Fárková, E. and Kopřivová, J. (2020) 'Block the light and sleep well: Evening blue light filtration as a part of cognitive behavioral therapy for insomnia.' *Chronobiology International*, 37(2) pp. 248–259.

Jann, B. and Hinz, T. (2016) 'Research Question and Design for Survey Research.' *In* Wolf, C., Joye, D., Smith, T., and Fu, Y. (eds) *The SAGE Handbook of Survey Methodology*. Thousand Oaks, California: SAGE Publications Ltd, pp. 105–121.

Jansson-Fröjmark, M. and Norell-Clarke, A. (2018) ‘The cognitive treatment components and therapies of cognitive behavioral therapy for insomnia: A systematic review.’ *Sleep Medicine Reviews*, 42 pp. 19–36.

Johnson, D. A., Billings, M. E. and Hale, L. (2018) ‘Environmental Determinants of Insufficient Sleep and Sleep Disorders: Implications for Population Health.’ *Current Epidemiology Reports*, 5(2) pp. 61–69.

Johnson, T. P. and Wislar, J. S. (2012) ‘Response rates and nonresponse errors in surveys.’ *JAMA - Journal of the American Medical Association*, 307(17) pp. 1805–1806.

Joint Formulary Committee (2021) *British National Formulary*. British National Formulary (online), London: BMJ Group and Pharmaceutical Press.

Jolley, S., Garety, P., Peters, E., Fornells-Ambrojo, M., Onwumere, J., Harris, V., Brabban, A. and Johns, L. (2015) ‘Opportunities and challenges in Improving Access to Psychological Therapies for people with Severe Mental Illness (IAPT-SMI): Evaluating the first operational year of the South London and Maudsley (SLaM) demonstration site for psychosis.’ *Behaviour Research and Therapy*, 64 pp. 24–30.

Jones, S. R. and Fernyhough, C. (2006) ‘The roles of thought suppression and metacognitive beliefs in proneness to auditory verbal hallucinations in a non-clinical sample.’ *Personality and Individual Differences*, 41(8) pp. 1421–1432.

Jordan, A. S., McSharry, D. G. and Malhotra, A. (2014) ‘Adult obstructive sleep apnoea.’ *The Lancet*, 383(9918) pp. 736–747.

Jung, Y. and St. Louis, E. K. (2016) ‘Treatment of REM Sleep Behavior Disorder.’ *Current Treatment Options in Neurology*, 18(11).

Kalmbach, D. A., Cuamatzi-Castelan, A. S., Tonnu, C. V., Tran, K. M., Anderson, J. R., Roth, T. and Drake, C. L. (2018) ‘Hyperarousal and sleep reactivity in insomnia: Current insights.’ *Nature and Science of Sleep*, 10 pp. 193–201.

Kalucy, M. J., Grunstein, R., Lambert, T. and Glozier, N. (2013) ‘Obstructive sleep apnoea and schizophrenia--a research agenda.’ *Sleep medicine reviews*, 17, October, pp. 357–65.

Kang, S. G., Lee, H. J., Jung, S. W., Cho, S. N., Han, C., Kim, Y. K., Kim, S. H., Lee, M. S., Joe, S. H., Jung, I. K. and Kim, L. (2007) ‘Characteristics and clinical correlates of restless legs syndrome in schizophrenia.’ *Progress in Neuro-Psychopharmacology and Biological Psychiatry*, 31(5) pp. 1078–1083.

Kaplan, K. A., Hardas, P. P., Redline, S. and Zeitzer, J. M. (2017) ‘Correlates of sleep quality in midlife and beyond: a machine learning analysis.’ *Sleep Medicine*, 34 pp. 162–167.

Kaplan, K. a and Harvey, A. G. (2013) ‘Behavioral treatment of insomnia in bipolar disorder.’ *The American journal of psychiatry*, 170(7) pp. 716–20.

Kapur, V. K., Rapoport, D. M., Sanders, M. H., Enright, P., Hill, J., Iber, C. and Romaniuk, J. (2000) ‘Rates of sensor loss in unattended home polysomnography:

The influence of age, gender, obesity, and sleep-disordered breathing.' *Sleep*, 23(5) pp. 682–688.

Kaskie, R. E., Graziano, B. and Ferrarelli, F. (2017) 'Schizophrenia and sleep disorders: Links, risks, and management challenges.' *Nature and Science of Sleep*, 9 pp. 227–239.

Keeney, S., Hasson, F. and McKenna, H. (2006) 'Consulting the oracle: Ten lessons from using the Delphi technique in nursing research.' *Journal of Advanced Nursing*, 53(2) pp. 205–212.

Keeney, S., Hasson, F. and McKenna, H. P. (2001) 'A critical review of the Delphi technique as a research methodology for nursing.' *International Journal of Nursing Studies*, 38(2) pp. 195–200.

Keijzer, H., Smits, M. G., Duffy, J. F. and Curfs, L. M. G. (2014) 'Why the dim light melatonin onset (DLMO) should be measured before treatment of patients with circadian rhythm sleep disorders.' *Sleep Medicine Reviews*, 18(4) pp. 333–339.

Kellett, S., Stockton, C., Marshall, H., Hall, J., Jennings, C. and Degadillo, J. (2018) 'Efficacy of narrative reformulation during cognitive analytic therapy for depression: Randomized dismantling trial.' *Journal of Affective Disorders*, 239(June) pp. 37–47.

Kelly, C. M., Jorm, A. F. and Kitchener, B. A. (2009) 'Development of mental health first aid guidelines for panic attacks: a Delphi study.' *BMC Psychiatry*, 9(49).

Kelly, C. M., Jorm, A. F. and Kitchener, B. A. (2010) 'Development of mental health first aid guidelines on how a member of the public can support a person affected by a traumatic event: a Delphi study.' *BMC Psychiatry*, 10 p. 49.

Kerz, M., Folarin, A., Meyer, N., Begale, M., MacCabe, J. and Dobson, R. J. (2016) 'SleepSight: A wearables- based relapse prevention system for Schizophrenia.' *In Proceedings of the 2016 ACM International Joint Conference on Pervasive and Ubiquitous Computing*. Association for Computing Machinery, pp. 113–116.

Khademagha, P., Aries, M. B. C., Rosemann, A. L. P. and van Loenen, E. J. (2016) 'Implementing non-image-forming effects of light in the built environment: A review on what we need.' *Building and Environment*, 108 pp. 263–272.

Kielhofner, G. (2008) *Model of human occupation: Theory and application.* Kielhofner, G. (ed.). Philadelphia: Lippincott Williams & Wilkins.

Kim, H. and Newman, M. G. (2019) 'The paradox of relaxation training: Relaxation induced anxiety and mediation effects of negative contrast sensitivity in generalized anxiety disorder and major depressive disorder.' *Journal of Affective Disorders*, 259(June) pp. 271–278.

King, C. and Voruganti, L. N. P. (2002) 'What's in a name? The evolution of the nomenclature of antipsychotic drugs.' *Journal of Psychiatry and Neuroscience*, 27(3) pp. 168–175.

Kinn, L. G. and Aas, R. W. (2009) 'Occupational therapists ' perception of their practice : A phenomenological study.' *Australian Occupational Therapy Journal*, 56

pp. 112–121.

Kirsch, D. B. (2011) ‘There and back again: A current history of sleep medicine.’ *Chest*. The American College of Chest Physicians, 139(4) pp. 939–946.

Klingaman, E. A., Palmer-Bacon, J., Bennett, M. E. and Rowland, L. M. (2015) ‘Sleep Disorders Among People With Schizophrenia: Emerging Research.’ *Current Psychiatry Reports*, 17(10).

Knapp, P., Raynor, D. K., Silcock, J. and Parkinson, B. (2011) ‘Can user testing of a clinical trial patient information sheet make it fit-for-purpose?--a randomized controlled trial.’ *BMC medicine*, 9(89).

Knowles, M. M., Foden, P., El-Deredy, W. and Wells, A. (2016) ‘A Systematic Review of Efficacy of the Attention Training Technique in Clinical and Nonclinical Samples.’ *Journal of Clinical Psychology*, 72(10) pp. 999–1025.

Kolla, B. P., Foroughi, M., Saeidifard, F., Chakravorty, S., Wang, Z. and Mansukhani, M. P. (2018) ‘The impact of alcohol on breathing parameters during sleep: A systematic review and meta-analysis.’ *Sleep Medicine Reviews*, 42 pp. 59–67.

Konis, K. (2018) ‘Field evaluation of the circadian stimulus potential of daylit and non-daylit spaces in dementia care facilities.’ *Building and Environment*, 135(March) pp. 112–123.

Krauchi, K. and Deboer, T. (2010) ‘The interrelationship between sleep regulation and thermoregulation.’ *Frontiers in Bioscience 15*, 15(1) pp. 604–625.

Kredlow, M. A., Capozzoli, M. C. and Otto, M. W. (2015) ‘The effects of physical activity on sleep : a meta-analytic review.’ *Journal of Behavioral Medicine*, 38 pp. 427–449.

Kripke, D. F. (2016) ‘Mortality Risk of Hypnotics: Strengths and Limits of Evidence.’ *Drug Safety*, 39(2) pp. 93–107.

Krumpal, I. (2013) ‘Determinants of social desirability bias in sensitive surveys: A literature review.’ *Quality and Quantity*, 47(4) pp. 2025–2047.

Kuck, J., Pantke, M. and Flick, U. (2014) ‘Effects of social activation and physical mobilization on sleep in nursing home residents.’ *Geriatric Nursing*, 35(6) pp. 455–461.

Kumar, P. N. S., Andrade, C., Bhakta, S. G. and Singh, N. M. (2007) ‘Melatonin in schizophrenic outpatients with insomnia: A double-blind, placebo-controlled study.’ *Journal of Clinical Psychiatry*, 68(2) pp. 237–241.

Kyle, S. D., Aquino, M. R. J., Miller, C. B., Henry, A. L., Crawford, M. R., Espie, C. A. and Spielman, A. J. (2015) ‘Towards standardisation and improved understanding of sleep restriction therapy for insomnia disorder: A systematic examination of CBT-I trial content.’ *Sleep Medicine Reviews*, 23 pp. 83–88.

Kyle, S. D., Miller, C. B., Rogers, Z., Siriwardena, A. N., Macmahon, K. M. and

Espie, C. A. (2014) ‘Sleep restriction therapy for insomnia is associated with reduced objective total sleep time, increased daytime somnolence, and objectively impaired vigilance: implications for the clinical management of insomnia disorder.’ *Sleep*, 37(2) pp. 229–37.

Kyle, S. D., Morgan, K., Spiegelhalder, K. and Espie, C. a (2011) ‘No pain, no gain: an exploratory within-subjects mixed-methods evaluation of the patient experience of sleep restriction therapy (SRT) for insomnia.’ *Sleep medicine*, 12(8) pp. 735–47.

Lai, C. K. Y., Lai, D. L. L., Ho, J. S. C., Wong, K. K. Y. and Cheung, D. S. K. (2016) ‘Interdisciplinary collaboration in the use of a music-with-movement intervention to promote the wellbeing of people with dementia and their families: Development of an evidence-based intervention protocol.’ *Nursing and Health Sciences*, 18(1) pp. 79–84.

Lam, A. H. Y. and Chien, W. T. (2016) ‘The effectiveness of mindfulness-based intervention for people with schizophrenia: A systematic review.’ *Neuropsychiatry*, 6(5) pp. 208–222.

Lambert, R., Harrison, D. and Watson, M. (2007) ‘Complexity, Occupational Therapy, Unpredictability and the Scientific Method: a Response to Creek et al (2005) and Duncan et al (2007).’ *British Journal of Occupational Therapy*, 70(12) pp. 534–536.

Lancaster, G. A., Dodd, S. and Williamson, P. R. (2004) ‘Design and analysis of pilot studies: Recommendations for good practice.’ *Journal of Evaluation in Clinical Practice*, 10(2) pp. 307–312.

Laposky, A. D., Van Cauter, E. and Diez-Roux, A. V. (2016) ‘Reducing health disparities: The role of sleep deficiency and sleep disorders.’ *Sleep Medicine*, 18 pp. 3–6.

Laursen, T. M., Munk-Olsen, T. and Gasse, C. (2011) ‘Chronic somatic comorbidity and excess mortality due to natural causes in persons with schizophrenia or bipolar affective disorder.’ *PLoS ONE*, 6(9).

Lederman, O., Ward, P. B., Firth, J., Maloney, C., Carney, R., Vancampfort, D., Stubbs, B., Kalucy, M. and Rosenbaum, S. (2019) ‘Does exercise improve sleep quality in individuals with mental illness ? A systematic review and meta-analysis.’ *Journal of Psychiatric Research*, 109(July 2018) pp. 96–106.

Léger, D., Torres, M. J., Bayon, V., Hercberg, S., Galan, P., Chennaoui, M. and Andreeva, V. A. (2019) ‘The association between physical and mental chronic conditions and napping.’ *Scientific Reports*, 9(1) pp. 3–9.

Leland, N. E., Fogelberg, D., Sleight, A., Mallinson, T., Vigen, C., Blanchard, J., Carlson, M. and Clark, F. (2016) ‘Napping and nighttime sleep: Findings from an occupation-based intervention.’ *American Journal of Occupational Therapy*, 70(4) pp. 1–7.

Lemyre, A., Belzile, F., Landry, M., Bastien, C. H. and Beaudoin, L. P. (2020) ‘Pre-sleep cognitive activity in adults: A systematic review.’ *Sleep Medicine Reviews*, 50 pp. 1–13.

Lewis, K. J. S., Di Florio, A., Forty, L., Gordon-Smith, K., Perry, A., Craddock, N., Jones, L. and Jones, I. (2018) 'Mania triggered by sleep loss and risk of postpartum psychosis in women with bipolar disorder.' *Journal of Affective Disorders*, 225(July 2017) pp. 624–629.

Lieberman, J. A. and First, M. B. (2018) 'Psychotic disorders.' *New England Journal of Medicine*, 379(3) pp. 270–280.

Lim, A., Hoek, H. W., Deen, M. L., Blom, J. D., Bruggeman, R., Cahn, W., de Haan, L., Kahn, R. S., Meijer, C. J., Myin-Germeys, I., van Os, J. and Wiersma, D. (2016) 'Prevalence and classification of hallucinations in multiple sensory modalities in schizophrenia spectrum disorders.' *Schizophrenia Research*, 176(2–3) pp. 493–499.

Lo, J. C., Groeger, J. a, Santhi, N., Arbon, E. L., Lazar, A. S., Hasan, S., von Schantz, M., Archer, S. N. and Dijk, D.-J. (2012) 'Effects of partial and acute total sleep deprivation on performance across cognitive domains, individuals and circadian phase.' *PloS one*, 7(9) p. e45987.

Loddo, G., Lopez, R., Cilea, R., Dauvilliers, Y. and Provini, F. (2019) 'Disorders of Arousal in adults: new diagnostic tools for clinical practice.' *Sleep Science and Practice*, 3(1) pp. 1–13.

Loh, S. Y., Sapihis, M., Danaee, M. and Chua, Y. P. (2020) 'The role of occupational-participation, meaningful-activity and quality-of-life of colorectal cancer survivors: findings from path-modelling.' *Disability and Rehabilitation*, 0(0).

Lovato, N., Micic, G., Gradisar, M., Ferguson, S. A., Burgess, H. J., Kennaway, D. J. and Lack, L. (2016) 'Can the circadian phase be estimated from self-reported sleep timing in patients with Delayed Sleep Wake Phase Disorder to guide timing of chronobiologic treatment?' *Chronobiology International*, 33(10) pp. 1376–1390.

Lovato, N., Miller, C. B., Gordon, C. J., Grunstein, R. R. and Lack, L. (2019) 'The efficacy of biofeedback for the treatment of insomnia: a critical review.' *Sleep Medicine*, 56 pp. 192–200.

Lu, S. M., Lin, M. F. and Chang, H. J. (2020) 'Progressive muscle relaxation for patients with chronic schizophrenia: A randomized controlled study.' *Perspectives in Psychiatric Care*, 56(1) pp. 86–94.

Lucas, R. J., Peirson, S. N., Berson, D. M., Brown, T. M., Cooper, H. M., Czeisler, C. A., Figueiro, M. G., Gamlin, P. D., Lockley, S. W., O'Hagan, J. B., Price, L. L. A., Provencio, I., Skene, D. J. and Brainard, G. C. (2014) 'Measuring and using light in the melanopsin age.' *Trends in Neurosciences*, 37(1) pp. 1–9.

Luik, A. I., van der Zweerde, T., van Straten, A. and Lancee, J. (2019) 'Digital Delivery of Cognitive Behavioral Therapy for Insomnia.' *Current Psychiatry Reports*, 21(7).

Lunsford-avery, J. R., Lebourgeois, M. K., Gupta, T. and Mittal, V. A. (2015) 'Actigraphic-measured sleep disturbance predicts increased positive symptoms in adolescents at ultra high-risk for psychosis : A longitudinal study.' *Schizophrenia Research*, 164(1–3) pp. 15–20.

Lyne, J., Quinvan, L., Byrne, C., Malone, K. and Walsh, C. (2011) ‘Sleep Hygiene Use in a Psychiatry Outpatient Setting Sleep Hygiene Use in a Psychiatry Outpatient Setting.’ *Irish Medical Journal*, 104(2) pp. 49–50.

van Maanen, A., Meijer, A. M., van der Heijden, K. B. and Oort, F. J. (2016) ‘The effects of light therapy on sleep problems: A systematic review and meta-analysis.’ *Sleep Medicine Reviews*, 29 pp. 52–62.

MacDonald, J., Garvie, C., Gordon, S., Huthwaite, M., Mathieson, F., Wood, A.-J. and Romans, S. (2015) ‘“Is it the crime of the century?”’ *International Clinical Psychopharmacology*, 30(4) pp. 193–201.

Mace, C. (2007) ‘Mindfulness in psychotherapy: An introduction.’ *Advances in Psychiatric Treatment*, 13(2) pp. 147–154.

Mack, L. J. and Rybarczyk, B. D. (2011) ‘Behavioral treatment of insomnia: A proposal for a stepped-care approach to promote public health.’ *Nature and Science of Sleep*, 3 pp. 87–99.

Madden, M. and Speed, E. (2017) ‘Beware Zombies and Unicorns: Toward Critical Patient and Public Involvement in Health Research in a Neoliberal Context.’ *Frontiers in Sociology*, 2(June) pp. 1–6.

Malkani, R. G., Abbott, S. M., Reid, K. J. and Zee, P. C. (2018) ‘Diagnostic and treatment challenges of sighted non-24-hour sleep-wake disorder.’ *Journal of Clinical Sleep Medicine*, 14(4) pp. 603–613.

Manber, R., Carney, C. C., Erdinger, J., Dana, E., Freisman, L., Haynes, P. L., Karlin, B. E., Pigeon, W., Siebern, A. T. and Trockel, M. (2012) ‘Dissemination of |CBTi to the non-sleep specialist: protocol Development and Training issues.’ *Journal of clinical sleep medicine*, 8(2) pp. 209–18.

Manoach, D. S., Mylonas, D. and Baxter, B. (2020) ‘Targeting sleep oscillations to improve memory in schizophrenia.’ *Schizophrenia Research*, July(221) pp. 63–70.

Manoach, D. S., Pan, J. Q., Purcell, S. M. and Stickgold, R. (2016) ‘Review Reduced Sleep Spindles in Schizophrenia : A Treatable Endophenotype That Links Risk Genes to Impaired Cognition ?’ *Biological Psychiatry*, 80(8) pp. 599–608.

Mantua, J., Gravel, N. and Spencer, R. M. C. (2016) ‘Reliability of sleep measures from four personal health monitoring devices compared to research-based actigraphy and polysomnography.’ *Sensors (Switzerland)*, 16(646).

Marino, M., Li, Y., Rueschman, M. N., Winkelman, J. W., Ellenbogen, J. M., Solet, J. M., Dulin, H., Berkman, L. F. and Buxton, O. M. (2013) ‘Measuring Sleep: Accuracy, Sensitivity, and Specificity of Wrist Actigraphy Compared to Polysomnography.’ *Sleep*, 36(11) pp. 1747–1755.

Martinez, G. J., Mattingly, S., Young, J., Faust, L., Dey, A., Campbell, A., Choudhury, M., Mirjafari, S., Nepal, S., Robles-Granda, P., Saha, K. and Striegel, A. D. (2020) ‘Improved Sleep Detection Through the Fusion of Phone Agent and Wearable Data Streams.’ *In 2020 IEEE International Conference on Pervasive Computing and Communications Workshops (PerCom Workshops)*. Austin, TX,

USA, pp. 1–6.

Maruani, J. and Geoffroy, P. A. (2019) ‘Bright Light as a Personalized Precision Treatment of Mood Disorders.’ *Frontiers in Psychiatry*, 10(March) pp. 1–9.

Mathie, E., Wilson, P., Poland, F., Mcneilly, E., Howe, A., Staniszewska, S., Cowe, M., Munday, D. and Goodman, C. (2014) ‘Consumer involvement in health research: A UK scoping and survey.’ *International Journal of Consumer Studies*, 38(1) pp. 35–44.

Matthews, E. E., Arnedt, J. T., McCarthy, M. S., Cuddihy, L. J. and Aloia, M. S. (2013) ‘Adherence to cognitive behavioral therapy for insomnia: A systematic review.’ *Sleep Medicine Reviews*, 17(6) pp. 453–464.

Matthews, E. E., Schmiege, S. J., Cook, P. F., Berger, A. M. and Aloia, M. S. (2012) ‘Adherence to Cognitive Behavioral Therapy for Insomnia (CBTI) Among Women Following Primary Breast Cancer Treatment: A Pilot Study.’ *Behavioral Sleep Medicine*, 10(3) pp. 217–229.

Matthews, L. and Simpsons, S. A. (2020) ‘Evaluation of Behaviour change interventions.’ *In* Martin S. Hagger, Linda D. Cameron, Kyra Hamilton, Nelli Hankonen, T. L. (ed.) *The Handbook of Behaviour Change*. Cambridge University Press.

Maurer, L. F., Espie, C. A. and Kyle, S. D. (2018) ‘How does sleep restriction therapy for insomnia work? A systematic review of mechanistic evidence and the introduction of the Triple-R model.’ *Sleep Medicine Reviews*, 42 pp. 127–138.

Maurer, L. F., Espie, C. A., Omlin, X., Reid, M. J., Sharman, R., Gavriloff, D., Emsley, R. and Kyle, S. D. (2020) ‘Isolating the role of time in bed restriction in the treatment of insomnia: a randomised, controlled, dismantling trial comparing sleep restriction therapy with time in bed regularisation.’ *Sleep*, (May) pp. 1–12.

Mays, N., Pope, C. and Popay, J. (2005) ‘Systematically reviewing qualitative and quantitative evidence to inform management and policy-making in the health field.’ *Journal of health services research & policy*, 10(1) pp. 6–20.

McFadden, E., Jones, M. E., Schoemaker, M. J., Ashworth, A. and Swerdlow, A. J. (2014) ‘The relationship between obesity and exposure to light at night: Cross-sectional analyses of over 100,000 women in the breakthrough generations study.’ *American Journal of Epidemiology*, 180(3) pp. 245–250.

McGowan, S. K. and Behar, E. (2013) ‘A Preliminary Investigation of Stimulus Control Training for Worry: Effects on Anxiety and Insomnia.’ *Behavior Modification*, 37(1) pp. 90–112.

McHill, A. W., Phillips, A. J. K., Czeisler, C. A., Keating, L., Yee, K., Barger, L. K., Garaulet, M., Scheer, F. A. J. L. and Klerman, E. B. (2017) ‘Later circadian timing of food intake is associated with increased body fat.’ *American Journal of Clinical Nutrition*, 106(5) pp. 1213–1219.

McPherson, S., Wicks, C. and Tercelli, I. (2020) ‘Patient experiences of psychological therapy for depression: A qualitative metasynthesis.’ *BMC Psychiatry*,

20(1) pp. 1–18.

Means, M. K., Lichstein, K. L., Epperson, M. T. and Johnson, C. T. (2000) 'Relaxation therapy for insomnia: Nighttime and day time effects.' *Behaviour Research and Therapy*, 38(7) pp. 665–678.

Medic, G., Wille, M. and Hemels, M. E. H. (2017) 'Short- and long-term health consequences of sleep disruption.' *Nature and Science of Sleep*, 9 pp. 151–161.

Melo-Dias, C., Lopes, R. C., Cardoso, D. F. B., Bobrowicz-Campos, E. and Apóstolo, J. L. A. (2019) 'Schizophrenia and Progressive Muscle Relaxation – A systematic review of effectiveness.' *Heliyon*, 5(4).

Melo, D. L. M., Carvalho, L. B. C., Prado, L. B. F. and Prado, G. F. (2019) 'Biofeedback Therapies for Chronic Insomnia: A Systematic Review.' *Applied Psychophysiology Biofeedback*, 44(4) pp. 259–269.

Menet, J. S. and Rosbash, M. (2011) 'When brain clocks lose track of time: Cause or Consequence of neuropsychiatric disorders.' *Current Opinion in Neurobiology*, 21(6) pp. 849–857.

Meyer, A. (1922) 'The Philosophy of Occupational Therapy.' *Archives of Occupational Therapy*, 1(1).

Meyer, N. (2020) *Sleep and Circadian Rhythm Disturbance and Deterioration and Relapse in Psychosis : A Digital Phenotyping Study*. King's College London.

Meyer, N., D.W. Joyce, C. Karr, Hees, V. va., S. Faulkner, D-J. Dijk, J. MacCabe, Vos, M. d. and A. Skeldon (2019) 'Desynchronisation of sleep-wake rhythms in schizophrenia: a theoretical intervention framework.' *Sleep Medicine*, 64(Supplement 1) pp. S253–S254.

Meyer, N., Faulkner, S. M., Mccutcheon, R. A., Pillinger, T., Dijk, D. and Maccabe, J. H. (2020) 'Sleep and Circadian Rhythm Disturbance in Remitted Schizophrenia and Bipolar Disorder: A Systematic Review and Meta-analysis.' *Schizophrenia Bulletin*, 46(5) pp. 1126–1143.

Meyer, N., Kerz, M., Folarin, A., Joyce, D. W., Jackson, R., Karr, C., Dobson, R. and Maccabe, J. (2018) 'Capturing rest-activity profiles in schizophrenia using wearable and mobile technologies: Development, implementation, feasibility, and acceptability of a remote monitoring platform.' *JMIR mHealth and uHealth*, 6(10).

Meyhöfer, I., Kumari, V., Hill, A., Petrovsky, N. and Ettinger, U. (2017) 'Sleep deprivation as an experimental model system for psychosis: Effects on smooth pursuit, prosaccades, and antisaccades.' *Journal of Psychopharmacology*, 31(4) pp. 418–433.

Michels, F., Schilling, C., Rausch, F., Eifler, S., Zink, M., Meyer-Lindenberg, A. and Schredl, M. (2014) 'Nightmare frequency in schizophrenic patients, healthy relatives of schizophrenic patients, patients at high risk states for psychosis, and healthy controls.' *International Journal of Dream Research*, 7(1) pp. 9–13.

Michie, S., Atkins, L. and West, R. (2014) *The Behaviour Change Wheel: A Guide to*

Designing Interventions. 1st ed., Sutton, Surrey: Silverback Publishing.

Michie, S., Stralen, M. M. van and West, R. (2011) 'The behaviour change wheel: A new method for characterising and designing behaviour change interventions.' *Implementation Science*, 6(42).

Mikkelsen, K., Stojanovska, L., Polenakovic, M., Bosevski, M. and Apostolopoulos, V. (2017) 'Exercise and mental health.' *Maturitas*, 106(August) pp. 48–56.

Miller, C. B., Espie, C. A., Epstein, D. R., Friedman, L., Morin, C. M., Pigeon, W. R., Spielman, A. J. and Kyle, S. D. (2014) 'The evidence base of sleep restriction therapy for treating insomnia disorder.' *Sleep Medicine Reviews*, 18(5) pp. 415–424.

Minato, M. and Zemke, R. (2004) 'Time use of people with schizophrenia living in the community.' *Occupational Therapy International*, 11(3) pp. 177–191.

Mishima, K. (2017) 'Pathophysiology and strategic treatment of sighted non-24-h sleep–wake rhythm disorders.' *Sleep and Biological Rhythms*, 15(1) pp. 11–20.

Mishra, A., Maiti, R., Ranjan, B., Jena, M., Nath, S. and Sahu, P. (2020) 'Effect of add-on ramelteon therapy on sleep and circadian rhythm disruption in patients with schizophrenia : A randomized controlled trial.' *European Neuropsychopharmacology*, 31 pp. 109–118.

Mistlberger, R. E. and Skene, D. J. (2004) 'Social influences on mammalian circadian rhythms: Animal and human studies.' *Biological Reviews of the Cambridge Philosophical Society*, 79(3) pp. 533–556.

Mitchell, L. J., Bisdounis, L., Ballesio, A., Omlin, X. and Kyle, S. D. (2019) 'The impact of cognitive behavioural therapy for insomnia on objective sleep parameters: A meta-analysis and systematic review.' *Sleep Medicine Reviews*, 47 pp. 90–102.

Miyazaki, S., Liu, C. Y. and Hayashi, Y. (2017) 'Sleep in vertebrate and invertebrate animals, and insights into the function and evolution of sleep.' *Neuroscience Research*. Elsevier Ireland Ltd and Japan Neuroscience Society, 118 pp. 3–12.

Moher, D., Liberati, A., Tetzlaff, J. and Altman, D. G. (2009) 'Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement.' *PLoS medicine*, 6(7).

Momomura, S. I. (2012) 'Treatment of Cheyne-Stokes respiration-central sleep apnea in patients with heart failure.' *Journal of Cardiology*, 59(2) pp. 110–116.

Montero-Marin, J., Garcia-Campayo, J., Pérez-Yus, M. C., Zabaleta-Del-Olmo, E. and Cuijpers, P. (2019) 'Meditation techniques v. relaxation therapies when treating anxiety: a meta-analytic review.' *Psychological Medicine*, 49(13) pp. 2118–2133.

Monti, J. M. and Monti, D. (2004) 'Sleep in schizophrenia patients and the effects of antipsychotic drugs.' *Sleep Medicine Reviews*, 8(2) pp. 133–148.

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., O'Cathain, A., Tinati, T., Wight, D. and Baird, J. (2015) 'Process evaluation of complex interventions: Medical Research Council guidance.' *British medical*

journal, 350 pp. h1258–h1258.

Morera-Fumero, A. L., Fernandez-Lopez, L. and Abreu-Gonzalez, P. (2020) 'Melatonin and melatonin agonists as treatments for benzodiazepines and hypnotics withdrawal in patients with primary insomnia. A systematic review.' *Drug and Alcohol Dependence*, 212(November 2019) p. 107994.

Morin, C. M., Davidson, J. R. and Beaulieu-Bonneau, S. (2017) 'Chapter 85, Cognitive Behavior Therapies for Insomnia I: Approaches and Efficacy.' *In* Kryger, M., Roth, T., and Dement, W. C. (eds) *Principles and Practice of Sleep Medicine*. 6th ed., Amsterdam: Elsevier Inc., pp. 804-813.e5.

Morin, C. M., Vallières, A. and Ivers, H. (2007) 'Dysfunctional beliefs and attitudes about sleep (DBAS): validation of a brief version (DBAS-16).' *Sleep*, 30(11) pp. 1547–1554.

Morken, G. (2012) *NCT00235365, Metacognitive Therapy for Comorbid Insomnia*. ClinicalTrials.gov. [Online] [Accessed on 4th September 2020] https://clinicaltrials.gov/ct2/show/NCT00235365.

Morrison, A. P., Pyle, M., Chapman, N., French, P., Parker, S. K. and Wells, A. (2014) 'Metacognitive therapy in people with a schizophrenia spectrum diagnosis and medication resistant symptoms: A feasibility study.' *Journal of Behavior Therapy and Experimental Psychiatry*, 45(2) pp. 280–284.

Morrison, A. P. and Wells, A. (2000) 'Thought control strategies in schizophrenia: A comparison with non-patients.' *Behaviour Research and Therapy*, 38(12) pp. 1205–1209.

Mulligan, L. D., Haddock, G., Emsley, R., Neil, S. T., Kyle, S. D., Mulligan, L. D., Haddock, G., Emsley, R., Neil, S. T. and Kyle, S. D. (2016) 'High Resolution Examination of the Role of Sleep Disturbance in Predicting Functioning and Psychotic Symptoms in Schizophrenia : A Novel Experience Sampling Study High Resolution Examination of the Role of Sleep Disturbance.' *Journal of Abnormal Psychology*, 125(6) pp. 788–797.

Munch, M. and Bromundt, V. (2012) 'Light and chronobiology: Implications for health and disease.' *Dialogues in Clinical Neuroscience*, 14(4) pp. 448–453.

Münch, M., Nowozin, C., Regente, J., Bes, F., De Zeeuw, J., Hädel, S., Wahnschaffe, A. and Kunz, D. (2017) 'Blue-Enriched Morning Light as a Countermeasure to Light at the Wrong Time: Effects on Cognition, Sleepiness, Sleep, and Circadian Phase.' *Neuropsychobiology*, 74(4) pp. 207–218.

Muñoz, J. P., Farnworth, L. and Dieleman, C. (2016) 'Harnessing the Power of Occupation to Meet the Needs of People in Criminal Justice Settings.' *Occupational therapy international*, 23(3) pp. 221–228.

Murphy, M., Black, N., Lamping, D., McKee, C. M., Sanderson, C., Askham, J. and Marteau, T. (1998) 'Consensus development methods, and their use in clinical guideline development.' *Health technology assessment (Winchester, England)*, 2(3) pp. i–iv, 1–88.

Muzet, A. (2007) ‘Environmental noise, sleep and health.’ *Sleep Medicine Reviews*, 11(2) pp. 135–142.

Myers, E., Startup, H. and Freeman, D. (2011) ‘Cognitive behavioural treatment of insomnia in individuals with persistent persecutory delusions: a pilot trial.’ *Journal of behavior therapy and experimental psychiatry*, 42(3) pp. 330–6.

Myles, H., Vincent, A., Myles, N., Adams, R., Chandratilleke, M., Liu, D., Mercer, J., Vakulin, A., Wittert, G. and Galletly, C. (2018) ‘Obstructive sleep apnoea is more prevalent in men with schizophrenia compared to general population controls: results of a matched cohort study.’ *Australasian Psychiatry* p. 103985621877224.

Näher, A. F. and Krumpal, I. (2012) ‘Asking sensitive questions: The impact of forgiving wording and question context on social desirability bias.’ *Quality and Quantity*, 46(5) pp. 1601–1616.

Nair, R., Aggarwal, R. and Khanna, D. (2011) ‘Methods of Formal Consensus in Classification/Diagnostic Criteria and Guideline Development.’ *Seminars in Arthritis and Rheumatism*, 41(2) pp. 95–105.

Nathaniel, W., Badr, M. S., Belenky, G., Bliwise, D. L. and Buxton, O. M. (2015) ‘SLEEP - Recommended Amount of Sleep for a Healthy Adult: A Joint Consensus Statement of the American Academy of Sleep Medicine and Sleep Research Society.’ *Sleep*, 38(6) pp. 843–844.

National Collaborating Centre for Mental Health (2014) *Psychosis and schizophrenia in adults: treatment and management, National Clinical Guideline Number 178*. *Commissioned by the National Institute for Health Care Excellence*.

Nelson, D. L. and Mathiowetz, V. (2004) ‘Randomized controlled trials to investigate occupational therapy research questions.’ *American Journal of Occupational Therapy*, 58(1) pp. 24–34.

Nguyen, A., Frobert, L., McCluskey, I., Golay, P., Bonsack, C. and Favrod, J. (2016) ‘Development of the positive emotions program for schizophrenia: An intervention to improve pleasure and motivation in schizophrenia.’ *Frontiers in Psychiatry*, 7(Feb) pp. 1–9.

NHS (2016) *Occupational therapy - Clinical trials.* ongoing clinical trials. [Online] [Accessed on 21st April 2016] http://www.nhs.uk/Conditions/occupational-therapy/Pages/clinical-trial.aspx.

NHS (2019) *The NHS Long Term Plan*.

NHS (2020a) *10 Tips to Beat Insomnia*. www.nhs.uk. [Online] [Accessed on 17th September 2020] https://www.nhs.uk/live-well/sleep-and-tiredness/10-tips-to-beat-insomnia/.

NHS (2020b) *Occupational therapy*. NHS website. [Online] [Accessed on 24th February 2020] https://www.nhs.uk/conditions/occupational-therapy/.

NHS England (2016) *The five year forward view for mental health*. *The Mental Health Taskforce*.

Nicassion, P. M., Boylan, M. B. and McCabe, T. G. (1982) 'Progressive relaxation, EMG biofeedback and biofeedback placebo in the treatment of sleep-onset insomnia.' *British Journal of Medical Psychology*, 55(2) pp. 159–166.

NICE (2004) 'Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia, NICE technology appraisal guidance 77.'

NICE (2013) *Clinical Knowledge Summaries: Sleep disorders - shift work and jet lag, Last revised in August 2013*. [Online] [Accessed on 29th June 2015] http://cks.nice.org.uk/sleep-disorders-shift-work-and-jet-lag.

NICE (2014) 'Psychosis and schizophrenia in adults: treatment and management, NICE clinical guideline 178.'

NICE (2015a) *Clinical Knowledge Summaries: Insomnia, Last revised in April 2015*. [Online] [Accessed on 29th June 2015] http://cks.nice.org.uk/insomnia.

NICE (2015b) *Hypnotics: Key therapeutic topic*. (last upda.

NICE (2015c) 'Psychosis and schizophrenia in adults, Quality Standard, QS80,' (February).

De Niet, G., Tiemens, B., Lendemeijer, B. and Hutschemaekers, G. (2009) 'Music-assisted relaxation to improve sleep quality: Meta-analysis.' *Journal of Advanced Nursing*, 65(7) pp. 1356–1364.

Nobarany, S., Oram, L., Rajendran, V. K., Chen, C. H., McGrenere, J. and Munzner, T. (2012) 'The design space of opinion measurement interfaces: Exploring Recall Support for rating and ranking.' *Conference on Human Factors in Computing Systems - Proceedings* pp. 2035–2044.

Nock, M. K. and Ferriter, C. (2005) 'Parent management of attendance and adherence in child and adolescent therapy: A conceptual and empirical review.' *Clinical Child and Family Psychology Review*, 8(2) pp. 149–166.

Noon, M. (2010) 'The shackled runner: Time to rethink positive discrimination?' *Work, Employment and Society*, 24(4) pp. 728–739.

Norell-Clarke, A., Jansson-Fröjmark, M., Tillfors, M., Holländare, F. and Engström, I. (2015) 'Group cognitive behavioural therapy for insomnia: Effects on sleep and depressive symptomatology in a sample with comorbidity.' *Behaviour Research and Therapy*, 74 pp. 80–93.

Norton, C., Flood, D., Brittin, A. and Miles, J. (2015) 'Improving sleep for patients in acute hospitals.' *Nursing standard (Royal College of Nursing (Great Britain) : 1987)*, 29(28) pp. 35–42.

Nourredine, M., Gering, A., Fourneret, P., Rolland, B., Falissard, B., Cucherat, M., Geoffray, M. M. and Jurek, L. (2021) 'Association of Attention-Deficit/Hyperactivity Disorder in Childhood and Adolescence with the Risk of Subsequent Psychotic Disorder: A Systematic Review and Meta-analysis.' *JAMA Psychiatry*, 78(5) pp. 519–529.

Novak, C., Packer, E., Paterson, A., Roshi, A., Locke, R., Keown, P., Watson, S. and Anderson, K. N. (2020) 'Feasibility and utility of enhanced sleep management on in-patient psychiatry wards.' *BJPsych Bulletin*, 44(6) pp. 255–260.

Novati, A., Roman, V., Cetin, T., Hagewoud, R., Boer, J. A. Den, Luiten, P. G. M. and Meerlo, P. (2008) 'Chronically Restricted Sleep Leads to Depression-Like Changes in Neurotransmitter Receptor Sensitivity and Neuroendocrine Stress Reactivity in Rats.' *SLEEP*, 31(11) pp. 1579–1585.

Nuevo, R., Chatterji, S., Verdes, E., Naidoo, N., Arango, C. and Ayuso-Mateos, J. L. (2012) 'The continuum of psychotic symptoms in the general population: A cross-national study.' *Schizophrenia Bulletin*, 38(3) pp. 475–485.

Núñez, C., Stephan-Otto, C., Cuevas-Esteban, J., Maria Haro, J., Huerta-Ramos, E., Ochoa, S., Usall, J. and Brébion, G. (2015) 'Effects of caffeine intake and smoking on neurocognition in schizophrenia.' *Psychiatry Research*, 230(3) pp. 924–931.

Nurit, W. and Michal, A. (2003) 'Rest: A qualitative exploration of the phenomenon.' *Occupational Therapy International*, 10(4) pp. 227–238.

O'callaghan, F., Muurlink, O. and Reid, N. (2018) 'Effects of caffeine on sleep quality and daytime functioning.' *Risk Management and Healthcare Policy*, 11 pp. 263–271.

O'Sullivan, M., Rahim, M. and Hall, C. (2015) 'The prevalence and management of poor sleep quality in a secondary care mental health population.' *Journal of Clinical Sleep Medicine*, 11(2) pp. 111–116.

Ochoa, S., Usall, J., Cobo, J., Labad, X. and Kulkarni, J. (2012) 'Gender Differences in Schizophrenia and First-Episode Psychosis: A Comprehensive Literature Review.' *Schizophrenia Research and Treatment*, 2012 pp. 1–9.

Oldham, M. A. and Ciraulo, D. A. (2014a) 'Bright light therapy for depression: A review of its effects on chronobiology and the autonomic nervous system.' *Chronobiology International*, 31(3) pp. 305–319.

Oldham, M. A. and Ciraulo, D. A. (2014b) 'Use of bright light therapy among psychiatrists in Massachusetts: An e-mail survey.' *Primary Care Companion to the Journal of Clinical Psychiatry*, 16(3).

Oliveira, P., Coroa, M. and Madeira, N. (2019) 'Treatment Options for Insomnia in Schizophrenia: A Systematic Review.' *Pharmacopsychiatry*, 52(4) pp. 165–169.

Oliver, M. D. and Datta, S. (2019) 'Electrophysiological correlates of the sleep-wake cycle.' *In The Behavioral, Molecular, Pharmacological, and Clinical Basis of the Sleep-Wake Cycle*, pp. 17–26.

Oren, D. A., Cubells, J. F. and Litsch, S. (2001) 'Bright Light Therapy for Schizoaffective Disorder.' *Am J PsychiatryPsychiatry*, 158(2) pp. 2086–2087.

Palagini, L., Bruno, R. M., Paolo, T., Caccavale, L., Gronchi, A., Mauri, M., Riemann, D. and Drake, C. L. (2016) 'Association Between Stress-Related Sleep Reactivity and Metacognitive Beliefs About Sleep in Insomnia Disorder: Preliminary

Results.' *Behavioral Sleep Medicine*, 14(6) pp. 636–649.

Papageorgiou, N., Marquis, R., Dare, J. and Batten, R. (2016) 'Occupational Therapy and Occupational Participation in Community Dwelling Older Adults: A Review of the Evidence.' *Physical and Occupational Therapy in Geriatrics*, 34(1) pp. 21–42.

Parker, S. (2019) *ISRCTN41029608: Investigation of attention training for people with psychosis*. ISRCTN.com. [Online] [Accessed on 1st October 2021] https://doi.org/10.1186/ISRCTN41029608.

Parshotam, R. K. and Joubert, P. M. (2015) 'Views of schizophrenia patients on the effects of cannabis on their mental health.' *South African Journal of Psychiatry*, 21(2) pp. 57–61.

Paterson, M., Higgs, J. and Wilcox, S. (2006) 'Developing expertise in judgement artistry in occupational therapy practice.' *British Journal of Occupational Therapy*, 69(3) pp. 115–123.

Patterson, S., Mairs, H. and Borschmann, R. (2011) 'Successful recruitment to trials: A phased approach to opening gates and building bridges.' *BMC Medical Research Methodology*, 11(May).

Paudel, S., Coman, D. and Freudenreich, O. (2020) 'Subjective experience of cognitive difficulties as an important attribute of quality of life among individuals with schizophrenia spectrum disorders.' *Schizophrenia Research*, 215 pp. 476–478.

Paul, M. A., Gray, G. W., Lieberman, H. R., Love, R. J., Miller, J. C., Trouborst, M. and Arendt, J. (2011) 'Phase advance with separate and combined melatonin and light treatment.' *Psychopharmacology*, 214(2) pp. 515–523.

Peacey, J., Miller, H., Huthwaite, M. A. and Romans, S. E. (2012) 'Sleep medication in acute psychiatric illness: patient's knowledge and prescription patterns in New Zealand.' *The Journal of nervous and mental disease*, 200(1) pp. 83–87.

Pearson, L., Parker, S. and Mansell, W. (2020) 'The development of a theoretically derived measure exploring extreme appraisals of sleep in bipolar disorder: a Delphi study with professionals.' *Behavioural and Cognitive Psychotherapy* pp. 1–13.

Pentland, D., Kantartzis, S., Clausen, M. G. and Witemyre, K. (2018) *Occupational therapy and complexity : defining and describing practice*. London: Royal College of Occupational Therapists.

Perez-Pozuelo, I., Zhai, B., Palotti, J., Mall, R., Aupetit, M., Garcia-Gomez, J. M., Taheri, S., Guan, Y. and Fernandez-Luque, L. (2020) 'The future of sleep health: a data-driven revolution in sleep science and medicine.' *npj Digital Medicine*, 3(1) pp. 1–15.

Perlis, M. L., Smith, M. T., Jungquist, C., Nowakowski, S., Orff, H. and Soeffing, J. (2010) 'Cognitive-Behavioral Therapy for Insomnia.' *In* Attarian, H. P. and Schuman, C. (eds) *Clinical Handbook of Insomnia*. Berlin, Heidelberg.: Springer Science+Business Media, pp. 281–296.

Perlis, M., Shaw, P., Cano, G. and Espie, C. (2010) 'Models of Insomnia.' *In* Kryger,

M., Roth, T., and Dement, W. (eds) *Principles and Practice of Sleep Medicine*. Fifth Edit, Philadelphia: W.B.Saunders, pp. 850–866.

Perogamvros, L., Castelnovo, A., Samson, D. and Dang-Vu, T. T. (2020) 'Failure of fear extinction in insomnia: An evolutionary perspective.' *Sleep Medicine Reviews*, 51 p. 101277.

Petticrew, M. (2011) 'When are complex interventions "complex"? When are simple interventions "simple"?' *European Journal of Public Health*, 21(4) pp. 397–398.

Phillips, A. J. K., Clerx, W. M., O'Brien, C. S., Sano, A., Barger, L. K., Picard, R. W., Lockley, S. W., Klerman, E. B. and Czeisler, C. A. (2017) 'Irregular sleep/wake patterns are associated with poorer academic performance and delayed circadian and sleep/wake timing.' *Scientific Reports*, 7(1) pp. 1–13.

Phillips, A. J. K., Vidafar, P., Burns, A. C., McGlashan, E. M., Anderson, C., Rajaratnam, S. M. W., Lockley, S. W. and Cain, S. W. (2019) 'High sensitivity and interindividual variability in the response of the human circadian system to evening light.' *Proceedings of the National Academy of Sciences of the United States of America*, 116(24) pp. 12019–12024.

Picard, M. M. (2012) 'Occupational Therapy's Role in Sleep.' *American Occupational Therapy Association*.

Piesman, M., Hwang, I., Maydonovitch, C. and Wong, R. K. H. (2007) 'Nocturnal reflux episodes following the administration of a standardized meal. Does timing matter?' *American Journal of Gastroenterology*, 102(10) pp. 2128–2134.

Pilcher, J. J., Ginter, D. R. and Sadowsky, B. (1997) 'Sleep quality versus sleep quantity: relationships between sleep and measures of health, well-being and sleepiness in college students.' *Journal of Psychosomatic Research*, 42(6) pp. 583–596.

Piotrowski, P., Gondek, T. M., Królicka-Deręgowska, A., Misiak, B., Adamowski, T. and Kiejna, A. (2017) 'Causes of mortality in schizophrenia: An updated review of European studies.' *Psychiatria Danubina*, 29(2) pp. 108–120.

Pluye, P. and Hong, Q. N. (2014) 'Combining the power of stories and the power of numbers: Mixed methods research and mixed studies reviews.' *Annual Review of Public Health*, 35 pp. 29–45.

Pokorska-Bocci, A., Stewart, A., Sagoo, G. S., Hall, A., Kroese, M. and Burton, H. (2014) '"Personalized medicine": What's in a name?' *Personalized Medicine*, 11(2) pp. 197–210.

Popay, J., Roberts, H., Sowden, A., Petticrew, M., Arai, L., Rodgers, M., Britten, N., Roen, K. and Duffy, S. (2006) *Guidance on the Conduct of Narrative Synthesis in Systematic Reviews. ESRC Methods Programme*.

Potočnik, J. and Košir, M. (2021) 'Influence of geometrical and optical building parameters on the circadian daylighting of an office.' *Journal of Building Engineering*, 42(March).

Potuzaka, M., Ravichandran, C., Lewandowskia, K. E., Ongüra, D. and Cohena, B. M. (2012) 'Categorical vs dimensional classifications of psychotic disorders.' *Comprehensive Psychiatry*, 53(8) pp. 1118–1129.

Price, A., Schroter, S., Snow, R., Hicks, M., Harmston, R., Staniszewska, S., Parker, S. and Richards, T. (2018) 'Frequency of reporting on patient and public involvement (PPI) in research studies published in a general medical journal: A descriptive study.' *BMJ Open*, 8(3) pp. 1–10.

Pritchett, D., Wulff, K., Oliver, P. L., Bannerman, D. M., Davies, K. E., Harrison, P. J., Peirson, S. N. and Foster, R. G. (2012) 'Evaluating the links between schizophrenia and sleep and circadian rhythm disruption.' *Journal of Neural Transmission*, 119(10) pp. 1061–1075.

Pruiksma, K. E., Hale, W. J., Mintz, J., Peterson, A. L., Young-McCaughan, S., Wilkerson, A., Nicholson, K., Dondanville, K. A., Fina, B. A., Borah, E. V., Roache, J. D., Litz, B. T., Bryan, C. J. and Taylor, D. J. (2020) 'Predictors of Cognitive Behavioral Therapy for Insomnia (CBTi) Outcomes in Active-Duty U.S. Army Personnel.' *Behavior Therapy*, 51(4) pp. 522–534.

Prytys, M., Garety, P. A., Jolley, S., Onwumere, J. and Craig, T. (2011) 'Implementing the NICE guideline for schizophrenia recommendations for psychological therapies: A qualitative analysis of the attitudes of CMHT staff.' *Clinical Psychology and Psychotherapy*, 18(1) pp. 48–59.

Pullman, R. E., Roepke, S. E. and Duffy, J. F. (2012) 'Laboratory Validation of an In-Home Method for Assessing Circadian Phase Using the Dim Light Melatonin Onset (DLMO).' *Sleep Medicine*, 13(6) pp. 703–706.

Rahman, S. A. (2015) 'Are We Ready to Assess Circadian Phase at Home ?' *Sleep*, 38 pp. 889–897.

Rahman, S. A., St Hilaire, M. A., Chang, A. M., Santhi, N., Duffy, J. F., Kronauer, R. E., Czeisler, C. A., Lockley, S. W. and Klerman, E. B. (2017) 'Circadian phase resetting by a single short-duration light exposure.' *JCI insight*, 2(7) p. e89494.

Rajaratnam, S. M. and Arendt, J. (2001) 'Health in a 24-h society.' *Lancet*, 358(9286) pp. 999–1005.

Razjouyan, J., Lee, H., Parthasarathy, S., Mohler, J., Sharafkhaneh, A. and Najafi, B. (2017) 'Information from postural/sleep position changes and body acceleration: A comparison of chest-worn sensors, wrist actigraphy, and polysomnography.' *Journal of Clinical Sleep Medicine*, 13(11) pp. 1301–1310.

Reddy, L. F., Irwin, M. R., Breen, E. C., Reavis, E. A. and Green, M. F. (2019) 'Social exclusion in schizophrenia: Psychological and cognitive consequences.' *Journal of Psychiatric Research*, 114(August 2018) pp. 120–125.

Reed, D. L. and Sacco, W. P. (2016) 'Measuring sleep efficiency: what should the denominator be?' *Journal of Clinical Sleep Medicine*, 12(2) pp. 263–266.

Reed, K. L., Andersen, L. T., Reed, K. L., Andersen, L. T. and Clarke, E. (2017) 'Eleanor Clarke Slagle : Facts and Myths.' *Occupational Therapy in Healthcare*,

31(4) pp. 291–311.

Reeve, S., Emsley, R., Sheaves, B. and Freeman, D. (2018) 'Disrupting Sleep: The Effects of Sleep Loss on Psychotic Experiences Tested in an Experimental Study With Mediation Analysis.' *Schizophrenia Bulletin*, 44(3) pp. 662–671.

Reeve, S., Sheaves, B. and Freeman, D. (2015) 'The role of sleep dysfunction in the occurrence of delusions and hallucinations : A systematic review.' *Clinical Psychology Review*, 42 pp. 96–115.

Reeve, S., Sheaves, B. and Freeman, D. (2019) 'Sleep Disorders in Early Psychosis: Incidence, Severity, and Association with Clinical Symptoms.' *Schizophrenia Bulletin*, 45(2) pp. 287–295.

Rehman, A., Waite, F., Sheaves, B., Biello, S., Freeman, D. and Gumley, A. (2017) 'Clinician perceptions of sleep problems, and their treatment, in patients with non-affective psychosis.' *Psychosis*, 9(2) pp. 129–139.

Reitz, S. M. (1992) 'A Historical Review of Occupational Therapy's Role in Preventive Health and Wellness.' *American Journal of Occupational Therapy*, 46(1).

Revell, V. L. and Eastman, C. I. (2005) 'How to trick mother nature into letting you fly around or stay up all night.' *Journal of Biological Rhythms*, 20(4) pp. 353–365.

Richardson, C. E., Gradisar, M. and Barbero, S. C. (2015) 'Are cognitive "insomnia" processes involved in the development and maintenance of delayed sleep wake phase disorder?' *Sleep Medicine Reviews*, 26 pp. 1–8.

Riedy, S. M., Smith, M. G., Rocha, S. and Basner, M. (2021) 'Noise as a sleep aid: A systematic review.' *Sleep Medicine Reviews*, 55 p. 101385.

Ritonja, J., Aronson, K. J., Matthews, R. W., Boivin, D. B. and Kantermann, T. (2019) 'Working time society consensus statements: Individual differences in shift work tolerance and recommendations for research and practice.' *Industrial Health*, 57(2) pp. 201–212.

Ritsner, M., Kurs, R., Ponizovsky, A. and Hadjez, J. (2004) 'Perceived quality of life in schizophrenia: Relationships to sleep quality.' *Quality of Life Research*, 13(4) pp. 783–791.

Robinson, O. C. (2014) 'Sampling in Interview-Based Qualitative Research: A Theoretical and Practical Guide.' *Qualitative Research in Psychology*, 11(1) pp. 25–41.

Rodriguez, M. L. and Messer, L. S. (2017) 'Patterns of Bedtime Preparation for In-patients with Schizophrenia: A Pilot Study.' *Archives of Psychiatric Nursing*, 31(2) pp. 231–232.

Roehrs, T. and Roth, T. (2019) 'The sleep-wake cycle: An overview.' *In* Murillo-Rodríguez, E. (ed.) *The Behavioral, Molecular, Pharmacological, and Clinical Basis of the Sleep-Wake Cycle*. Amsterdam, Netherlands: Elsevier Inc., pp. 2–16.

Roenneberg, T. and Merrow, M. (1999) 'Circadian systems and metabolism.'

Journal of Biological Rhythms, 14(6) pp. 449–459.

Roenneberg, T. and Merrow, M. (2016) 'The circadian clock and human health.' *Current Biology*, 26(10) pp. R432–R443.

Roley, S. S., DeLany, J. V., Barrows, C. J., Brownrigg, S., Honaker, D., Sava, D. I., Talley, V., Voelkerding, K., Amini, D. A., Smith, E., Toto, P., King, S. and Lieberman, D. (2008) *Occupational Therapy Practice Framework: Domain & Process 2nd Edition*. *The American Journal of Ocupational Therapy*. North Bethesda, MD: AOTA Press.

Roopram, S. M., Burger, A. M., van Dijk, D. A., Enterman, J. and Haffmans, J. (2016) 'A pilot study of bright light therapy in schizophrenia.' *Psychiatry Research*. Elsevier, 245 pp. 317–320.

Rosner, B., Glynn, R. J. and Lee, M. L. T. (2006) 'The Wilcoxon signed rank test for paired comparisons of clustered data.' *Biometrics*, 62(1) pp. 185–192.

Rotenberg, V., Indurski, P., Kimhi, R., Hadjez, J., Gutman, Y., Shamir, E., Barak, Y. and Elizur, A. (2000) 'The relationship between objective sleep variables and subjective sleep estimation in schizophrenia.' *International journal of psychiatry in clinical practice*, 4(1) pp. 63–7.

Rowe, G. and Wright, G. (1999) 'The Delphi technique as a forecasting tool: issues and analysis.' *International Journal of Forecasting*, 15 pp. 353–375.

Rusch, H. L., Rosario, M., Levison, L. M., Olivera, A., Livingston, W. S., Wu, T. and Gill, J. M. (2019) 'The effect of mindfulness meditation on sleep quality: a systematic review and meta-analysis of randomized controlled trials.' *Ann N Y Acad Sci.*, 1445(1) pp. 5–16.

Sadeh, A. (2011) 'The role and validity of actigraphy in sleep medicine: An update.' *Sleep Medicine Reviews*, 15(4) pp. 259–267.

Salminen, A. V. and Winkelmann, J. (2018) 'Restless Legs Syndrome and Other Movement Disorders of Sleep—Treatment Update.' *Current Treatment Options in Neurology*, 20(12).

Sanders, S. and Oberst, J. (2017) *Changing perspectives on daylight: science, technology, and culture. Supplement to Science*. *Science / AAS Custom Publishing Office*.

Sarfan, L. D., Hilmoe, H. E., Gumport, N. B., Gasperetti, C. E., Zieve, G. G. and Harvey, A. G. (2021) 'Outcomes of the Transdiagnostic Intervention for Sleep and Circadian Dysfunction (TranS-C) in a community setting: Unpacking comorbidity.' Behaviour Research and Therapy. Elsevier Ltd, 145(August) p. 103948.

Sarkar, S. (2016) 'Poly-pharmacy in psychiatric practice, etiology and potential consequences.' *Journal of Psychiatry*, 19(07) pp. 12–26.

Sateia, M., Buysse, D., Krystal, A., Neubauer, D. and Heald, J. (2017) 'Clinical Guideline for the Evaluation and Management of Chronic Insomnia in Adults.' *J Clin Sleep Med. Journal of Clinical Sleep Medicine*, 13(5) pp. 307–349.

Sateia, M. J. (2014) ‘International classification of sleep disorders-third edition highlights and modifications.’ *Chest*, 146(5) pp. 1387–1394.

Sateia, M. J., Sherrill, W. C., Winter-Rosenberg, C. and Heald, J. L. (2017) ‘Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults: An American Academy of Sleep Medicine Clinical Practice Guideline.’ *Journal of Clinical Sleep Medicine*, 13(2) pp. 307–349.

Saxena, D. B., Kumar, P., Rana, M., Shah, H. M. and Education, F. L. (2012) ‘A case study on use of modified delphi technique for developing consensus on designing contents of a module for imparting sex education to adolescents in schools, in India.’ *Global Journal of Medicine and Public Health*, 1(June) pp. 3–7.

Saxvig, I. W., Wilhelmsen-Langeland, A., Pallesen, S., Vedaa, Ø., Nordhus, I. H. and Bjorvatn, B. (2014) ‘A randomized controlled trial with bright light and melatonin for delayed sleep phase disorder: Effects on subjective and objective sleep.’ *Chronobiology International*, 31(1) pp. 72–86.

Schweizer, C. A., Hoggatt, K. J., Washington, D. L., Bean-Mayberry, B., Yano, E. M., Mitchell, M. N., Alessi, C. A. and Martin, J. L. (2019) ‘Use of alcohol as a sleep aid, unhealthy drinking behaviors, and sleeping pill use among women veterans.’ *Sleep Health*, 5(5) pp. 495–500.

Scott, H. and Woods, H. C. (2018) ‘Fear of missing out and sleep: Cognitive behavioural factors in adolescents’ nighttime social media use.’ *Journal of Adolescence*, 68(July) pp. 61–65.

Sekhon, M., Cartwright, M. and Francis, J. J. (2017) ‘Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework.’ *BMC Health Services Research*, 17(1) pp. 1–13.

Sekhon, M., Cartwright, M. and Francis, J. J. (2018) ‘Acceptability of health care interventions: A theoretical framework and proposed research agenda.’ *British Journal of Health Psychology*, 23(3) pp. 519–531.

Sella, E., Cellini, N., Miola, L., Sarlo, M. and Borella, E. (2019) ‘The Influence of Metacognitive Beliefs on Sleeping Difficulties in Older Adults.’ *Applied Psychology: Health and Well-Being*, 11(1) pp. 20–41.

Selsick, H. and O’Regan, D. (2018) ‘Sleep disorders in psychiatry.’ *BJPsych Advances*, 24(4) pp. 273–283.

Shamir, E., Laudon, M., Barak, Y., Anis, Y., Rotenberg, V., Elizur, A. and Zisapel, N. (2000) ‘Melatonin Inproves Sleep Quality of Patients With Chronic Schizophrenia.’ *Journal of Clinical Psychiatry*, 61(5) pp. 373–377.

Sheaves, B. and Espie, C. (n.d.) *Having trouble with your sleep? Try following these 10 top tips for better sleep, Sleep and Circadian Neuroscience Institute (SCNi): University of Oxford*. [Online] [Accessed on 16th October 2020] https://www.ndcn.ox.ac.uk/research/sleep-circadian-neuroscience-institute/training-and-dissemination/having-trouble-with-your-sleep/sleep-tips_041214.pdf.

Sheaves, B., Freeman, D., Isham, L., McInerney, J., Nickless, A., Yu, L.-M., Rek, S.,

Bradley, J., Reeve, S., Attard, C., Espie, C. A., Foster, R., Wirz-justice, A., Chadwick, E. and Barrera, A. (2017) 'Stabilising sleep for patients admitted at acute crisis to a psychiatric hospital (OWLS):' *Psychological Medicine*, 48 pp. 1694–1704.

Sheaves, B., Freeman, D., Isham, L., McInerney, J., Nickless, A., Yu, L. M., Rek, S., Bradley, J., Reeve, S., Attard, C., Espie, C. A., Foster, R., Wirz-Justice, A., Chadwick, E. and Barrera, A. (2018) 'Stabilising sleep for patients admitted at acute crisis to a psychiatric hospital (OWLS): An assessor-blind pilot randomised controlled trial.' *Psychological Medicine*, 48(10) pp. 1694–1704.

Sheaves, B., Isham, L., Bradley, J., Espie, C., Barrera, A., Waite, F., Harvey, A. G., Attard, C. and Freeman, D. (2018a) 'Adapted CBT to Stabilize Sleep on Psychiatric Wards: A Transdiagnostic Treatment Approach.' *Behavioural and Cognitive Psychotherapy*, 46(6) pp. 661–675.

Sheaves, B., Isham, L., Bradley, J., Espie, C., Barrera, A., Waite, F., Harvey, A. G., Attard, C. and Freeman, D. (2018b) 'Adapted CBT to Stabilize Sleep on Psychiatric Wards: A Transdiagnostic Treatment Approach.' *Behavioural and Cognitive Psychotherapy*, 46(6) pp. 661–675.

Sheaves, B., Onwumere, J., Keen, N., Stahl, D. and Kuipers, E. (2015) 'Nightmares in patients with psychosis: The relation with sleep, psychotic, affective, and cognitive symptoms.' *Canadian Journal of Psychiatry*, 60(8) pp. 354–361.

Sheffield, J. M., Karcher, N. R. and Barch, D. M. (2018) 'Cognitive Deficits in Psychotic Disorders: A Lifespan Perspective.' *Neuropsychology Review*, 28(4) pp. 509–533.

Shiffman, S., Stone, A. A. and Hufford, M. R. (2008) 'Ecological momentary assessment.' *Annual Review of Clinical Psychology*, 4 pp. 1–32.

Sin, C. W. M., Ho, J. S. C. and Chung, J. W. Y. (2009) 'Systematic review on the effectiveness of caffeine abstinence on the quality of sleep.' *Journal of Clinical Nursing*, 18(1) pp. 13–21.

Skeldon, A. C., Phillips, A. J. K. and Dijk, D.-J. (2017) 'The effects of self-selected light-dark cycles and social constraints on human sleep and circadian timing: a modeling approach.' *Scientific Reports*, 7(45158).

Sloane, P. D., Williams, C. S., Mitchell, C. M., Preisser, J. S., Wood, W., Barrick, A. L., Hickman, S. E., Gill, K. S., Connell, B. R., Edinger, J. and Zimmerman, S. (2007) 'High-Intensity Environmental Light in Dementia: Effect on Sleep and Activity.' *Journal of the American Geriatrics Society*, 55(10) pp. 1524–1533.

Smith, G. D. and Egger, M. (2008) 'Going beyond the grand mean : subgroup analysis in meta-analysis of randomised trials.' *In* Egger, M., Smith, G. D., and Altman, D. (eds) *Systematic Reviews in Health Care: Meta-Analysis in Context*. 2nd ed., London: BMJ Books, pp. 143–156.

Solet, J. M. (2014) 'Sleep and rest.' *In* Schell, B. A., Gillen, G., Scaffa, M., and Cohn, E. S. (eds) *Willard and Spackman's Occupational Therapy*. 12th ed., Philadelphia: Wolters Kluwer - Lippincott Williams and Wilkins, pp. 714–730.

Van Someren, E. J. W., Swaab, D. F., Colenda, C. C., Cohen, W., McCall, W. V. and Rosenquist, P. B. (1999) 'Bright light therapy: Improved sensitivity to its effects on rest- activity rhythms in Alzheimer patients by application of nonparametric methods.' *Chronobiology International*, 16(4) pp. 505–518.

Sotelo, M. I., Tyan, J., Dzera, J. and Eban-Rothschild, A. (2020) 'Sleep and motivated behaviors, from physiology to pathology.' *Current Opinion in Physiology*, 15 pp. 159–166.

Spanakis, P., Peckham, E., Mathers, A., Shiers, D. and Gilbody, S. (2021) 'The digital divide: Amplifying health inequalities for people with severe mental illness in the time of COVID-19.' *British Journal of Psychiatry*, 219(4) pp. 529–531.

Spencer, T., Rademaker, L., Williams, P. and Loubier, C. (2021) 'Online, Asynchronous Data collection in Qualitative Research.' *In* Leavy, P. (ed.) *Popularizing Scholarly Research: Research Methods and Practices*. Oxford: Oxford University Press.

Spiegel, K., Knutson, K., Leproult, R., Tasali, E. and Van Cauter, E. (2005) 'Sleep loss: a novel risk factor for insulin resistance and Type 2 diabetes.' *Journal of applied physiology*, 99(5) pp. 2008–19.

Spiegelhalder K., Nissen C., R. D. (2017) 'Clinical Sleep–Wake Disorders II: Focus on Insomnia and Circadian Rhythm Sleep Disorders.' *In* Landolt HP., D. D. (ed.) *Sleep-Wake Neurobiology and Pharmacology. Handbook of Experimental Pharmacology, Volume 253*. Springer, Cham, pp. 261–278.

Spira, A. P., Chen-Edinboro, L. P., Wu, M. N. and Yaffe, K. (2014) 'Impact of Sleep on the Risk of Cognitive Decline and Dementia.' *Current opinion in psychiatry*, 27(6) pp. 478–483.

Stanchina, M. L., Abu-Hijleh, M., Chaudhry, B. K., Carlisle, C. C. and Millman, R. P. (2005) 'The influence of white noise on sleep in subjects exposed to ICU noise.' *Sleep Medicine*, 6(5) pp. 423–428.

Staples, P., Torous, J., Barnett, I., Carlson, K., Sandoval, L., Keshavan, M. and Onnela, J. P. (2017) 'A comparison of passive and active estimates of sleep in a cohort with schizophrenia.' *npj Schizophrenia*, 3(1).

Stepanski, E. J. and Wyatt, J. K. (2003) 'Use of sleep hygiene in the treatment of insomnia.' *Sleep Medicine Reviews*, 7(3) pp. 215–225.

Stephenson, K. M., Schroder, C. M., Bertschy, G. and Bourgin, P. (2012) 'Complex interaction of circadian and non-circadian effects of light on mood: Shedding new light on an old story.' *Sleep Medicine Reviews*, 16(5) pp. 445–454.

Stiver, K., Sharma, N., Geller, K., Smith, L., Stephens, J., Daoud, E., Moffatt-Bruce, S. and Mazzaferri, E. (2017) '"Quiet at Night": Reduced overnight vital sign monitoring linked to both safety and improvements in patients' perception of hospital sleep quality.' *Patient Experience Journal*, 4(1) pp. 90–96.

van Straten, A., van der Zweerde, T., Kleiboer, A., Cuijpers, P., Morin, C. M. and Lancee, J. (2018) 'Cognitive and behavioral therapies in the treatment of insomnia:

A meta-analysis.' *Sleep Medicine Reviews,* 38 pp. 3–16.

Stummer, L., Markovic, M. and Maroney, M. (2018) 'Pharmacologic Treatment Options for Insomnia in Patients with Schizophrenia.' *Medicines,* 5(3) p. 88.

Stutz, J., Eiholzer, R. and Spengler, C. M. (2019) 'Effects of Evening Exercise on Sleep in Healthy Participants: A Systematic Review and Meta-Analysis.' *Sports Medicine,* 49(2) pp. 269–287.

Sun, X., Briel, M., Walter, S. D. and Guyatt, G. H. (2010) 'Is a subgroup effect believable? Updating criteria to evaluate the credibility of subgroup analyses.' *BMJ (Online),* 340(7751) pp. 850–854.

Svetnik, V., Snyder, E. S., Ma, J., Tao, P., Lines, C. and Herring, W. J. (2017) 'EEG spectral analysis of NREM sleep in a large sample of patients with insomnia and good sleepers: effects of age, sex and part of the night.' *Journal of Sleep Research,* 26(1) pp. 92–104.

Sweetman, A., McEvoy, R. D., Smith, S., Catcheside, P. G., Antic, N. A., Chai-Coetzer, C. L., Douglas, J., O'Grady, A., Dunn, N., Robinson, J., Paul, D., Williamson, P. and Lack, L. (2020) 'The effect of cognitive and behavioral therapy for insomnia on week-to-week changes in sleepiness and sleep parameters in patients with comorbid insomnia and sleep apnea: a randomized controlled trial.' *Sleep,* (January) pp. 1–13.

Tahara, Y. and Shibata, S. (2016) 'Circadian rhythms of liver physiology and disease: Experimental and clinical evidence.' *Nature Reviews Gastroenterology and Hepatology,* 13(4) pp. 217–226.

Takaesu, Y., Inoue, Y., Murakoshi, A., Komada, Y., Otsuka, A., Futenma, K. and Inoue, T. (2016) 'Prevalence of circadian rhythm sleep-wake disorders and associated factors in euthymic patients with bipolar disorder.' *PLoS ONE,* 11(7) pp. 1–10.

Tamrat, R., Huynh-Le, M. P. and Goyal, M. (2014) 'Non-pharmacologic interventions to improve the sleep of hospitalized patients: A systematic review.' *Journal of General Internal Medicine,* 29(5) pp. 788–795.

Tang, N. K. Y. and Harvey, A. G. (2006) 'Altering misperception of sleep in insomnia: Behavioral experiment versus verbal feedback.' *Journal of Consulting and Clinical Psychology,* 74(4) pp. 767–776.

Taylor, D. J. and Pruiksma, K. E. (2014) 'Cognitive and behavioural therapy for insomnia (CBT-I) in psychiatric populations: A systematic review.' *International review of psychiatry,* 26(2) pp. 205–13.

Taylor, H. L., Hailes, H. P. and Ong, J. (2015) 'Third-Wave Therapies for Insomnia.' *Current Sleep Medicine Reports,* 1(3) pp. 166–176.

Taylor, R. R. (2003) 'Extending Client-Centered Practice The Use of Participatory Methods to Empower Clients.' *Occupational Therapy in Mental Health,* 19(2).

Telford, R., Beverley, C. a., Cooper, C. L. and Boote, J. D. (2002) 'Consumer

involvement in health research: fact or fiction?' *British Journal of Clinical Governance*, 7(2) pp. 92–103.

Telford, R. and Faulkner, A. (2004) 'Learning about service user involvement in mental health research.' *Journal of Mental Health*, 13(6) pp. 549–559.

Terman, M. and Terman, J. S. (2005) 'Light Therapy for Seasonal and Nonseasonal Depression: Efficacy, Protocol, Safety, and Side Effects.' *CNS Spectrums*, 10(8) pp. 647–663.

Thompson, D. M., Hall, D. A., Walker, D. M. and Hoare, D. J. (2017) 'Psychological Therapy for People with Tinnitus: A Scoping Review of Treatment Components.' *Ear and Hearing*, 38(2) pp. 149–158.

Thompson, L., Pennay, A., Zimmermann, A., Cox, M. and Lubman, D. I. (2014) '"Clozapine makes me quite drowsy, so when I wake up in the morning those first cups of coffee are really handy": an exploratory qualitative study of excessive caffeine consumption among individuals with schizophrenia.' *BMC psychiatry*, 14(1) p. 116.

Thompson, S. G. and Higgins, J. B. T. (2002) 'How should meta-regression analysis be undertaken and interpreted?' *Stat Med*, 21(11) pp. 1559–1573.

Topyurek, M., Tibbo, P., Núñez, C., Stephan-Otto, C. and Good, K. (2019) 'Caffeine effects and schizophrenia: Is there a need for more research?' *Schizophrenia Research*, 211 pp. 34–35.

Touitou, Y., Reinberg, A. and Touitou, D. (2017) 'Association between light at night, melatonin secretion, sleep deprivation, and the internal clock: Health impacts and mechanisms of circadian disruption.' *Life Sciences*, 173 pp. 94–106.

Tourangeau, R. (2017) 'Confidentiality, Privacy, and Anonymity.' *In* Krosnick, D. L. V. & J. A. (ed.) *The Palgrave Handbook of Survey Research*. Palgrave Macmillan, pp. 501–507.

Trevelyan, E. G. and Robinson, N. (2015) 'Delphi methodology in health research: How to do it?' *European Journal of Integrative Medicine*, 7(4) pp. 423–428.

Troxel, W. M., Conrad, T. S., Germain, A. and Buysse, D. J. (2013) 'Predictors of treatment response to Brief Behavioral Treatment of Insomnia (BBTI) in older adults.' *Journal of Clinical Sleep Medicine*, 9(12) pp. 1281–1289.

Troxel, W. M., Germain, A. and Buysse, D. J. (2012) 'Clinical Management of Insomnia with Brief Behavioural Treatment (BBTI).' *Behavioral sleep medicineral Sleep Medicine*, 10(4) pp. 266–279.

Upthegrove, R., Marwaha, S. and Birchwood, M. (2017) 'Depression and Schizophrenia: Cause, Consequence, or Trans-diagnostic Issue?' *Schizophrenia bulletin*, 43(2) pp. 240–244.

Vallières, A. and Morin, C. M. (2003) 'Actigraphy in the Assessment of Insomnia.' *Sleep*, 26(7) pp. 902–6.

Vancampfort, D., Firth, J., Schuch, F. B., Rosenbaum, S., Mugisha, J., Hallgren, M., Probst, M., Ward, P. B., Gaughran, F., De Hert, M., Carvalho, A. F. and Stubbs, B. (2017) 'Sedentary behavior and physical activity levels in people with schizophrenia, bipolar disorder and major depressive disorder: a global systematic review and meta-analysis.' *World Psychiatry*, 16(3) pp. 308–315.

Vandelanotte, C., Dwyer, T., Van Itallie, A., Hanley, C. and Mummery, W. K. (2010) 'The development of an internet-based outpatient cardiac rehabilitation intervention: a Delphi study.' *BMC Cardiovasc Disord*, 10 p. 27.

Verkuil, B., Brosschot, J. F., Korrelboom, K., Reul-Verlaan, R. and Thayer, J. F. (2011) 'Pretreatment of worry enhances the effects of stress management therapy: A randomized clinical trial.' *Psychotherapy and Psychosomatics*, 80(3) pp. 189–190.

Vgontzas, A. N., Fernandez-Mendoza, J., Bixler, E. O., Singareddy, R., Shaffer, M. L., Calhoun, S. L., Liao, D., Basta, M. and Chrousos, G. P. (2012) 'Persistent insomnia: The role of objective short sleep duration and mental health.' *Sleep: Journal of Sleep and Sleep Disorders Research*, 35(1) pp. 61–68.

Vijay, A., Becker, J. E. and Ross, J. S. (2018) 'Patterns and predictors of off-label prescription of psychiatric drugs.' *PLoS ONE*, 13(7) pp. 1–14.

Vogel, J. S., van der Gaag, M., Slofstra, C., Knegtering, H., Bruins, J. and Castelein, S. (2019) 'The effect of mind-body and aerobic exercise on negative symptoms in schizophrenia: A meta-analysis.' *Psychiatry Research*, 279(March) pp. 295–305.

Vols, H., Mackert, A. and Stieglitz, R. (1991) 'Side Effects of Phototherapy in Nonseasonal Depressiv Disorder.' *Pharmacopsychiatry*, 24(4) pp. 141–143.

Waite, F., Bradley, J., Chadwick, E., Reeve, S., Bird, J. and Freeman, D. (2018) 'The experience of sleep problems and their treatment in young people at ultra-high risk of psychosis: a thematic analysis.' *Frontiers in psychiatry*, 9(August) pp. 1–8.

Waite, F., Evans, N., Myers, E., Startup, H., Lister, R., Harvey, A. G. and Freeman, D. (2015) 'The patient experience of sleep problems and their treatment in the context of current delusions and hallucinations.' *Psychology and Psychotherapy: Theory, Research and Practice*, 89 pp. 181–193.

Waite, F., Myers, E., Harvey, A. G., Espie, C. a., Startup, H., Sheaves, B. and Freeman, D. (2015) 'Treating Sleep Problems in Patients with Schizophrenia.' *Behavioural and Cognitive Psychotherapy*, 44(3) pp. 273–287.

Waite, F. and Sheaves, B. (2020) 'Better Sleep: Evidence-Based Interventions.' *In* Badcock, J. and Paulik-White, G. (eds) *A Clinical Introduction to Psychosis: Foundations for Clinical Psychologists and Neuropsychologists*. 1st ed., Amsterdam: Elsevier Inc., pp. 465–492.

Waite, F., Sheaves, B., Isham, L., Reeve, S. and Freeman, D. (2020) 'Sleep and schizophrenia: From epiphenomenon to treatable causal target.' *Schizophrenia Research*, 221 pp. 44–56.

Wams, E. J., Woelders, T., Marring, I., Van Rosmalen, L., Beersma, D. G. M., Gordijn, M. C. M. and Hut, R. A. (2017) 'Linking light exposure and subsequent

sleep: A field polysomnography study in humans.' *Sleep*, 40(12).

Wan, G. J., Counte, M. A. and Cella, D. F. (1997) 'The influence of personal expectations on cancer patients' reports of health-related quality of life.' *Psycho-Oncology*, 6(1) pp. 1–11.

Waters, F., Chiu, V. W., Janca, A., Atkinson, A. and Ree, M. (2015) 'Preferences for different insomnia treatment options in people with schizophrenia and related psychoses: a qualitative study.' *Frontiers in Psychology*, 6 pp. 1–10.

Waters, F., Ree, M. J. and Chiu, V. (2017) *Delivering CBT for Insomnia in Psychosis: A Clinical Guide (Practical Clinical Guidebooks)*. New York: Routledge.

Waters, W. F., Hurry, M. J., Binks, P. G., Carney, C. E., Lajos, L. E., Fuller, K. H., Betz, B., Johnson, J., Anderson, T. and Tucci, J. M. (2003) 'Behavioral and hypnotic treatments for insomnia subtypes.' *Behavioral sleep medicine*, 1(2) pp. 81–101.

Weaver, E., Gradisar, M., Dohnt, H., Lovato, N. and Douglas, P. (2010) 'The effect of presleep video-game playing on adolescent sleep.' *Journal of Clinical Sleep Medicine*, 6(2) pp. 184–189.

Wehrens, S. M. T., Christou, S., Isherwood, C., Middleton, B., Gibbs, M. A., Archer, S. N., Skene, D. J. and Johnston, J. D. (2017) 'Meal Timing Regulates the Human Circadian System.' *Current Biology*, 27(12) pp. 1768-1775.e3.

Weinstein, A. A., Koehmstedt, C. and Kop, W. J. (2017) 'Mental health consequences of exercise withdrawal: A systematic review.' *General Hospital Psychiatry*, 49(February) pp. 11–18.

Wells, A. (2009) *Metacognitive therapy for anxiety and depression*. London: The Guilford Press.

Whitehead, A. L., Sully, B. G. O. and Campbell, M. J. (2014) 'Pilot and feasibility studies: Is there a difference from each other and from a randomised controlled trial?' *Contemporary Clinical Trials*, 38(1) pp. 130–133.

Wiegand, M. H. (2008) 'Antidepressants for the treatment of insomnia: A suitable approach?' *Drugs*, 68(17) pp. 2411–2417.

Williams, W. P. T., McLin, D. E., Dressman, M. A. and Neubauer, D. N. (2016) 'Comparative Review of Approved Melatonin Agonists for the Treatment of Circadian Rhythm Sleep-Wake Disorders.' *Pharmacotherapy*, 36(9) pp. 1028–1041.

Wilson, P., Mathie, E., Keenan, J., McNeilly, E., Goodman, C., Howe, A., Poland, F., Staniszewska, S., Kendall, S., Munday, D., Cowe, M. and Peckham, S. (2015) 'ReseArch with Patient and Public invOlvement: a RealisT evaluation - the RAPPORT study.' *Health Serv Deliv Res*, 3(38).

Winsky-Sommerer, R., de Oliveira, P., Loomis, S., Wafford, K., Dijk, D. J. and Gilmour, G. (2019) 'Disturbances of sleep quality, timing and structure and their relationship with other neuropsychiatric symptoms in Alzheimer's disease and schizophrenia: Insights from studies in patient populations and animal models.' *Neuroscience and Biobehavioral Reviews*, 97(August) pp. 112–137.

Witham, G., Beddow, A. and Haigh, C. (2015) 'Reflections on access: too vulnerable to research?' *Journal of Research in Nursing*, 20(1) pp. 28–37.

Woelders, T., Wams, E. J., Gordijn, M. C. M., Beersma, D. G. M. and Hut, R. A. (2018) 'Integration of color and intensity increases time signal stability for the human circadian system when sunlight is obscured by clouds.' *Scientific Reports*, 8(1) pp. 1–10.

World Health Organisation (1992) *The ICD-10 classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines.* Geneva.

Wright, H., Lack, L. and Bootzin, R. (2006) 'Relationship between dim light melatonin onset and the timing of sleep in sleep onset insomniacs.' *Sleep and Biological Rhythms*, 4(1) pp. 78–80.

Wright, K. P., McHill, A. W., Birks, B. R., Griffin, B. R., Rusterholz, T. and Chinoy, E. D. (2013) 'Entrainment of the human circadian clock to the natural light-dark cycle.' *Current Biology*, 23(16) pp. 1554–1558.

Wu, J. Q., Appleman, E. R., Salazar, R. D. and Ong, J. C. (2015) 'Cognitive Behavioral Therapy for Insomnia Comorbid With Psychiatric and Medical Conditions.' *JAMA Internal Medicine*, 175(9) pp. 1461–72.

Wulff, K. (2012) 'Biological rhythms that influence sleep.' *In* Green, A. and Westcombe, A. (eds) *Sleep – Multiprofessional perspectives*. London: Jessica Kingsley Publishers, pp. 41–67.

Wulff, K., Dijk, D.-J., Middleton, B., Foster, R. G. and Joyce, E. M. (2012) 'Sleep and circadian rhythm disruption in schizophrenia.' *The British journal of psychiatry : the journal of mental science*, 200(4) pp. 308–16.

Wulff, K., Gatti, S., Wettstein, J. G. and Foster, R. G. (2010) 'Sleep and circadian rhythm disruption in psychiatric and neurodegenerative disease.' *Nature Reviews Neuroscience*, 11(8) pp. 589–599.

Wulff, K. and Joyce, E. (2011) 'Circadian rhythms and cognition in schizophrenia.' *The British Journal of Psychiatry*, 198(4) pp. 250–252.

www.RE-AIM.org (2019). [Online] [Accessed on 17th June 2019] www.re-aim.org.

Xie, H., Kang, J. and Mills, G. H. (2009) 'Clinical review: The impact of noise on patients' sleep and the effectiveness of noise reduction strategies in intensive care units.' *Critical care (London, England)*, 13(2) p. 208.

Xu, Q. and Lang, C. P. (2018) 'Revisiting the alerting effect of light: A systematic review.' *Sleep Medicine Reviews*, 41 pp. 39–49.

Youngstedt, S. D., Elliott, J. A. and Kripke, D. F. (2019) 'Human circadian phase–response curves for exercise.' *Journal of Physiology*, 597(8) pp. 2253–2268.

Yu, L., Buysse, D. J., Germain, A., Moul, D. E., Stover, A., Dodds, N. E., Johnston, K. L. and Pilkonis, P. A. (2011) 'Development of Short Forms From the PROMIS™ Sleep Disturbance and Sleep-Related Impairment Item Banks.' *Behavioral Sleep*

Medicine, 10(1) pp. 6–24.

Zachariae, R., Lyby, M. S., Ritterband, L. M. and O'Toole, M. S. (2016) 'Efficacy of internet-delivered cognitive-behavioral therapy for insomnia - A systematic review and meta-analysis of randomized controlled trials.' *Sleep Medicine Reviews*, 30 pp. 1–10.

Ziv, N., Rotem, T., Arnon, Z. and Haimov, I. (2008) 'The effect of music relaxation versus progressive muscular relaxation on insomnia in older people and their relationship to personality traits.' *Journal of Music Therapy*, 45(3) pp. 360–380.

Appendices:

Appendix 1: "Use of the Pittsburgh Sleep Quality Index in People With Schizophrenia Spectrum Disorders: A Mixed Methods Study"

frontiers in Psychiatry

ORIGINAL RESEARCH
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Use of the Pittsburgh Sleep Quality Index in People With Schizophrenia Spectrum Disorders: A Mixed Methods Study

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The Pittsburgh Sleep Quality Index (PSQI) is a measure of self-reported sleep quality and sleep disturbance. Though the PSQI is widely used, it is unclear if it adequately assesses self-reported sleep disturbance in people with schizophrenia spectrum disorders. We used mixed methods to examine the relationship between scores on the PSQI and qualitative self-report during in-depth interview in a group of participants diagnosed with schizophrenia spectrum disorders (N = 15). Although the PSQI appears to accurately capture issues related to sleep initiation, average duration, and interruption by physical complaints, it did not adequately assess other salient issues including irregularity in sleep duration and timing, shallow unrefreshing sleep, prolonged sleep inertia, hypersomnia, and sleep interrupted by mental or psychological complaints. In interview by contrast these types of problems were readily reported and described as important by participants. Our findings suggest that using the PSQI summary score as a measurement of general sleep disturbance in this population may be misleading, as this failed to capture some of the types of sleep problems that are particularly common in this group.

Keywords: screening, outcome measure, psychometric, interview, qualitative, psychosis, circadian rhythm disorder, insomnia

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INTRODUCTION

The Pittsburgh Sleep Quality Index (PSQI) is a widely used self-reported questionnaire measure of sleep (1). The PSQI is practical and brief, returning a single score representing overall sleep quality, which incorporates qualitative and quantitative aspects of sleep; scores above 5 are suggested as indicative of a potential sleep problem. The PSQI includes open-ended questions that can be used to identify the nature and possible causes of sleep problems to help direct treatment (2), and gives subscale scores that can indicate the type of sleep problems (sleep duration, latency, disturbances, quality, efficiency, daytime dysfunction, and use of sleep medication), as well as some questions on indicators of sleep apnea.

The PSQI was initially developed with a sample of people with depression, healthy sleepers, and people with sleep disorders (2). Many authors, including those who developed the PSQI, have subsequently developed new measures; some of which utilize more modern standards for patient involvement and psychometric analysis (1, 3). The widespread adoption of the PSQI has led to a

large literature that appears to facilitate comparison between samples, and now acts as a motivating factor for researchers and clinicians to continue to use the PSQI in preference of other measures. This includes some populations for which it has not been validated (4).

The PSQI is often used as a global measure of self-reported sleep disturbance in people with schizophrenia spectrum disorders, but the validity of the PSQI (English version) as a global measure of sleep disturbance in this population has, to our knowledge, not been evaluated. We explored the content validity of the PSQI for assessing patient-reported sleep quality and sleep disturbance in people with schizophrenia spectrum disorders.

METHODS

We recruited 15 adults with schizophrenia spectrum disorders, who were in contact with specialist mental health services in the United Kingdom, and had a self-reported problem with sleep initiation, maintenance, quality, timing, or refreshingness. People whose predominant complaint was of parasomnia or sleep apnea were not included, in order to focus on insomnia and circadian rhythm problems. All participants' data are included in the current analysis. Written informed consent was obtained after participants reviewed the participant information sheet and had sufficient opportunity for further explanation or questions. Ethical approval was obtained through the NHS Research Ethics Committee Proportionate Review Service (14/NS/1085).

Demographic data were collected, and symptoms and functioning were rated using the Global Assessment of Functioning (GAF) split version (GAF-F and GAF-S). Participants completed the PSQI and were invited to report their experience as they went through the questionnaire; this was followed by an in-depth interview that further explored their sleep experiences and complaints (see **Supplementary File S1**). In addition to the planned questions, the interviewer used continuers and active listening techniques; interview questions later went on to cover other research aims including exploring acceptability of potential treatments, and barriers to improving sleep; these results are reported elsewhere (5). The use of in-depth interview is an additional complementary approach to quantitative psychometrics in evaluating the validity of standardized self-report questionnaires, and it has been used informatively to examine interpretation of other self-reported health measures (6).

Transcription noted long pauses and we made field notes on nonverbal expressions (e.g., frowning, and nonlexical utterances such as "Errrr…"). Analysis was facilitated by Nvivo (qualitative analysis software), creating an audit trail, and ensuring themes were linked back to the data. Transcript content was coded in relation to the PSQI question each section related to, and in relation to emergent themes and subthemes from in-depth analysis of participant interviews. The qualitative analysis used a framework approach, and samples of the data were independently analyzed by a second researcher to enhance reliability. The mixing of methods was approached through qualitization of individual PSQI component scores, and summarizing and classification of the sleep problems described in interviews, to facilitate comparison of component and total PSQI scores, with the clinical presentation as described in each participant's qualitative account (7).

RESULTS

Fifteen participants were recruited, including acute inpatients (n = 2), outpatients receiving intensive (daily) support (n = 3), those under Community Mental Health Teams (n = 8), and under outpatient clinic only (n = 2); none were currently in paid employment. There were 10 males and 5 females, with a mean age of 45.9 (SD = 10.55), diagnosed with schizophrenia (n = 8), schizoaffective disorder (n = 6), and delusional disorder (n = 1). All were prescribed either one (n = 8) or two antipsychotics (n = 7); dosages as a fraction of defined daily doses (8) ranged from 0.36 to 5.5 (mean 2.19, SD 1.28). GAF-F and GAF-S scores ranged from 38 to 85, and from 21 to 80, respectively (mean 62.3, SD 12.16 and mean 47.7, SD 19.40, respectively). For itemized PSQI component scores and raw values, see **Table 1**. Overall, the areas in which these participants scored higher (indicating worse problems) were sleep latency, sleep quality, and daytime dysfunction, while sleep duration scored very low (which should suggest minimal problems). **Table 2** shows summary statements describing the nature of sleep complaints described in interview, and a breakdown of participants endorsing various types of problems.

Acceptability

Most participants reported no problem completing the measure and felt it asked relevant questions. Although some noted a preference for open questions, this is not an issue specific to the PSQI. A minority of participants suggested there should be more questions relating to psychological or mental health-related causes of sleep disruption.

Sleep Duration

Nine participants scored 0 for sleep duration; however, four of these participants were sleeping 11 to 14.5 h, and expressed concerns about this:

> "I've looked it up on Google and it says things like, a higher risk of heart attack, diabetes or early death [laughs]. […] I do feel guilty, quite a lot, yeah. I would like to be able to … I would love to be able to just be a morning person" (r05, reported sleep duration = 14.5 h, score on this item = 0)

Hypersomnia was seen as a potential health concern, and a cause for negative self-concept:

> "you're lazy … you're wasting your life away" (r12).

Participants who described a large amount of nightly variation found average sleep duration difficult to calculate accurately:

TABLE 1 | Participant itemized PSQI scores, hours of sleep, and minutes sleep latency.

Respondent	Hours of actual sleep: h/score[1]	Sleep latency: min/score[1]	Sleep disturbances[1]	Daytime dysfunction[1]	Habitual sleep efficiency[1]	Self-reported quality[1]	Use of sleeping medication[1]	Total PSQI score[2]
r01	11/0	60/3	0	0	0	0	0	**3**
r02	4.5/3	3/0	1	2	1	2	3	**12**
r03	12/0	10/0	1	2	0	0	3	**6**
r04	6/1	60/1	0	0	0	0	0	**2**
r05	14.5/0	180/3	1	3	0	1	0	**8**
r06	6.5/1	60/3	1	3	1	1	0	**10**
r07	4/3	120/3	1	1	2	2	3	**15**
r08	8.5/0	20/1	1	1	0	1	3	**7**
r09	11/0	30/2	2	1	1	1	0	**7**
r10	4.5/3	30/2	1	3	3	3	3	**18**
r11	8/0	30/1	1	0	1	1	0	**4**
r12	3/3	180/3	1	2	3	1	0	**13**
r13	8/0	60/3	1	0	0	2	3	**9**
r14	9/0	10/2	1	0	0	0	0	**3**
r15	7/0	60/3	2	2	1	2	3	**13**
Averages	7.83/0.9	61/2.0	1.0	1.3	0.9	1.1	1.4	**8.7**

Number of participants PSQI indicates have poor sleep quality = 11

[1]Minimum score = 0 (better), maximum score = 3 (worse). [2]Minimum score = 0 (better), maximum score = 21 (worse), Total >5 associated with poor sleep quality. PSQI, Pittsburgh Sleep Quality Index.

TABLE 2 | Qualitative summaries of participant's description of their sleep problems.

Self-report regarding sleep	r01	r02	r03	r04	r05	r06	r07	r08	r09	r10	r11	r12	r13	r14	r15
Frequent problem with long sleep latency[1]				x			x					x	x		x
Occasional severe problem with long sleep latency[1]	x	x									x				
Problem maintaining sleep or excessively early rising[1]		x			x	x	x			x		x	x		
Problem with difficulty rising or waking[1]	x			x	x				x					x	x
Problem with too long sleep duration[1]			x		x					x				x	
Unusually long sleep, not a problem at present[2]	x								x						
Usually regularly naps[2]	x				x	x			x	x	x	x			x
Problem with prolonged sleep inertia[1]		x	x	x	x	x			x					x	
Significantly troubled by bad dreams[1]		x						x		x		x	x		x

[1]Items are selected where this was a major and consistent aspect of the participant's self-reported complaint; items are only selected where the participant subjectively perceived this as a problem.
[2]Items are selected where this was a frequent occurrence, may not subjectively be a problem.

> "sometimes [waking up] will be 6 o'clock for like three weeks, but very rarely it's 11 o'clock […] if I'm feeling too enthusiastic I'll be awake all night because of the excitement from the day […] yeah so it asks for a fixed time, but it's quite hard to estimate, it varies a lot" (r02, reported average sleep duration = 4.5 h, score on this item = 3)

Seven of the 15 participants tried to give ranges, which were sometimes several hours apart; three participants described nights of getting almost no sleep at all, followed by very long sleep when they did eventually sleep. These participants' mean total sleep time did not capture this issue as the very long and very short sleep times were averaged to a normal duration. Some distinguished "actual sleep" from light sleep/partial sleep, so were unsure how best to respond. Some answers weren't internally consistent (e.g., time to bed till time to wake, minus sleep latency and sleep interruptions, was inconsistent with reported total sleep time). It should be acknowledged that the latter of these issues could affect many retrospective self-report measures.

It is important also to note that daytime naps are not included within the sleep duration total, and for over half in this sample (eight participants), naps were a significant source of sleep:

> "Respondent: […] I always go to sleep in the afternoon
>
> Interviewer: Most days?
>
> Respondent: Yeah I'd say every day.
>
> Interviewer: How long for?
>
> Respondent: One and a half to two hours" (r10, reported sleep duration = 4.5 h, score on this item = 3)

Other participants described 3- or 4-h naps; hence, the PSQI total sleep time question missed roughly half of their actual total sleep for that day.

Sleep Timing

Average sleep timings are measured by the PSQI, but do not contribute directly to the score. The times recorded give useful information for clinicians on circadian preference or social commitments when sleep timing is regular; in this group, however, times varied and averages may be less meaningful. This variability may have been missed altogether if times were averaged by participants without comment. Dissatisfaction with sleep timing, and unpredictability of sleep timing, were significant sources of dysfunction and distress in participant accounts; participants described the impact on their ability to take on work, education, or social commitments. Satisfaction with or regularity of sleep timing is not part of the PSQI scoring so a problem with sleep timing does not directly impact the score.

Sleep Latency

Sleep latencies reported in answering the PSQI and in interview were similar. While it is interesting that some participants had long sleep latency (60 min, score 3 = worst) and were untroubled by this, this constitutes a quantitative aspect of their sleep disturbance, which is accurately summarized by the PSQI.

Sleep Disturbance

It is not clear how decisions were made regarding what are considered normal frequencies for some of the listed types of sleep disturbance, resulting in floor and ceiling effects. Participants who described "problems" with going to the bathroom at night went several times per night, the highest option to select being ×3 per week. Someone who woke to use the toilet twice a week explained that they felt this was probably less than most people. With regards to the impact of bad dreams, it seemed that frequency of bad dreams bore limited relation to the distress caused; in this sample, no one endorsed 3× per week, but some described less frequent but intense bad dreams causing significant distress, which was not well captured:

> "Oh jeeze I'm always having bad dreams … I'd say maybe twice a week." (r12)

Significantly, in interview the vast majority of the sample complained of problems with poor sleep maintenance and depth, in terms of "broken" sleep, sleep that was "not deep," or was not "proper sleep"; however, the average score for sleep disturbance was 1.0 (0 = best, 3 = worse). This can largely be attributed to the aggregation of scores from physical and psychological causes of sleep disturbance where there are more physical causes listed. It was noted that sleep, which was disturbed by a wide range of causes, scored higher than sleep very often disturbed, but generally by the same cause. Comparison of individual accounts and sleep disturbance scores showed that sleep that felt broken, but without a complete awakening, did not readily translate to a high score for "sleep disturbance."

"Another Reason…"

Although perhaps a trivial matter, the phrasing of this question proved problematic for well over half of participants, causing a pause in completion and questions regarding either the first part or both parts of this question:

> "…but what does that mean, how often during the past month have you had trouble sleeping because of this, because of what?" (r10)

It was also noted that this question rarely elicited information, as participants brought up many "other reasons" in interview (e.g., hypnopompic hallucinations), but wrote "N/A" on the PSQI. This may contribute to the unusually low scores for sleep disturbance, as these "other reasons" were not scored.

Daytime Dysfunction

The PSQI asks about trouble staying awake "while driving, eating meals, or engaging in social activity"; this question appeared not to be sensitive to sleepiness in those who did not drive and socialized infrequently:

> "My sleep's a bit spontaneous, my body don't plan it […] I'm always falling asleep watching films […] but no, I'm trying to think now how often I do a social activity, it's less than once a week isn't it. So it's less than once a week isn't it falling asleep." (r15, score on this item = 0)

Many asked if falling asleep in front of the television counted, and some then answered yes for this question.

The other question concerns "enthusiasm to get things done"; some noted they had difficulty with enthusiasm due to mood or psychotic symptoms, rather than their sleep. Daytime dysfunction questions did not pick up on the impact on daytime

functioning, where participants were napping or sleeping for excessive periods to counter tiredness:

> "I'm really fed up because I'd like to get out and do things instead of sleeping the days away" (r01, daytime dysfunction score = 0)

> "It can be as short as half an hour or as long as two hours […] I go to sleep because I'm tired in the day time, not because I'm bored." (r14, daytime dysfunction score = 0)

Sleep inertia and difficulty waking were also major complaints discussed by participants within the current study (n = 6 of 15). These should be detected as a form of daytime dysfunction; however, half of those expressing this complaint scored 0 for daytime dysfunction (see **Tables 1** and **2**).

Sleep Efficiency

Sleep efficiency has been found to be lower on average in groups with schizophrenia (9); in this sample, average sleep efficiency score does not suggest that this was a particular difficulty (average = 0.9). Interview accounts described difficulties initiating sleep, or maintaining sleep, suggesting poor sleep efficiency. Of those who reported one or more of these difficulties (n = 11), the average sleep efficiency score was 1.09; only four reporting such complaints scored 0. This suggests that the sleep efficiency score detected relevant problems to some extent in most cases.

Quality

Interestingly, over half of participants rated quality as very good (0) or fairly good (1), but went on to state significant concerns with their sleep and its impact on their life, including that their sleep was not restorative, that their poor sleep pattern was a barrier to getting a job, or that their sleep was "medicated sleep" and therefore substandard:

> "[If I wasn't on medication] That I'd actually sleep, yeah. And I think I'd be able to do more things as well, you know, in the day, if I wasn't on the medication, sometimes, if I managed to get natural sleep." (r03, sleep quality rated "very good" = 0)

For some, there seemed to be a direct contradiction between self-reported "sleep quality" on the PSQI and their view of their sleep during interview:

> "Interviewer: …how would you describe your sleep, if you were sort of telling someone about it?
>
> Respondent: Umm, not very good.
>
> Interviewer: No?
>
> Respondent: No. Not like other people … go on like sleep's supposed to be, you know?
>
> Interviewer: What?
>
> Respondent: Like, when they say have a nice sleep and you'll feel refreshed and all this nonsense.
>
> Interviewer: They say that.
>
> Respondent: Yes, and I don't feel like that.
>
> Interviewer: No.
>
> Respondent: I feel like, jeez, what's happened?" (r12, sleep quality rated "fairly good" = 1)

In the context of the rest of the analysis (5), this can be attributed to lowered expectations, so "fairly good" could mean good—when all is considered, good—compared to others with the same condition. It is also possible that participants responded regarding sleep quality by evaluating individual periods of sleep obtained, in contrast to the adequateness of their day-to-day sleep as a whole. Potentially also more rapport was built during the in-depth interview and participants felt more open and prepared to describe problems.

Sleeping Medication

The present sample's highest scoring domain was use of sleeping medication. This did not, however, represent high levels of hypnotic use in this sample; in six out of seven of those scoring 3 (highest), their answer related to their oral antipsychotic being "sleeping medication" (although some felt this was an ineffective sleeping medication). Some described in interview using their antipsychotic to control their sleep onset, but answered "never" to this question on the PSQI, and some raised the dilemma of whether their antipsychotic counted or not. Answers were therefore dictated by semantic interpretation rather than any meaningful differences between perceptions or behaviors.

Sleep Disordered Breathing

The PSQI includes questions regarding snoring or breathing among its sleep disturbance questions, and also a section for completion by the person's bed partner/roommate to screen for sleep disordered breathing, in acknowledgement of people's reduced awareness of their own breathing during sleep. Participants in this study did endorse snoring, but rarely endorsed "cannot breathe comfortably," rather clarifying that they breathed heavily, not had *difficulty* breathing:

> "…cause I'm a big lad as well so when I'm lying down … I'd say not it's hard to breathe but I breathe heavily." (r15, cannot breathe comfortably = 1, cough or snore loudly = 3, circled 'loudly' for emphasis).

It was never designed as such, and it is important that the PSQI is not considered to be an effective screening for sleep disordered breathing, particularly without the bed partner/roommate questions being completed.

Total Scores

The total PSQI scores indicated that seven participants were either good sleepers or had only mild sleep problems (n = 4 score <5, n = 3, score 6–7). Of these seven, four described significant and severe concerns during interview, while the other three described milder but definite problems. Of those whose PSQI scores suggested moderate or severe problems (score 8–18), the global impression from the interview was also of moderate or severe problems.

DISCUSSION

The sample reported multiple and complex problems with sleep initiation, continuity, quality, and timing, with attendant daytime dysfunction; the PSQI was capable to assess some, but not all, of these issues. The PSQI appeared to be suitable for identifying self-reported short sleep, long sleep latency, or complete awakenings during the night, but poorly represented some other problems such as variable and inconsistent sleep length, poor sleep depth or quality, increased sleep inertia, hypersomnia, and inappropriate or inconsistent sleep timing. While issues with sleep timing are beyond the intended scope of the PSQI, sleep duration, quality, and daytime dysfunction are within its scope and were poorly captured. Furthermore, it is common for total PSQI scores to be treated as a global measure of sleep disturbance, which these findings suggest is not valid. Reliance on total PSQI score as a measure of sleep dysfunction is particularly inappropriate for those with schizophrenia spectrum disorders whose sleep problems include more circadian dysregulation than other groups (10), and who as a result experience more inconsistent and variable sleep, and more difficulties timing sleep patterns to fit with life expectations (5, 11, 12). Some of the measurement issues highlighted also have potential implications for interpretation of PSQI scores in other populations.

Measuring Sleep Duration, Variability, and Depth

As some participants feared, both excessively short and excessively long sleep are indeed associated with increased mortality (13), and it has previously been recommended that the relationship of sleep duration to assumed sleep quality on the PSQI should be U-shaped and not linear (14). Our findings support this suggestion, concurring that unusually long sleep, as well as too short sleep, caused concerns for participants. It is also important to note that in people taking significant naps, as was common in this sample, the PSQI can mischaracterize (underestimate) a person's total sleep time, as might also occur in regional populations in whom biphasic sleep is common. These issues with calculation and scoring of sleep duration of course affect the use of the PSQI in many other clinical and nonclinical samples, not just in those with schizophrenia spectrum disorders.

Participant PSQI scores were similar to those from research with the Japanese version of this instrument in a similar sample (14), where sleep latency, sleep quality, and daytime dysfunction received higher scores on the PSQI, while sleep duration scored very low [which should suggest minimal problems; Doi et al. (14) also noted hypersomnia was not captured]. In contrast to our study, the subgroup of the Japanese sample with schizophrenia (n = 24) scored low regarding sleeping medication, perhaps owing to different phrasing in the translation (14).

Insufficient detection of problems with sleep depth is significant particularly for this population, for whom levels of shallow sleep (stage 1) are often elevated, and deeper sleep (Stage 2 and Stage 3 non-REM sleep) is often reduced (9). Although objective assessment of sleep depth requires polysomnography or spectral analysis, the experience of deep sleep was important to participants. Even apart from importance to individuals, subjective evaluations of sleep have often been found to be equally if not more predictive of health and functioning outcomes than some more objective measures (15, 16), suggesting even "inaccurate" experiences may be equally important to capture.

Our findings are consistent with those of Waters et al. (12) who found only small and statistically nonsignificant differences in PSQI scores between people with schizophrenia and healthy controls, but found increased variability in sleep latency, efficiency, and duration in schizophrenia when using actigraphy. Actigraphy or sleep diaries can be recommended to assess variability. However, retrospective self-report is less burdensome and has the potential to offer some insight; a future measure might include questions that assess how frequently various sleep values deviate from the average, by more than a certain amount (e.g., "How many times in the last month? was it 2 h more or less than this?"). Appropriate phrasing, format, and content would require development and testing.

Clinical Assessment of Sleep

For current clinical practice, supplementary questions or additional measures should be used when using the PSQI as a screening for sleep problems. For instance, the PSQI should not be relied upon to screen for sleep disordered breathing; a ready alternative is the STOP-Bang questionnaire, which has been found to be reasonably accurate in detection (17) and is freely available and brief (18). Measures of circadian preference might be added (19, 20); however, these do not measure regularity of rhythm. It is possible to measure and quantify regularity of rest-activity rhythms through actigraphy, describing both amplitude (relative amplitude) and regularity of rhythm (interday stability) (21), as has been more extensively utilized in samples with dementia (22) who also experience circadian dysregulation. At least one retrospective self-report measure of regularity is available [e.g., (23)], although none has yet been tested in schizophrenia spectrum disorders. During clinical interview, therefore, additional questions are recommended regarding regularity of sleep timing, and the match between sleep timing and individual lifestyle choices and requirements.

Outcome Measurement

Whether for research or clinical outcome measurement for quality improvement, the findings of the present study caution against relying on the PSQI total score alone, as improvements in sleep timing or regularity (often accompanied by improved quality of life and functioning) may go undetected. There are more recently developed tools, including the PROMIS sleep dysfunction item bank (1), and the Glasgow Sleep Impact Scale (3), which have been specifically designed to act as a barometer of the patient's perceived standard of sleep. Both tools were developed with patient involvement and

have undergone validation in healthy controls and those with sleep disorders, or in insomnia, respectively. These measures are very promising and may offer a useful adjunct to clinical assessments of sleep issues for people with schizophrenia spectrum disorders, and, by virtue of their use of modern psychometric methods, may also offer a reliable means of comparison across diagnostic groups.

These tools, however, are designed to measure change for research or clinical outcome measurement; they do not simultaneously help to characterize the sleep problem—as might be desired by a clinician. And in this respect, they do not replace the PSQI. Asking the patient to specify sleep latency, sleep times, and causes of sleep disturbance, as the PSQI does, can help identify the problem and therefore direct treatment. Unfortunately, the PSQI alone is likely to give an incomplete and sometimes misleading picture, in the case of people with schizophrenia spectrum disorders, and possibly many other groups.

Limitations and Future Directions

The generalizability of the findings from a small sample might be questioned, although as the types of problems described are similar to those found in larger samples studied using quantitative methodologies, we believe these findings are transferable. Although the diversity in the type and extent of problems is potentially representative of the diverse problems experienced in this group, it also limits the number of cases with each particular type of problem (e.g., with short sleep, or with hypersomnia). Furthermore, diversity in the environmental context of the participants, particularly the inclusion of both inpatients and outpatients, complicates interpretation. It would also have been useful to find out the approximate length of time since diagnosis, and length of time on antipsychotic medication, to better describe the sample and facilitate comparison with other studies. In hindsight, it would also have been useful if participants had been asked to comment on the recommended interpretation of their component or total PSQI scores (for instance, "This score suggests overall you have good/slightly disturbed/severely disturbed sleep. Do you agree?"), which might have provided a further point of reference.

This study did not set out to make statistical analysis of sensitivity or specificity, but these findings suggest a hypothesis of too low sensitivity, and missed cases, but no issues with overdetection. Future studies comparing PSQI to other measures such as actigraphy or polysomnography might confirm or quantify this, and could further examine which types of problem are underdetected in a larger sample. More detailed description of the weaknesses this study has highlighted would support improved interpretation of the considerable body of important work, which has used the PSQI to describe their sample or to measure change.

Our analysis demonstrates that the PSQI is insensitive to some sleep issues, which are described as important to people with schizophrenia spectrum disorders. This disparity between the range of issues highlighted in our interviews and those covered by the PSQI may suggest a need for a disease-specific measure to achieve high sensitivity to the particular problems of this group. Another possibility is the development of a measure of sleep disturbance, which can equally measure sleep problems of circadian, insomniac, or combined cause and nature, which could be used trans-diagnostically. A future measure could attempt also to take into account different environmental contexts; for instance, in many institutional settings, patients may more commonly go "to bed" far in advance of intending to sleep, as their bedroom may be the only private space in which to wind down for sleep. This can lead to underestimation of sleep efficiency, as has previously been noted in relation to sleep diaries (24); and alternative phrasing around "into bed" has been recommended. There may also be utility in a measure that examines or considers the impact of a mismatch between environment, occupational routine, and the individual, upon sleep, as well as factors that are more inherent to the person.

Self-Report Items versus Self-Evaluated Items

The PSQI is of course not unique among self-report measures in being affected by participants calibrating some of their responses in relation to their own context and peer group, as we found here regarding rating of sleep quality. Similar findings of peer group-dependent evaluations were presented by Adamson et al. (6) regarding the evaluation of general health:

> "Mrs K: Oh, I suppose for my age my health is excellent., I mean to say, it wasn't until I went up for the assessment I knew there was anything wrong with my heart" [(6), p142]

This context-dependent evaluation may equally measure a difference in a person's perceived peer group, as much as based on a change in self-perceived sleep, and makes it difficult to use exclusively self-evaluated items to compare between populations. It may therefore be desirable to include some quantitative self-report elements, which are more influenced by the individual's perception of their sleep than contextual factors.

CONCLUSION

Future research should develop a valid and reliable tool, with a similar shared utility for both clinicians and researchers as the PSQI has uniquely offered; this shared utility no doubt facilitates understanding between clinicians and researchers, and accounts for its enduring popularity. The authors suggest the development of a new measure that can act as a clinical screening and initial interview, and as an outcome measure in research.

ETHICS STATEMENT

Ethical approval was obtained through the NHS Research Ethics Committee Proportionate Review Service (14/NS/1085), North of Scotland Research Ethics Committee 1. Written informed consent was obtained after participants reviewed the participant information sheet and had sufficient opportunity for further explanation or questions. A disclosure or risk protocol and a distress

protocol were followed during data collection, and information sharing with care providers was discussed with participants in advance (information was shared on participant's request, or if any immediate risks necessitated information sharing).

AUTHOR CONTRIBUTIONS

SF designed and conducted the study, collected and analyzed the data, and wrote the first draft of the manuscript. SF and CS-G were involved in editing, conceptual formulation, and discussion of the findings and implications of the study.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2019.00284/full#supplementary-material

FILE S1 | Question schedule and optional prompts.

REFERENCES

1. Buysse DJ, Yu L, Moul DE, Germain A, Stover A, Dodds NE, et al. Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments. *Sleep* (2010) 33(6):781–92. [online]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2880437 doi: 10.1093/sleep/33.6.781
2. Buysse DJ, Reynolds CF 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res* (1989) 28(2):193–213. [online]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/2748771 doi: 10.1016/0165-1781(89)90047-4
3. Kyle SD, Crawford MR, Morgan K, Spiegelhalder K, Clark AA, Espie CA. The Glasgow Sleep Impact Index (GSII): a novel patient-centred measure for assessing sleep-related quality of life impairment in insomnia disorder. *Sleep Med* (2013) 14(6):493–501. doi: 10.1016/j.sleep.2012.10.023
4. Garrow AP, Yorke J, Khan N, Vestbo J, Singh D, Tyson S. Systematic literature review of patient-reported outcome measures used in assessment and measurement of sleep disorders in chronic obstructive pulmonary disease. *Int J Chron Obstruct Pulmon Dis* (2015) 10:293–307. [online]. Available from: http://www.scopus.com/inward/record.url?eid=2-s2.0-84922743032&partnerID=tZOtx3y1
5. Faulkner S, Bee P. Experiences, perspectives and priorities of people with schizophrenia spectrum disorders regarding sleep disturbance and its treatment: a qualitative study. *BMC Psychiatry* (2017) 17(1):158. [online]. Available from: DOI 10.1186/s12888-017-1329-8 doi: 10.1186/s12888-017-1329-8
6. Adamson J, Gooberman-Hill R, Woolhead G, Donovan J. 'Questerviews': using questionnaires in qualitative interviews as a method of integrating qualitative and quantitative health services research. *J Health Serv Res Policy* (2004) 9(3):139–45. [online]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15272971 [Accessed November 4, 2014]. doi: 10.1258/1355819041403268
7. Migiro SO, Magangi BA. Mixed methods: a review of literature and the future of the new research paradigm. *Afr J Bus Manage* (2011) 5(10):3757–64. [online]. Available from: http://www.academicjournals.org/AJBM
8. WHO. WHO Collaborating Centre for Drug Statistics Methodology., p. ATC/DDD Index. [online]. Available from: https://www.whocc.no/atc_ddd_index/ [Accessed March 12, 2017].
9. Chan MS, Chung KF, Yung KP, Yeung WF. Sleep in schizophrenia: a systematic review and meta-analysis of polysomnographic findings in case-control studies. *Sleep Med Rev* (2017) 32:69–84. [online]. Available from: doi.org/10.1016/j.smrv.2016.03.001 doi: 10.1016/j.smrv.2016.03.001
10. Pritchett D, Wulff K, Oliver PL, Bannerman DM, Davies KE, Harrison PJ, et al. Evaluating the links between schizophrenia and sleep and circadian rhythm disruption. *J Neural Transm* (2012) 119(10):1061–75. doi: 10.1007/s00702-012-0817-8
11. Waite F, Evans N, Myers E, Startup H, Lister R, Harvey AG, et al. The patient experience of sleep problems and their treatment in the context of current delusions and hallucinations. *Psychol Psychother: Theory Res Pract* (2015) 89:181–93. [online]. Available from: http://doi.wiley.com/10.1111/papt.12073 doi: 10.1111/papt.12073
12. Waters F, Sinclair C, Rock D, Jablensky A, Foster RG, Wulff K. Daily variations in sleep-wake patterns and severity of psychopathology: a pilot study in community-dwelling individuals with chronic schizophrenia. *Psychiatry Res* (2011) 187(1–2):304–6. [online]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21272939 [Accessed October 28, 2014]. doi: 10.1016/j.psychres.2011.01.006
13. Cappuccio FP, D'Elia L, Strazzullo P, Miller MA. Sleep duration and all-cause mortality: a systematic review and meta-analysis of prospective studies. *Sleep* (2010) 33(5):585–92. [online]. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2864873&tool=pmcentrez&rendertype=abstract doi: 10.1093/sleep/33.5.585
14. Doi Y, Minowa M, Uchiyama M, Okawa M, Kim K, Shibui K, et al. Psychometric assessment of subjective sleep quality using the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J) in psychiatric disordered and control subjects. *Psychiatry Res* (2000) 97:165–72. doi: 10.1016/S0165-1781(00)00232-8
15. Harvey AG, Tang NKY. (Mis)perception of sleep in insomnia: a puzzle and a resolution. *Psychol Bull* (2012) 138(1):77–101. [online]. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3277880&tool=pmcentrez&rendertype=abstract [Accessed October 22, 2014]. doi: 10.1037/a0025730
16. Pilcher JJ, Ginter DR, Sadowsky B. Sleep quality versus sleep quantity: relationships between sleep and measures of health, well-being and sleepiness in college students. *J Psychosom Res* (1997) 42(6):583–96. doi: 10.1016/S0022-3999(97)00004-4
17. Abrishami A, Khajehdehi A, Chung F. A systematic review of screening questionnaires for obstructive sleep apnea. *Can J Anaesth* (2010) 57(5):423–38. doi: 10.1007/s12630-010-9280-x
18. Chung F, Subramanyam R, Liao P, Sasaki E, Shapiro C, Sun Y. *STOP-Bang Questionnaire*. Toronto: Toronto Western Hospital (2018). [online]. Available from: http://www.stopbang.ca/osa/screening.php [Accessed August 1, 2018].

19. Roenneberg T, Wirz-Justice A, Merrow M. Life between clocks: daily temporal patterns of human chronotypes. *J Biol Rhythms* (2003) 18(1):80–90. doi: 10.1177/0748730402239679
20. Randler C, Díaz-Morales JF, Rahafar A, Vollmer C. Morningness–eveningness and amplitude—development and validation of an improved composite scale to measure circadian preference and stability (MESSi). *Chronobiol Int* (2016) 33(7):832–48. [online]. Available from: http://dx.doi.org/10.3109/07420528.2016.1171233 doi: 10.3109/07420528.2016.1171233
21. Van Someren EJW, Swaab DF, Colenda CC, Cohen W, McCall WV, Rosenquist PB. Bright light therapy: improved sensitivity to its effects on rest-activity rhythms in Alzheimer patients by application of nonparametric methods. *Chronobiol Int* (1999) 16(4):505–18. doi: 10.3109/07420529908998724
22. Gonçalves BSB, Adamowicz T, Louzada FM, Moreno CR, Araujo JF. A fresh look at the use of nonparametric analysis in actimetry. *Sleep Med Rev* (2015) 20:84–91. [online]. Available from: http://dx.doi.org/10.1016/j.smrv.2014.06.002 doi: 10.1016/j.smrv.2014.06.002
23. Monk TH, Buysse DJ, Kennedy KS, Pods JM, DeGrazia JM, Miewald JM. Measuring sleep habits without using a diary: the sleep timing questionnaire. *Sleep* (2003) 26(2):208–12. doi: 10.1093/sleep/26.2.208
24. Carney CE, Buysse DJ, Ancoli-israel S, Edinger JD, Krystal AD, Lichstein KL, et al. The Consensus Sleep Diary: standardizing prospective sleep self-monitoring. *Sleep* (2012) 35(2):287–302. doi: 10.5665/sleep.1642

Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Appendix 2: PPI advert

Would you like to contribute toward the design and running of a research project?

Developing occupational therapy for sleep problems in schizophrenia and related conditions

The research project:

We know that people with conditions which cause symptoms such as hearing voices, paranoia, or unusual beliefs, often also have poor sleep. This research project will design, develop and test a non-drug treatment, a 'behavioural' treatment, to help improve sleep in people with these conditions.

Patient and carer involvement:

We want to involve people in the design and running of the project, who have some lived experience of the difficulties we are trying to help. It is known that this can help make sure research is well informed. Research involvement like this, is different from participating in research as a 'subject' or participant. This is a bit more like working on the research project.

What does it involve:

We have a lot of areas which we would like help with. These might include tasks like:

- Giving feedback on written documents – Does the language make sense? Will the way it is written come across well to patients, carers and the public?
- Meetings to help analyse qualitative (words not numbers) data.
- Meetings to talk about results from the research and how we should interpret them.
- Helping choose between different technology to use within the therapy – You might look at different devices (watches which track activity levels, other items like light boxes, or phone apps) and give your opinions.

There is some flexibility, not everyone has to do the same tasks, or the same amount.

We would like to establish a core group of involvement contributors who would plan to stay involved until the end of the research project (2022!). We will ask for expressions of interest in longer term involvement, from people who have been involved earlier on.

Payment: Payment will be provided for your time at £10/hr (rounded up to 1hr if it is less than 1hr), and travel expenses where relevant. Refreshments will be provided for in person group meetings. At longer sessions which fall at lunchtime, lunch will be provided.

Who can get involved:

- People with conditions which cause symptoms like hearing voices, paranoia, or unusual beliefs. This might include: schizophrenia, schizoaffective disorder, delusional disorder.
- We will also have some places for people who are family or close friends of someone with one of these conditions – you might class yourself as a carer.
- It is useful if you are able to travel to meetings by some method (travel expenses paid), although there is a possibility to do some tasks from home.
- You do not need to have any previous experience of research.
- You do not need any formal qualifications.

This is an opportunity to help to conduct the research project in the kind of ways described above. If you are more interested in participating in the research at a one off discussion group, or in having the therapy which is developed from this study, you can ask us to contact you later on, when we are recruiting participants for those activities.

For details or to arrange to be involved, please contact:

Sophie Faulkner (Occupational Therapist / Clinical Doctoral Research Fellow)

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Appendix 3: Supplements to Study A - "Light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuro-psychiatric illness: A systematic review and meta-analysis"

Supplement S1: Changes from protocol

Outcomes:

Self-reported / carer reported sleepiness: Separated self-reported daytime sleepiness from carer reported daytime sleepiness / daytime sleep propensity due to dissimilar methods used to measure these. Carer reported sleepiness was not via carer asking participant but by observed falling asleep or nearly falling asleep.

Sleep onset latency: Sleep onset latency in dementia was not included in the meta-analysis on sleep onset latency as when reported this either did not use self-reported or carer observed lights out and relied solely on actigraphy, or description was unclear.

Global subjective appraisal of sleep: The contents of composite measures of sleep disturbance appear quite different in meaning than a visual analogue scale for sleep quality, and we had no basis on which to privilege one over the other in our hierarchy (see Table S5), therefore self-reported sleep disturbance and self-reported sleep quality were presented separately.

Comparison between diagnostic groups:

It was our working assumption that there would be some similarity in outcomes between diagnostic groups, the decision to run a statistical comparison to test for differences of outcomes between groups was made post-hoc.

Meta-regressions:

Melatonin and CBT-i: An additional meta-regression was run for the effect of including real melatonin or CBT-i alongside light schedule intervention.

It was not possible or appropriate to examine the effect of the following owing to too little data, colinearity or confounding:

Sleep schedule instructions: this was too highly correlated with diagnosis, there were too few studies in any individual diagnosis to undertake meta-regression, except in the case of dementia.

Personalisation of timing of intervention: In the populations where there was personalisation of timing to the individual's circadian phase, all but one study personalised timing, so due to insufficient variation it was not possible to examine associations with effects in those populations. Personalisation of timing was rarely undertaken in dementia, and was more commonly used in mental health conditions, therefore it was not appropriate to examine the effect of personalisation across these categories as it was confounded by the effect of diagnosis.

The effect of season: only in 8 cases (out of 48) was a particular season specified, and only in one case was the season summer. Many studies were undertaken all year, bringing uncertainty to the proportion of participants participating at different

times of year (e.g., may be mostly summer, mostly summer, or equally distributed), just under half of studies did not specify the season or months of intervention.

Latitude: due to the lack of information regarding season, it was not possible to meaningfully analyse the effect of latitude, as the effect of latitude on light levels varies depending on the time of year.

Melanopic lux: It had been planned to convert photopic lux to melanopic lux using the Human Centric Lighting Toolkit v14.21 (www.lightingforpeople.eu, http://lightingforpeople.eu/2016/wp-content/uploads/2016/10/SSL-erate-Report_on_metric_to_quantify_biological_light_exposure_doses.pdf) (http://lightingforpeople.eu/2016/wp-content/uploads/2015/08/HCL-needs-new-quantities-for-light-intensity.pdf) (Current versions available from the International Commission on Illumination "CIE"). In other studies this metric has been found to better correlate with treatment effects than photopic lux (Gimenez et al, 2016), as it better accounts for the amount of the wavelengths the circadian system is most sensitive to. There were too few studies giving accurate enough information regarding the spectral properties of the light used in this review, often even the bulb type was not given and light simply described as 'white' or 'cool white'.

Sensitivity analysis:

Risk of bias sensitivity analysis: as there were so few studies classified as low risk of bias, due to the average ratings being lowered by the lack of a plausible control intervention (a problem ubiquitous across this field) it was determined to identify medium risk of bias studies and include these in analyses. Sensitivity analyses including only low risk studies appeared uninformative, excessively weighted the remaining one or two studies, or contained no studies, therefore findings instead focus on the effects of removing high risk of bias studies.

Qualitative synthesis - adherence, attrition and acceptability:

Secondary outcomes analysis: Due to the amount of material for inclusion within the meta-analysis (controlled studies), and the number of reportable outcomes it was decided to complete the qualitative synthesis regarding adherence, attrition and acceptability subsequently, and report it separately.

Study inclusion: It had been planned to include single group studies in a narrative synthesis regarding outcomes, however due to the large volume of controlled studies it was decided alongside the decision to report qualitative synthesis separately, to include single group studies only in the qualitative synthesis described above.

Supplement S2: Example search, MEDLINE database, Ovid interface

# ▲	Searches	Results
1	(Delayed sleep or advanced sleep or irregular sleep or non 24 or circadian rhythm disorder* or circadian misalignment or circadian phase or circadian rhythm sleep disorder* or circadian mismatch or sleep pattern* or (sleep adj2 wake) or (rest adj2 activ*) or (sleep adj2 timing) or daytime sleep).mp. or Sleep Disorders, Circadian Rhythm/	35208
2	(Insomnia or sleep quality or sleep disorder or sleep problem or poor sleep or sleepiness or sleep maintenance or broken sleep or sleep disruption or sleep dysfunction or sleep initiation or sleep inertia or difficulty rising or difficulty waking).mp. or "Sleep Initiation and Maintenance Disorders"/ or Circadian Rhythm/ or Sleep Wake Disorders/	118784
3	(psychosis or psychotic or delusional or schizo* or psychiatric or (mental adj1 health) or (mental adj1 illness) or bipolar or bi-polar or manic or (affective adj1 disorder*) or depress* or (personality adj1 disorder*)).mp. or Mental Disorders/ or psychotic disorders/ or schizophrenia/ or delusions/ or Bipolar Disorder/ or Depression/ or Mood Disorders/ or Personality Disorders/ or Mental Disorders/ or Depressive Disorder/	1016661
4	dementia/ or alzheimer disease/ or aphasia, primary progressive/ or creutzfeldt-jakob syndrome/ or dementia, vascular/ or diffuse neurofibrillary tangles with calcification/ or frontotemporal lobar degeneration/ or kluver-bucy syndrome/ or lewy body disease/ or dementia.mp. or alzheimer's.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	201210
5	huntington disease/ or (huntingdon* or Multiple Sclerosis).mp. or Multiple Sclerosis/	83553
6	(seasonal affective disorder or winter depression).mp. or Seasonal Affective Disorder/	1697
7	1 or (2 and (circadian.mp. or circadian rhythm/))	97463

8	((light adj2 therap*) or phototherap* or heliotherap* or (light adj2 exposure) or (light adj2 schedule) or (light adj2 manipulation) or (light adj2 intervention) or daylight or (bright adj2 light) or artificial light or natural light or sunlight or sun light or (outdoor adj2 light) or (light adj2 restriction) or (light adj2 block) or (dark adj2 therapy) or dimly lit or dim light* or ambient light* or (environment* adj2 light*) or (blue adj2 block*) or amber lens* or amber glasses or chronotherapy or zeitgeber* or social rhythm therapy or light box or lightbox or artificial dawn or dawn simulation).mp. or Phototherapy/ or Heliotherapy/	61036
9	(trial* or ((singl* or double or treb* or tripl*) adj (blind* or mask*)) or placebo* or randomly allocated or (allocated adj2 random*) or experiment* or pilot or feasibility or single group or pre-test or post-test or cross-over or cross over or intervention study or treatment effect* or open study or open label study or outcome* or improvement* or patient satisfaction or acceptability or patient experience* or service user experience* or participant experience* or adherence or compliance or attrition or contraindication* or side effect* or side-effect* or adverse effect* or complication*).tw. or randomized controlled trial/ or random allocation/ or double blind method/ or single blind method/ or clinical trial/ or placebos/ or qualitative research/ or Treatment Outcome/ or Patient Satisfaction/ or Patient Compliance/ or "Patient Acceptance of Health Care".mp. or Feasibility Studies/ or Pilot Projects/ [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	5961696
10	3 or 4 or 5 or 6 or 7	1345040
11	(sleep or insomnia).mp. or sleep/ or circadian.mp. or circadian rhythm/ or "Sleep Initiation and Maintenance Disorders"/ or Sleep Wake Disorders/ or (rest adj2 activ*).mp. or difficulty rising.mp. or difficulty waking.mp.	238546
12	8 and 11 and 10	5756
13	9 and 12	1941
14	limit 13 to animal	616
15	13 not 14	1325

Table S3: Full detail inclusion criteria with common synonyms

POPULATION A: Circadian rhythm sleep disorders (CRSD)	
condition	**alternative terms and phrases that may be used**
delayed sleep phase disorder	'Sleep onset insomnia with difficulty waking in the morning' 'difficulty rising, with delayed sleep onset' 'delayed sleep schedule'
advanced sleep phase disorder	'sleep maintenance insomnia with excessively early retiring to bed', 'excessive evening sleepiness', 'early sleep schedule'
irregular sleep-wake rhythm	'poor sleep maintenance, and increased daytime napping', 'increased daytime sleep and reduced night-time sleep / increased night-time activity'
non-24-hour / free-running sleep	Circadian Rhythm Sleep Disorder, Non-entrained Type 'lack of entrainment'
Formal diagnosis of CRSD not required if participants meet ICSD-3 or DSM-5 criteria.	
Exclude: shift work disorder, jet lag disorder, circadian dysregulation specifically caused by the arctic winter, during space flight, or secondary to general anaesthetic.	
OR	
POPULATION B: Diagnosis of mental health or neurological condition frequently associated with circadian dysregulation	
general diagnostic category	**specific diagnoses and alternative terms**
psychotic illnesses	Schizophrenia (any 'type' e.g., paranoid, catatonic…) schizoaffective disorder 'non-affective psychosis' psychotic illness / psychotic disorder delusional disorder psychotic depression puerperal psychosis / post-natal psychosis Exclude: drug induced psychosis (where diagnosed as such) psychosis induced by sepsis or delirium 'at risk groups' or 'high risk' or 'ultra high risk' or 'prodromal'
personality disorder (PD)	borderline PD / emotionally unstable PD Paranoid PD, Schizoid PD, Schizotypal PD, Antisocial PD / Dissocial PD Histrionic PD, Narcissistic PD, Avoidant PD / Anxious (avoidant) PD Dependent PD, Obsessive-compulsive PD / Anankastic PD Personality disorder, unspecified Cluster A (the "odd, eccentric" cluster) Cluster B (the "dramatic, emotional, erratic" cluster) Cluster C (the "anxious, fearful" cluster)

bipolar	Manic depression, bipolar I, bipolar II. Mania, hypomania. Exclude: cyclothymia
depression	Mild / moderate / severe depression, dysthymia Major depressive disorder postnatal depression Seasonal Affective Disorder (SAD) / winter depression / seasonal depression 'Bipolar depression'
Alzheimer's disease and other dementias	Alzheimer's, senile dementia, 'demented', mixed dementia vascular dementia Dementia with Lewy bodies (DLB) frontotemporal dementia Exclude: Creutzfeldt-Jakob disease (CJD) Korsakoff's / Wernick Korsakoff syndrome / alcoholic dementia HIV associated dementia Parkinson's
Huntingdon's chorea	Huntingdon's disease
Multiple sclerosis (MS)	
%: Over 70% of participants had the condition, or subgroups with the condition were presented separately. If no figures were given but the term `most', or equivalent, was used – then include. **Inclusion by setting:** If conditions unspecified - secondary care mental health / specialist mental health / inpatient mental health / outpatient mental health / psychiatric setting / psychiatric outpatients / psychiatric inpatients / mental health rehab Care home / hospital / rehab setting where it specifies it is a setting predominantly for clients with dementia	
Age: - Participants were adults or adolescents (over 13), or over 70% were adults or adolescents.	

AND

<table>
<tr><th colspan="2">INTERVENTION: Light exposure / light restriction / altering timing of light AND intending to improve sleep</th></tr>
<tr><th colspan="2">Light exposure / light restriction / altering timing of light</th></tr>
<tr><td>light therapy / bright light therapy
(e.g., light box, light therapy lamp, SAD lamp)
dark therapy (avoiding light)
amber lenses / blue blocking lensed glasses
dawn simulation
‘circadian lighting’
Light visor
Green light flashes through closed eyelids</td><td><u>Exclude:</u>
Light wholly outside the visible spectrum – i.e. not transcranial near-infrared (Photobiomodulation)

Light applied not via the circadian photoreception system (eyes-> optic nerve->SCN) e.g., topical application of light / lasers to the skin for skin conditions, x-rays.</td></tr>
<tr><td>Include interventions which don’t necessarily have a specific light / dark equipment, but instead purposely alter exposure to natural or artificial light already present in the environment
(e.g., prescribing to go outside for outdoor light, altering normal room lighting, increasing or avoiding use of light emitting e-reader and computer use) - where this is explicitly mentioned, described, advised, or monitored.</td><td>Exclude: interventions without intentional alteration of light exposure, no explicit mention of this (e.g., wake therapy or sleep therapy might incidentally alter light exposure, but if no explicit recommendations or measurements are made exclude. Exercise might often be done outside and involve incidental light exposure, but if not explicitly discussed, not a core non-optional aspect of the intervention - exclude)</td></tr>
<tr><td>May be a single component intervention, or a core part of a multi-component intervention (i.e. core, not optional intervention component) e.g., For instance, this could be delivered as part of CBTi, if it is explicitly described we will include.
e.g., include ‘light and wake therapy’, include ‘augmentation of mirtazapine with light therapy’</td><td>Exclude studies exploring mechanisms which utilise protocols which are definitely not intended as a sleep improving / healthcare intervention.</td></tr>
<tr><th colspan="2">AND intending to improve sleep</th></tr>
<tr><td colspan="2">Intervention will be classified as ‘intending to improve sleep’, if:
1. It is explicitly stated that it was an aim or target of the intervention to improve sleep
OR
2. The authors state they are testing an a priori hypothesis that the intervention would improve sleep (not applicable if this is secondary analysis of a previous study whose intervention was not targeting sleep)
If aims, purposes or hypothesis are clearly stated and improvement in sleep is not amongst them, then assume this was not the purpose and exclude</td></tr>
</table>

IF it is unclear based on the above:
then the decision will be based on whether participant inclusion criteria specify a sleep problem
If no sleep problem in participant inclusion and the stated target of Ix or hypothesis is unclear then exclude

AND

Outcome: Sleep	
Self reported:	**Objective measures:**
sleep quality or depth sleep duration sleep timing sleep onset latency / time to fall asleep satisfaction with sleep timing satisfaction with sleep difficulty awakening / sleep inertia. subjective sleepiness Any kind of self-report sleep measure should be relevant. Or 'clinician rated' / 'assessed' by someone Not sufficient for inclusion: fatigue, "sleep-related daytime dysfunction"	of sleep timing, quality or structure Actigraphy Activity monitoring devices ('wrist worn', 'wearables') Polysomnography (PSG) Sleep laboratory measurement Activity / sleep pattern - rest activity pattern assessed by actigraphy or any other type of activity monitoring device or method.

Study type:
Intervention study (not observational and correlational studies)
Exclude case studies (<5 people)
Pre-post measurements made. No further criteria around control group / comparison.

Publication type:
Peer reviewed journal articles
conference abstracts, dissertations, unpublished reports – collect in another list / folder if relevant

Table S4: Outcomes and their relevance in included populations

Condition / Construct	ASPD	DSPD	Depression and SAD	Other MH	Dementia
Sleep timing	Relevant *(want phase delay)*	Relevant *(want phase advance)*	Unclear [1]	Unclear [1]	Not relevant [2]
Sleep inertia	Not relevant [3]	Relevant	Unclear [1]	Unclear [1]	Not relevant [4]
Daytime sleepiness	Relevant	Relevant	Relevant	Relevant	Relevant
SOL	Not relevant [5]	Relevant	Relevant	Unclear [1]	Unclear [6]
Subjective sleep quality	Relevant	Relevant	Relevant	Relevant	Relevant [7]
Subjective sleep disturbance	Relevant	Relevant	Relevant	Relevant	Relevant [7]
TST	Relevant	Relevant	Unclear [1]	Unclear [1]	Unclear [1]
SE%	Relevant	Relevant	Relevant	Relevant	Relevant
Sleep continuity	Relevant	Not relevant [8]	Relevant	Relevant	Relevant
Rhythmicity	Relevant [9]	Relevant [9]	Relevant	Relevant	Relevant
Amplitude	Relevant [10]	Relevant [10]	Relevant	Relevant	Relevant

1 Dependent on complaints of the sub-group at baseline (long or short sleep, or varied within sample), study population complaints will be checked to inform interpretation of analysis.
2 Unclear that either an advance or a delay in sleep timing is clinically desirable.
3 People with ASPD wake too early and cannot fall back asleep, they get tired later in the day due to insufficient sleep, but do not particularly complain of sleep inertia as they are more alert in the mornings.
4 Although Excessive sleep inertia would always be a problem, this is not specifically a symptom associated with dementia.
5 People with ASPD complain of falling asleep too early, not of increased SOL.
6 Although increased SOL is a potential concern for people with dementia, unless a self-reported 'light-out' (now attempting to sleep) marker or sleep diary has been used this measurement will not be informative.
7 Relevant, although issues acknowledged with self-report particularly in more severe impairment.
8 People with DSPD do not particularly complain of sleep maintenance issues, and generally struggle to fall asleep until later than desired, then remain asleep until later than desired unless forcibly woken by an alarm.
9 Extremes of sleep timing preference increases the likelihood of variability in sleep timing between socially scheduled days and free-days 10 Attempting and struggling to sleep at times which are counter to the internal clock as is frequent in ASPD and DSPD results in reduced rest activity amplitude, increased synchronisation should increase amplitude.

Table S5: Constructs, hierarchy of outcomes, and considerations in synthesis

Construct	Working definition	Relevant outcomes, hierarchy of relevance	Considerations regarding synthesis and hierarchy
Sleep timing delay	The average timing at which sleep occurs within the day.	1. Sleep onset time 2. Mid sleep 3. Self-selected bed time (not instructed by protocol) 4. L5 onset 5. Sleep offset time (wake time) 6. Chronotype questionnaires 7. Acrophase For each: 1. EEG, 2. diary, 2. Actigraphy.	The most relevant outcome depends on whether the desired intervention outcome is to advance or delay sleep. Earlier sleep onset is most difficult to achieve and therefore of most relevance for phase advancing in DSPD.
Sleep timing advance	The average timing at which sleep occurs within the day.	1. Sleep offset time (wake time) 2. Mid sleep 3. L5 onset 4. Sleep onset time 5. Self-selected bed time (not instructed by protocol) 6. Chronotype questionnaires 7. Acrophase For each: 1. EEG, 2. diary, 2. Actigraphy	The most relevant outcome depends on whether the desired intervention outcome is to advance or delay sleep. Later wake time is most relevant as it is most difficult to achieve for those with ASPD.
Sleep Inertia	Difficulty moving fully from sleep to wake. May include one or both of: Difficulty waking, such as lots of effort, help of	1. Self-reported measures of sleep inertia 2. Self-reported difficulty waking	Normal durations for some degree of sleep inertia can be anywhere between 10 minutes and 2 hrs, so decisions regarding timings which are relevant had to be somewhat arbitrary. A complaint of sleep inertia should be judged based on severity and impact on functioning not just

Construct	Working definition	Relevant outcomes, hierarchy of relevance	Considerations regarding synthesis and hierarchy
	others, or multiple alarms needed. May complain of taking a long time to 'fully wake up'.	3. Sleepiness measured within a short period of waking (e.g., 30 minutes) 4. Sleepiness measured within a very short period of awakening (e.g., 5 minutes) 5. Sleepiness measured any time in the morning.	duration, therefore self-rated scales are preferred. For this reason sleepiness that is not localised to the morning (daytime sleepiness) will not be synthesised with sleep inertia.
Daytime Sleepiness	The feeling of being sleepy for all or a large part of the day, distinguished from sleep inertia, and late evening sleepiness.	1. Daytime sleepiness self-report measure relating to whole day 2. Daytime sleepiness self-report measure relating to specific time point(s) in daytime 3. Objective measures of sleep propensity	Some respondents it is acknowledged consider sleepiness and fatigue as equivalent, although these are distinguished within sleep research and theory. The subjective experience of feelings of sleepiness does not always correlate strongly with actual sleep propensity assessed using objective measures (Johns 2000, Chervin 2000).
Sleep Onset Latency (SOL)	The time taken from getting into bed with the intention to sleep ('lights out'), to falling asleep (into Stage 1 sleep).	1. EEG plus diary 2. Diary plus actigraphy 3. Diary without actigraphy 4. EEG with reported 'lights out' but no reported 'time to sleep' 5. Actigraphy with reported 'lights out' but no reported 'time to sleep'	Sleep onset latency is difficult to measure without a self-reported component, when measured from EEG without use of an event marker or a sleep diary it is difficult to assess the time from when the person intended to fall asleep to their actually falling asleep. Furthermore, actigraphy often underestimates SOL through interpreting a lack of movement as sleep. Therefore measurements of SOL using only actigraphy or only EEG without self-report will be treated with caution. Measures of SOL where no self-reported 'lights out' time was used will not be used.

Construct	Working definition	Relevant outcomes, hierarchy of relevance	Considerations regarding synthesis and hierarchy
Global subjective appraisal of sleep	Any form of global self-appraisal of how 'good' sleep was, or how disrupted sleep was.	• Scaled ratings of sleep quality. • Sleep disturbance or insomnia self-report measures	Sleep quality is a difficult term to define and may have varied meaning for different individuals and groups, nevertheless measures which all ask about 'sleep quality' all do to some extent measure related constructs. Other self-report measures of sleep are more diverse in their focus, with some focusing on self-reported quantitative sleep metrics, others focusing on qualitative appraisal, and others still weighting different sleep issues depending on participants priorities, interpretation of the synthesis of these outcomes therefore requires caution. For this reason separate syntheses will be presented.
Total Sleep Time	The total amount of time the person was asleep, according to their perception or an objective or pseudo-objective measure. Should exclude wake time within sleep period, but in some cases may not.	1. EEG 2. Diary 3. Actigraphy 4. Third party report.	Any synthesis of TST outcomes is potentially problematic unless there is a clear desired direction of change in the population in question. For instance, an increase in TST may sound desirable but can actually be indicative of a worsening of sleep depth or quality in some cases. Even taking a normative value (e.g., 8 hrs) may help somewhat, but as sleep need varies highly between individuals and populations, a move toward or away from any average is uninformative.

Construct	Working definition	Relevant outcomes, hierarchy of relevance	Considerations regarding synthesis and hierarchy
SE%	Sleep efficiency attempts to represent the proportion of time spent trying to sleep, where sleep took place, and should be calculated TST / time spent trying to sleep (x100) = SE%	1. EEG (plus diary) 2. Diary plus actigraphy 3. Diary without actigraphy 4. Actigraphy 5. Third party report	As SE% is affected by SOL, WASO, and TST it can be considered a composite measure; therefore alterations in SE% may be driven by different changes in different populations, and synthesis should be treated with caution. Furthermore, inconsistencies in how SE% is calculated cause additional problems with interpretation. (non-sleep activity undertaken in bed may be included in some studies, where strictly it should not be. Also, time after the final wake time spent trying without success to return to sleep may be excluded, where strictly it should be included).
Sleep continuity	The ability to remain asleep continuously (or with only normal brief awakenings) until wake time, not waking intermittently during sleep.	1. Length of longest unbroken sleep period 2. L5 3. Average frequency of wakes 4. No of awakenings during night 5. Amount of activity during night 6. % of total activity occurring during major sleep period 7. WASO	There are a large number of measures which relate to this construct, whose measurement focuses on varied aspects of sleep continuity, for instance, WASO focuses on the duration of time awake during sleep (one long period awake could drive up WASO), whilst the L5 focuses on the amount of activity within the least active period (intensity as well as frequency of activity is measured), whilst other outcomes measure the longest period of uninterrupted sleep, or various presentations of frequency of awakening (per hour, per night, etc). The extent to which these outcomes reflect sleep continuity reduces further down the presented hierarchy. Sensitivity analysis excluding less relevant measures will be examined.

Construct	Working definition	Relevant outcomes, hierarchy of relevance	Considerations regarding synthesis and hierarchy
Rhythmicity	The regularity of the day to day rhythm of sleep-wake, the opposite of which is a totally arrhythmic pattern.	1. Inter-day stability (non-parametric) 2. Fit to the cosine model (parametric)	Studies have shown that rhythmicity when measured via fit to the cosine model was poor at detecting change or improvement in sleep and circadian rhythm symptoms after treatment (49).
Amplitude of rhythm	The contrast between biological day and night in relation to levels of sleep / inactivity and wake / activity. Very low amplitude rhythm might often include lots of night-time sleep disruption, and lots of daytime naps.	1. Relative amplitude (non-parametric) 2. Amplitude (non-parametric) 3. Proportion / percentage of sleep in daytime compared to night-time 4. Amplitude (parametric) 5. Daytime sleep	Amplitude values which are normalised (relative) may be more informative, however, it is acknowledged that there are multiple methods of normalising these values. Furthermore, where amplitude is calculated for the difference between a set regular wake period and sleep period it may be influenced by rhythmicity, whilst calculation per individual days is not.

Table S6: Measures and outcomes reported in included studies

		Measurement method:					Outcomes reported and included										
Author & Year	**Diagnostic group**	**Self-report scales**	**Sleep diary**	**Actigraphy**	**EEG**	**Staff / carer report**	**Sleep timing delay**	**Sleep timing advance**	**Self-report sleepiness**	**Carer reported daytime sleep**	**Sleep onset latency**	**Self-report sleep quality**	**Self-report sleep disturbance**	**Total sleep time**	**Sleep efficiency**	**Sleep continuity disruption**	**Rhythmicity**	**Amplitude**
Campbell 1993 (11)	ASPD				x		x							x	x	x		
Figueiro 2015 (18)	ASPD			x			x								x			
Lack 2005 (26)	ASPD		x				x							x		x		
Palmer 2003 (39)	ASPD		x				x							x	x	x		
Ando 1999 (2)	DSPD		x					x						x				
Cole 2002 (12)	DSPD	x		x				x	x			x	x					
Geerdink 2016 (21)	DSPD	x		x				x	x		x				x			
Gradisar 2011 (22)	DSPD	x	x	x				x	x		x			x				
Lack 2007 (27)	DSPD		x					x						x				
Lack 2007b (28)	DSPD	x	x	x				x	x		x		x	x				
Langevin 2014 (29)	DSPD	x	x					x	x			x		x				
Saxvig 2014 (40, 41)	DSPD	x	x	x				x	x		x	x	x	x	x			
Avery 1998 (3)	SAD with hypersomnia		x											x				
Avery 2002 (4)	SAD with hypersomnia	x							x									
Bogen 2016 (6, 7)	Depression	x										x						
Esaki 2017 (17)	Depression	x	x								x	x						
Kragh 2017 (24, 25)	Depression		x											x		x		
Lieverse 2011 (30)	Depression		x	x							x			x	x			
McEnany 2005 (34)	Depression				x									x	x	x		
Barbini 2005 (5)	Other MH					x								x				
Bromundt 2013 (8)	Other MH			x										x				
Henriksen 2016 (23)	Other MH	x		x										x		x		
Sheaves 2018 (42, 43)	Other MH	x											x					
Sit 2017 (44)	Other MH	x											x					
Ancoli-Israel 2002 (1)	Dementia			x													x	x
Burns 2009 (9, 10)	Dementia			x						x						x		
Connell 2007 (13)	Dementia			x										x		x		
Dowling 2005 (15, 16)	Dementia			x						x				x	x	x	x	x
Dowling 2008 (14)	Dementia			x						x				x		x	x	x
Fontana Gasio 2003 (19)	Dementia			x										x	x	x		
Friedman 2012 (20)	Dementia		x	x		x				x				x	x	x		x
Lyketsos 1999 (31)	Dementia		x											x				
McCurry 2005 (32)	Dementia			x						x				x	x	x		x
McCurry 2011 (33)	Dementia			x						x				x	x	x		x
Mishima 1998 (35)	Dementia			x												x		x
Nowak 2011 (36, 37)	Dementia			x		x				x					x	x		
Ouslander 2006 (38)	Dementia			x	x	x				x				x	x	x		x
Sloane 2007 (45)	Dementia			x		x				x				x		x	x	x
Sloane 2015 (46)	Dementia			x		x				x				x	x	x	x	x
Van Someren 1997 (47, 48)	Dementia			x												x	x	x

*MH=mental health conditions, ASPD=advanced sleep phase disorder, DSPD=delayed sleep phase disorder, SAD=seasonal affective disorder

Table S7: Risk of bias assessments for included studies

Study author & year	selection bias	participant blinding	assessor blinding	attrition bias	reporting bias	other bias	overall risk of bias
Ancoli-Israel 2002 (1)	unclear	medium	low	low	low	n/a	low
Ando 1999 (2)	medium	medium	medium	high	unclear	n/a	high
Avery 1998 (3)	unclear	low	medium	unclear	low	n/a	medium
Avery 2002 (4)	unclear	unclear	high	high	high	n/a	high
Barbini 2005 (5)	medium	high	high	low	low	n/a	medium
Bogen 2016 (6)(7)	low	medium	medium	low	medium	n/a	medium
Bromundt 2013 (8)	high	high	medium	low	medium	n/a	high
Burns 2009 (9)(10)	low	medium	low	low	medium	n/a	low
Campbell 1993 (11)	high	medium	medium	low	low	n/a	medium
Cole 2002 (12)	unclear	medium	low	low	medium	low	low
Connell 2007 (13)	unclear	medium	low	medium	low	medium	medium
Dowling 2008 (14)	low	high	medium	low	low	n/a	medium
Dowling 2005 (15)(16)	medium	high	low	low	medium	low	medium
Esaki 2017 (17)	low	medium	low	medium	low	n/a	low
Figueiro 2015 (18)	high	medium	low	low	low	medium	medium
Fontana-Gasio 2003 (19)	low	medium	medium	high	low	high	high
Friedman 2012 (20)	low	medium	low	low	low	n/a	low
Geerdink 2016 (21)	medium	medium	medium	medium	medium	n/a	medium
Gradisar 2011 (22)	low	high	medium	medium	low	low	medium
Henriksen 2016 (23)	low	medium	medium	high	low	n/a	medium
Kragh 2017 (24)(25)	low	high	medium	medium	medium	medium	medium
Lack 2005 (26)	high	medium	medium	low	low	n/a	medium
Lack 2007 (27)	unclear	medium	medium	low	low	high	medium
Lack 2007b (28)	unclear	low	medium	medium	medium	medium	medium
Langevin 2014 (29)	low	medium	medium	low	low	medium	medium
Lieverse 2011 (30)	low	medium	low	low	low	n/a	low
Lyketsos 1999 (31)	unclear	medium	low	medium	medium	high	medium
McCurry 2005 (32)	low	medium	low	low	low	n/a	low
McCurry 2011 (33)	low	low	low	low	low	low	low
McEnany 2005 (34)	unclear	medium	low	medium	low	high	medium
Mishima 1998 (35)	med	medium	medium	low	low	n/a	medium
Nowak 2008 (36) (37)	low	medium	medium	low	low	medium	medium
Ouslander 2006 (38)	high	medium	medium	medium	low	n/a	medium
Palmer 2003 (39)	unclear	medium	medium	medium	low	low	medium
Saxvig 2014 (40) (41)	low	medium	low	low	low	medium	low
Saxvig 2014 #2	low	high	low	low	low	high	high
Sheaves 2018 (42) (43)	low	high	low	low	low	n/a	medium
Sit 2017 (44)	low	medium	medium	low	low	n/a	low
Sloane 2007 (45)	low	medium	low	low	medium	medium	medium
Sloane 2015 (46)	medium	medium	medium	low	low	medium	medium
Van Someren 1997 (47)(48)	medium	medium	medium	medium	low	high	medium

Figures S8-S20: Forest plots with study details

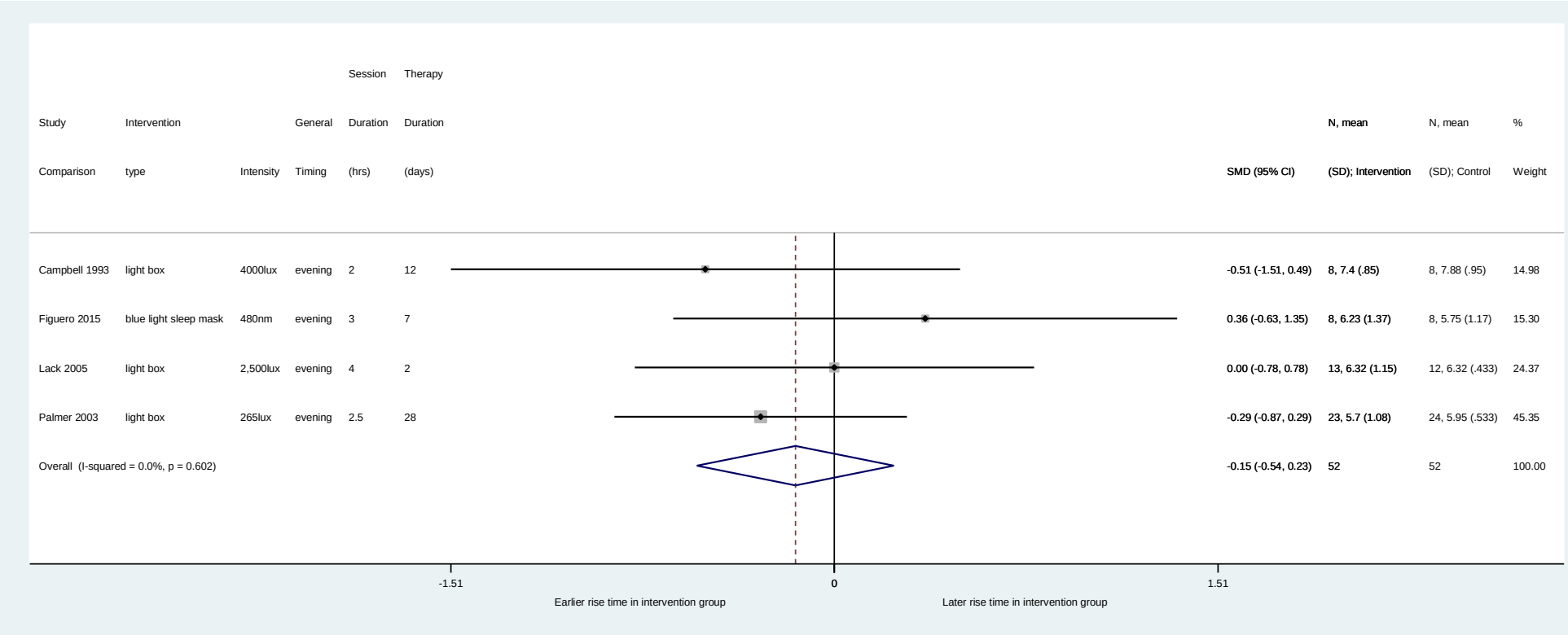


Figure S8: Effect of evening light aiming to delay sleep timing in ASPD

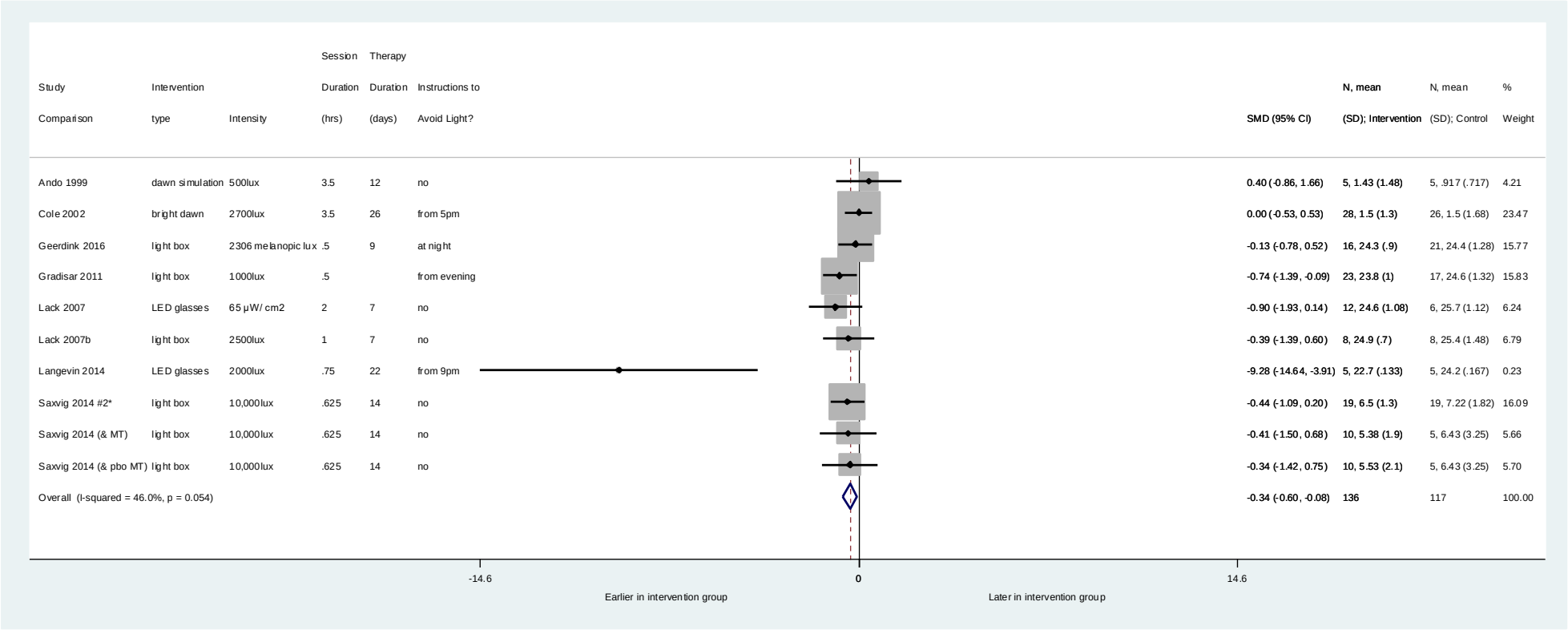


Figure S9: Effect of morning light to advance sleep timing in DSPD

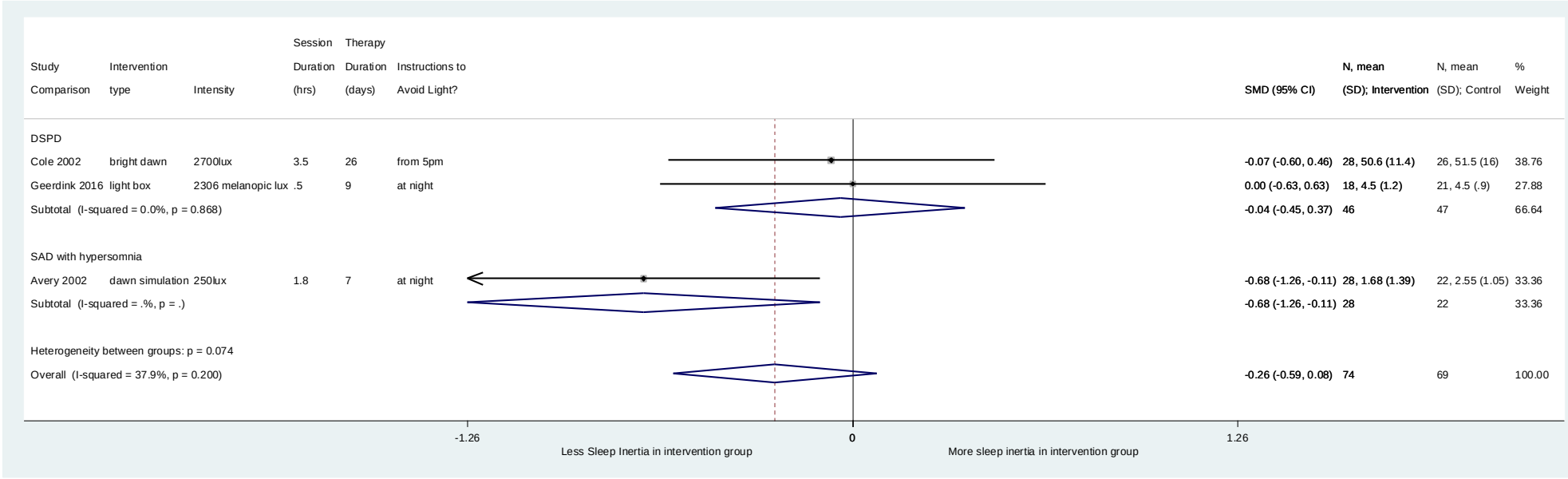


Figure S10: Effect of morning light on sleep inertia

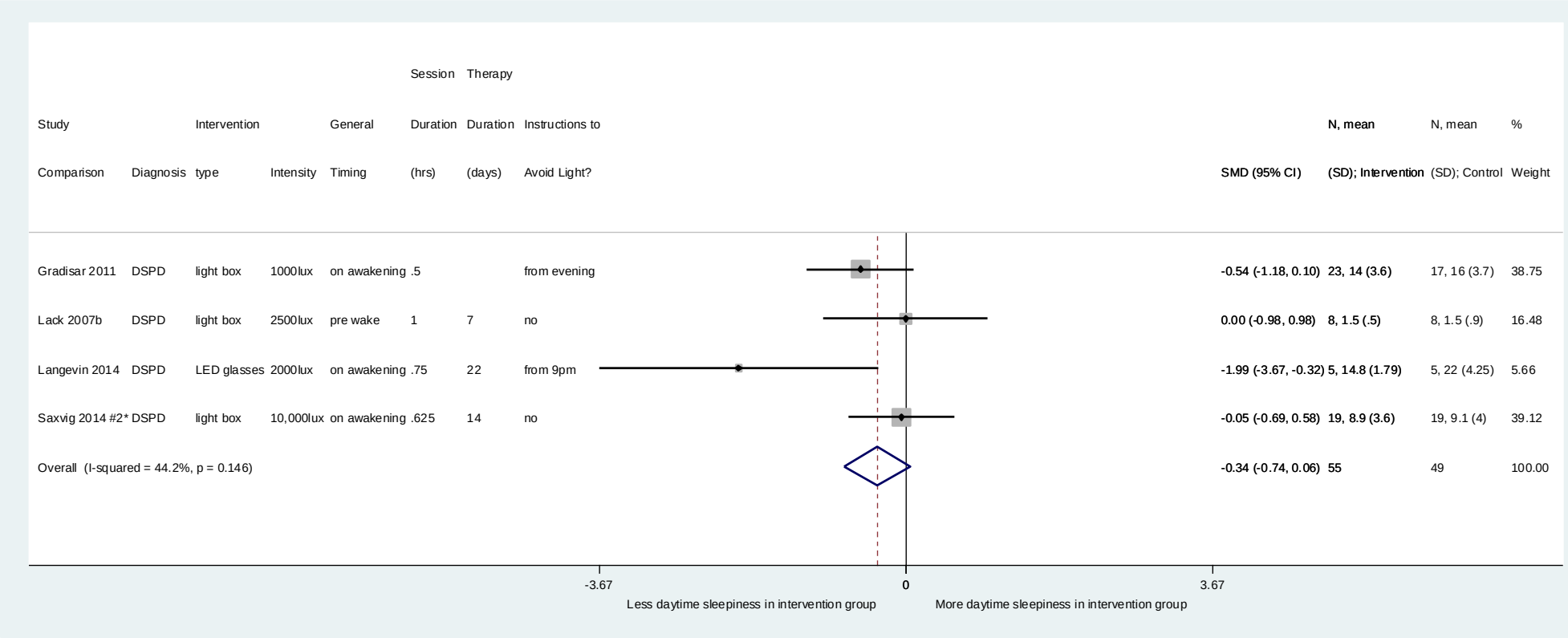


Figure S11: Effect of morning light on self-reported daytime sleepiness in DSPD

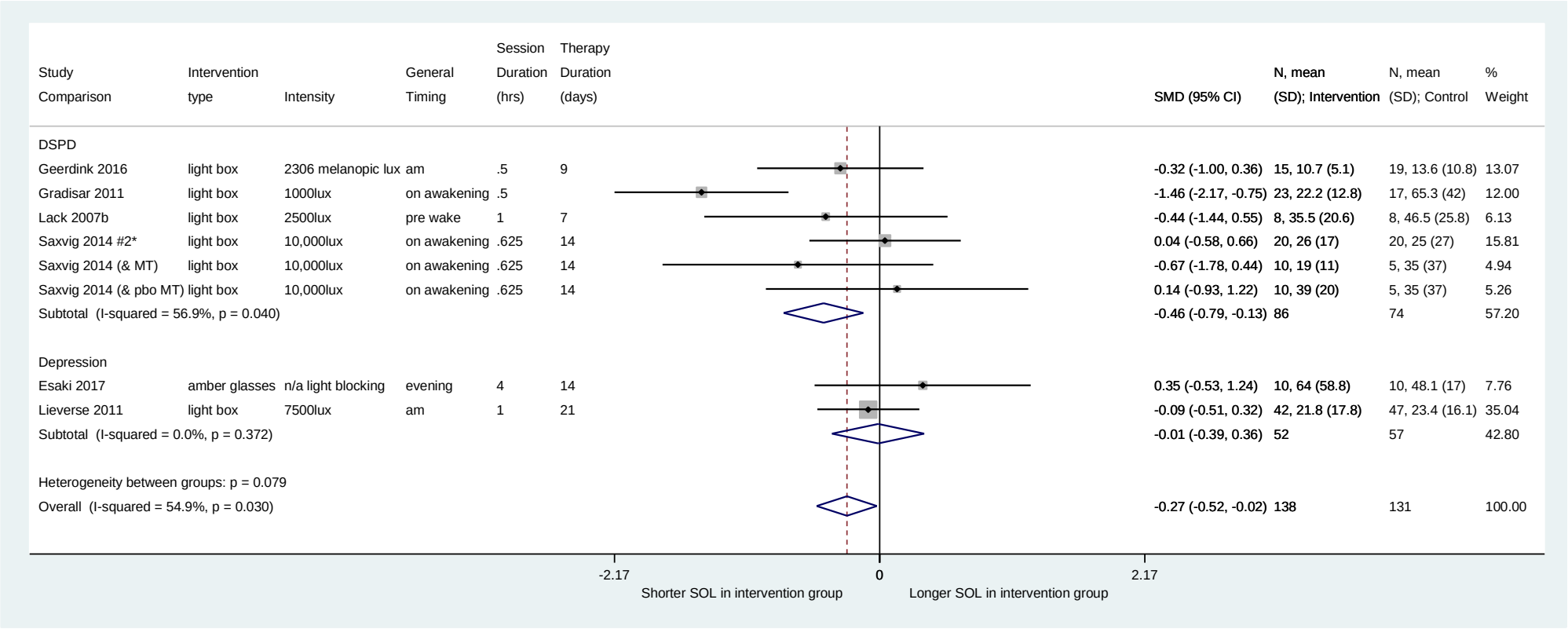


Figure S12: Effect of light schedule interventions on SOL

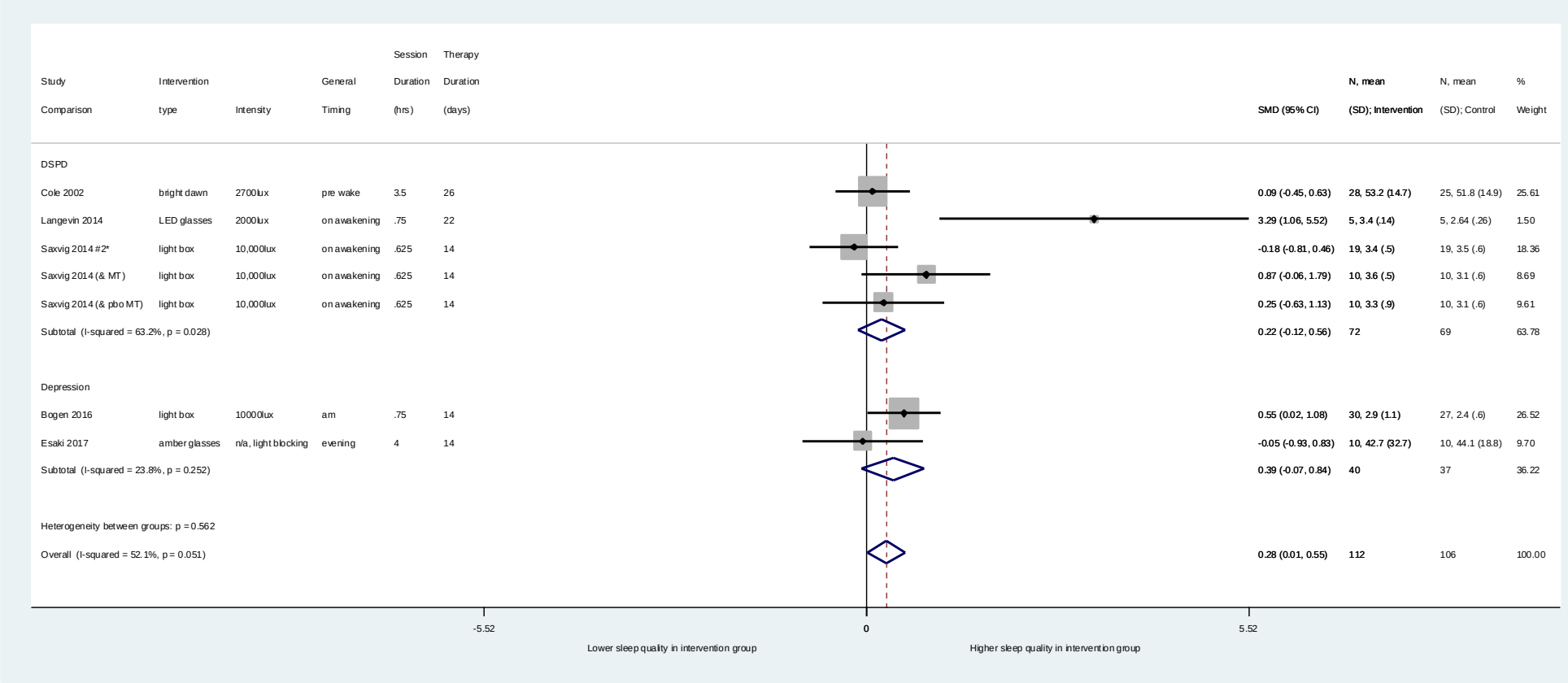


Figure S13: Effect of light schedule interventions on self-reported sleep quality

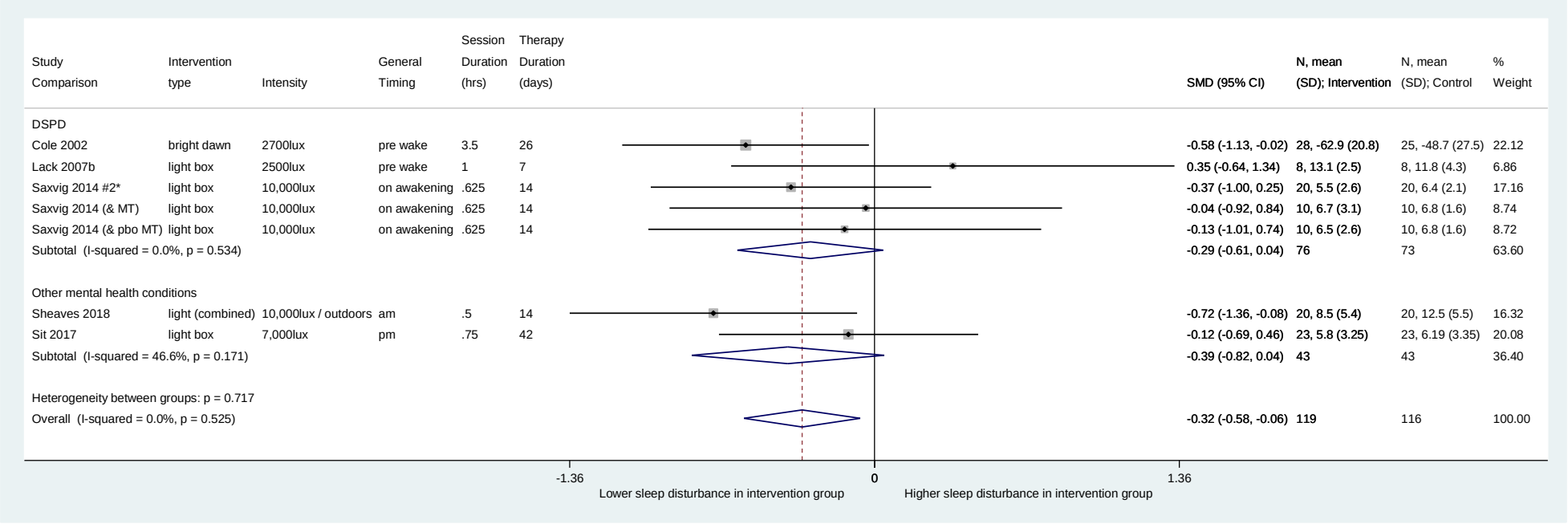


Figure S14: Effect of light schedule interventions on self-reported sleep disturbance (on composite psychometric measures)

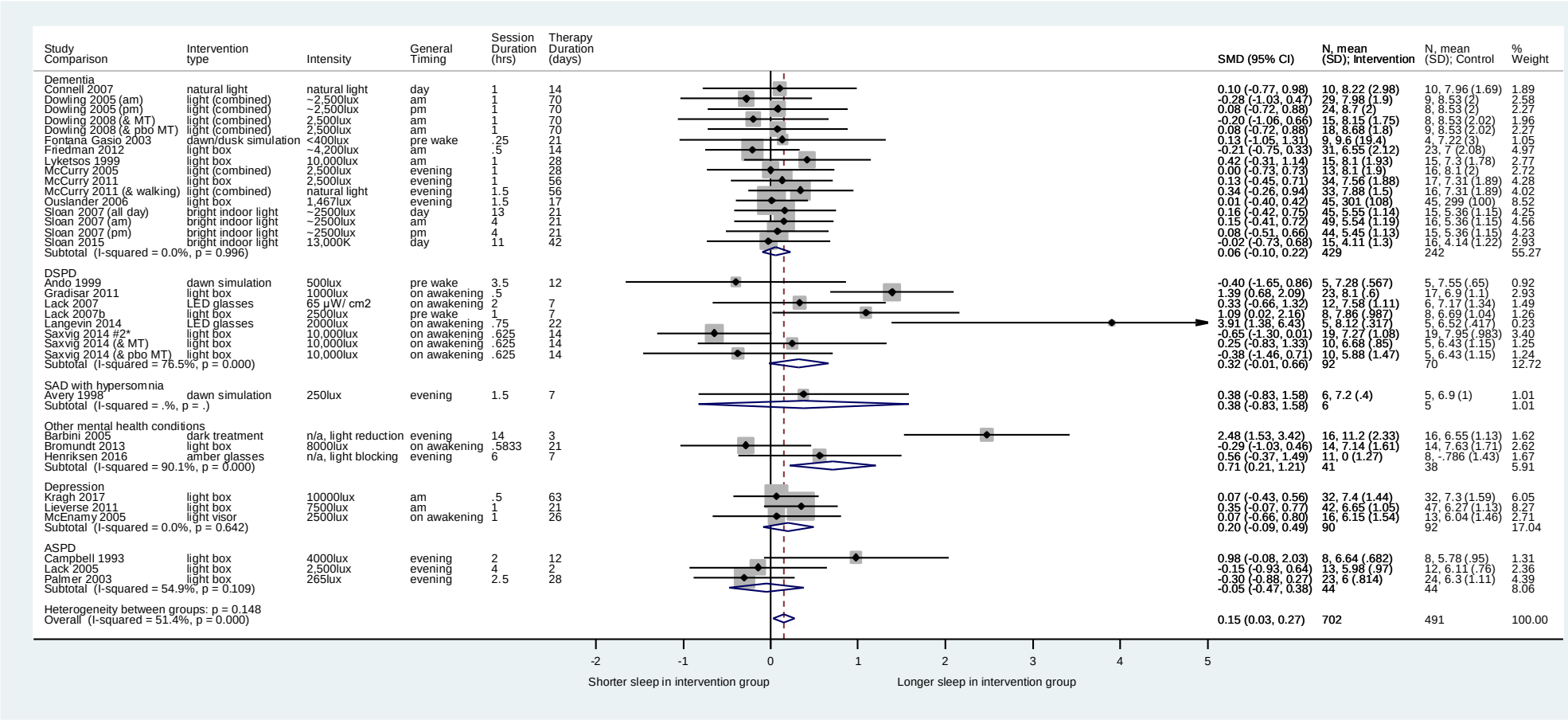


Figure S15: Effect of light schedule interventions on total sleep time

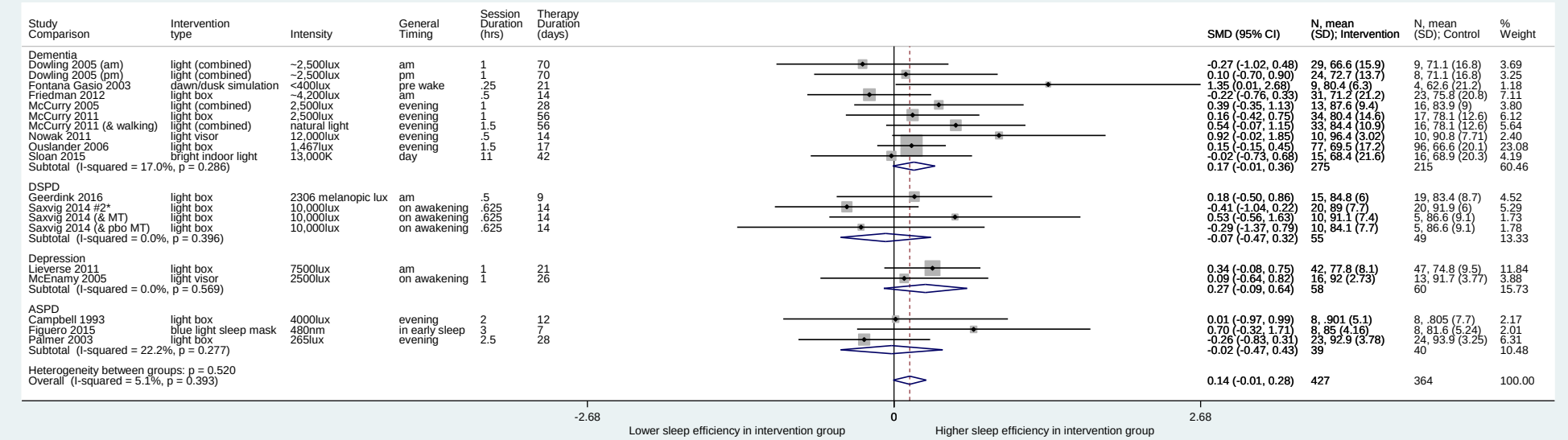


Figure S16: Effect of light schedule interventions on sleep efficiency (%)

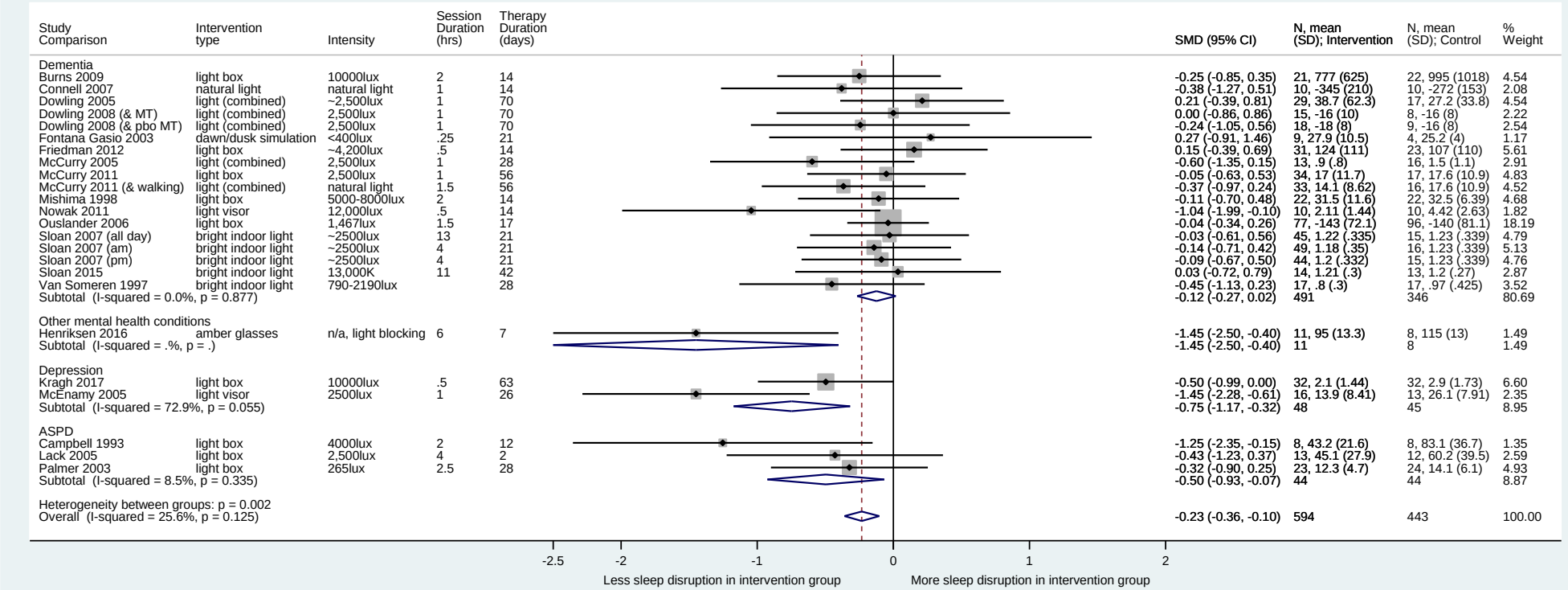


Figure S17: Effect of light schedule interventions on sleep continuity disruption

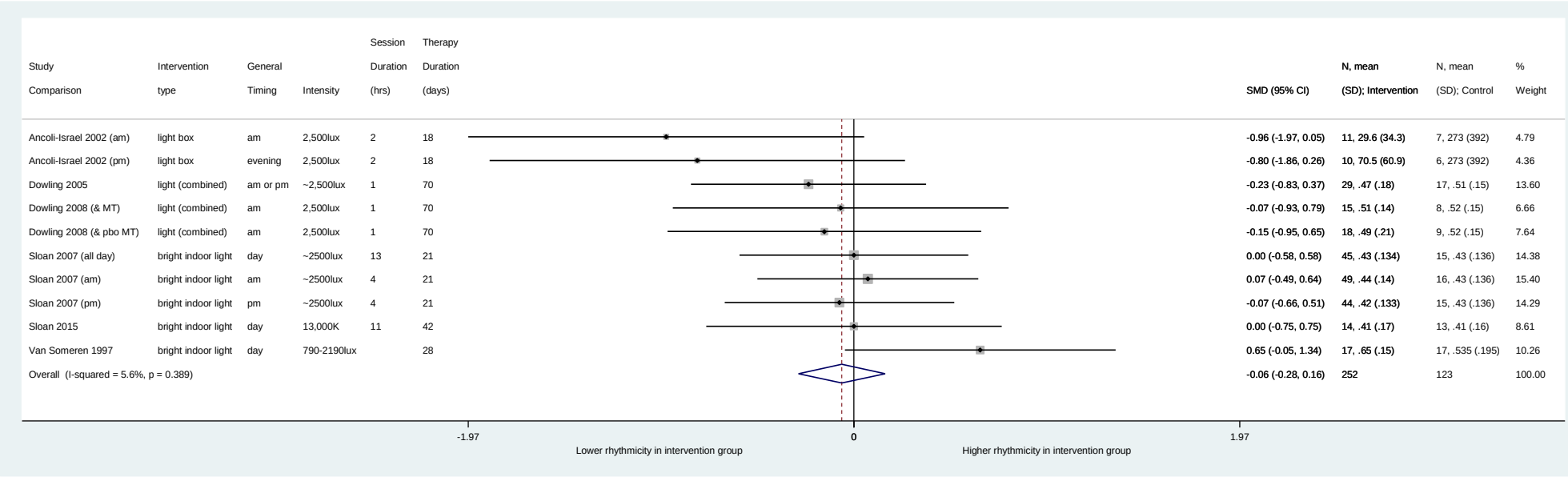


Figure S18: Effect of light schedule interventions on rhythmicity of rest activity rhythm in dementia

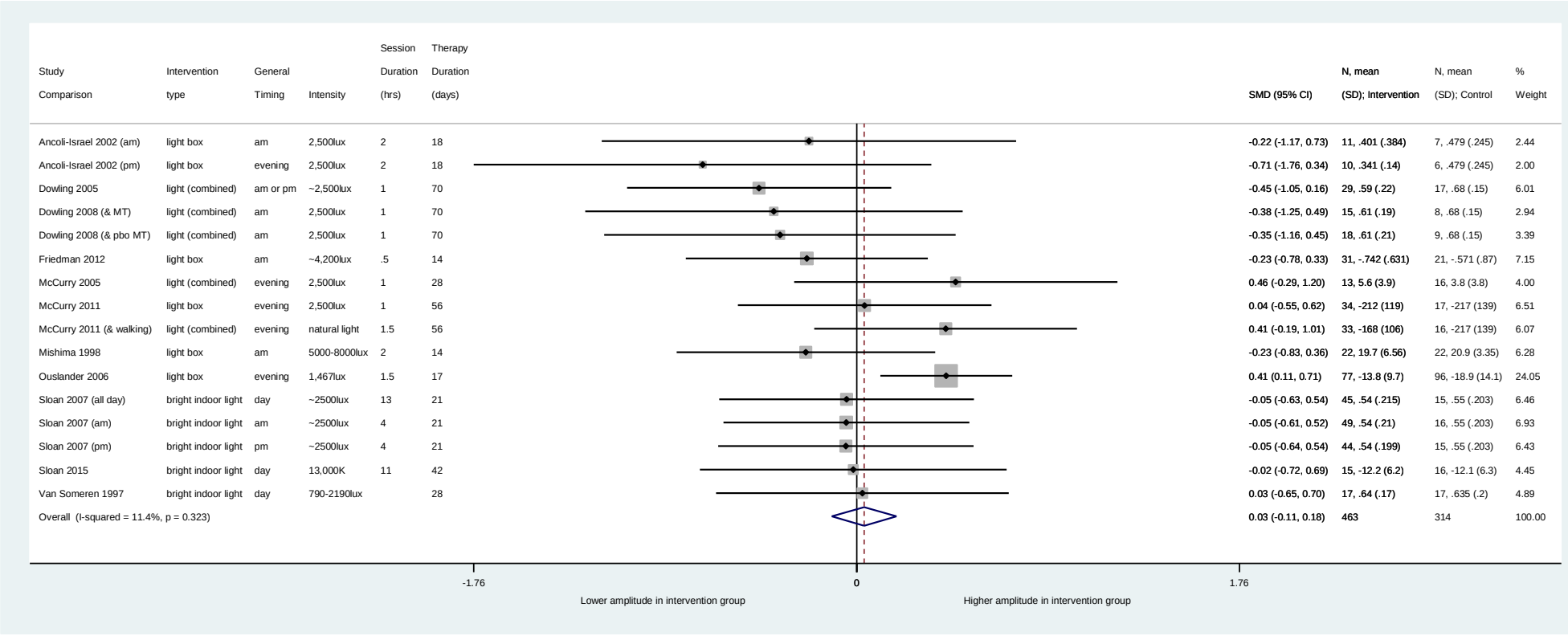


Figure S19: Effect of light schedule interventions on amplitude of rest activity rhythm in dementia

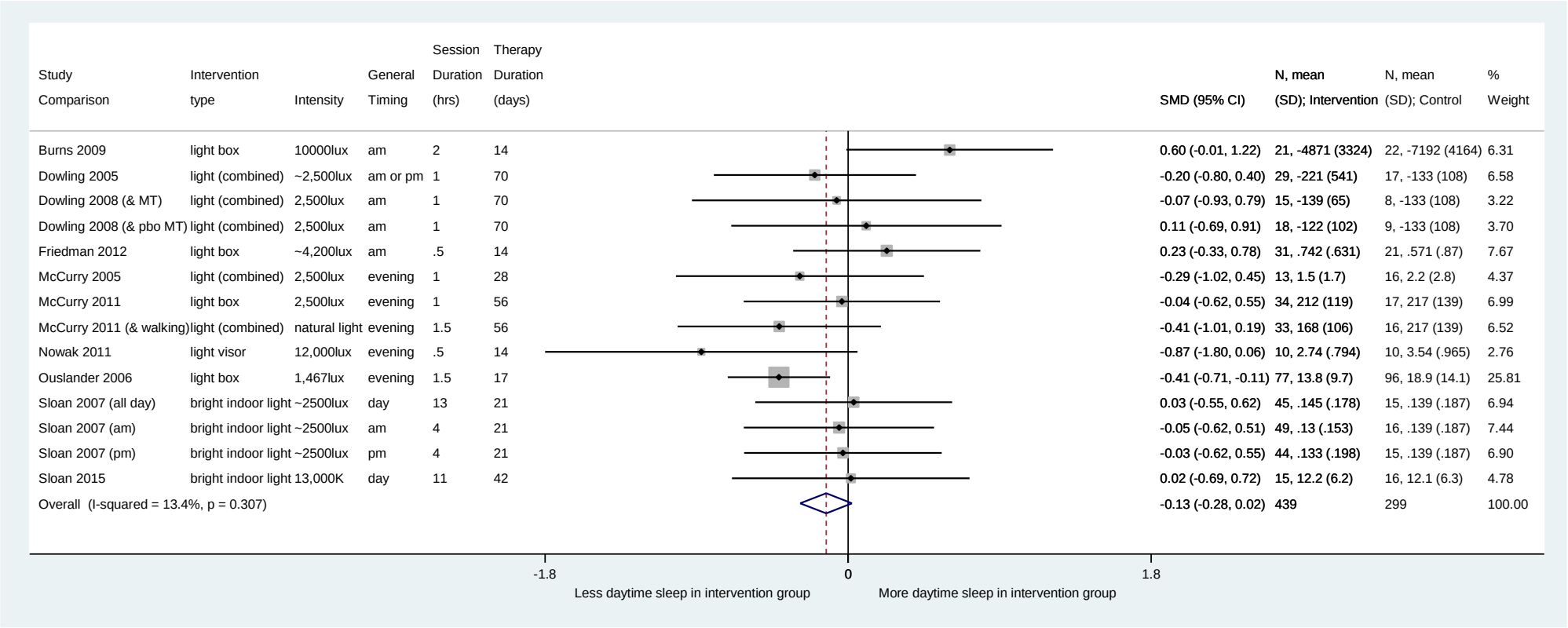


Figure S20: Effect of light schedule interventions on carer reported daytime sleep in dementia

Table S21: Results of sensitivity analyses **(full details shown where significance affected)**

	Included			Effect				Heterogeneity	
Outcome	N_s	N_c	n (Ix / Cx)	Direction of effect in Ix group	SMD (g)	95% CI	p=	I^2	p=
Sleep timing in ASPD	Remained non-significant								
Sleep timing in DSPD	Remained significant, ES -0.32 to -0.36								
Sleep inertia	Remained non-significant								
Self-reported daytime sleepiness	Remained non-significant								
Sleep onset latency (SOL)	**6**	**8**	**138/131**	**Shorter SOL**	**-0.27**	**-0.52, -0.02**	**0.033**	**54.9 %**	**0.030**
sensitivity: removing high RoB	6	7	118/111	Shorter SOL	-0.33	-0.60, -0.06	0.017	58.2%	0.026
sensitivity: excluding if no sleep inclusion	5	7	96/84	Shorter SOL	-0.36	-0.67, -0.06	0.020	58.5%	0.025
sensitivity: excluding assumed (not diagnosed) DSPD	4	6	115/104	Shorter SOL	-0.25	-0.52, 0.03	0.078	67.4%	0.009
Sleep quality (on VAS), original	**5**	**7**	**113/107**	**Higher sleep quality**	**0.28**	**0.00, 0.55**	**0.046**	**52.5 %**	**0.049**
sensitivity: removing 1 positive outlier	4	6	108/102	Higher sleep quality	0.23	-0.04, 0.50	0.098	9.0%	0.358
sensitivity: removing high RoB	5	6	93/87	Higher sleep quality	0.38	0.08, 0.69	0.013	50.4%	0.073
sensitivity: excluding if no sleep inclusion	4	6	83/80	Higher sleep quality	0.18	-0.14, 0.50	0.266	55.6%	0.047
Self-reported sleep disturbance	Remained significant, ES -0.38 to -0.31								
Total sleep time (TST)	**27**	**34**	**703/492**	**Longer TST**	**0.15**	**0.03, 0.27**	**0.015**	**57.6 %**	**0.000**
sensitivity: removing 2 positive outliers	25	32	682/471	Longer TST	0.10	-0.02, 0.22	0.097	14.0%	0.244
sensitivity: removing high RoB	24	29	655/449	Longer TST	0.20	0.07, 0.32	0.002	51.3%	0.001
sensitivity: excluding if no sleep inclusion	16	21	332/222	Longer TST	0.11	-0.06, 0.29	0.209	48.9%	0.006
sensitivity: excluding assumed (not diagnosed) DSPD / ASPD	23	31	630/421	Longer TST	0.16	0.03, 0.28	0.019	54.9%	0.000
Sleep efficiency (%)	Remained non-significant, other than one significant sensitivity analysis as below								
sensitivity: removing high RoB	14	17	398/340	Higher sleep efficiency in Ix group	0.15	0.00, 0.30	0.045	0.0%	0.686
Sleep continuity disruption	Remained significant, ES -0.20 to -0.27								
Rhythmicity of rest activity rhythm	Remained non-significant								
Amplitude of rest activity rhythm	Remained non-significant								
Carer reported daytime sleep propensity	Remained non-significant								

Ns= number of studies, Nc= number of comparisons, n (Ix / Cx)=number of participants in combined intervention and control groups, n.s.=not significant, ASPD=advanced sleep phase disorder, DSPD=delayed sleep phase disorder.

Table S22: Results of all meta-regressions

Outcome	Covariate	coefficient	p	interpretation: favours
Sleep timing in DSPD	sleep schedule component	-.2453907	0.796	favours yes, n/s
	personalised VS set timing	colinear		
	am VS pm light	colinear		
	Light avoidance (any)[1]	.1100317	0.782	favours no, n/s
	Light avoidance (pm / evening)[2]	.0017733	0.997	favours no, n/s
	Intensity in lux	-7.68e-06	0.909	favours brighter, n/s
	Session duration (hrs)	.1622396	0.267	favours longer, n/s
	Therapy duration (days)	.0174653	0.560	favours shorter, n/s
	Melatonin	-0.1171304	0.809	favours yes, n/s
	CBT-i	-.4787087	0.360	favours yes, n/s
Total sleep time	sleep schedule component	-.0984039	0.649	favours no, n.s
	personalised VS set timing	x confounded with pop -0.231042	0.991	favours no, n.s
	am VS pm light (dementia only)	.0984165	0.601	favours pm, n/s
	Light avoidance (any)[1]	0.6477418	**0.004**	larger affect with light avoidance
	Light avoidance (pm / evening)[2]	1.48552	**0.000**	larger effect still with light avoidance from pm / evening
	Light avoidance (any)[1] #2*	0.6944778	**0.006**	larger affect with light avoidance
	Light avoidance (pm / evening)[2] #2*	1.69882	**0.009**	larger effect still when light avoidance from pm / evening
	Intensity in lux	-0.000463	0.202	favours dimmer, n.s
	Session duration (hrs)	0.0479878	0.103	favours longer, n.s
	Therapy duration (days)	0.0046178	0.297	favours longer, n.s.
	Melatonin	-.2712442	0.554	favours no, only 1 with mel, n.s
	CBT-i	colinear		
Sleep Efficiency (%)	sleep schedule component	-.0645299	0.682	favours no, n.s.
	personalised VS set timing	-.2443844	0.130	favours no, n.s conf with pop
	am VS pm light	.1538095	0.360	favours pm, n.s conf with pop
	am VS pm light (dementia only)	.3421787	0.236	favours pm, n.s
	Light avoidance (any)[1]	0.2991469	0.115	favours yes, n.s.
	Light avoidance (pm / evening)[2]	colinear		
	Intensity in lux	6.93e-06	0.806	favours brighter, n/s
	Session duration (hrs)	-.0167748	0.661	favours shorter, n/s conf with pop
	Therapy duration (days)	-0.0004371	0.920	favours shorter, n/s
	Melatonin	-.3302447	0.283	favours no, conf with pop
	CBT-i	colinear		
Sleep continuity disruption	sleep schedule component	.0822707	0.635	favours no, n.s
	personalised VS set timing	-.2123408	0.261	favours yes, n.s
	am VS pm light	-.0623557	0.758	favours pm, n.s
	am VS pm light (dementia only)	-.0664125	0.692	favours pm, n.s
	Light avoidance (any)[1]	-.080844	0.687	favours yes, n.s
	Light avoidance (pm / evening)[2]	-.2208885	0.506	favours yes, n.s only 2 with yes
	Intensity in lux	-0.000338	0.187	n/s
	Session duration (hrs)	0.0134877	0.616	favours shorter, n/s
	Therapy duration (days)	0.0030153	0.451	favours shorter, n/s
	Melatonin	.2573755	0.621	favours no, n.s. only 1 with yes
	CBT-i	colinear		
Rhythmicity of rest activity rhythm	sleep schedule component	colinear		
	personalised VS set timing	colinear		
	am VS pm light	-0.0906289	0.757	favours am, n/s
	Light avoidance (any)[1]	colinear		
	Light avoidance (pm / evening)[2]	colinear		
	Intensity in lux	-0.0007953	0.069	favours dimmer, minimal variation, n/s

Outcome	Covariate	coefficient	p	interpretation: favours
	Session duration (hrs)	0.0240023	0.399	favours longer, n/s
	Therapy duration (days)	-0.0013863	0.815	favours shorter, n/s
	Melatonin	-.0057915	0.991	favours yes, n.s only 1 with
	CBT-i	colinear		
Amplitude of rest activity rhythm	sleep schedule component	0.4587271	**0.010**	more likely improvement, less deterioration in studies with schedule
	personalised VS set timing	x only 1 with		
	am VS pm light	**0.3586116**	**0.093**	favours pm, n/s
	Light avoidance (any)[1]	0.2117737	0.341	favours yes, n/s
	Light avoidance (pm / evening)[2]	colinear		
	Intensity in lux	-0.0001147	0.115	n/s
	Melatonin	x only 1 with		
	CBT-i	colinear		
	Session duration (hrs)	-0.0014715	0.957	n/s
	Therapy duration (days)	-.0036591	0.422	favours shorter, n.s
Carer reported daytime sleep propensity	sleep schedule component	-0.276876	0.114	n/s
	personalised VS set timing	.3649344	0.291	favours no, n.s. only 1 with yes
	am VS pm light	-0.5007139	**0.019**	larger effects for pm
	Light avoidance (any)[1]	-.1680625	0.491	favours yes, n.s
	Light avoidance (pm / evening)[2]	colinear		
	Intensity in lux	0.000289	0.278	n/s
	Session duration (hrs)	0.016622	0.519	n/s
	Therapy duration (days)	-0.0010834	0.814	n/s
	Melatonin	.0358179	0.941	favours no, n.s only 1 is yes
	CBT-i	colinear		

[1] Includes where light avoidance / reduction is only 'at night' or in the bedroom during sleep. [2] Only includes where light avoidance / reduction is from afternoon or evening – i.e. during some waking hours

*To rule out population effects, the meta-regression with the covariate "Avoid light (any)" was also run for this outcome excluding those studies in ASPD and depression, where none involved avoiding light. Meta-regression with the covariate "Avoid light (pm / eve)" was also run for this outcome removing ASPD, depression and dementia, where none involved avoiding light except in the bedroom at night.

Figures S23-S34: Forest plots sub-grouped by intervention type

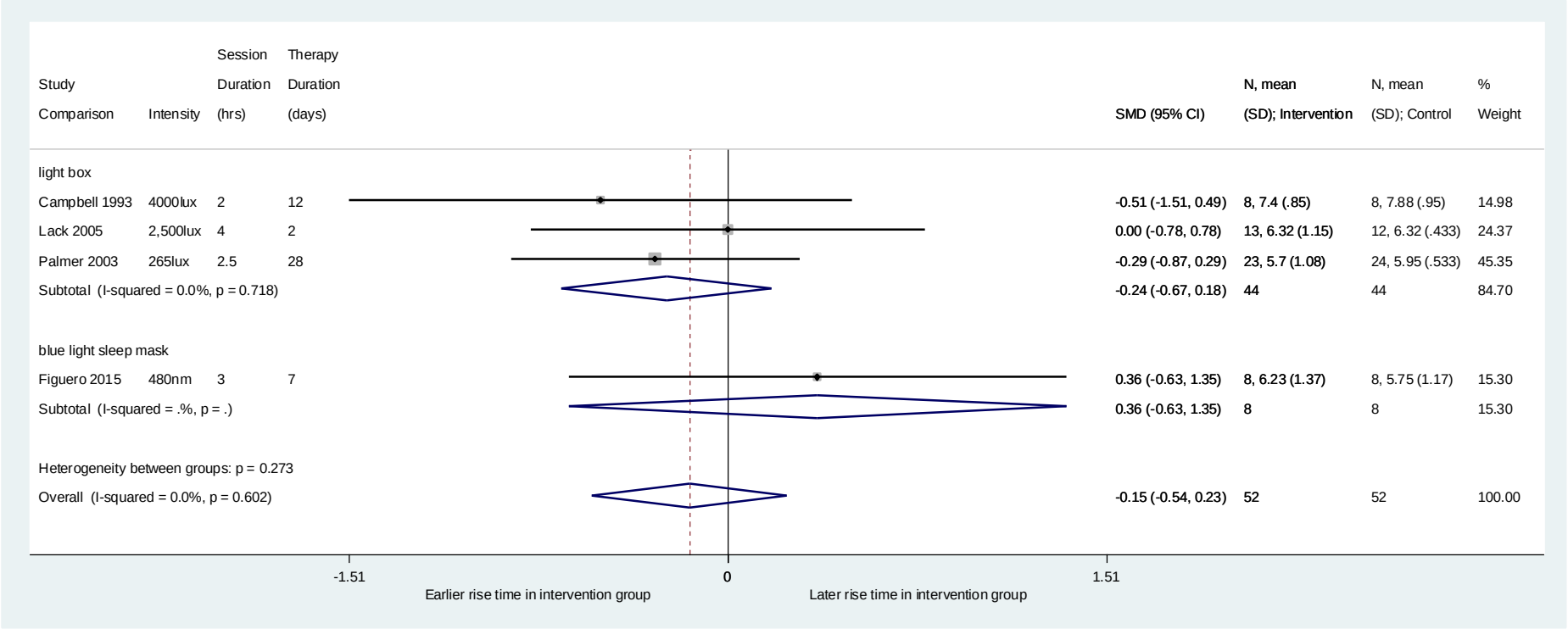


Figure S23: Effect of evening light aiming to delay sleep timing in ASPD

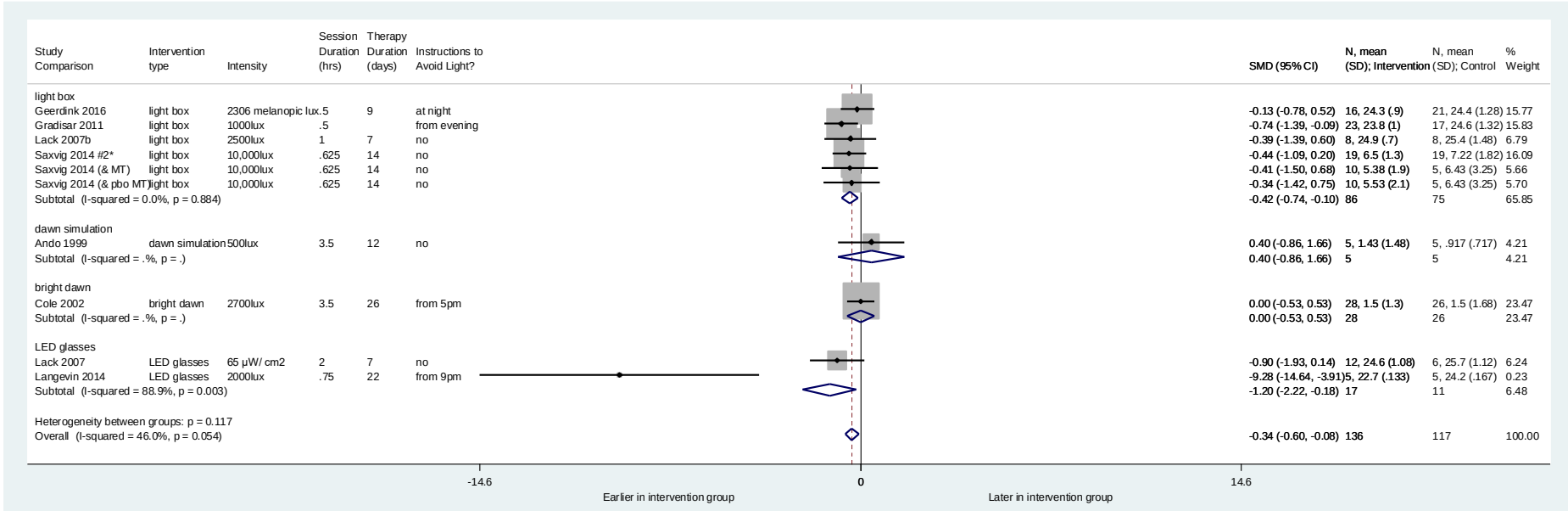


Figure S24: Effect of morning light to advance sleep timing in DSPD

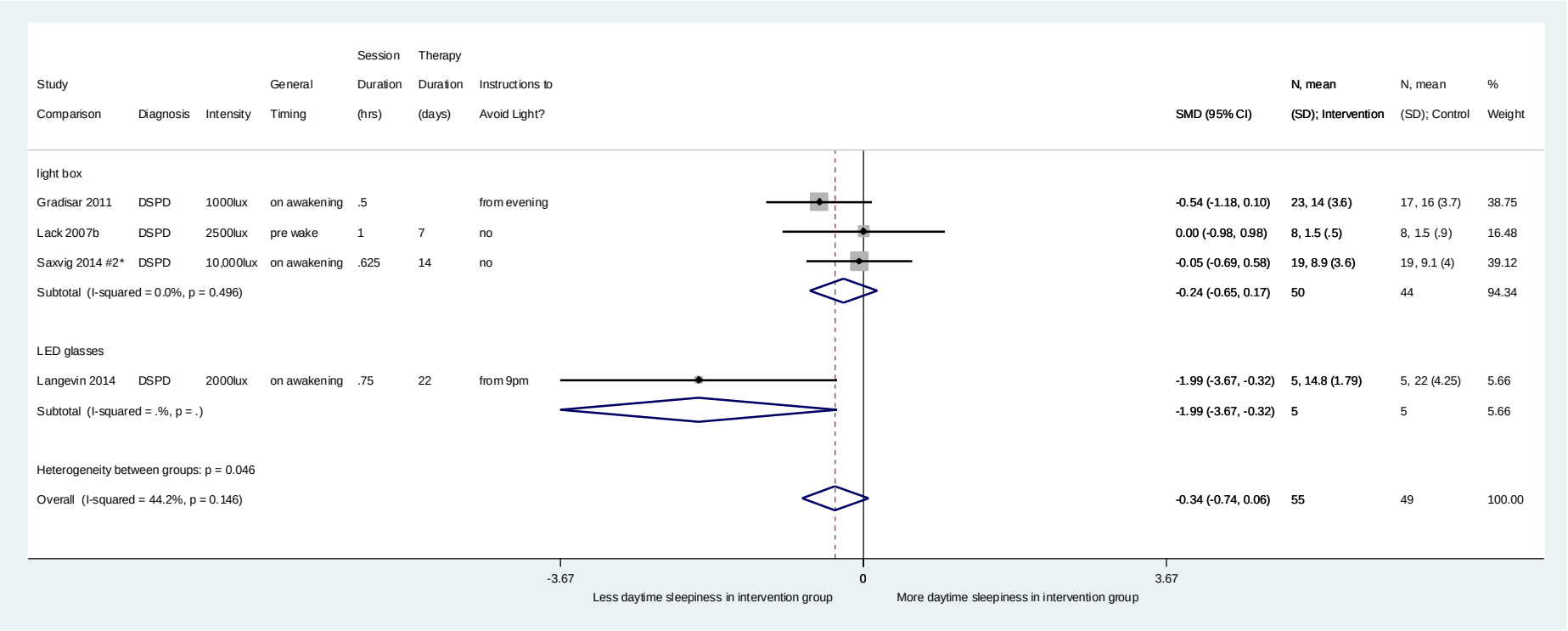


Figure S25: Effect of morning light on self-reported daytime sleepiness in DSPD

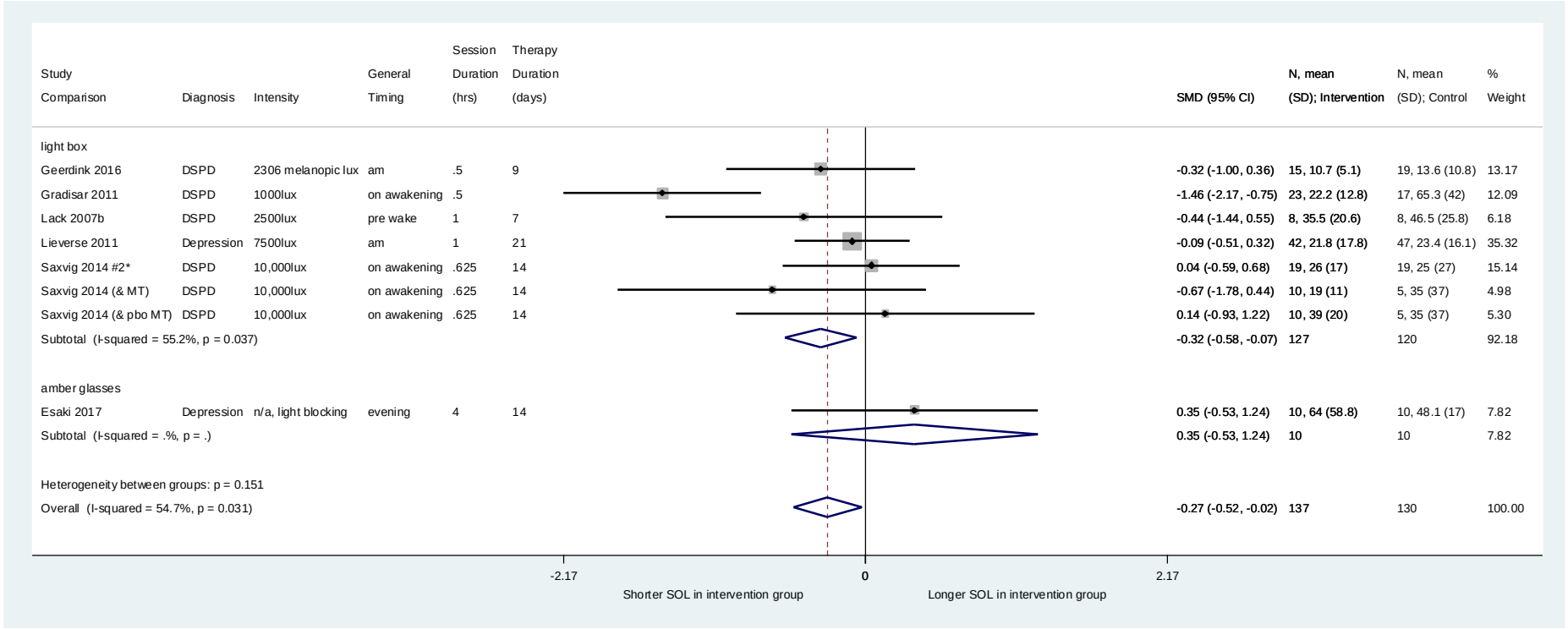


Figure S26: Effect of light schedule interventions on SOL

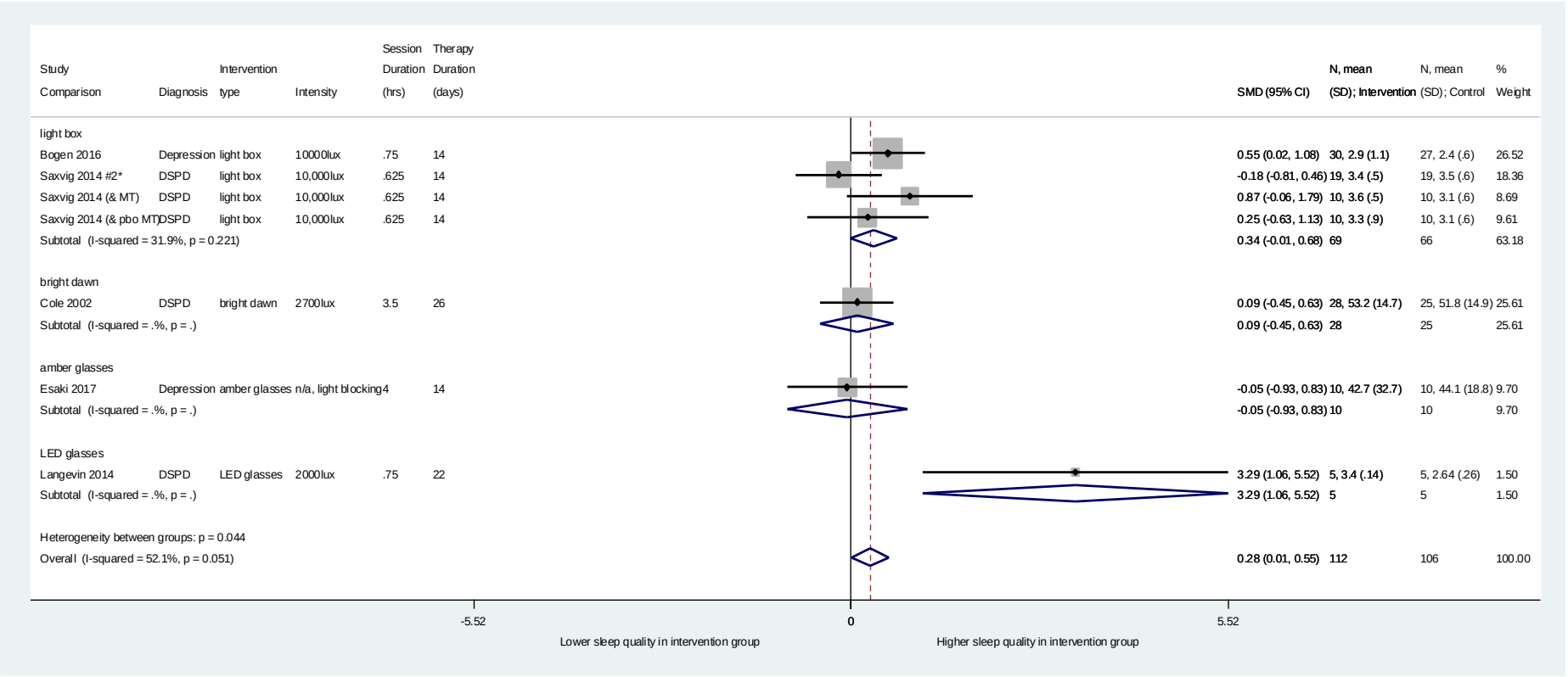


Figure S27: Effect of light schedule interventions on self-reported sleep quality

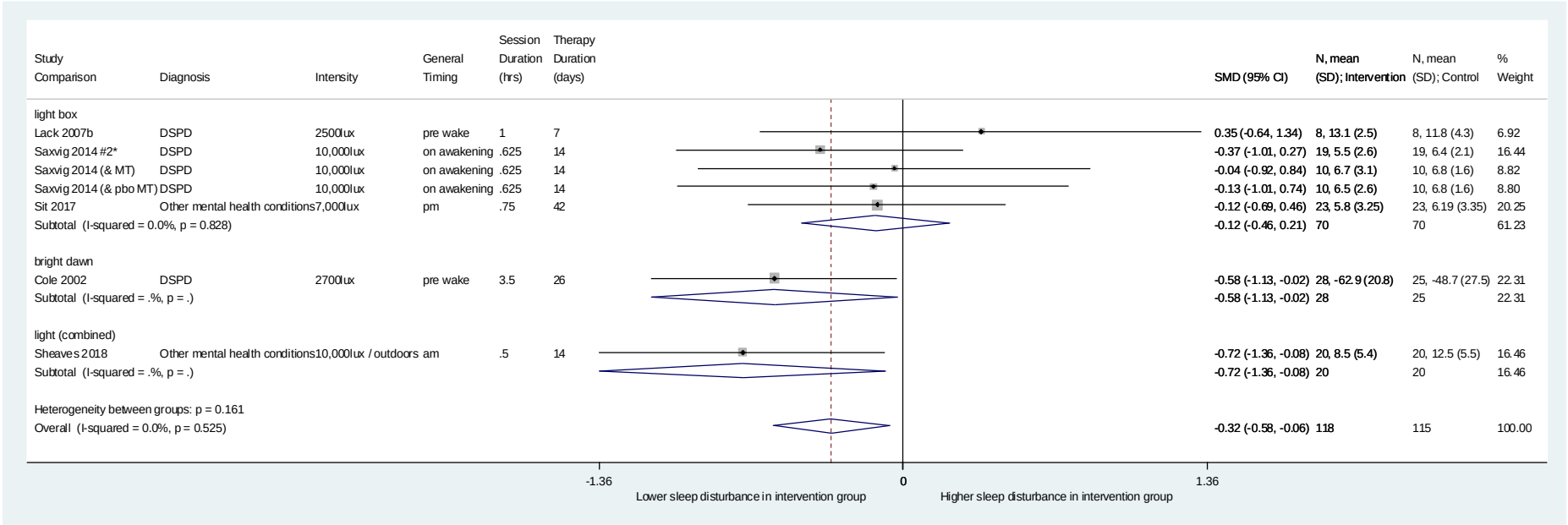


Figure S28: Effect of light schedule interventions on self-reported sleep disturbance (on composite psychometric measures)

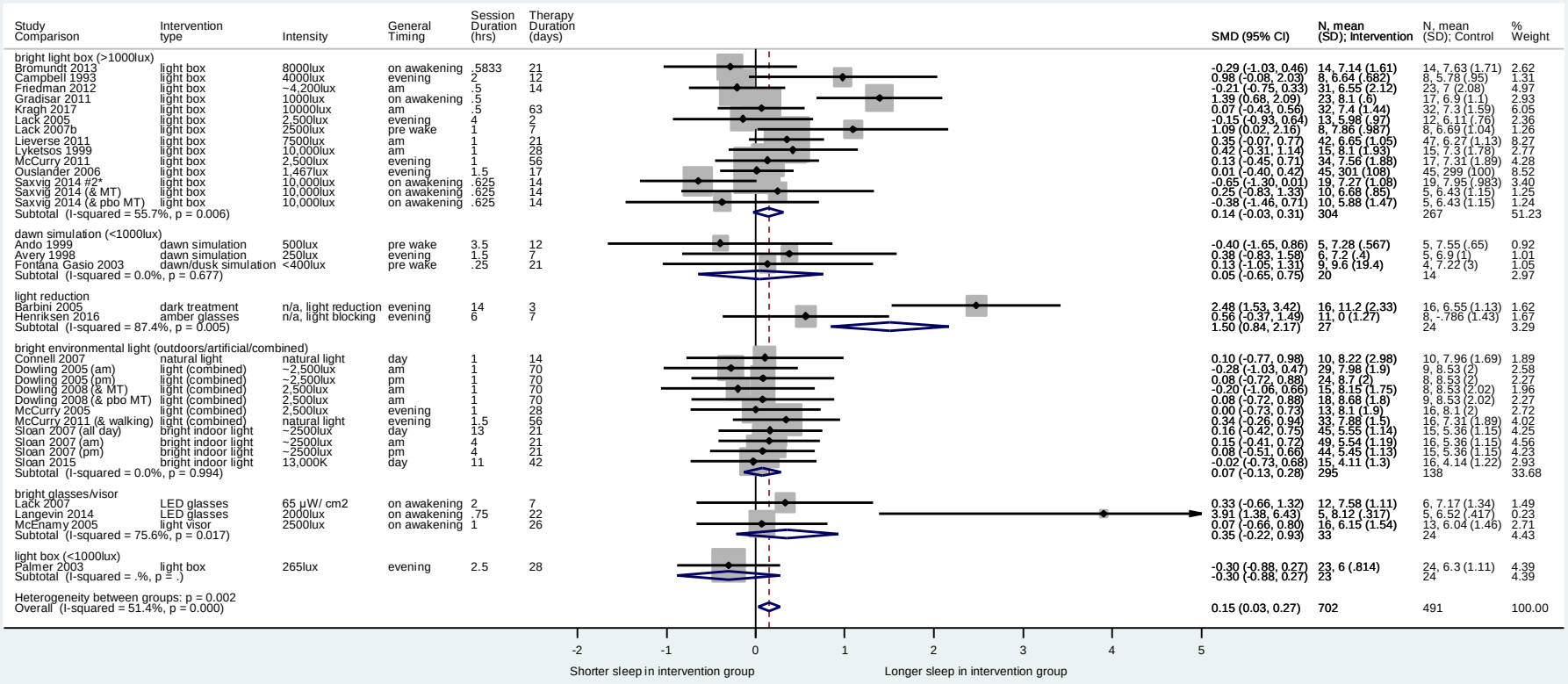


Figure S29: Effect of light schedule interventions on total sleep time

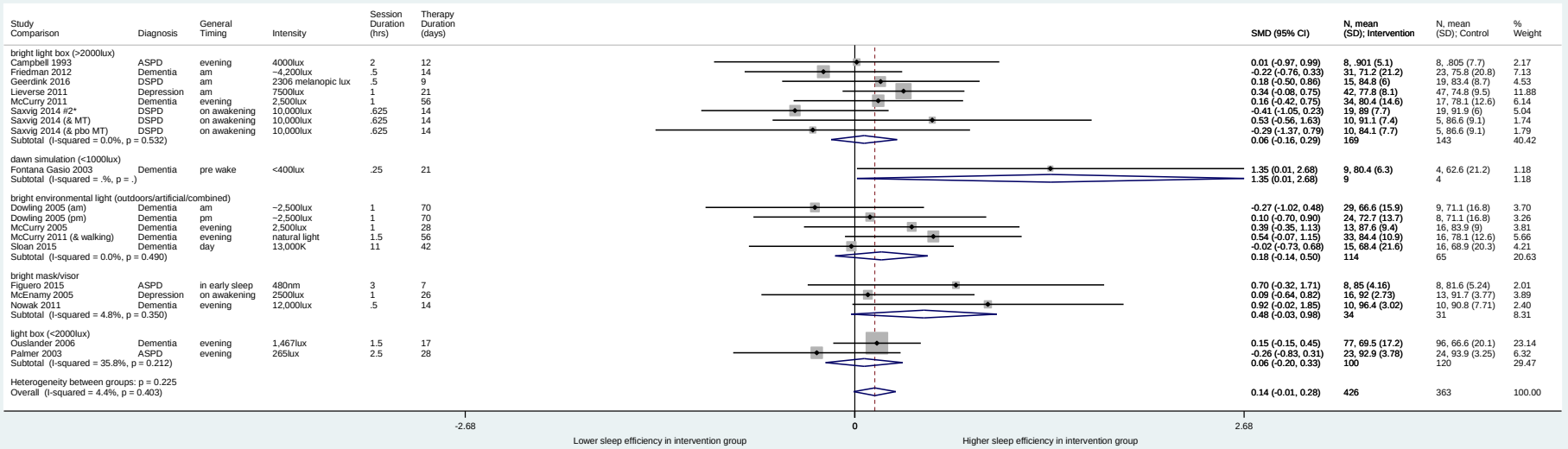


Figure S30: Effect of light schedule interventions on sleep efficiency (%)

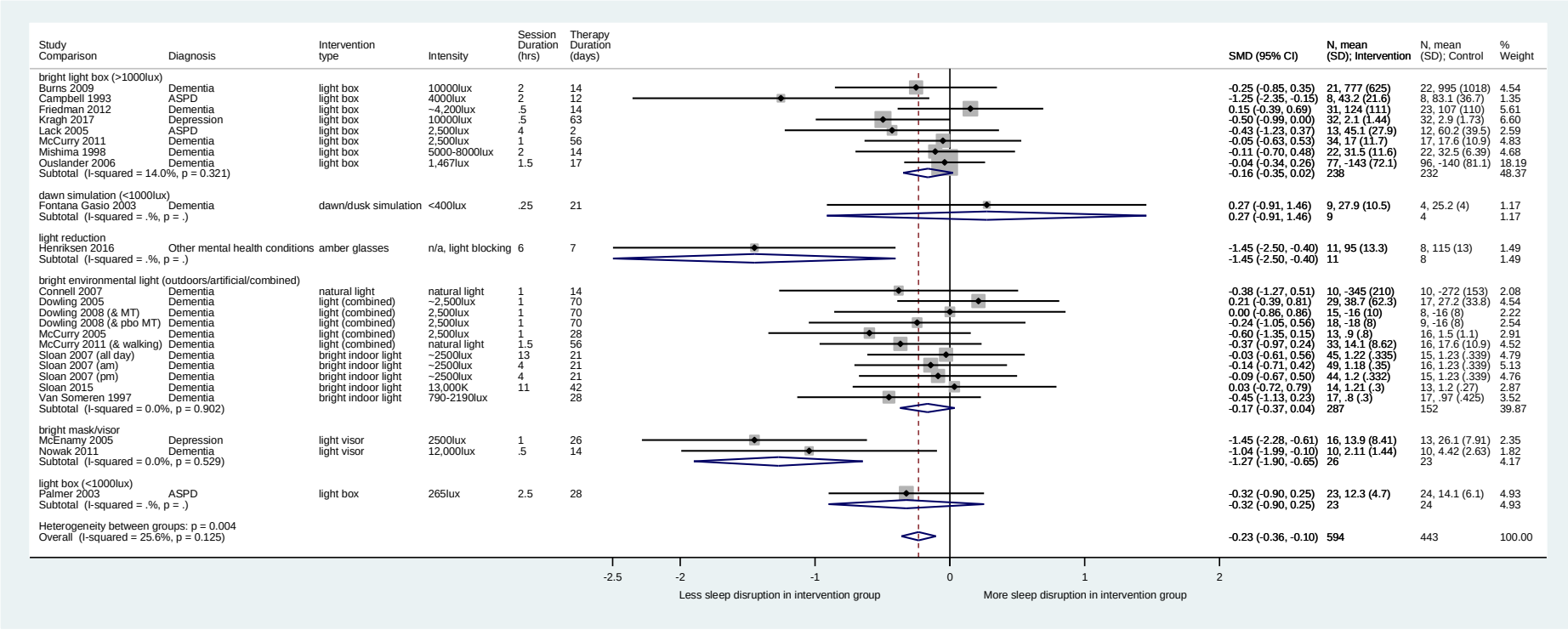


Figure S31: Effect of light schedule interventions on sleep continuity disruption

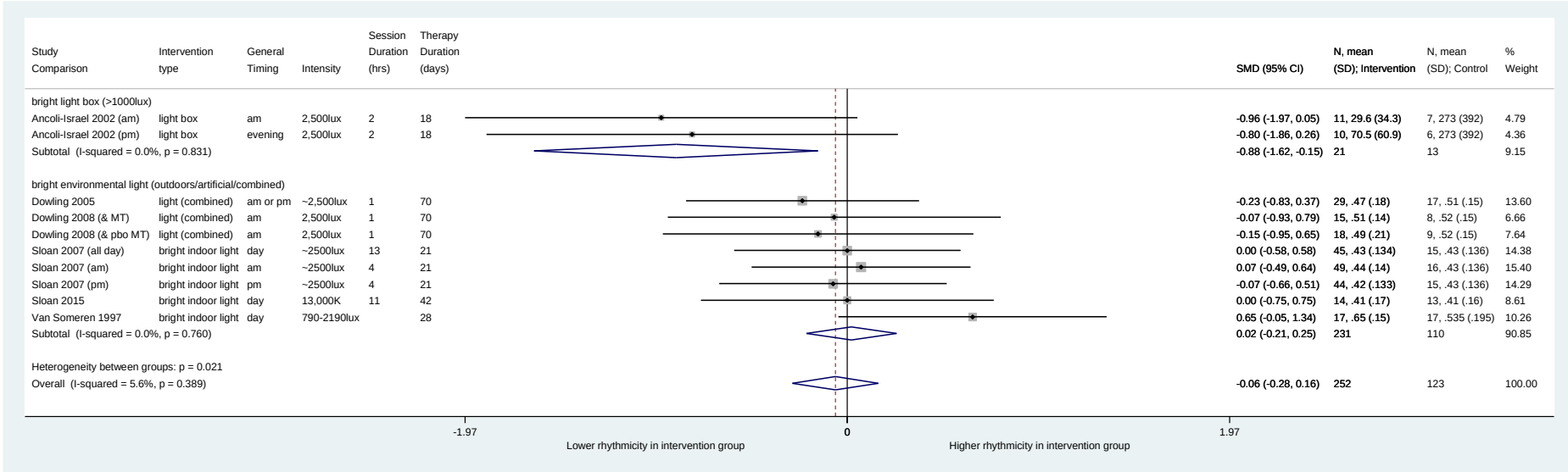


Figure S32: Effect of light schedule interventions on rhythmicity of rest activity rhythm in dementia

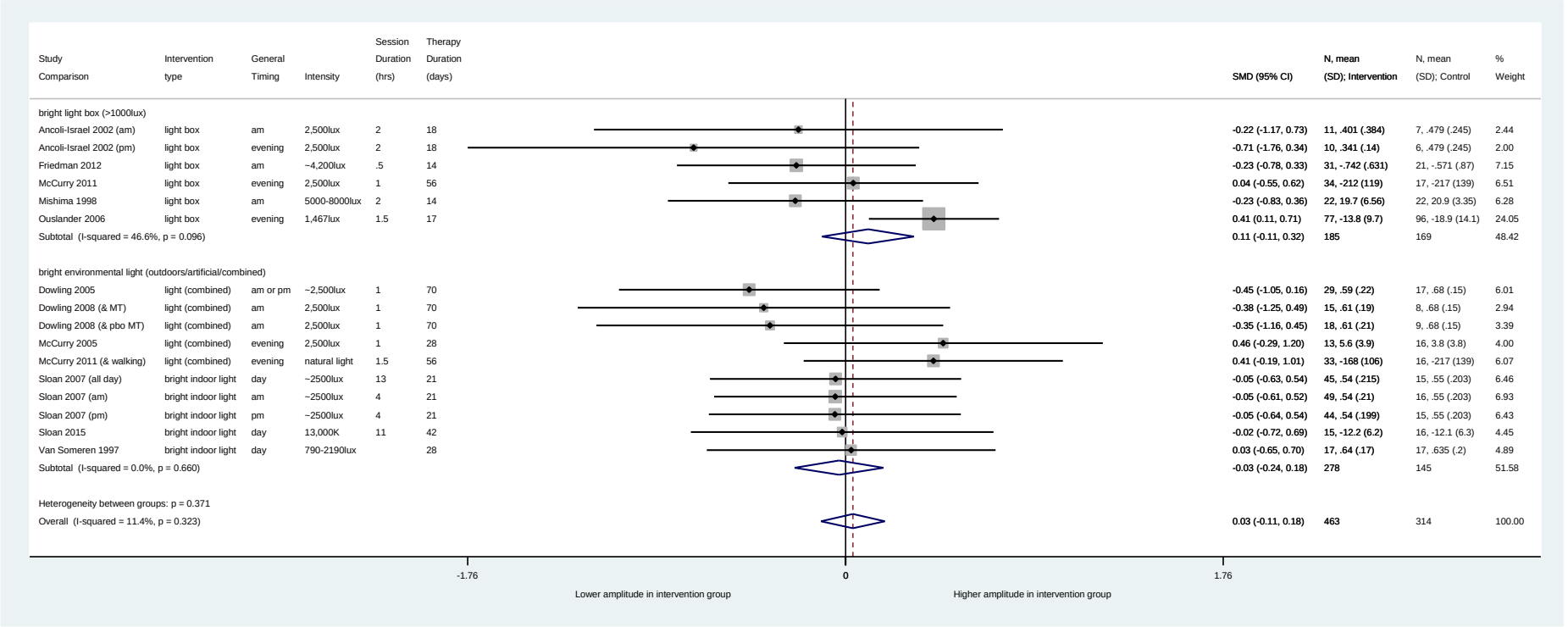


Figure S33: Effect of light schedule interventions on amplitude of rest activity rhythm in dementia

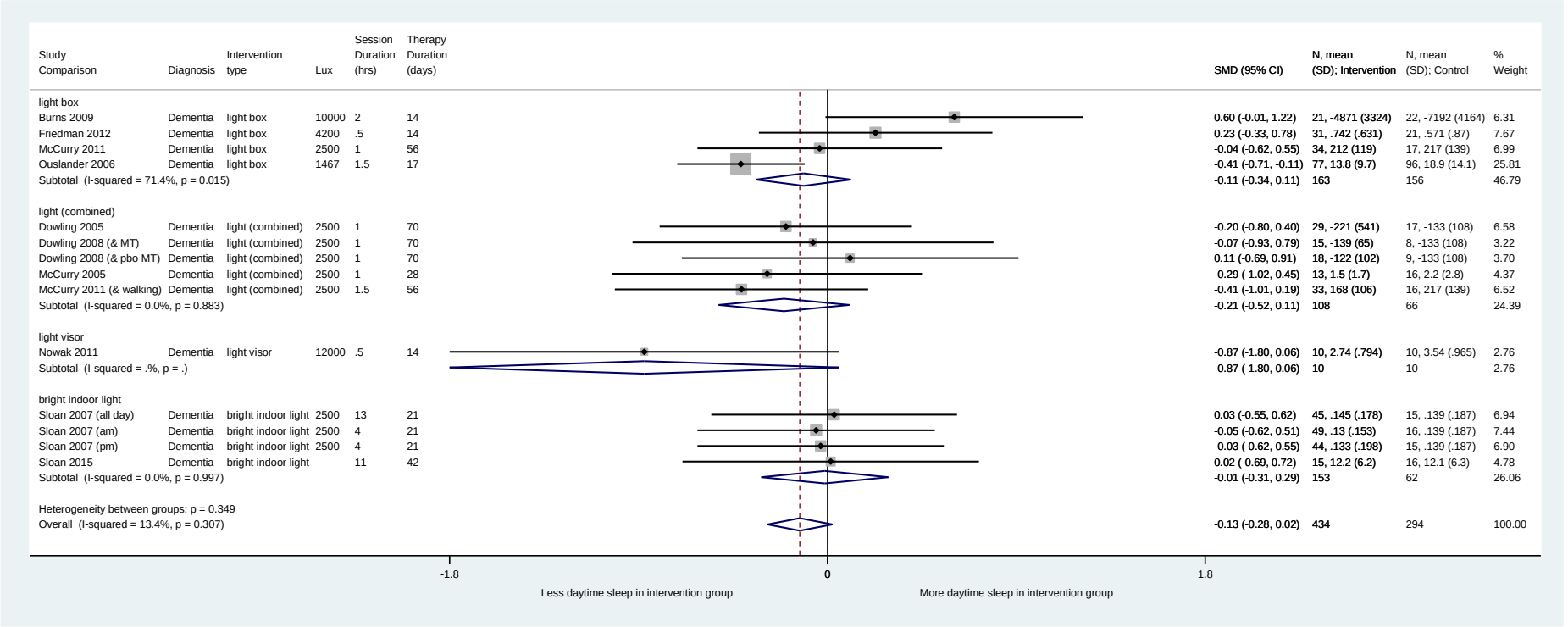


Figure S34 Effect of light schedule interventions on carer reported daytime sleep in dementia

References cited in these supplements:

Gimenez M, Schlangen L, Lang D, Novotny P, Plischke H, Wulff K, et al. D3.7 Report on metric to quantify biological light exposure doses: Accelerate SSL Innovation for Europe. SSL-erate Consortium 2016.; 2016.

Johns MW. Sensitivity and specificity of the multiple sleep latency test (MSLT), the maintenance of wakefulness test and the Epworth sleepiness scale: Failure of the MSLT as a gold standard. J Sleep Res. 2000;9:5–10.

Chervin RD. Sleepiness, Fatigue, tiredness and Lack of Energy in Obstructive Sleep Apnea. Chest [Internet]. 2000;118(2):372–9. Available from: http://dx.doi.org/10.1378/chest.118.2.372

References of included studies:

1. Ancoli-Israel S, Martin JL, Kripke DF, Marler M, Klauber MR. Effect of light treatment on sleep and circadian rhythms in demented nursing home patients. J Am Geriatr Soc. 2002;50(2):282–9.

2. Katsuhisa Ando, Kripke DF, Cole RJ, Elliot JA. Light mask 500 lux treatment for elayed sleep phase syndrome. Vol. 23, Progress in neuro-psychopharmacology & biological psychiatry. 1999. p. 15–24.

3. Avery DH, Bolte MA, Ries R. Dawn Simulation Treatment of Abstinent Alcoholics With Winter Depression. J Clin ps. 1998;59(1):35–44.

4. Avery DH, Kouri ME, Monaghan K, Bolte MA, Hellekson C, Eder D. Is dawn simulation effective in ameliorating the difficulty awakening in seasonal affective disorder associated with hypersomnia? J Affect Disord. 2002;69:231–6.

5. Barbini B, Benedetti F, Colombo C, Dotoli D, Bernasconi A, Cigala-Fulgosi M, et al. Dark therapy for mania: A pilot study. Bipolar Disord. 2005;7(1):98–101.

6. Bogen S, Legenbauer T, Gest S, Holtmann M. Morning bright light therapy: A helpful tool for reducing comorbid symptoms of aff ective and behavioral dysregulation in juvenile depressed inpatients? A pilot trial. Z Kinder Jugendpsychiatr Psychother. 2017;45(1):34–41.

7. Bogen S, Legenbauer T, Gest S, Holtmann M. Lighting the mood of depressed youth: Feasibility and efficacy of a 2 week-placebo controlled bright light treatment for juvenile inpatients. J Affect Disord. 2016;190:450–6.

8. Bromundt V, Wirz-Justice A, Kyburz S, Opwis K, Dammann G, Cajochen C. Circadian sleep-wake cycles, well-being, and light therapy in borderline personality disorder. J Pers Disord [Internet]. 2013;27(5):680–96. Available

from:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=22928852

9. Burns A, Allen H, Tomenson B, Duignan D, Byrne J. Bright light therapy for agitation in dementia: A randomized controlled trial. Int Psychogeriatrics. 2009;21(4):711–21.

10. Sutherland D, Woodward Y, Byrne J. The use of light therapy to lower agitation in people with dementia. Nurs Times. 2004;100(45):32–4.

11. Scott S Campbell, Dawson D, Anderson MW. Alleviation of sleep maintenance insomnia with timed exposure to bright light. J - Am Geriatr Soc. 1993;41:829–36.

12. Cole RJ, Smith JS, Alcalá YC, Elliott JA, Kripke DF. Bright-light mask treatment of delayed sleep phase syndrome. J Biol Rhythms. 2002;17(1):89–101.

13. Connell BR, Sanford JA, Lewis D. Therapeutic Effects of an Outdoor Activity Program on Nursing Home Residents with Dementia. J Hous Elderly [Internet]. 2007;21(3–4):194–209. Available from: http://www.tandfonline.com/doi/abs/10.1300/J081v21n03_12?journalCode=wjhe20#.UjW4Kz_fKSo

14. Dowling GA, Burr RL, Van Someren EJW, Hubbard EM, Luxenberg JS, Mastick J, et al. Melatonin and bright-light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease. J Am Geriatr Soc. 2008;56(2):239–46.

15. Dowling GA, Mastick J, Hubbard EM, Luxenberg JS, Burr RL. Effect of timed bright light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease. Int J Geriatr Psychiatry. 2005;20(8):738–43.

16. Dowling GA, Hubbard EM, Mastick J, Luxenberg JS, Burr RL, Someren EJW Van. Effect of morning bright light treatment for rest–activity disruption in institutionalized patients with severe Alzheimer's disease. Int Psychogeriatrics. 2005;17(2):221–36.

17. Esaki Y, Kitajima T, Takeuchi I, Tsuboi S, Furukawa O, Moriwaki M, et al. Effect of blue-blocking glasses in major depressive disorder with sleep onset insomnia: A randomized, double-blind, placebo-controlled study. Chronobiol Int [Internet]. 2017;34(6):753–61. Available from: https://doi.org/10.1080/07420528.2017.1318893

18. Figueiro MG. Individually tailored light intervention through closed eyelids to Promote Circadian Alignment and Sleep Health. Sleep Heal. 2015;1(1):75–82.

19. Fontana Gasio P, Kräuchi K, Cajochen C, Van Someren E, Amrhein I, Pache M, et al. Dawn-dusk simulation light therapy of disturbed circadian rest-activity cycles in demented elderly. Exp Gerontol. 2003;38(1–2):207–16.

20. Friedman L, Spira AP, Hernandez B, Mather C, Sheikh J, Ancoli-Israel S, et al. Brief morning light treatment for sleep/wake disturbances in older memory-impaired individuals and their caregivers. Sleep Med. 2012;13(5):546–9.

21. Geerdink M, Walbeek TJ, Beersma DGM, Hommes V, Gordijn MCM. Short blue light pulses (30 Min) in the morning support a sleep-advancing protocol in a home setting. J Biol Rhythms. 2016;31(5):483–97.

22. Gradisar M, Dohnt H, Gardner G, Paine S, Starkey K, Menne A, et al. A Randomized Controlled Trial of Cognitive-Behavior Therapy Plus Bright Light.pdf. Sleep [Internet]. 2011;34(12):1671–80. Available from: http://dx.doi.org/10.5665/sleep.1432

23. Henriksen TE, Skrede S, Fasmer OB, Schoeyen H, Leskauskaite I, Bjørke-Bertheussen J, et al. Blue-blocking glasses as additive treatment for mania: A randomized placebo-controlled trial. Bipolar Disord. 2016;18(3):221–32.

24. Kragh M, Martiny K, Videbech P, Møller DN, Wihlborg CS, Lindhardt T, et al. Wake and light therapy for moderate-to-severe depression – a randomized controlled trial. Acta Psychiatr Scand. 2017;136(6):559–70.

25. Kragh M, Møller DN, Wihlborg CS, Martiny K, Larsen ER, Videbech P, et al. Experiences of wake and light therapy in patients with depression: A qualitative study. Int J Ment Health Nurs. 2017;26(2):170–80.

26. Lack L, Wright H, Kemp K, Gibbon S. The treatment of early-morning awakening insomnia with 2 evenings of bright light. Sleep. 2005;28(5):616–23.

27. Lack L, Bramwell T, Wright H, Kemp K. Morning blue light can advance the melatonin rhythm in mild delayed sleep phase syndrome. Sleep Biol Rhythms. 2007;5(1):78–80.

28. Lack L, Wright H, Paynter D. The treatment of sleep onset insomnia with bright morning light. Sleep Biol Rhythms. 2007;5(3):173–9.

29. Langevin RH, Laurent A, Sauvé Y. Preliminary assessment on the effectiveness of the Luminette® in adolescents with a delayed sleep phase syndrome (DSPS): Randomized single blind placebo-controlled study. Med du Sommeil [Internet]. 2014;11(2):91–7. Available from: https://www.scopus.com/inward/record.uri?eid=2-s2.0-84901654831&doi=10.1016%2Fj.msom.2014.03.003&partnerID=40&md5=5d7ccbe0a24ebfa91a811148ee50dff6

30. Lieverse R, Van Someren EJ, Nielen MM, Uitdehaag BM, Smit JH, Hoogendijk WJ. Bright light treatment in elderly patients with nonseasonal major. Arch Gen Psychiatry. 2011;68(1):61–70.

31. Lyketsos CG, Veiel LL, Baker A, Steele C. A randomized, controlled trial of bright light therapy for agitated behaviors in dementia patients residing in long-term care. Int J Geriatr Psychiatry. 1999;14(7):520–5.

32. McCurry SM, Gibbons LE, Logsdon RG, Vitiello M V., Teri L. Nighttime Insomnia Treatment and Education for Alzheimer's Disease: A randomized, controlled trial. J Am Geriatr Soc. 2005;53(5):793–802.

33. McCurry S, Pike K. Increasing Walking and Bright Light Exposure to Improve Sleep in Community-Dwelling Persons with Alzheimer's Disease: Results of a Randomized, Controlled Trial. J Am Geriatr Soc [Internet]. 2011;59(8):1393–402. Available from: http://onlinelibrary.wiley.com/doi/10.1111/j.1532-5415.2011.03519.x/full

34. McEnany GW, Lee KA. Effects of light therapy on sleep, mood, and temperature in women with nonseasonal major depression. Issues Ment Health Nurs [Internet]. 2005;26(7):781–94. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc4&NEWS=N&AN=2005-10414-009

35. Mishima K, Hishikawa Y, Okawa M. Randomized, dim light controlled, crossover test of morning bright light therapy for rest-activity rhythm disorders in patients with vascular dementia and dementia of alzheimer's type. Chronobiol Int. 1998;15(6):647–54.

36. Nowak L, Davis J. Qualitative analysis of therapeutic light effects on global function in alzheimer's disease. West J Nurs Res. 2011;33(7):933–52.

37. Nowak L. The effect of timed blue-green light on sleep-wake patterns in womenwith alzheimer's disease. Wayne State University. 2008.

38. Ouslander JG, Connell BR, Bliwise DL, Endeshaw Y, Griffiths P, Schnelle JF. A nonpharmacological intervention to improve sleep in nursing home patients: Results of a controlled clinical trial. J Am Geriatr Soc. 2006;54(1):38–47.

39. Palmer CR, Kripke DF, Savage HCJ, Cindrich LA, Loving RT, Elliott JA. Efficacy of Enhanced Evening Light for Advanced Sleep Phase Syndrome. Behav Sleep Med. 2003;1(4):213–26.

40. Saxvig IW, Wilhelmsen-Langeland A, Pallesen S, Vedaa Ø, Nordhus IH, Bjorvatn B. A randomized controlled trial with bright light and melatonin for delayed sleep phase disorder: Effects on subjective and objective sleep. Chronobiol Int. 2014;31(1):72–86.

41. Wilhelmsen-Langeland A, Saxvig IW, Pallesen S, Vedaa Ø, Nordhus IH, Bjorvatn B. A randomized controlled trial with bright light and melatonin for delayed sleep phase disorder: Effects on subjective and objective sleepiness and cognitive function. J Biol Rhythms. 2013;28(5):306–21.

42. Sheaves B, Isham L, Bradley J, Espie C, Barrera A, Waite F, et al. Adapted CBT to Stabilize Sleep on Psychiatric Wards: a Transdiagnostic Treatment Approach. Behav Cogn Psychother. 2018;(April):1–15.

43. Sheaves B, Freeman D, Isham L, McInerney J, Nickless A, Yu L-M, et al. Stabilising sleep for patients admitted at acute crisis to a psychiatric hospital (OWLS): Psychol Med. 2017;48:1694–704.

44. Sit DK, McGowan J, Wiltrout C, Diler RS, Dills J, Luther J, et al. Adjunctive bright light therapy for bipolar depression: A randomized double-blind placebo-controlled trial. Am J Psychiatry. 2017;175(2):131–9.

45. Sloane PD, Williams CS, Mitchell CM, Preisser JS, Wood W, Barrick AL, et al. High-Intensity Environmental Light in Dementia: Effect on Sleep and Activity. J Am Geriatr Soc [Internet]. 2007;55(10):1524–33. Available from: http://doi.wiley.com/10.1111/j.1532-5415.2007.01358.x

46. Sloane P, Figueiro M, Cohen L, Reed D, Williams C, Preisser J, et al. Effect of home-based light treatment on persons with dementia and their caregivers. Light Res Technol. 2015;47(2):161–76.

47. Van Someren EJ, Kessler A, Mirmiran M, Swaab DF. Indirect Bright Light Improves Circadian Rest-Activity Rhythm Disturbances in Demented Patients. Biol Psychiatry. 1997;41:955–63.

48. Van Someren EJW, Swaab DF, Colenda CC, Cohen W, McCall WV, Rosenquist PB. Bright light therapy: Improved sensitivity to its effects on rest- activity rhythms in Alzheimer patients by application of nonparametric methods. Chronobiol Int. 1999;16(4):505–18.

Appendix 4: Supplement to Study B - "Adherence and acceptability of light therapies to improve sleep in intrinsic circadian rhythm sleep disorders and neuropsychiatric illness: systematic review and mixed methods synthesis"

Contents:

Table A1: Inclusion criteria

Study type	Intervention study (not observational and correlational studies) Exclude: case studies (<5 people)
Population	Intrinsic CRSWD (DSWPD, ASWPD, ISWD or non-24) OR Psychiatric or neurodegenerative disease with high levels of circadian dysregulation: dementia, psychotic disorders, personality disorder, affective disorders (bi-polar or unipolar, seasonal or non-seasonal) AND Over 70% of the sample meet the above criteria, or subgroups reported Adults or adolescents (over 13)
Intervention	Interventions altering light exposure (amount, timing, or spectral qualities) as a core (not optional) component, with primary or secondary aim of improving sleep. Examples: light boxes, light visors, dark treatment, amber glasses, increasing daylight exposure, increasing or decreasing indoor lighting.
Comparison	Including controlled and pre-post studies.
Outcome	Including studies that stated a primary or secondary aim of the intervention was to improve one or more sleep-related parameters. Including studies irrespective of the degree they report on adherence and acceptability.

*CRSWD=circadian rhythm sleep-wake disorder, DSWPD=delayed sleep-wake phase disorder, ASWPD= advanced sleep-wake phase disorder, ISWD=irregular sleep-wake rhythm disorder, non-24=non-24-hour sleep-wake rhythm disorder.

Appendix A2: Changes from Protocol

The protocol for this review was prospectively published on Prospero, and is available at: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017072387. The original protocol describes the current analysis as a secondary aim of a systematic review with meta-analysis, which is now published elsewhere (Faulkner SM, Bee PE, Meyer N, Dijk DJ, Drake RD, 2019, Light therapies to improve sleep in intrinsic circadian rhythm sleep-wake disorders and neuro-psychiatric illness: A systematic review and meta-analysis, Sleep Medicine Reviews, 46, pp108-123, https://doi.org/10.1016/j.smrv.2019.04.012).

Due to the amount of material found for inclusion within this meta-analysis (controlled studies), and the number of reportable outcomes, it was decided to complete the present synthesis regarding adherence, attrition and acceptability subsequently, and report it separately, in order to give adequate attention and space to this.

Table A3: Included studies, grouped by population

First author (year)	Design	Sample	n=	Setting	Country	Sleep outcome primary / secondary	Intervention(s)	Sleep schedule	Light avoidance	Control condition	expectations	acceptability	adherence	recruitment	attrition	adverse effects
Campbell (1993) [1]	controlled	ASWPD	16	at home	UK	primary	evening BLT	no	no	dim light box			x			
Figueiro (2015a) [2]	crossover	ASWPD	8	at home	USA	primary	blue flashing light mask in early sleep	no	no	red flashing light mask in early sleep			x		x	
Lack (2005) [3]	controlled	ASWPD	25	clinic	Australia	primary	evening BLT	no	no	dim red light			x			
Lack (1993) [4]	pre-post	ASWPD	9	clinic	South Australia	primary	evening BLT	no	no	n/a					x	
Palmer (2003) [5]	controlled	ASWPD	47	at home	USA	primary	evening light	no	no	dim light box		x	x	x	x	x
Suhner (2002) [6]	pre-post	ASWPD	15	at home	USA	primary	Evening BLT	no	yes	TAU					x	
Ando (1999) [7]	controlled	DSWPD	10	at home	USA	primary	dawn simulation mask	no	no	dim dawn mask			x		x	
Cole (2002) [8]	RCT	DSWPD	54	at home	USA	primary	BLT dawn simulation mask	yes	yes	dim red light mask	x	x	x	x	x	x
Danielsson (2016a) [9]	RCT (wrong comparison)	DSWPD	36	at home	Sweden	primary	am BLT / + - CBTi	yes	yes	see left			x	x	x	x
Danielsson (2016b) [10]	pre-post	DSWPD	44	at home	Sweden	primary	am BLT	yes	yes	n/a			x	x	x	
Esaki (2016) [11]	pre-post	DSWPD	9	at home	Japan	primary	evening amber glasses	no	yes	n/a				x	x	
Geerdink (2016) [12]	RCT, quasi-random	DSWPD	39	at home	Netherlands	primary	am blue light pulses	yes	yes	am amber light pulses			x		x	x
Gradisar (2011) [13]	RCT	DSWPD	40	at home	Australia	primary	am BLT, CBT-i	yes	yes	TAU			x		x	
Lack (2007a) [14]	RCT	DSWPD	18	at home	Australia	primary	am blue light glasses	no	no	TAU / red light						x
Lack (2007b) [15]	RCT	DSWPD	16	at home	Australia	primary	am BLT	yes	no	dim light			x	x	x	
Langevin (2014) [16]	RCT	DSWPD	10	at home	Canada	primary	am blue light glasses	no	yes	orange light glasses				x		

First author (year)	Design	Sample	n=	Setting	Country	Sleep outcome primary / secondary	Intervention(s)	Sleep schedule	Light avoidance	Control condition	expectations	acceptability	adherence	recruitment	attrition	adverse effects
Rosenthal (1990) [17]	crossover	DSWPD	33	at home	USA	primary	am BLT, dark glasses evening	no	yes	dim light, clear glasses	x		x	x		
Saxvig (2014) [18, 19]	RCT	DSWPD	40	at home	Norway	primary	am BLT, + - melatonin	yes	no	dim red light / TAU				x	x	
Okawa (1998) [20]	pre-post	DSWPD & non-24	20	at home	Japan	primary	am window light, vitamin B12, phase delay chronotherapy, Benzodiazepines	yes	no	n/a					x	
Yamadera (1996) [21]	pre-post	Mixed CRSWD	116	at home	Japan	primary	am BLT, vitamin B12, phase delay chronotherapy, hypnotics	yes	no	n/a	x					
Yamadera (1998) [22]	pre-post	Mixed CRSWD	126	at home	Japan	primary	am BLT, vitamin B12, phase delay chronotherapy, hypnotics	yes	no	n/a						
Ancoli-Israel (2003) [23, 24]	RCT	Dementia	92	nursing home	USA	equal / not stated	am / pm BLT	no	no	am dim red light			x			
Ancoli-Israel (2002) [25]	RCT	Dementia	77	nursing home	USA	primary	am / pm BLT	no	no	dim red light			x		x	
Burns (2009) [26, 27]	RCT	Dementia	46	nursing homes	UK	secondary	am BLT	no	no	standard light			x		x	x
Calkins (2007) [28]	pre-post	Dementia	17	nursing homes	USA	equal / not stated	daytime outdoor light	no	no	indoor activity / no activity			x		x	x
Chong (2013) [29]	pre-post	Dementia	228	inpatient	China	primary	daytime indoor light			n/a						
Colenda (1997) [30]	pre-post	Dementia	5	at home	USA	primary	am BLT visor	no	no	n/a			x		x	

First author (year)	Design	Sample	n=	Setting	Country	Sleep outcome primary / secondary	Intervention(s)	Sleep schedule	Light avoidance	Control condition	expectations	acceptability	adherence	recruitment	attrition	adverse effects
Connell (2007) [31]	RCT	Dementia	20	nursing home	USA	primary	daytime outdoor light, activities	no	no	indoor similar activities			x	x	x	
Dowling (2005) [32, 33]	RCT (crossover phase 2)	Dementia	70	care home	USA	primary	am / pm BLT / indoor / outdoor light	no	no	standard light, TAU			x			
Dowling (2008) [34]	RCT	Dementia	50	care home	USA	primary	am BLT / indoor / outdoor light / + - melatonin			TAU, placebo melatonin			x			
Fetveit (2003) [35-37]	pre-post	Dementia	11	nursing home	Norway	primary	am BLT	no	yes	n/a			x	x	x	x
Figueiro (2015b) [38]	pre-post	Dementia	35	at home	USA	primary	daytime indoor light	no	no	n/a			x			
Fontana Gasio (2003) [39]	RCT	Dementia	13	inpatient	Switzerland	primary	dawn-dusk simulation	no	no	dim red dawn-dusk simulation			x	x		
Friedman (2012) [40]	RCT	Dementia	54	at home	USA	primary	am BLT, SH	yes	yes	dim red light				x	x	
Gibson (2016) [41]	pre-post	Dementia	15	at home	New Zealand	primary	am BLT / outdoor light, exercise, SH	yes	yes	n/a			x		x	
Ito (1999) [42, 43]	pre-post	Dementia	27	inpatient	Japan	primary	am BLT	no	no	n/a					x	
Ito (2001) [44]	RCT (wrong comparison)	Dementia	28	at home	Japan	primary	am BLT, + - vitamin B12	no	no	see left						
Kobayashi (2001) [45]	pre-post	Dementia	10	inpatient	Japan	primary	mid-day BLT	no	no	n/a						x
Koyama (1999) [46]	pre-post	Dementia	6	nursing homes	Japan	secondary	late am BLT	no	no	n/a						
Lyketsos (1999) [47]	RCT crossover	Dementia	15	care home	USA	primary	am BLT	no	no	dim blinking light					x	x
Martin (2007) [48]	RCT	Dementia	118	care home	USA	primary	late am outdoor light	no	yes	TAU			x		x	

First author (year)	Design	Sample	n=	Setting	Country	Sleep outcome primary / secondary	Intervention(s)	Sleep schedule	Light avoidance	Control condition	expectations	acceptability	adherence	recruitment	attrition	adverse effects
McCurry (2005) [49]	RCT	Dementia	36	at home	USA	primary	evening BLT / outdoor light, carer education & support, SH, walking	yes	yes	carer education & support, SH			x	x	x	
McCurry (2011) [50]	RCT	Dementia	70	at home	USA	primary	evening BLT, SH / + - walking	yes	yes	SH			x	x	x	
Mishima (1998) [51]	RCT crossover	Dementia	22	inpatient	Japan	equal / not stated	BLT	no	no	dim light			x			
Mishima (1994) [52]	pre-post	Dementia	14	inpatient	Japan	equal / not stated	am BLT	no	no	n/a						
Nowak (2008) [53, 54]	RCT	Dementia	20	nursing home	USA	primary	blue-green light visor			dim red light visor			x		x	x
Ouslander (2006) [55]	cluster crossover	Dementia	173	nursing home	USA	equal / not stated	evening BLT, exercise	yes	yes	TAU					x	
Satlin (1992) [56]	pre-post	Dementia	10	nursing home	USA	primary	evening BLT	no	no	n/a						
Sekiguchi (2017) [57]	pre-post	Dementia	17	at home	Japan	secondary	am BLT	no	no	n/a			x			
Skjerve (2004) [58]	pre-post	Dementia	11	care home	Norway	primary	am BLT	no	no	n/a			x		x	x
Sloane (2007) [59]	cluster crossover	Dementia	60	care home	USA	primary	am / pm / all day bright indoor light	no	no	standard light			x		x	x
Sloane (2015) [60]	RCT crossover	Dementia	17	at home	USA	primary	all day bright indoor light	no	no	standard light / red light			x	x	x	
Van Someren (1997) [61, 62]	crossover	Dementia	22	care come	Netherlands	primary	daytime indoor light	no	no	TAU			x		x	
Bogen (2016) [63, 64]	RCT	Depression	57	inpatient	Germany	secondary	am BLT	no	no	dim light	x				x	x

First author (year)	Design	Sample	n=	Setting	Country	Sleep outcome primary / secondary	Intervention(s)	Sleep schedule	Light avoidance	Control condition	expectations	acceptability	adherence	recruitment	attrition	adverse effects
Dietzel (1986) [65]	pre-post	Depression	10	inpatient	Austria	equal / not stated	am / pm indoor light	yes	no	n/a						
Esaki (2017) [66]	RCT	Depression	20	at home	Japan	equal / not stated	evening amber glasses	no	yes	clear glasses	x		x	x	x	x
Gest (2016) [67]	RCT (wrong comparison)	Depression	62	inpatient	Germany	secondary	am BLT / + - wake therapy	no	no	see left			x		x	x
Jacobsen (1990) [68]	pre-post	Depression	25	at home	USA	primary	pre-waking indoor light	no	no	n/a						x
Kragh (2017) [69, 70]	RCT, + qualitative	Depression	64	inpatient	Denmark	secondary	am BLT, wake therapy	yes	no	TAU		x	x	x	x	x
Lieverse (2011) [71]	RCT	Depression	89	at home	Netherlands	secondary	am BLT	no	no	dim red light	x		x	x	x	x
McEnany (2005) [72]	RCT	Depression	29	at home	USA	equal / not stated	BLT visor on waking	no	no	light blocking glasses 1 hr before bed					x	
Sheaves (2018) [73, 74]	RCT	Mixed MH	40	inpatient	UK	primary	am BLT / outdoor light, CBT-i	yes	yes	TAU		x	x	x	x	
Swanson (2018) [75]	pre-post	Post-partum depression	8	at home	USA	secondary	am blue-green light glasses	no	no	n/a			x		x	x
Haynes (2016) [76]	pre-post	PTSD & MDD	24	at home	USA	equal / not stated	indoor / outdoor light, CBSRT			n/a			x	x	x	
Bromundt (2013) [89]	crossover	Borderline personality disorder	14	at home	Switzerland	primary	am BLT	yes	no	TAU						
Avery (2001) [77]	RCT	SAD	33	at home	USA	secondary	am LT / dawn simulation	yes	no	dim red dawn	x				x	x
Avery (1998) [78]	RCT	SAD	11	at home	USA	secondary	dawn simulation	yes	yes	dim red dawn	x					x
Avery (2002) [79]	controlled	SAD	50	at home	USA	primary	dawn simulation	yes	yes	dim red dawn						x

First author (year)	Design	Sample	n=	Setting	Country	Sleep outcome primary / secondary	Intervention(s)	Sleep schedule	Light avoidance	Control condition	expectations	acceptability	adherence	recruitment	attrition	adverse effects
Avery (1992) [80]	RCT (wrong comparison)	SAD	13	at home	USA	secondary	gradual / rapid dawn simulation mask	yes	yes	see left	x		x		x	x
Ceisielczyk (2004) [81]	pre-post	SAD	17	clinic	Poland	equal / not stated	am BLT			n/a						
Meesters (2011) [82]	RCT (wrong comparison)	SAD	22	clinic	Netherlands	secondary	BLT, blue / white light	no	no	see left	x		x		x	x
Partonen (1992) [83]	pre-post	SAD	12	clinic	Finland	primary	am BLT	no	no	n/a			x			
Rastad (2017) [84]	qualitative	SAD	18	clinic	Sweden	secondary	am indoor light	no	no	n/a		x	x		x	x
Winkler (2005) [85]	pre-post	SAD	17	at home	Vienna	primary	am BLT	no	no	n/a						
Sit (2017) [86]	RCT	Bipolar depression	46	at home	USA	secondary	midday BLT	no	no	dim red light	x		x		x	x
Barbini (2005) [87]	controlled	Bipolar mania	32	inpatient	Italy	secondary	darkness 6pm-8am	no	yes	TAU					x	
Henriksen (2016) [88]	RCT	Bipolar mania	19	inpatient	Norway	secondary	evening amber glasses	no	yes	clear glasses	x	x	x	x	x	x
		mean (SD)	37 (38)			total reporting on:					12	6	47	22	49	28

Appendix A4: References of included studies (Order grouped by diagnostic group, as per Table A3 above)

1. Scott S Campbell, Dawson D, Anderson MW. Alleviation of sleep maintenance insomnia with timed exposure to bright light. J - Am Geriatr Soc. 1993;41:829-836.

2. Figueiro MG. Individually tailored light intervention through closed eyelids to Promote Circadian Alignment and Sleep Health. Sleep Heal. 2015;1(1):75-82. doi:10.1016/j.sleh.2014.12.009.Individually

3. Lack L, Wright H, Kemp K, Gibbon S. The treatment of early-morning awakening insomnia with 2 evenings of bright light. Sleep. 2005;28(5):616-623. doi:10.1093/sleep/28.5.616

4. Lack L, Wright H. The effect of evening bright light in delaying the circadian rhythms and lengthening the sleep of early morning awakening insomniacs. Sleep. 1993;16(5):436-443. doi:10.1093/sleep/16.5.436

5. Palmer CR, Kripke DF, Savage HCJ, Cindrich LA, Loving RT, Elliott JA. Efficacy of Enhanced Evening Light for Advanced Sleep Phase Syndrome. Behav Sleep Med. 2003;1(4):213-226. doi:10.1207/S15402010BSM0104

6. Suhner AG, Murphy PJ, Campbell SS. Failure of timed bright light exposure to alleviate age-related sleep maintenance insomnia. J Am Geriatr Soc. 2002;50(4):617-623. doi:10.1046/j.1532-5415.2002.50154.x

7. Katsuhisa Ando, Kripke DF, Cole RJ, Elliot JA. Light mask 500 lux treatment for elayed sleep phase syndrome. Prog Neuropsychopharmacol Biol Psychiatry. 1999;23:15-24.

8. Cole RJ, Smith JS, Alcalá YC, Elliott JA, Kripke DF. Bright-light mask treatment of delayed sleep phase syndrome. J Biol Rhythms. 2002;17(1):89-101. doi:10.1177/074873002129002366

9. Danielsson K, Jansson-Fröjmark M, Broman JE, Markström A. Cognitive Behavioral Therapy as an Adjunct Treatment to Light Therapy for Delayed Sleep Phase Disorder in Young Adults: A Randomized Controlled Feasibility Study. Behav Sleep Med. 2016;14(2):212-232. doi:10.1080/15402002.2014.981817

10. Danielsson K, Jansson-Fröjmark M, Broman JE, Markström A. Light Therapy With Scheduled Rise Times in Young Adults With Delayed Sleep Phase Disorder: Therapeutic Outcomes and Possible Predictors. Behav Sleep Med. 2016;16(4):325-336. doi:10.1080/15402002.2016.1210150

11. Esaki Y, Kitajima T, Ito Y, et al. Wearing blue light-blocking glasses in the evening advances circadian rhythms in the patients with delayed sleep phase disorder: An open-label trial. Chronobiol Int. 2016;33(8):1037-1044. doi:10.1080/07420528.2016.1194289

12. Geerdink M, Walbeek TJ, Beersma DGM, Hommes V, Gordijn MCM. Short blue light pulses (30 Min) in the morning support a sleep-advancing protocol in a home setting. J Biol Rhythms. 2016;31(5):483-497. doi:10.1177/0748730416657462

13. Gradisar M, Dohnt H, Gardner G, et al. A Randomized Controlled Trial of Cognitive-Behavior Therapy Plus Bright Light.pdf. Sleep. 2011;34(12):1671-1680. http://dx.doi.org/10.5665/sleep.1432.

14. Lack L, Bramwell T, Wright H, Kemp K. Morning blue light can advance the melatonin rhythm in mild delayed sleep phase syndrome. Sleep Biol Rhythms. 2007;5(1):78-80. doi:10.1111/j.1479-8425.2006.00250.x

15. Lack L, Wright H, Paynter D. The treatment of sleep onset insomnia with bright morning light. Sleep Biol Rhythms. 2007;5(3):173-179. doi:10.1111/j.1479-8425.2007.00272.x

16. Langevin RH, Laurent A, Sauvé Y. Preliminary assessment on the effectiveness of the Luminette® in adolescents with a delayed sleep phase syndrome (DSPS): Randomized single blind placebo-controlled study. Med du Sommeil. 2014;11(2):91-97. doi:10.1016/j.msom.2014.03.003

17. Rosenthal NE, Joseph-vanderpool JR, Levendosky AA, et al. Phase-Shifting Effects of Bright Morning Light as Treatment for Delayed Sleep Phase Syndrome. Sleep. 1990;13(January):354-361.

18. Saxvig IW, Wilhelmsen-Langeland A, Pallesen S, Vedaa Ø, Nordhus IH, Bjorvatn B. A randomized controlled trial with bright light and melatonin for delayed sleep phase disorder: Effects on subjective and objective sleep. Chronobiol Int. 2014;31(1):72-86. doi:10.3109/07420528.2013.823200

19. Wilhelmsen-Langeland A, Saxvig IW, Pallesen S, Vedaa Ø, Nordhus IH, Bjorvatn B. A randomized controlled trial with bright light and melatonin for delayed sleep phase disorder: Effects on subjective and objective sleepiness and cognitive function. J Biol Rhythms. 2013;28(5):306-321. doi:10.3109/07420528.2013.823200

20. Okawa M, Uchiyama M, Ozaki S, Shibui K, Ichikawa H. Circadian rhythm sleep disorders in adolescents: Clinical trials of combined treatments based on chronobiology. Psychiatry Clin Neurosci. 1998;52(5):483-490. doi:10.1046/j.1440-1819.1998.00449.x

21. Yamadera H, Takahashi K, Okawa M. A multicenter study of sleep-wake rhythm disorders: Therapeutic effects of vitamin B12, bright light therapy, chronotherapy and hypnotics. Psychiatry Clin Neurosci. 1996;50:203-209.

22. Yamadera W, Sasaki M, Itoh H, Ozone M, Ushijima S. Clinical features of circadian rhythm sleep disorders in outpatients. Psychiatry Clin Neurosci. 1998;52(3):311-316. doi:10.1046/j.1440-1819.1998.00395.x

23. Ancoli-israel S, Gehrman P, Martin JL, et al. Increased Light Exposure Consolidates Sleep and Strengthens Circadian Rhythms in Severe Alzheimer ' s Disease. Behav Sleep Med. 2003;1(1):22-36. doi:10.1207/S15402010BSM0101

24. Ancoli-Israel S, Martin JL, Gehrman P, et al. Effect of Light on Agitation in Institutionalized Patients With Severe Alzheimer Disease. Am J Geriatr Psychiatry. 2003;11:194–203.

25. Ancoli-Israel S, Martin JL, Kripke DF, Marler M, Klauber MR. Effect of light treatment on sleep and circadian rhythms in demented nursing home patients. J Am Geriatr Soc. 2002;50(2):282-289. doi:10.1046/j.1532-5415.2002.50060.x

26. Burns A, Allen H, Tomenson B, Duignan D, Byrne J. Bright light therapy for agitation in dementia: A randomized controlled trial. Int Psychogeriatrics. 2009;21(4):711-721. doi:10.1017/S1041610209008886

27. Sutherland D, Woodward Y, Byrne J. The use of light therapy to lower agitation in people with dementia. Nurs Times. 2004;100(45):32-34.

28. Calkins M, Szmerekovsky JG, Biddle S. Effect of Increased Time Spent Outdoors on Individuals with Dementia Residing in Nursing Homes. J Hous Elderly. 2007;21(3-4):211-228. doi:10.1300/J081v21n03

29. Chong M, Tan K, Tay L, Wong Y, Ancoli-Israel S. Bright light therapy as part of a multicomponent management program improves sleep and functional outcomes in delirious older hospitalized adults. Clin Interv Aging. 2013;8:565-572. doi:10.2147/CIA.S44926

30. Colenda CC, Cohen W, McCall WV, Rosenquist PB. Phototherapy for Patients with Alzheimer Disease with Disturbed Sleep Patterns: Results of a Community-Based Pilot Study. Alzheimer Dis Assoc Disord. 1997;11(3):175-178.

31. Connell BR, Sanford JA, Lewis D. Therapeutic Effects of an Outdoor Activity Program on Nursing Home Residents with Dementia. J Hous Elderly. 2007;21(3-4):194-209. doi:10.1300/J081v21n03

32. Dowling GA, Hubbard EM, Mastick J, Luxenberg JS, Burr RL, Someren EJW Van. Effect of morning bright light treatment for rest–activity disruption in institutionalized patients with severe Alzheimer's disease. Int Psychogeriatrics. 2005;17(2):221-236. doi:10.1016/j.drugalcdep.2008.02.002.A

33. Dowling GA, Mastick J, Hubbard EM, Luxenberg JS, Burr RL. Effect of timed bright light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease. Int J Geriatr Psychiatry. 2005;20(8):738-743.

34. Dowling GA, Burr RL, Van Someren EJW, et al. Melatonin and bright-light treatment for rest-activity disruption in institutionalized patients with Alzheimer's disease. J Am Geriatr Soc. 2008;56(2):239-246. doi:10.1111/j.1532-5415.2007.01543.x

35. Fetveit A, Skjerve A, Bjorvatn B. Bright light treatment improves sleep in institutionalised elderly - An open trial. Int J Geriatr Psychiatry. 2003;18(6):520-526. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed6&NEWS=N&AN=2003255958.

36. Fetveit A, Bjorvatn B. The effects of bright-light therapy on actigraphical measured sleep last for several weeks post-treatment. A study in a nursing home population. J Sleep Res. 2004;13(2):153-158. doi:10.1111/j.1365-2869.2004.00396.x

37. Fetveit A, Bjorvatn B. Bright-light treatment reduces actigraphic-measured daytime sleep in nursing home patients with dementia: A pilot study. Am J Geriatr Psychiatry. 2005;13(5):420-423. doi:10.1097/00019442-200505000-00012

38. Figueiro MG, Hunter CM, Higgins PA, et al. Tailored lighting intervention for persons with dementia and caregivers living at home. Sleep Heal. 2015;1(4):322-330. doi:10.1016/j.sleh.2015.09.003

39. Fontana Gasio P, Kräuchi K, Cajochen C, et al. Dawn-dusk simulation light therapy of disturbed circadian rest-activity cycles in demented elderly. Exp Gerontol. 2003;38(1-2):207-216. doi:10.1016/S0531-5565(02)00164-X

40. Friedman L, Spira AP, Hernandez B, et al. Brief morning light treatment for sleep/wake disturbances in older memory-impaired individuals and their caregivers. Sleep Med. 2012;13(5):546-549. doi:10.1016/j.sleep.2011.11.013

41. Gibson RH, Gander PH, Dowell AC, Jones LM. Non-pharmacological interventions for managing dementia-related sleep problems within community dwelling pairs: A mixed-method approach. Dementia. 2017;16(8):967-984. doi:10.1177/1471301215625821

42. Ito T, Yamadera H, Ito R, Endo S. [Effects of bright light on cognitive disturbances in Alzheimer-type dementia]. Nippon Ika Daigaku Zasshi. 1999;66(4):229-238.

43. Ito T, Yamadera H, Ito R, Endo S. Effects of bright light on cognitive disturbances in Alzheimer-type dementia. Nippon Ika Daigaku Zasshi. 2000;66(4):229-238. doi:10.1272/jnms.66.229

44. Ito T, Yamadera H, Ito R, Endo S. Effects of vitamin B on bright light on cognitive and 12 sleep–wake rhythm in Alzheimer-type dementia. Psychiatry Clin Neurosci. 2001;55:281–282.

45. Kobayashi R, Fukuda N, Kohsaka M, et al. Effects of bright light at lunchtime on sleep in patients in a geriatric hospital II. Psychiatry Clin Neurosci. 2001;55(3):287-289. doi:10.1046/j.1440-1819.2001.00864.x

46. Koyama E, Matsubara H, Nakano T. Bright light treatment for sleep-wake disturbances in aged individuals with dementia. Psychiatry Clin Neurosci. 1999;53(2):227-229. doi:10.1046/j.1440-1819.1999.00483.x

47. Lyketsos CG, Veiel LL, Baker A, Steele C. A randomized, controlled trial of bright light therapy for agitated behaviors in dementia patients residing in long-term care. Int J Geriatr Psychiatry. 1999;14(7):520-525. doi:10.1002/(SICI)1099-1166(199907)14:7<520::AID-GPS983>3.0.CO;2-M

48. Martin JL, Marler MR, Harker JO, Josephson KR, Alessi C a. A Multicomponent Nonpharmacological Intervention Improves Activity Rhythms Among Nursing Home Residents With Disrupted Sleep / Wake Patterns. J or Gerontol. 2007;62(1):67-72. doi:10.1093/gerona/62.1.67

49. McCurry SM, Gibbons LE, Logsdon RG, Vitiello M V., Teri L. Nighttime Insomnia Treatment and Education for Alzheimer's Disease: A randomized, controlled trial. J Am Geriatr Soc. 2005;53(5):793-802. doi:10.1111/j.1532-5415.2005.53252.x

50. McCurry S, Pike K. Increasing Walking and Bright Light Exposure to Improve Sleep in Community-Dwelling Persons with Alzheimer's Disease: Results of a Randomized, Controlled Trial. J Am Geriatr Soc. 2011;59(8):1393-1402. doi:10.1111/j.1532-5415.2011.03519.x.Increasing

51. Mishima K, Hishikawa Y, Okawa M. Randomized, dim light controlled, crossover test of morning bright light therapy for rest-activity rhythm disorders in patients with vascular dementia and dementia of alzheimer's type. Chronobiol Int. 1998;15(6):647-654. doi:10.3109/07420529808993200

52. Mishima K, Okawa M, Hishikawa Y, Hozumi S, Hori H, Takahashi K. Morning bright light therapy for sleep and behaviour disorders in elderly patients with dementia. Acta Psychiatr Scand. 1994;89:1-7.

53. Nowak L. The effect of timed blue-green light on sleep-wake patterns in womenwith alzheimer's disease. Wayne State Univ. 2008.

54. Nowak L, Davis J. Qualitative analysis of therapeutic light effects on global function in alzheimer's disease. West J Nurs Res. 2011;33(7):933-952. doi:10.1177/0193945910386248

55. Ouslander JG, Connell BR, Bliwise DL, Endeshaw Y, Griffiths P, Schnelle JF. A nonpharmacological intervention to improve sleep in nursing home patients: Results of a controlled clinical trial. J Am Geriatr Soc. 2006;54(1):38-47. doi:10.1111/j.1532-5415.2005.00562.x

56. Satlin A, Volicer L, Ross V, Herz L, Campbell S. Bright Light Treatment of Behvaioural and Sleep Disturbances in Patients with Alzheimers Disease. 1Am J Psychiatry. 1992;149:1028-1032.

57. Sekiguchi H, Iritani S, Fujita K. Bright light therapy for sleep disturbance in dementia is most effective for mild to moderate Alzheimer's type dementia: a case series. Psychogeriatrics. 2017;17(5):275-281. doi:10.1111/psyg.12233

58. Skjerve A, Holsten F, Aarsland D, Bjorvatn B, Nygaard HA, Johansen IM. Improvement in behavioral symptoms and advance of activity acrophase after short-term bright light treatment in severe dementia. Psychiatry Clin Neurosci. 2004;58(4):343-347. doi:10.1111/j.1440-1819.2004.01265.x

59. Sloane PD, Williams CS, Mitchell CM, et al. High-Intensity Environmental Light in Dementia: Effect on Sleep and Activity. J Am Geriatr Soc. 2007;55(10):1524-1533. doi:10.1111/j.1532-5415.2007.01358.x

60. Sloane P, Figueiro M, Cohen L, et al. Effect of home-based light treatment on persons with dementia and their caregivers. Light Res Technol. 2015;47(2):161-176. doi:10.1177/1477153513517255.Effect

61. Van Someren EJ, Kessler A, Mirmiran M, Swaab DF. Indirect Bright Light Improves Circadian Rest-Activity Rhythm Disturbances in Demented Patients. Biol Psychiatry. 1997;41:955-963.

62. Van Someren EJW, Swaab DF, Colenda CC, Cohen W, McCall WV, Rosenquist PB. Bright light therapy: Improved sensitivity to its effects on rest- activity rhythms in Alzheimer patients by application of nonparametric methods. Chronobiol Int. 1999;16(4):505-518. doi:10.3109/07420529908998724

63. Bogen S, Legenbauer T, Gest S, Holtmann M. Lighting the mood of depressed youth: Feasibility and efficacy of a 2 week-placebo controlled bright light treatment for juvenile inpatients. J Affect Disord. 2016;190:450-456. doi:10.1016/j.jad.2015.09.026

64. Bogen S, Legenbauer T, Gest S, Holtmann M. Morning bright light therapy: A helpful tool for reducing comorbid symptoms of aff ective and behavioral dysregulation in juvenile depressed inpatients? A pilot trial. Z Kinder Jugendpsychiatr Psychother. 2017;45(1):34-41. doi:10.1024/1422-4917/a000442

65. Dietzel M, B Saletu, O.M. Lesch, W Sieghart, M Schjerve. Light Treatment in Depressive Illness, Polysomnographic, sychometric and Neuroendocrinological Findings. Eur Neurol. 1986;25(suppl 2):93-103.

66. Esaki Y, Kitajima T, Takeuchi I, et al. Effect of blue-blocking glasses in major depressive disorder with sleep onset insomnia: A randomized, double-blind, placebo-controlled study. Chronobiol Int. 2017;34(6):753-761. doi:10.1080/07420528.2017.1318893

67. Gest S, Legenbauer T, Bogen S, Schulz C, Pniewski B, Holtmann M. Chronotherapeutics: An alternative treatment of juvenile depression. Med Hypotheses. 2014;82(3):346-349. doi:10.1016/j.mehy.2014.01.002

68. Jacobsen FM. Waking in a lighted room. Biol Psychiatry. 1990;27(3):372-374. doi:10.1016/0006-3223(90)90011-P

69. Kragh M, Møller DN, Wihlborg CS, et al. Experiences of wake and light therapy in patients with depression: A qualitative study. Int J Ment Health Nurs. 2017;26(2):170-180. doi:10.1111/inm.12264

70. Kragh M, Martiny K, Videbech P, et al. Wake and light therapy for moderate-to-severe depression – a randomized controlled trial. Acta Psychiatr Scand. 2017;136(6):559-570. doi:10.1111/acps.12741

71. Lieverse R, Van Someren EJ, Nielen MM, Uitdehaag BM, Smit JH, Hoogendijk WJ. Bright light treatment in elderly patients with nonseasonal major. Arch Gen Psychiatry. 2011;68(1):61-70.

72. McEnany GW, Lee KA. Effects of light therapy on sleep, mood, and temperature in women with nonseasonal major depression. Issues Ment Health Nurs. 2005;26(7):781-794. doi:10.1080/01612840591008410

73. Sheaves B, Isham L, Bradley J, et al. Adapted CBT to Stabilize Sleep on Psychiatric Wards: A Transdiagnostic Treatment Approach. Behav Cogn Psychother. 2018;46(6):661-675. doi:10.1017/S1352465817000789

74. Sheaves B, Freeman D, Isham L, et al. Stabilising sleep for patients admitted at acute crisis to a psychiatric hospital (OWLS): Psychol Med. 2017;48:1694-1704.

75. Swanson L, Burgess H, Zollars J, Arnedt J. An Open-Label Pilot Study of a Wearable Home Morning Light Therapy for Postpartum Depression. Arch Womens Ment Health. 2018. doi:https://doi.org/10.1007/s00737-018-0836-z

76. Haynes PL, Kelly M, Warner L, Quan SF, Krakow B, Bootzin RR. Cognitive Behavioral Social Rhythm Group Therapy for Veterans with posttraumatic stress disorder, depression, and sleep disturbance: Results from an open trial. J Affect Disord. 2016;192:234-243. doi:10.1016/j.jad.2015.12.012

77. Avery DH, Eder DN, Bolte MA, et al. Dawn simulation and bright light in the treatment of SAD: A controlled study. Biol Psychiatry. 2001;50(3):205-216. doi:10.1016/S0006-3223(01)01200-8

78. Avery DH, Bolte MA, Ries R. Dawn Simulation Treatment of Abstinent Alcoholics With Winter Depression. J Clin ps. 1998;59(1):35-44. doi:10.4088/JCP.v59n0109

79. Avery DH, Kouri ME, Monaghan K, Bolte MA, Hellekson C, Eder D. Is dawn simulation effective in ameliorating the difficulty awakening in seasonal affective disorder associated with hypersomnia? J Affect Disord. 2002;69:231-236. doi:10.1016/S0165-0327(00)00360-8

80. Avery DH, Bolte MAP, Cohen S, Millet MS. Gradual Versus Rapid Dawn Simulation Treatment of Winter Depression. J Clin Psychiatry. 1992;53:359-363.

81. Ciesielczyk K, Pracka D, Pracki T, Tafil-Klawe M. Changes of sleep quality and mood disorders under the influence of phototherapy on patients with seasonal affective disorders SAD. Psychiatr Pol. 2004;38(6):1105-1114.

82. Meesters Y, Dekker V, Schlangen LJM, Bos EH, Ruiter MJ. Low-intensity blue-enriched white light (750 lux) and standard bright light (10 000 lux) are equally effective in treating SAD. A randomized controlled study. BMC Psychiatry. 2011;11(1):17. doi:10.1186/1471-244X-11-17

83. Partonen T, Appelberg B, Kajaste S, Partinen M, Harma M, Laitinen J. Effects of light treatment on circadian rhytniciety in seasonal affective disorder. 1European Psychiatry. 1992;7:141-142.

84. Rastad C, Wetterberg L, Martin C. Patients' Experience of Winter Depression and Light Room Treatment. Psychiatry J. 2017;2017:1-11. doi:10.1155/2017/6867957

85. Winkler D, Pjrek E, Praschak-Rieder N, et al. Actigraphy in patients with seasonal affective disorder and healthy control subjects treated with light therapy. Biol Psychiatry. 2005;58(4):331-336. doi:10.1016/j.biopsych.2005.01.031

86. Sit DK, McGowan J, Wiltrout C, et al. Adjunctive bright light therapy for bipolar depression: A randomized double-blind placebo-controlled trial. Am J Psychiatry. 2017;175(2):131-139. doi:10.1176/appi.ajp.2017.16101200

87. Barbini B, Benedetti F, Colombo C, et al. Dark therapy for mania: A pilot study. Bipolar Disord. 2005;7(1):98-101. doi:10.1111/j.1399-5618.2004.00166.x

88. Henriksen TE, Skrede S, Fasmer OB, et al. Blue-blocking glasses as additive treatment for mania: A randomized placebo-controlled trial. Bipolar Disord. 2016;18(3):221-232. doi:10.1111/bdi.12390

89. Bromundt V, Wirz-Justice A, Kyburz S, Opwis K, Dammann G, Cajochen C. Circadian sleep-wake cycles, well-being, and light therapy in borderline personality disorder. J Pers Disord. 2013;27(5):680-696. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=22928852.

Figure A1: Duration of Therapy (days)

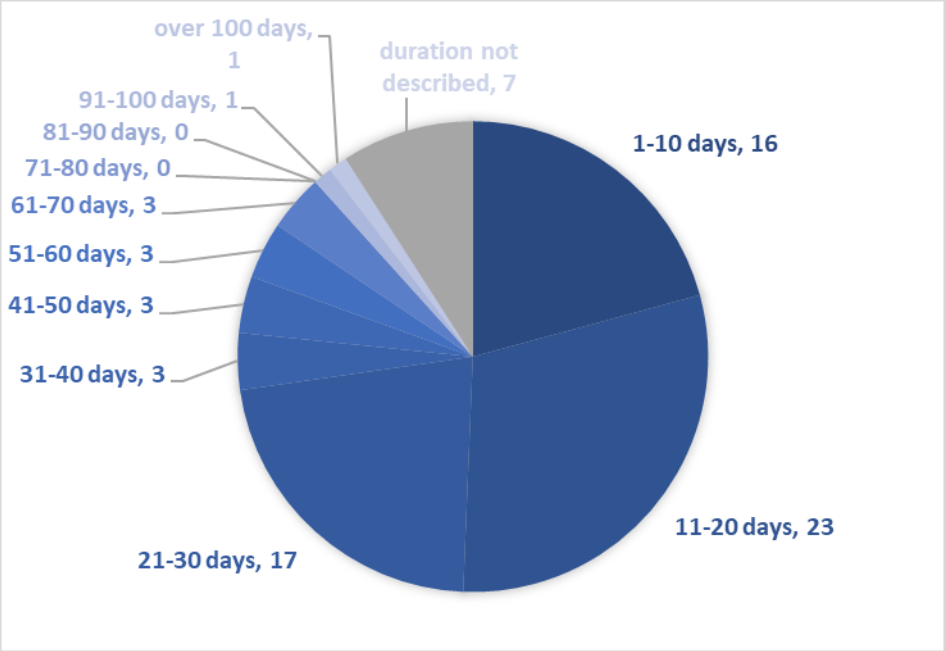


Figure A2: Colour temperatures of light used

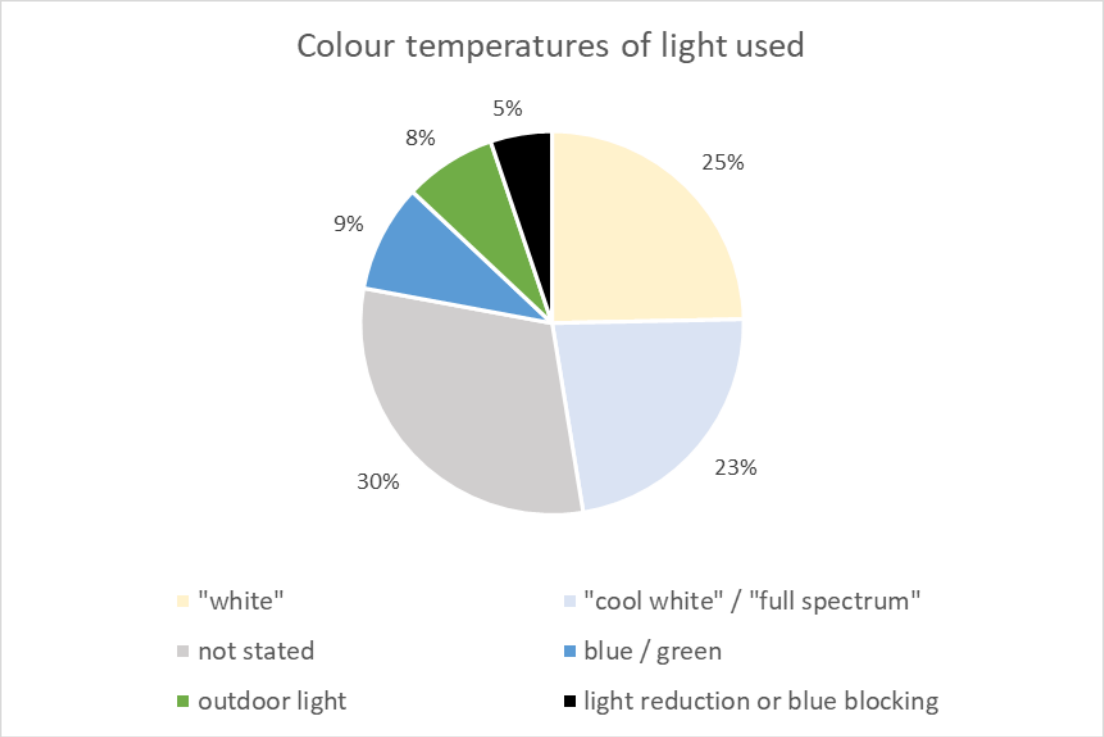


Table A5: Intervention personalisation organised by diagnostic sub-group

n (%)		ASWPD	DSWPD	mixed CRSWD	dementia	depression	SAD	bipolar	other MH*	total
total studies in population		6	12	3	32	8	9	3	4	77
intervention timing:	based on circadian bio-marker	2 (33%)	2 (16%)	0	0	0	0	0	0	4 (5%)
	via sleep phase preference assessment	0	0	0	0	2 (25%)	0	0	1 (25%)	3 (4%)
	based on sleep timing	1 (17%)	7 (58%)	2 (66%)	3 (9%)	2 (25%)	0	0	1 (25%)	17 (22%)
	participant preference	0	0	0	0	1 (13%)	0	0	2 (50%)	4 (5%)
	set time / set time range / staff convenience / not stated	3 (50%)	3 (25%)	1 (33%)	29 (91%)	3 (38%)	9 (100%)	3 (100%)	0	47 (61%)
intervention informed by baseline light exposure		0	0	0	0	0	0	0	0	0
other personalisation		1 (17%)	2 (16%)	1 (33%)	5 (16%)	1 (13%)	0	1 (33%)	2 (50%)	26 (33%)

Table A6: Pre-therapy expectations

Author(s) & Year	Sample & setting	Sleep outcome primary?	Intervention(s)	Dose: Intensity & duration	Control condition	Tool used to measure therapy expectation	expectation ratings, Ix group	expectation ratings, control group
Avery et al 1998	SAD, n=11 at home	secondary (primary outcome mood)	- dawn simulation lamp - set rise time 6am with alarm - darken bedroom, block out light, turn off nightlights - avoid daylight before 8am - avoid daytime direct sunlight (sunglasses)	250 lux, 90 min / day, 7 days	red dawn, 1.5 hr, 2 lux	Clinical global Impression scale = 0-5	3.2 (SD=0.4)	2.7 (SD=0.5)
Avery et al 1992	SAD, n=13, at home	secondary (primary outcome mood)	- gradual dawn (2.5 hrs) VS rapid dawn (over 10 min) - via a light mask, pre-waking - make room dark - avoid other light before 8am - sleep schedule 9pm-6am	275 lux, 2.5 hrs / 10 min day, 7 days	n/a	Clinical global Impression scale = 0-5	gradual dawn: 3.1, (SD=1.1) rapid dawn 3.1, (SD=0.9)	n/a
Cole et al 2002	DSWPD, n=54 at home	primary	- bright-dawn simulation mask - advance sleep timing - avoid naps - gradual rise time advance - avoid evening light	2700 lux, ? / day, 26 days	dim red light mask, gradual rise time advance	10cm visual analogue scale ratings (0-100) [converted to 0-5 scale]	67.04 (SD=17.56) [3.352 (SD=0.878)]	62.08 (SD=16.93) [3.1 (SD= 0.8465)]
Sit et al 2017	bipolar depression, n=46 at home	secondary (primary outcome mood)	- mid-day light box; titrated from 15 min to 60 min per day - adherence monitoring via machine	7,000 lux, 1 hr / day, 42 days	red light box(50 lux)	Expectations for degrees of improvement, categories	'minor […]' = 8 'moderate […]' = 12 'major […]' = 2 'full […]' = 1	'minor […]' = 5, 'moderate […]' = 11, 'major […]' = 5, 'full […]' = 2
Yamadera et al 1996	CRSWD n=116 at home	primary	- vitamin B12 - bright light therapy soon after waking - chronotherapy (phase delay chronotherapy) - hypnotics ("in that order as required, or sometimes in another order (e.g., BLT only)")	2500-3000 lux, hrs / day, duration in days not stated	n/a	Expectations for degrees of improvement, categories	'moderate / high expectation' = 43% 'low' = 4%	n/a (no control group)

Table A7: Acceptability and therapy satisfaction data

study	population	intervention	satisfaction & acceptability ratings:	Intervention condition:	Control condition:
Henriksen et al 2016	bipolar mania n=19	amber glasses 6pm till bed	using the glasses was comfortable using the glasses was irritating important to have different models to choose from participating was a positive experience would use again in future if proven Likert scale converted to % (95% CI)	80 (62.5-97.5) 20 (0-40) 81.25 (57.5-105) 92.5 (77.5-105) 92.5 (72.5-110)	65 (45-85) 50 (22.5-77.5) 60 (35.5-87.5) 85 (62.5-107.5) 77.5 (52.5-102.5)
Palmer et al 2003	ASWPD n=47	evening light box	enjoyed treatment (0=very much) ease of use (0=very easy) wish to continue (0=will continue) would recommend (0=will recommend) was helpful (0=very helpful) light was too bright (0=much too bright) 0-100 scale, mean (SD) - Reports the 'majority" kept the device and continued to use after the study.	20.82 (21.48) 5.74 (6.56) 14.86 (22.67) 18.23 (24.67) 36.57 (29.88) 38.87 (23.59) no figure given	36.90 (22.40) 15.30 (17.09) 41.95 (34.83) 50.43 (32.69) 55.90 (35.69) 57.23 (26.36)
Sheaves et al 2018	mixed acute mental health inpatients n=20 (intervention group only)	morning light (outdoor light or light box) reduce evening light - as part of adapted CBT-i	very satisfied mostly satisfied did not return satisfaction questionnaire	45% 35% 20%	n/a
Kragh et al 2017	depression n=9 (qualitative sub-study)	morning light box wake therapy (total sleep deprivation), in a lit area	would resume in future would recommend to others Several bought a lamp. One stopped treatment, relapsed and then resumed. Non-pharmacological nature of intervention made it attractive, seen as natural. Time requirement (30 min) could be positive (quiet start to the morning), or annoying. Advice to avoid TV and electronics light before bed was described as helpful.	88% 100% qualitative data	n/a
Rastad 2017	SAD n=18	light room, white room with shaded fluorescent tubes, in groups as outpatients	A calming and relaxing experience. Positive treatment effects described as quite dramatic and transformative, increased energy, mood and thinking, improved sleep and daytime rhythms. Wish to continue. Physical environment is important. Treatment is time-consuming (due to travel to clinic). Effects are short lived so much continue treatment.	qualitative data	n/a

Table A8: Attrition by study in intervention and control groups

Author(s) & Year	Sample	Intervention(s)	Dose (Intensity, duration - session / days)	Control condition	Ix (n)	Cx (n)	attrition % Ix	attrition Ix (n)	attrition % Cx	attrition Cx (n)
Cole et al 2002	DSWPD, n=54	bright-dawn simulation mask, rise time advance	2700 lux, 3.5 hrs / day, 26 days	dim red light mask, rise time advance	29	30	3%	1	13%	4
Kragh et al 2017	Depression, n=64	morning light box, wake therapy	10,000 lux, 30 min / day, 63 days	TAU (medication, exercise, talking therapies)	32	32	31%	10	44%	14
Nowak et al 2008	Dementia, n=20	blue green light cap visor	12,000 lux, 30 min / day, 14 days	dim red light cap visor	10	10	0%	0	10%	1
Avery 2001a	SAD with hypersomnia, n=33	BLT VS dawn simulation VS control	1.5 hrs (250 lux) or 30 min (10,000 lux) day, 6 weeks	dim red dawn signal	56	27	4%	2	0%	0
Bogen et al 2016	Depression, n=57	morning light box	10,000 lux, 45 min / day, 14 days	dim light (100–150 lux)	30	27	7%	2	19%	5
Esaki et al 2017	Depression (+sleep), n=20	evening amber glasses	(light blocking), ~3 hr / day, 14 days	clear glasses	10	10	10%	1	20%	2
Lieverse et al 2011	Depression, n=89	morning light box	7500 lux, 1 hr / day, 21 days	red light (50 lux)	42	47	2%	1	4%	2

Sit et al 2017	Other MH – bipolar depression, n=46	mid-day light box	7,000 lux, 1 hr / day, 42 days	red light box (50 lux)	23	23	4%	1	30%	7
Sloane et al 2007	Dementia, n=60	indoor light (am, pm or all day)	~2500 lux, 4 hrs / day or 14 hrs / day, 21 days	standard indoor light (~>500 lux)	45	46	0%	0	0%	0
Sheaves et al 2018	Other MH – mixed acute inpatients (+sleep), n=40	morning light box / natural light, adapted CBT-I	10,000 lux or outdoor light, 30 min+ / day, 14 days	TAU	20	20	0%	0	0%	0
Barbini et al 2005	Other MH – bipolar mania, n=32	enforced darkness 6pm-8am	(darkness), 2 hrs / day, 3 days	TAU, drug therapy alone	16	16	0%	0	0%	0
Campbell et al 1993	ASWPD, n=16	evening light box	4000 lux, 2 hrs / day, 12 days	dim light box	8	8	0%	0	0%	0
Gradisar et al 2011	DSWPD, n=40	light box on awakening, advance wake time, CBT-i	1000 lux, 30in / day, 56 days	wait list control	23	17	13%	3	35%	6
Mishima et al 1998	Dementia (+sleep), n=22	light box 9-11am	5000-8000 lux, 2 hrs / day, 14 days	dim light (300 lux)	22	23	0%	0	0%	0
							mean % (SD): 5% (8%)		mean % (SD): 13% (14%)	

Table A9: Studies reporting adherence, and levels of adherence reported, grouped by approach to adherence management

predominant approach to adherence management:	**% of session (mean)**		**% of participants 'adherent'**			
	studies using this approach reporting adherence	%	studies using this approach reporting adherence	%	**Studies reporting either**	average % of both
enforced	0 of 3		0 of 3		0 of 3	
environmental	0 of 7		0 of 7		0 of 7	
instruction	2 of 20	96%	3 of 20	93%	4 of 20	93%
explanation / education	2 of 10	85%	3 of 10	75%	4 of 10	74%
reminders	0 of 2		1 of 2	93%	1 of 2	93%
self-report log	0 of 3		0 of 3		0 of 3	
supervision	9 of 21	87%	7 of 21	94%	12 of 21	88%
time stamp remote monitoring	1 of 4	98%	2 of 4	94%	3 of 4	96%
across all studies:	14 of 78	89%	16 of 78	90%	24 of 78	88%

Table A10: Studies using various approaches to adherence management, by population

approach used to encourage / ensure adherence:	**studies using approach:**							
	total (of 77)		**in CRSWD (of 21)**		**in dementia (of 32)**		**in mental health conditions (of 25)**	
supervision	24	31%	1	5%	17	53%	6	24%
enforcement	3	4%	0	0%	2	6%	1	4%
instruction only	20	26%	9	43%	0	0%	11	44%
explanation / education	13	17%	6	29%	4	13%	3	12%
incentive	2	3%	2	10%	0	0%	0	0%
reminders	4	5%	2	10%	1	3%	1	4%
environmental (no action required by participant)	8	10%	1	5%	6	19%	1	4%
self-report log	3	4%	2	10%	0	0%	1	4%
time-stamp machine / remote adherence monitoring	4	5%	2	10%	0	0%	2	8%
approach to adherence not described	7	9%	0	0%	5	15%	2	8%

Table A11: Adverse effects by population and intervention

adverse effect	populations in which occurred	interventions in which occurred	colour temperature of light (where described)
headache	DSWPD x2 SAD x3 bipolar x1 depression x2 postpartum depression x1	morning light box / lamp x7 evening amber glasses x1 dawn simulation x2 morning light therapy glasses x1	natural light x1 white x3 blue-blocker (amber lenses) x2
tiredness	SAD x1, depression x1	morning light box / lamp x2	white x2
difficulty sleeping	SAD x2	morning light box / lamp x2 dawn simulation x1	white x1
restlessness / agitation / irritability	depression x1 dementia x1 postpartum depression x1	morning light box x2 morning light therapy glasses x1	white x2
hypomania	depression x2 SAD x1	morning light box / lamp x2	white x1
'eye-strain' / discomfort	DSWPD x1 SAD x1 dementia x1 depression x2	morning light box / lamp x2 morning light therapy glasses x2 evening amber glasses x1	white x3 blue x2
early awakening	DSWPD x1 SAD x4	dawn simulation visor x1 dawn simulation x4	white x2 blue x1
depression	bipolar x2 depression x1	evening amber glasses x2 morning light box / lamp x1	blue x1 blue-blocker (amber lenses) x2
mechanical discomfort from glasses / visor	DPSD x1 dementia x1 depression x1	bright dawn visor x1 morning LED mounted spectacles x2	not relevant
adverse effects from sleep schedule (not light itself)	DPSD x3	morning light box / lamp x2 morning light therapy glasses x2	not relevant
other	Orthostatic hypotension, anxiety. Disappointment when results were not better. Sensitivity. Concentration. Memory difficulties. Experience of light therapy brought bad memories. Nausea. Felt overexcited. Normal sleeping partner woken up by light. Sleepiness (only in placebo group).		

Table A12: Numbers of participants reporting side effects in those studies reporting this

Author(s) & Year / side effect reported	mechanical discomfort from glasses / visor	headache	tiredness	difficulty sleeping	restlessness / agitation / irritability	hypomania	eye-strain' / discomfort from the light manipulation itself	early awakening	depression
Henriksen et al 2016		1							2
Kragh et al 2017		51	35		34	1			
Burns et al 2009									
Nowak et al 2008	1								
Avery 2001a		1		1				1	
Avery 1992		1				1		1	
Danielsson 2016a		2							
Gest 2016		2							
Skjerve (2004)b					1				
Swanson (2018)		5			4		2		
Avery et al 1998								5	
Bogen et al 2016		20							
Esaki et al 2017	7						1		
Lieverse et al 2011									2
Lyketsos et al 1999					5				
TOTAL (n):	8	83	35	1	44	2	3	7	4
% of 505 (total n in these studies)	1.6%	16.4 %	6.9%	0.2%	8.7%	0.4%	0.6%	1.4%	0.8%

Table A13: Studies reporting headache

Author(s) & Year	Sample	Intervention(s)	assessed using a checklist?	n / % reporting headache	severe headache, or ceased due to headache (n / %)
Henriksen et al 2016	Other MH – bipolar mania, n=19	Amber glasses from 6pm	no	1 / 5.3%	0 / 0%
Kragh et al 2017	Depression, n=64 (n=9 interviews)	Morning light box, wake therapy (total sleep deprivation), in a lighted area	yes	0 / 80%	0 / 0%
Avery et al 2001a	SAD with hypersomnia, n=33	BLT VS dawn simulation VS control , set rise time 6:00-6:30	no	1 / 3%	1 / 3%
Avery et al 1992	SAD, n=13	Gradual dawn (2.5 hrs) VS rapid dawn (over 10 min), via a light mask, pre-waking, avoid light at night	no	1 / 7.7%	1 / 7.7%
Danielsson et al 2016a	DSWPD, 16-26 years old, n=36	Morning bright light energy lamp, with or without CBTi	no	2 / 5.5%	2 / 5.5%
Gest et al 2016	Depression, aged 13-18, n=62	Morning bright light treatment (between 8am and 10am), via light box	no	2 / 3.2%	0 / 0%
Swanson et al 2018	post-partum depression, n=9	Blue green light therapy glasses after waking	yes	5 / 56%	1 / 11%
Bogen et al 2016	Depression, n=57	Morning light box	yes	17 / 30%	1 / 1.8%

Appendix 5: Supplements to Study C - "A mixed methods expert opinion study on the optimal content and format for an occupational therapy intervention to improve sleep in schizophrenia spectrum disorders."

S1 Supporting Information. Data to support findings presented.

Qualitative data excerpts and graphed results of multiple choice and Likert responses,

organised by topics and themes

Notes to the reader:

The number of participants voicing the qualitative content represents how many specifically expressed this at least once. In some cases participants were asked their view on this topic by the survey or during discussion, and in some cases they brought up this topic themselves. Participants not counted among those expressing any given view does not necessarily mean they did not hold this view but that they did not explicitly express this in their qualitative data. Where for a thematic code a group is listed as 'n/a', this reflects that this group was not asked about this topic and / or that their responses were not coded regarding this topic.

Apparently opposing views listed below are not always mutually exclusive, often participants did express both views, and this content was coded and counted thus. In many such cases participants acknowledged a tension and a balance to be struck.

This content is presented in roughly the order of the findings in the manuscript, however, it is noted that there are of course some overlaps and links between themes. Quantitative data summaries on the same or related topics and questions are inserted throughout.

Overview of topic areas and themes:

1. INTERVENTION TARGETS AND SCOPE

Sleep problems and sleep interferers

- Sleep effort and frustration
- Worry, rumination, stress and anxiety
- Psychotic symptoms
- Fear of the dark
- Fear of silence
- Fear of the bed
- Fear of sleep
- Long sleep
- Difficulty rising & sleep inertia
- Physical illness / physical symptoms

How far to address 'other' sleep disorders

- Screen for sleep disordered breathing (SDB) and parasomnias
- Nightmares
- Assess nightmares
- Directly address nightmares specifically
- Nightmares may improve through treating sleep
- Refer on regarding nightmares

Stability

- How well or stable would clients need to be to benefit?
- Stability of social situation important
- Stability of medication important
- Concerns about exclusions

Transdiagnostic intervention?

- The intervention should be applied transdiagnostically
- The intervention should focus exclusively on people with a schizophrenia spectrum diagnosis within this study as they are harder to reach

2. THE ASSESSMENT

Format & manner of assessment

- Use an interview
- Use checklists and / or standardised questionnaires
- Rapport in assessment

Prioritisation of areas to assess

Longitudinal self-report of sleep & activity (activity & sleep diary)

- Sleep diary
- Activity diary
- Diary burden & difficulties
- Completing diaries as an intervention
- Format options, prompts and support
- Possibility of using an app

Passive monitoring within the assessment

Self-report and passive monitoring results will differ (useful to compare / need both)
Passive monitoring as an intervention

Measurement of light exposure

Measurement or self-reporting of light exposure at baseline and during intervention

3. INTERVENTION COMPONENTS

Sleep schedule

Address sleep schedule regularity
Regular rise time
Regular bedtime
Allowable flexibility in sleep schedule
Need to fit sleep in with life
It might be OK to be nocturnal
Gradual approach to sleep timing changes
Stabilise timing first before changing times
Support to change sleep times

Time in Bed restriction

Advocating Sleep Restriction Therapy (SRT)
Be cautious with SRT
SRT could trigger mania / psychosis
Do not use SRT
Use sleep compression instead of SRT
Not keen to try reducing time in bed
Already reduce time in bed, & advocate it

Napping

Allow napping
Avoid napping
Evaluate naps
Nap duration
Nap timing
Replace naps with activities
Schedule naps

Stimulus control, and managing awakenings

Avoid non-sleep activities in bed / bedroom
Use 'the 15-minute rule' or similar
Bad experience using 'the 15-minute rule' as self-help advice
Address activities to do if you awaken in the night
Provide education on awakenings being normal

Morning routine

Address type of activities
Use of alarms
Dawn simulator alarms
Education on sleep inertia
Experience of struggle with waking

Evening routine

Evening wind-down activities, lower stimulus
Preparation for bed before wind-down
Prepare for the next day - if relevant
Support to find suitable activities
Get ready for bed alarm

Daytime activity

Increasing amount of activity
Address activity type
Address activity timing
Scheduling activities
Routines and habit formation
Meaning, satisfaction and enjoyment
Support to find and plan activities

Addressing medications

Consider side effects
Addressing timing of prescribed medications

Addressing food and drink

Consider food and drink timing
Address avoiding late eating
Address skills and / or routines around meals
Night eating
Consider food and drink content

Addressing substance use

Substance use
Alcohol
Caffeine
Nicotine

Light Exposure

Modifying light exposure
Timing of modifications to light
Morning light exposure
Daytime light exposure
Increasing evening light
Reducing evening light exposure
Reducing light at night
Method to modify light
Light box
Light visor
Blue-blockers / amber glasses
Modifying light in the home & bedroom
Using outdoor light / natural light
Season is important
Embedding light in activity / occupation
Education regarding light, circadian rhythm and mood
Low expectation of efficacy regarding light
Acute alerting effects of light

Environmental assessment and intervention

Home environment
Bed or sleeping surface
Bedroom / bed not for non-sleep activities
Having other useable rooms
Noise in the bedroom
Temperature in the bedroom
Air quality
Sensory factors
Pets in the bedroom
Home environment intervention
Feeling safe in the home
Social environment & context
Social environment in the home
Support from friends, family and carers
Social commitments
Peer support
Loneliness
Cultural factors

Relaxation and / or mindfulness

Relaxation techniques
Breathing techniques
Mindfulness meditation

Thermoregulation

Addressing sensory factors

Cognitive or psychological approaches

Cognitive or psychological approaches
Psychological approaches better dealt with by psychological therapist

4. PERSONALISATION

The goals of the intervention should be individually determined
The methods of intervention should be personalised
Limits to personalisation

5. FORMAT, STRUCTURE AND PRAGMATIC CONSIDERATIONS

Personalisation and complexity vs simplicity to deliver

Personalisation
Keep it simple

Format of intervention and assessment materials

Format options & literacy
Use of technology in delivery of the intervention

Core vs optional components

Core vs optional components

Order of delivery

Order of delivery

Follow-up and ending of therapy

Maintenance plan
Follow-up / tapering of ending

6. THERAPEUTIC APPROACH AND THERAPIST FACTORS

Therapeutic approach, therapist attitude & manner

An educational approach
Education re: normal sleep
Normalising
Experimentation
Benefits of change, motivational interviewing approach
Therapeutic rapport & listening
Rapport required before home assessment

Therapist knowledge, skills & confidence

Therapist confidence in delivering the intervention
Relationship to OT role & skills
Generic working barrier to OT interventions

7. IMPLEMENTATION CONSIDERATIONS

Reaching referrals

Reaching referrals

MDT approach within intervention

MDT knowledge & attitude
MDT approach to intervention
MDT approach to medication
MDT approach to maintenance

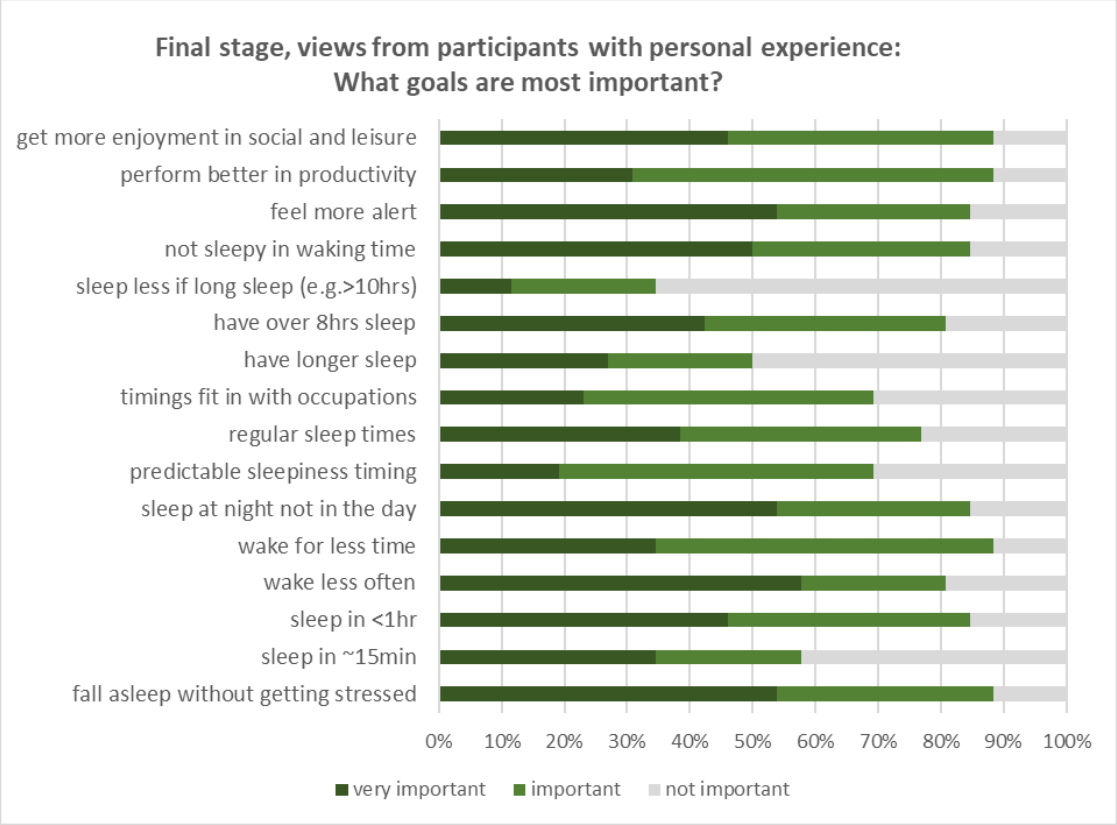
1. Intervention targets and scope

Sleep problems and sleep interferers

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Sleep effort and frustration	"It doesn't work. In fact, it makes it worse and then you get angry." (personal experience) "you think, I've got something to do tomorrow just sleep, you are forcing yourself to sleep and then you can't sleep then. I have that." (personal experience) "if I was to say, go and read a book for 15 minutes or just listen to some music, it just wakes me up completely. Whereas like I can still get a couple of hours sleep by staying there and I like "go to sleep, go to sleep"." (personal experience) "try and lie still" (personal experience) "…the more we focus on it the more we get worked up" (sleep OT clinician) "…when I asked them how they utilise relaxation, it is clear that the use as a bludgeon to try to knock themselves into unconsciousness. […] So we need to drop all of that it's a therapy of learning to let go and give up." (CBTi therapist)	10 (18%)	4 (15%)
	A minority of people with personal experience described sleep effort and frustration, with some passion. One person, however, explicitly described sleep effort being potentially effective, whilst others described similar sentiments around 'just lie still' and advocating staying in bed for long periods even if not asleep. Professionals varied in their focus on reducing sleep effort, with it being referred to as central by some and not explicitly mentioned by others.		
Worry, rumination, stress and anxiety	"No, you just lay there going through the day and just everything just swirls around in your head." (personal experience) "I know that I'm going to have nightmares, and then obviously your thoughts start racing thinking about it" (personal experience) "Clear mind at night don't over think." (personal experience) "No amount of tinkering with the environment will help if the individual's sleep is disrupted by worry. This has to be addressed if it is an issue" (OT CBTi therapist) "Treating rumination [suggested component]" (psychiatrist) "Not in-depth, unless the primary cause of insomnia is rumination, in which case why not refer to a specialist." (MH OT)	23 (41%)	18 (69%)
	People with personal experience described worry and rumination both about sleep or unrelated to sleep, both as a cause of sleep disruption and as what happens if they cannot sleep. Professionals gave varied amounts of focus to addressing worry, usually acknowledging its impact, but varying regarding to what extent they felt addressing this directly should be within the scope of this intervention (discussed below).		

Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
		This links to the discussions (below) of whether and when are psychological aspects better referred to a psychological therapist.		
Psychotic symptoms		"relationship between nightmares and delusions. Determine they are really nightmares not merely delusions" (sleep OT) "… because of the negative symptoms, and just being in the sick role, losing that structure to the day, that's why they have become bad sleepers and that's quite difficult [to work with]" (MH OT) "[voices] that's what keeps me up some nights." (personal experience)	11 (20%)	4 (15%)
Sleep-related fears	Fear of the dark	"Some patients may sleep better if there is some light if it makes them feel safe." (sleep specialist psychiatrist) "like dark bedroom, many pts are afraid in the night and have the lights on so try to help them with that." (circadian rhythm & MH clinician researcher) "Yeah, I still go to sleep in the pitch black. […] Which is stupid because I'm scared of the dark." (personal experience)	2 (4%)	2 (8%)
	Fear of silence	"I listen to the radio in mine. I never switch it off. […] Well, I'm afraid of the silence, you know [inaudible]. In a way it's a distraction" (personal experience)	1 (2%)	1 (4%)
	Fear of the bed	"scared to go to sleep in their bed as they had associated it with voices" (sleep & MH researcher)	5 (9%)	0 (0%)
	Fear of sleep	"People who have nightmares can often get to dread sleep (as might someone with sleep terrors)." (sleep OT) "fear of sleeping due to paranoid delusions an issue in some, but not many, patients." (sleep specialist psychiatrist)	3 (5%)	0 (0%)
Oversleeping	Long sleep.	"I have experience of clients sleeping 12-16 hours on these medications [Olanzapine and Clozapine]." (psychiatrist) "you might get people feeling they need 11hrs but then that might be because it is such poor quality." (MH sleep researcher) "so that's a whole work week extra you are spending on sleeping that you could be spending on something else" (psychiatrist) "Sometimes I sleep like 15 hours if nobody wakes me […] It really worries him that I've actually passed away in my sleep" (personal experience)	27 (48%)	4 (15%)
	Difficulty rising & sleep inertia	"even if you get them up and standing, they will have any recollection of what happened to them though being a trancelike state" (CBTi therapist) "I would be worried about the morning part […] Because I struggle to wake up […] even for alarms and stuff." (personal experience)	21 (38%)	8 (31%)
		People with personal experience described worry and rumination both about sleep or unrelated to sleep, both as a cause of sleep disruption and as what happens if they cannot sleep. Professionals gave varied amounts of focus to addressing worry, usually		

Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
		acknowledging its impact, but varying regarding to what extent they felt addressing this directly should be within the scope of this intervention (discussed below). This links to the discussions (below) of whether and when psychological aspects are better referred to a psychological therapist.		
Physical illness / physical symptoms effect on sleep		"physical setup of the mattress, pillows etc pertaining to physical injuries/pain or biomechanical support needs to improve comfort." (sleep OT) "menopause, hot flashes…" (sleep OT) "what keeps you awake? […] If it's worries it's worries, if it's pain it's pain." (sleep specialist psychiatrist) " [naps] Very dependent on individual's situation/needs/co-morbidities/medication" (sleep OT)	12 (21%)	4 (15%)



Please note the above are shortenings of how the questions were phrased.

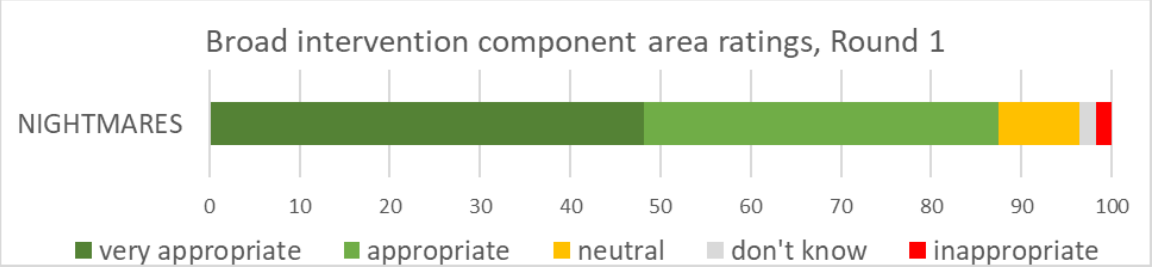
Falling asleep without getting stressed was highly endorsed, which relates well to comments made about worry and rumination. Other priorities which were most highly endorsed relate a lot to daytime functioning (first 4 listed, plus 'sleep in the night not in the day). These were followed by priorities around sleep maintenance. Sleeping within less than 15 minutes was by no means a universal priority.

Only limited time was devoted to the topic of what aspects of sleep were a priority to treat as previous work has explored this .

How far to address 'other' sleep disorders

Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
Screen for sleep disordered breathing (SDB) and parasomnias		"OSA/PLMD/RLS/parasomnia, the practitioner should have a basic understanding of these conditions, and be able to screen for them, and refer on if likely to be a problem" (sleep & MH researcher)	21 (38%)	1 (3%)
		Participants suggested screening for SDB and parasomnias in round 1, and it was accepted as consensus by round 2. We did not ask in the Nominal Group Technique stage / final stage (participants with personal experience) if we should screen for these but one person brought it up.		
Nightmares	Assess nightmares	"how often these occur and how distressing they are" (MH OT)	37 (66%)	0 (0%)
	Directly address nightmares specifically	"self-soothing techniques to address emotional dysregulation following nightmares" (sleep OT clinician) "Education on how you should not hold off your sleep in fear of having a nightmare as this can increase the likelihood that you experience a nightmare when falling asleep (REM rebound)" (OT CBTi therapist) "strategies for dealing with nightmares - e.g., rescripting, grounding" (MH & sleep clinical academic)	16 (28%)	0 (0%)
	Nightmares may improve through treating sleep	"Our CBTi […] resulted in decreased nightmares without specific "rescripting" interventions." (OT CBTi therapist)	6 (11%)	0 (0%)
	Refer on regarding nightmares	"Access to a clinician specialised in treating trauma" (MH & sleep clinical academic) "I feel they should be treated differently and receive something special for dealing with nightmares." (circadian rhythm researcher) "I don't get into dream content. […] Yes I don't feel comfortable doing that." (sleep OT clinician)	13 (23%)	0 (0%)
		There was a consensus to assess regarding nightmares, with some variation regarding importance and time to devote to this. Where it came to directly addressing nightmares, some suggested education, or developing strategies similar to for how to manage awakenings for other reasons, when rated in round 2 this was rated mostly as important or very important.. Some suggested use of specific nightmare interventions such as imagery rehearsal. Some felt this could be delivered by the		

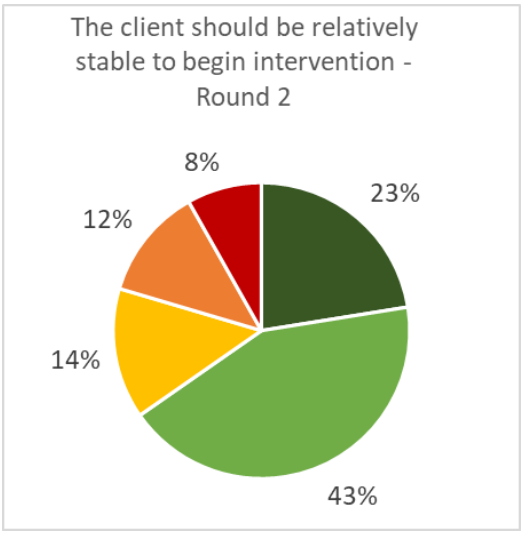
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	therapist, and some suggested referral onward. The possibility of trauma and increased suicidal risk were mentioned in relation to nightmares.		

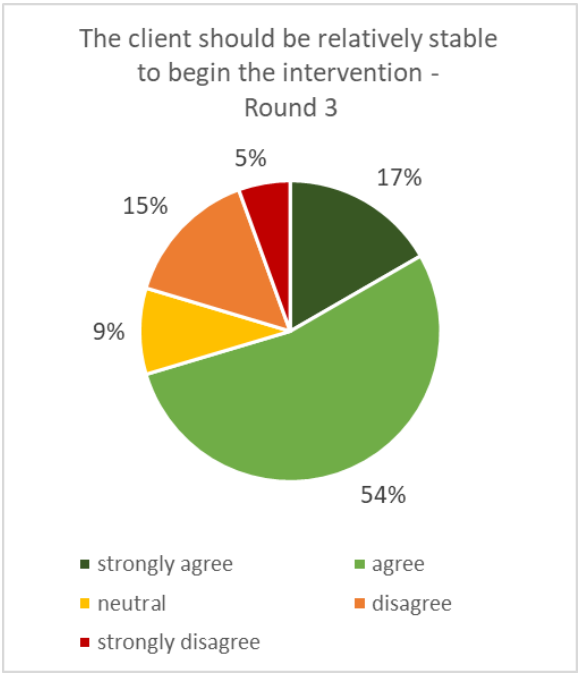


Stability

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
How well or stable would clients need to be to benefit?	"Mental health needs to be settled (non-acute) at the time the patient enters the programme" (sleep OT clinician) "[Too unwell would be] Too thought disordered to understand the purpose of the intervention or the instructions." (sleep specialist psychiatrist) "A lot of people who have high levels of residual symptoms are perfectly capable of understanding…" (sleep & MH researcher) "If they are unable to attend to conversation with clinician, retain information and implement suggested interventions" (sleep OT clinician) "…"acutely unwell" suggests the patient has been better relatively recently, and is likely to become less symptomatic in the near future, so this would suggest there would be a better time to offer the therapy." (psychiatrist) "[With severely ill patient] then I would suggest the simple … like starting with light, and dark bedroom is a simple thing." (sleep specialist psychiatrist)	48 (86%)	n/a
	A few participants who did not work in specialist mental health settings suggested the patient should be completely 'well' in other respects before sleep treatment commenced, however, the predominant view was to keep any such threshold low. Factors which would present too much of a barrier were around the ability to attend to and take in information and carry out recommendations, as well as regarding suicidal risk and risk to others.		

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	It was noted that those who were more acutely unwell might benefit from environmental interventions, or more intensively supported behavioural interventions, but that this might be better as a separate intervention.		
Stability of social situation important	"If the person is in very temporary accommodation or sleeping on a friends' couch or something temporary, it would be better to start the intervention when they are in more stable accommodation" (sleep OT clinician)	5 (9%)	n/a
Stability of medication important	"…change of anti-psychotic medication, it would be desirable for this to be done before the start of treatment" (sleep & MH clinical academic)	6 (11%)	n/a
Concerns about exclusions	"I think if the person has issues with sleep and wants to engage they should have the opportunity to." (MH OT) "…a sleep intervention could actually be a positive step in starting their recovery." (sleep & MH researcher)	4 (7%)	n/a
	Professionals were prompted to describe concerns with having exclusion criteria around stability or wellness but few were described. What was said links to suggestions above of potential for a separate intervention designed for during acute illness.		





Agreement converged toward 'agree', away from strongly disagree, and with fewer participants expressing 'neutral' opinion. This combined with the qualitative data suggests participants

converged toward a view that there were some aspects or degree of stability that were required to make this kind of intervention practicable, but that it could be applied fairly broadly.

Transdiagnostic intervention?

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
The intervention should be applied transdiagnostically	"Similar considerations would be relevant for various groups" (sleep researcher) "It is a bit "medical-model" to focus on the diagnosis itself, though I understand that the interventions should be tailored based on research to specific situations" (sleep OT clinician)	35 (62%)	n/a
	Participants raised that the intervention would be relevant transdiagnostically, so despite that our initial aim was to develop it for people with schizophrenia spectrum disorder diagnoses, we decided to ask participants in round 3 about this.		
The intervention should focus exclusively on people with a schizophrenia spectrum diagnosis within this study as they are harder to reach	"Very relevant. And perhaps easier to implement - as someone also working specifically in sleep-psychosis, I can't help feeling that sz is the tougher end of the spectrum in which to initiate change.. But that of course doesn't mean that we should be trying." (sleep specialist psychiatrist) "I think you'll have a much higher referral rate, if its non-schizophrenic, purely because practitioners will be weighing up whether they can participate and would want to… […] I've had quite a lot of people come round researching schizophrenia, and I've not been able to give them very many [referrals] …as a group of people, male especially, they tend to be less 'on' for participating in research than maybe some other groups of people." (MH OT) "My understanding is that the format of this intervention is designed to be more user-friendly and accessible to those with schizophrenia spectrum disorders, and those of other diagnoses could benefit greatly from this opportunity also." (sleep & MH researcher)	14 (25%)	n/a
	Participants saw many advantages and arguments for applying the intervention transdiagnostically, yet we stuck with testing the intervention in our narrower population. The researchers and PPI contributors and some participants felt that this group were more underserved in terms of sleep intervention, and might be harder to reach, thus we decided to maintain exclusive focus on this group in the feasibility study.		

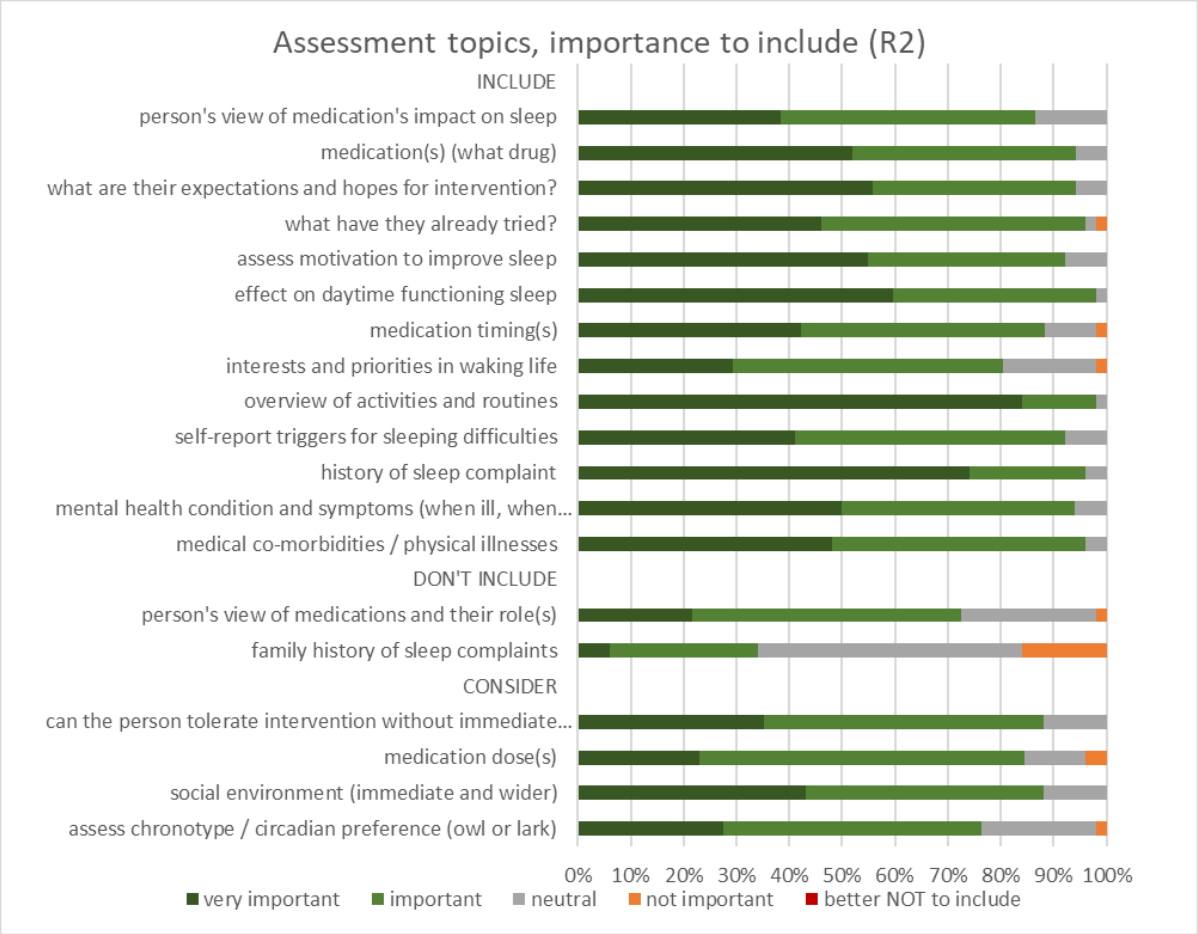
2. The Assessment

Format & manner of assessment

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Use an interview	"patient perspective is key" "Patient views" "A few open questions to start […][then] need to ask very detailed specific questions" "Detailed and skilled sleep history is the cornerstone of assessment."	27 (48%)	n/a
Use checklists and / or standardised questionnaires	"SDS-CL-25" "e.g., PSQI, ESS" "Brief screen for other sleep disorders eg Wilson et al would be realistic" "OCAIRS" "Interest checklist may be used." "social rhythm metric" "DBAS" "develop a sleep OT assessment kit" "Horne Ostberg Morningness-Eveningness Questionnaire"	31 (55%)	n/a
	Various validated sleep and occupation measures were suggested, and non-validated checklists. There was no indication of anyone suggesting this was instead of interviewing.		
Rapport in assessment	"Behaviour change is hard and there is nothing as critical as an effective therapeutic relationship/rapport." (sleep OT CBTi practitioner) "listening to what is on the client's mind - it may take time" "must emphasize good connection/good relation with the patient" (sleep specialist psychiatrist) "I don't like strangers so interaction in the community first would be necessary" (personal experience) "Home assessment would make me feel invaded." (personal experience)	5 (9%)	6 (23%)
	Some specifically advised or suggested how to improve rapport, whilst others might have assumed this was a given. Rapport came up with those with personal experience specifically in relation to the idea of 'home assessment', which may not be acceptable to some, and may require building trust for others. The intention and focus of the assessment must be made very clear.		

Prioritisation of areas to assess

Round 1 solicited short free text suggestions of assessment topics to cover. Answers were synthesised to produce these categories and rated in Round 2.



Round 3 comments on the above:

"Roughly agree with above ratings" (clinical psychologist)

"Looks good to me" (sleep & circadian rhythm researcher)

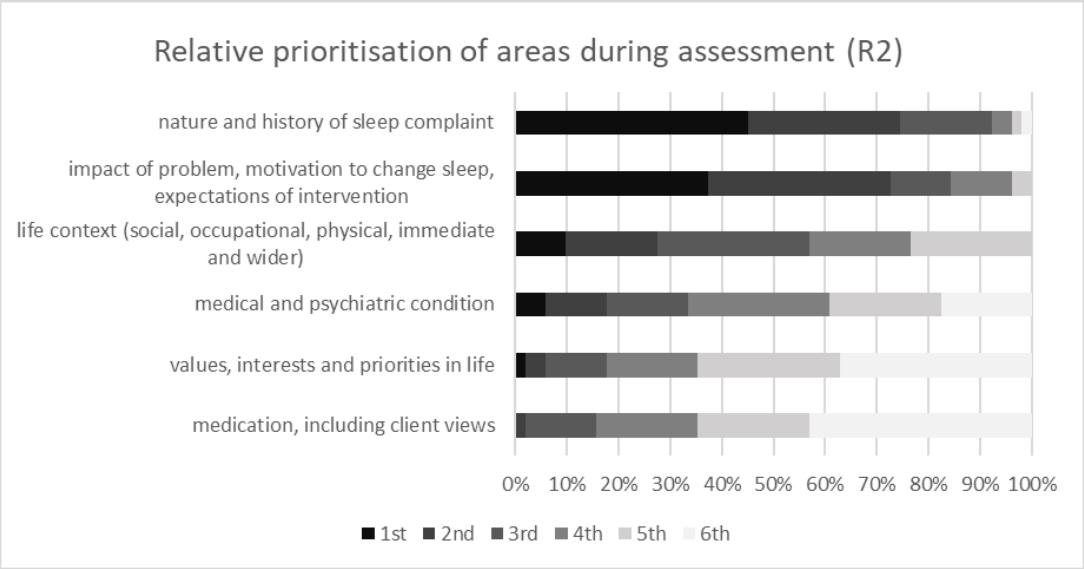
"I'm surprised medication isn't higher up. Its a significant factor in hypersomnia, which may maintain insomnia, and also a potentially modifiable factor (dose/timing). I would put this in the 'definitely include' category." (sleep specialist psychiatrist)

"Even though most agree to not ask re family history of sleep complaints, I wonder if specific questions should be asked to rule out restless legs syndrome and other parasomnias (if you don't ask, people may not recognise to tell you about that; strong familial component; easily missed as major cause of sleep onset insomnia)." (sleep OT researcher)

Almost all suggestions were rated mostly as important or very important, posing the dilemma (acknowledged by some participants) that the assessment could become very long (see more below).

In anticipation of everything being rated important, we forced ranking of topics to attempt to distinguish the most important topics to prioritise (below). This resulted in the two clear less important areas, to receive less time or attention, although participants made persuasive arguments

for the importance of these areas too. In conclusion on some topics, for some participants, it may be possible to move on sooner, whilst they may require more time for others.



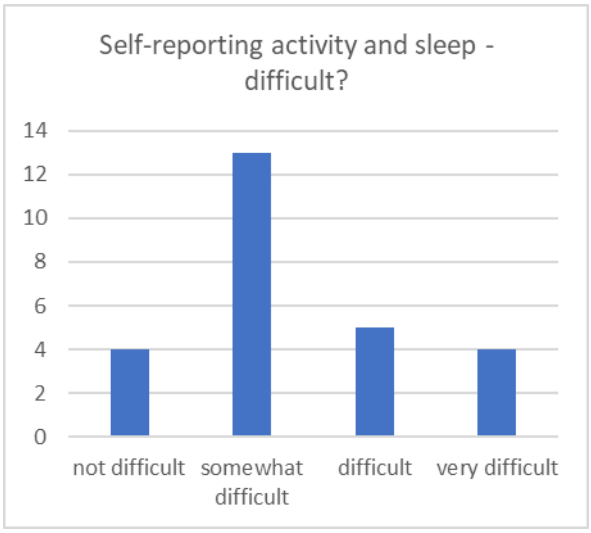
Furthermore, to shorten time needed, information on psychiatric condition and medication should be gathered from referrer or notes (also suggested by some participants).

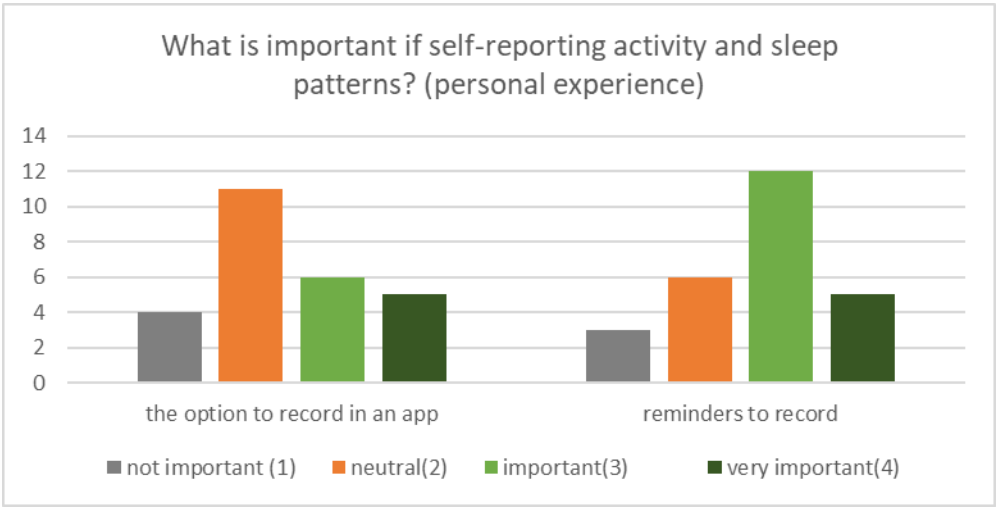
Longitudinal self-report of sleep & activity (activity & sleep diary)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Sleep diary	"Informative but not crucial. You'd get a gauge from actigraphy." (MH & sleep clinician researcher) "relying on patient's self-report, so information may not be complete/accurate." (sleep OT) "could be helpful if done often" (personal experience)	25 (43%)	4 (15%)
Activity diary	"activity and light paper logs […] to capture the activity being performed and whether an individual is inside or outside which can be very useful" (sleep & circadian rhythm researcher) "Activity diary as people both over and underestimate the amount of activity they undertake…" (psychiatrist) "I think it could add another layer of anxiety but it might be worthwhile (the data could be useful)" (personal experience)	16 (28%)	2 (8%)
Diary burden & difficulties	"its important but may be tricky to get services user's to remember to do this." (MH OT) "[activity diary] laborious […] at times has also felt too confronting for them when they realise how little they do during they day" (MH & sleep clinician researcher)	21 (38%)	6 (23%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	"just remembering to do so" (personal experience)		
Completing diaries as an intervention	"Passive monitoring (actigraphy) may be okay, but having the client actively recording activities/sleep may better enhance personal awareness/understanding" (sleep OT CBTi practitioner)	25 (45%)	0 (0%)
Format options, prompts and support	"In terms of high tech or low tech, I think people should be given an option." (sleep OT) "a call-in diary. Written activity day may be asking too much." (sleep OT) "…remind…" (professionals, 4 instances) "Would need help from family member / friend. But would give it a go with help." (personal experience)	24 (43%)	3 (12%)
Possibility of using an app	"A tablet with preloaded apps where people can choose to write/ an icon will make daily diaries easier." (MH OT) "…routine and the diary, sleep diary but if you've got that app with the watch, I suppose you wouldn't need to do it." (personal experience)	7 (12%)	2 (8%)
Overall most participants, professionals and those with personal experience alike, agreed that there were benefits to self-reported activity data above those of only passively recorded. To reduce the challenge and motivation involved in remembering to record reminders should be used, and the process made as easy as possible. One person with personal experience and one professional raised the possibility that the process could be anxiety provoking or distressing, but no-one suggested it should not be done for this reason. Most people were interested, or thought their clients would be interested, in seeing their data summarised.			

Regarding completing self-reported activity and sleep diaries (NGT, personal experience):





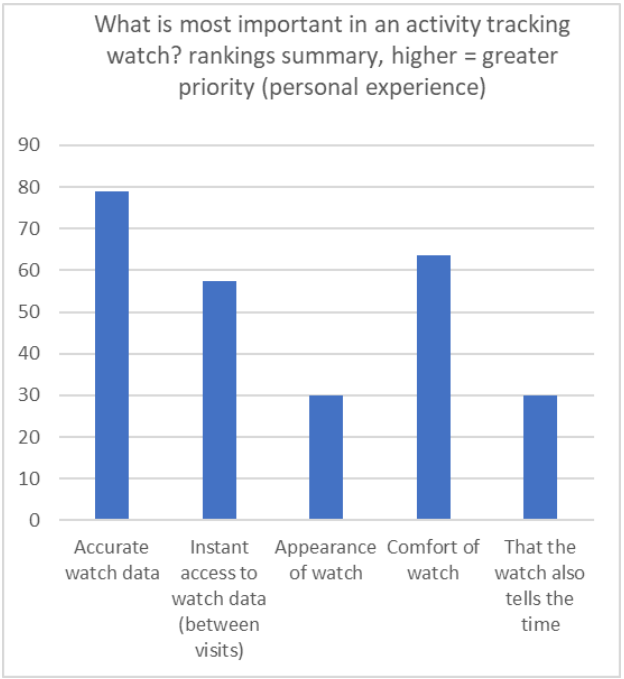
People with personal experience acknowledged / anticipated that recording one's own activities and sleep timing over a period of time might be challenging, but they also saw value in how this data might be informative or empowering.

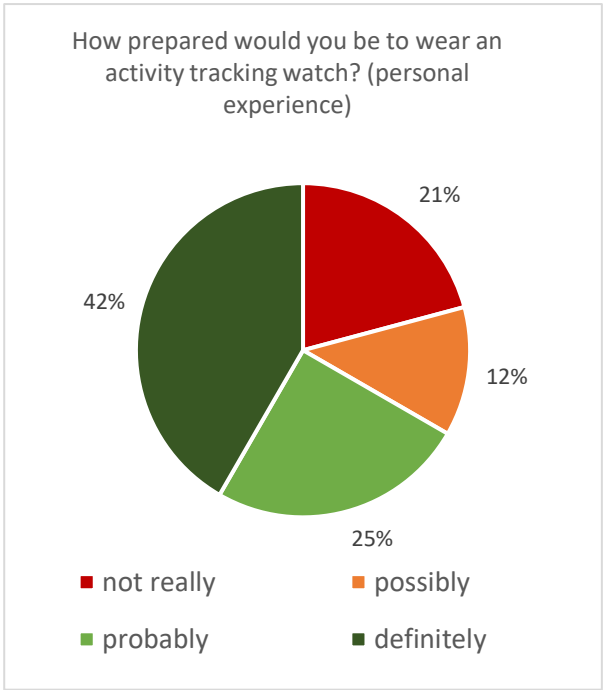
Passive monitoring within the assessment

Recommendation or issue raised	**Data excerpts**	**professionals n= (%)**	**personal exp. n= (%)**
Self-report and passive monitoring results will differ (useful to compare / need both)	"Objective and subjective assessments can be compared." (MH OT) "it is crucial to have this because an individual's impression of their patterns may be very different to what they are actually doing." (circadian rhythm researcher) One tricky thing though is when this doesn't match up with self-report […] put self-reported above when they don't match" (MH & sleep researcher)	22 (39%)	0 (0%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	Whilst the relative priority of objective and subjective measures varied between participants; overall there was consensus that both together and compared was optimum. Many mentioned the process of comparing these.		
Passive monitoring as an intervention	"diary and actigraphy to have proof of their pattern - often it comes as a great relief to them to have proof of what they felt but because of low self-trust they doubted they were right" (sleep & MH researcher) "to help service users understand how they spend their time could affect sleep" (MH OT) "I don't think the watch is going to work" (personal experience) "…why I said on the watch I'd like to have feedback" (personal experience)	16 (28%)	5 (19%)
	The feedback from the watch could have therapeutic value, particularly if it was accessible by the client between visits. Views on how useful this would be varied in those with personal experience.		

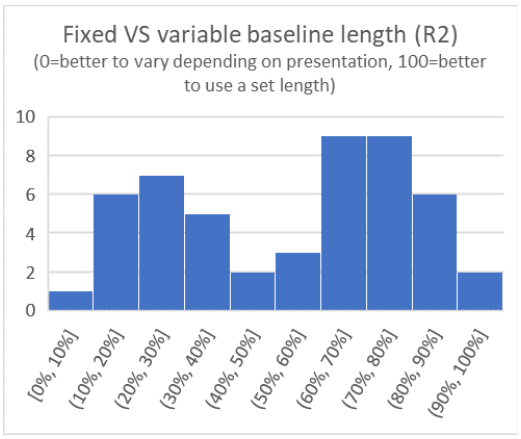
Final stage, views from participants with personal experience: activity tracking wearables acceptability:

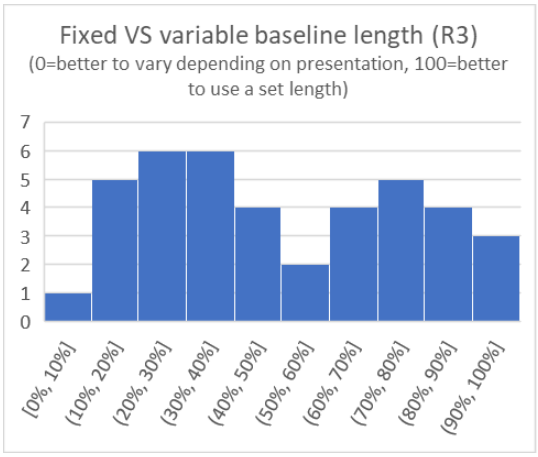


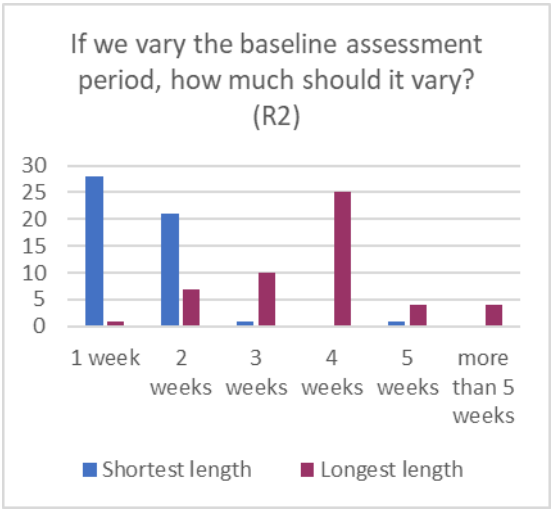


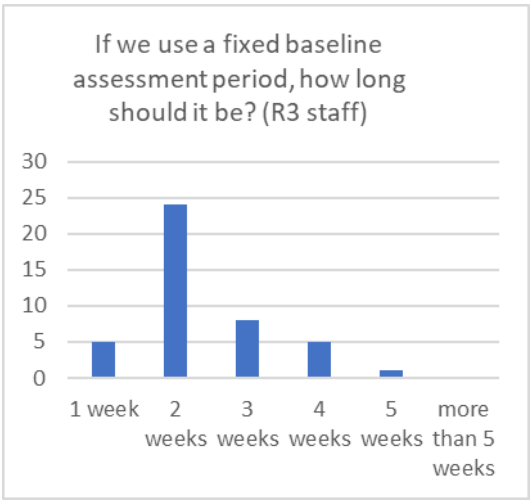
Duration of longitudinal measurement required (self-report and / or passive):

During round 1 some suggested varying the baseline length based on what type of sleep problem is being assessed, we asked about this in rounds 2 & 3.

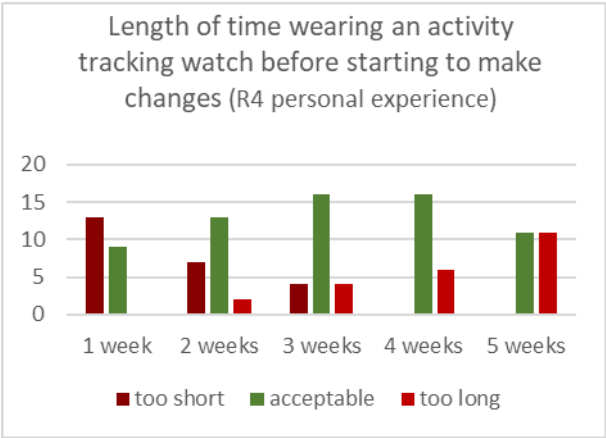








Professionals varied in how long they felt was needed to assess sleep pattern, with those working mostly in insomnia suggesting shorter periods and those in mental health and circadian researchers suggesting somewhat longer.



Overall professionals were more concerned about baseline period being too long than people with personal experience, who thought a longer period might be needed and were willing to wait.

"Pt's often want help immediately and already don't like to wait 2 weeks until the next appointment" (sleep OT)

Measurement of light exposure

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Measurement or self-reporting of light exposure at baseline and during intervention	"Assessment of […] how the person's current occupational routine results in exposure to light" (MH OT) "would certainly want to know about first exposure to daylight and the general level of light and duration of exposure." (sleep OT) "Good experience with wrist-worn light sensor combined with actigraph, not much covering, can use rubber band and instruct carefully […] Most problematic during nighttime, not valid because of blankets covering." (MH & circadian rhythm clinician researcher) "…an app that logs minutes looking at the phone screen), especially in the hours before bedtime, that could serve as a proxy for overall light exposure." (MH researcher) "The issue of light exposure is important, but measuring the light exposure accurately (e.g., by lux) doesn't seem as important as providing the education on how it can negatively impact sleep. I wouldn't sweat too much about accurate measurement (in lux) of light, unless you want to give a "teaching moment" to people." (sleep OT) "Important for people who don't leave home often or have turned day into night and may allow them the insight into how this could be effecting their sleep" (MH OT)	33 (59%)	1 (4%)

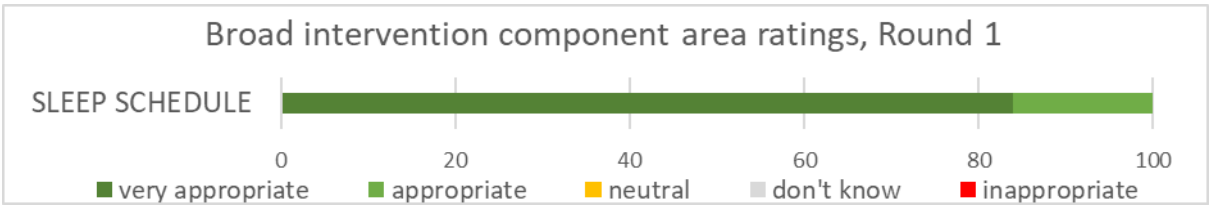
3. Intervention components

Sleep schedule

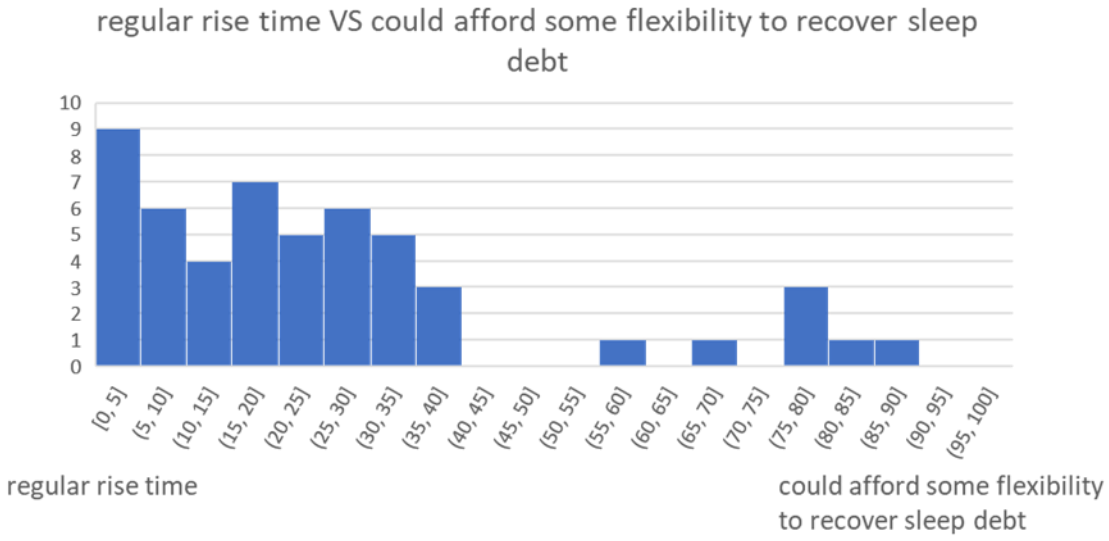
Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
Regularity	Address sleep schedule regularity	"Regular sleep times" (circadian rhythm researcher) "routine may help to gain better sleep over time" (sleep OT) "Routine may be helpful but may impact my social life" (personal experience)	37 (66%)	16 (62%)
	Regular rise time	"getting up at pre-agreed time when slept badly" (sleep OT)	25 (45%)	15 (57%)

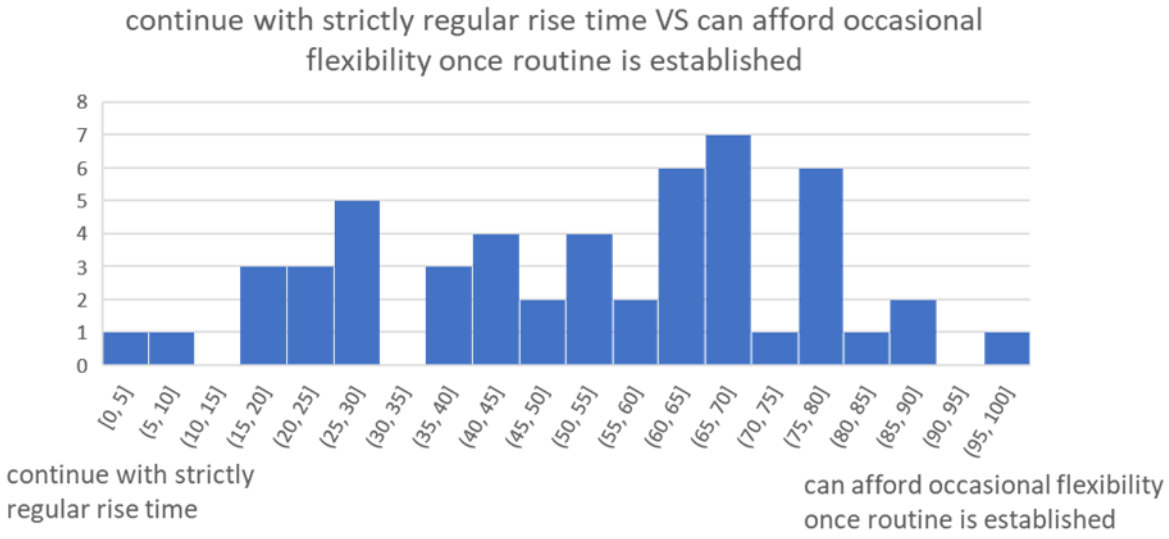
Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
		"Anchoring the rise time" (sleep specialist psychiatrist)		
	Regular bedtime	"Setting a bed time, is helpful to ensure the person doesn't sleep all the next day, particularly if they are a night owl." (MH OT)	9 (16%)	2 (8%)
Flexibility	Allowable flexibility in sleep schedule	"Regular rise time is essential during Tx and can be flexed slightly in maintenance" (CBT-i practitioner) "Schedule should allow for social participation/avoid isolation" (sleep OT) "While we emphasize consistency, if sleep debt grows opportunity to pay it off should be included." (sleep OT)	12 (21%)	0 (0%)
		Some participants thought it was better not to mention possible flexibility too early so that people can adhere to regular times during therapy, others suggested it was important to stress that totally rigid times were not forever to gain buy in.		
	Need to fit sleep in with life	"An idea of how many odd days they can have a lie in/late night etc before sleep is affected (otherwise life gets very boring!" (psychiatrist) "Goals for what they want their sleep to look like, possibly linked in to other things they want improving" (sleep & MH researcher)	10 (18%)	0 (0%)
		Schedules shouldn't remain so rigid that the person can't have a social life. Sleep shouldn't be at the expense of life.		
	It might be OK to be nocturnal	"but if you can't sleep at night and you feel like you could sleep during the day, you need to grab that sleep when you can" (personal experience) "There's no law on it" (personal experience)	0 (0%)	2 (8%)
		Although two participants discussed this suggestion they didn't sound very happy with being nocturnal, but felt it was better than getting no sleep at all.		

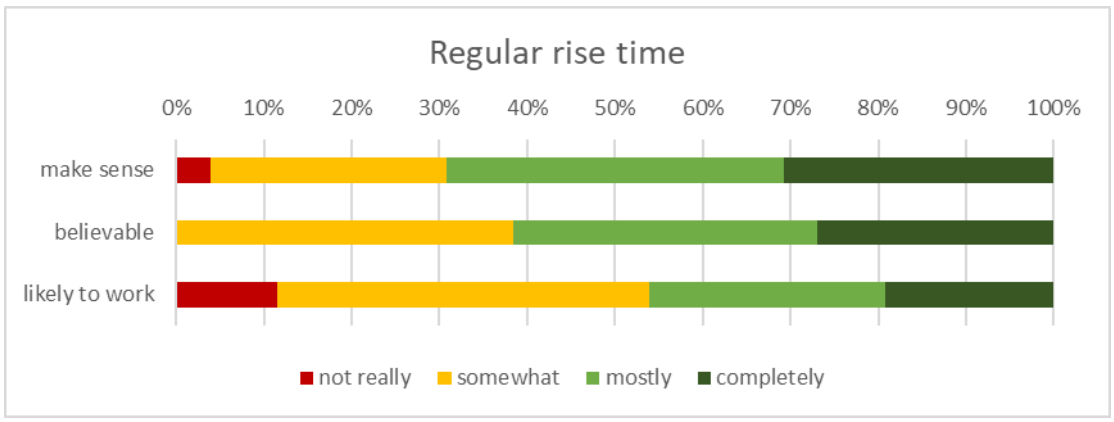
Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
Timing changes	Gradual approach to sleep timing changes	"Small steps" (sleep OT) "half an hour" (CBTi practioner) "Slowly bring forward" (sleep specialist psychiatrist) "Gradually adjusting wake/sleep rhythm […] making sure not to expose to light on wrong side of nadir" (MH & sleep researcher)	11 (20%)	0 (0%)
	Stabilise timing first before changing times	"[Those with a] severe delay, they don't have a clean severe delay, what they tend to be also is all over the place, and so it's really hard at the beginning to determine what's what […] So first get them stable […] [then] light exposure and start advancing that by half an hour a day" (CBTi practitioner)	2 (4%)	0 (0%)
	Support to change sleep times	"I would need the support." (personal experience) "Might consider morning calls if the client indicates they will get up for someone else when they can not manage it for themselves" (MH OT)	4 (7%)	4 (15%)

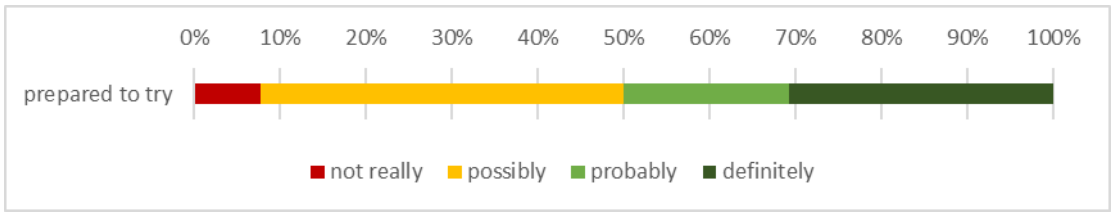


Regular Rise time was mentioned in Round 1 and asked about in Rounds 2 & 3:





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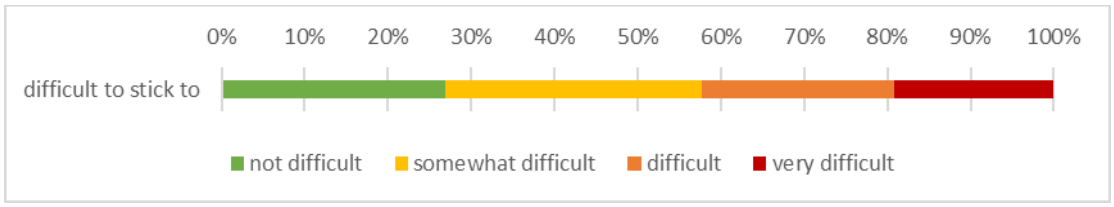
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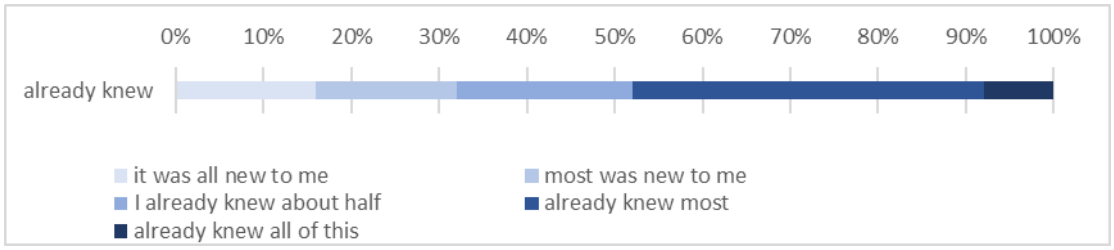
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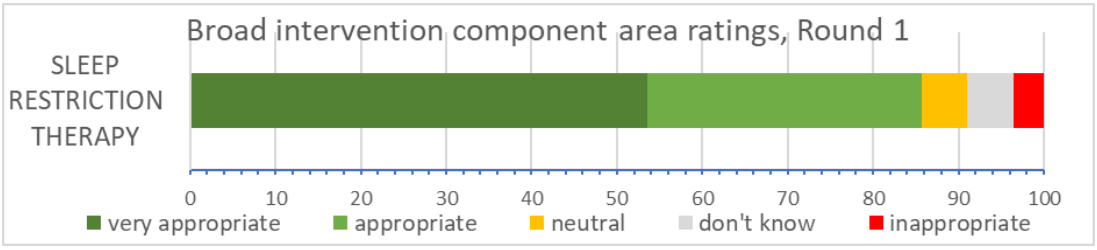
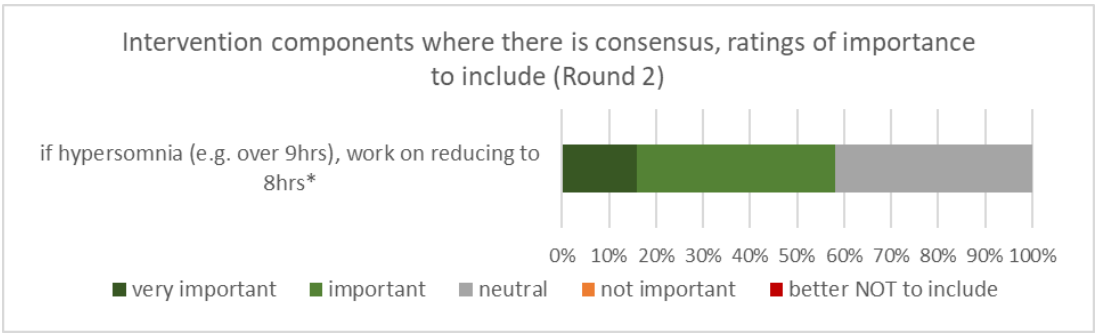
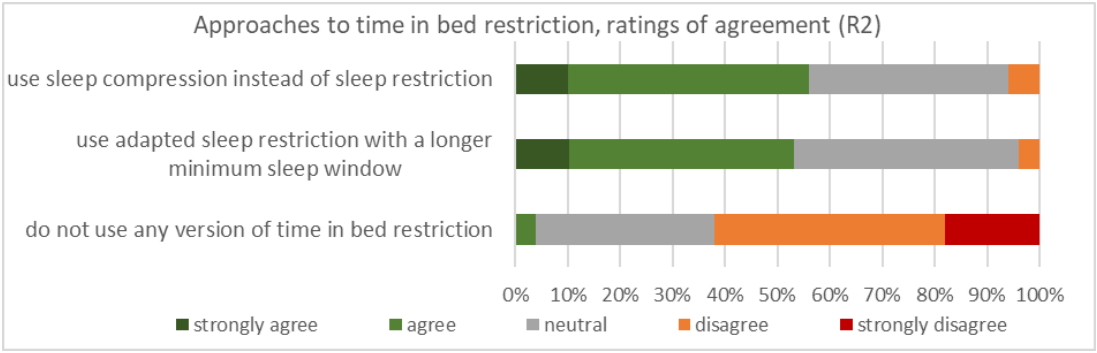
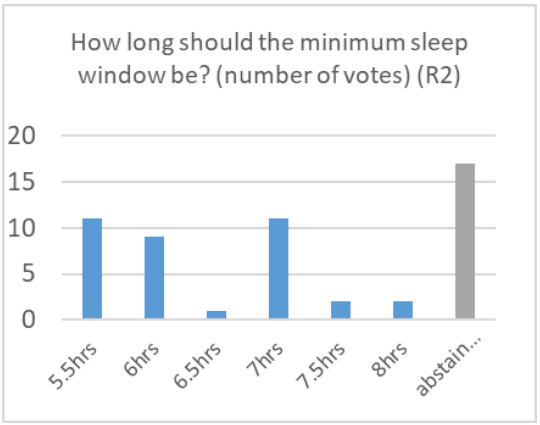
Time in Bed restriction

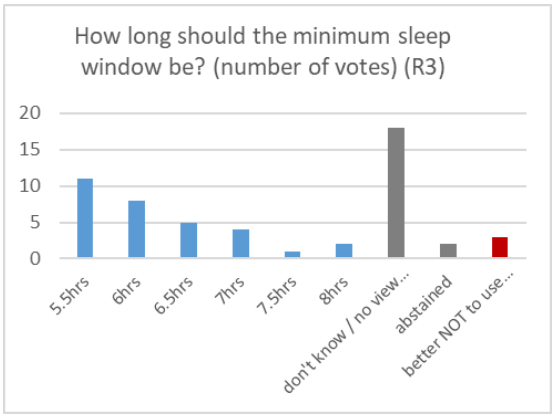
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Advocating Sleep Restriction Therapy (SRT)	"Stimulus control is also effective as a mono-therapy. but sleep restriction with stimulus control is the BOMB!" (sleep OT CBTi practitioner) "strong evidence base behind this component." (sleep & MH researcher)	17 (30%)	n/a
Be cautious with SRT	"Sleep restriction therapy only if the therapist has training and supervision" (MH & sleep researcher) "Patients should be monitored though" (psychiatrist)	18 (32%)	n/a
SRT could trigger mania / psychosis	"…i would be worried about using it in case it triggers them." (sleep & MH researcher) "Bear in mind that sleep deprivation has potential to trigger psychotic episode" (sleep & MH clinician researcher) "Consider individual's symptoms and medication to evaluate whether sleep restriction etc. could exacerbate problems" (sleep researcher)	16 (28%)	n/a
Do not use SRT	"sleep restriction therapy is probably contraindicated" (sleep OT) "If one chooses to focus on light exposure/not blue light in late evening and night, there will presumably be no need for sleep restriction" (sleep & MH researcher)	4 (7%)	n/a
Use sleep compression instead of SRT	"Sleep compression is appropriate if patient has any condition sensitive to short term sleep loss or if they are very anxious." (sleep specialist psychiatrist) "That is why I feel that sleep compression would be a good idea as there is literature that also backs using sleep compression with bipolar populations" (sleep OT CBTi practitioner)	6 (11%)	n/a
Not keen to try reducing time in bed	"If I go to bed later, I'm up until 3am instead of 1am, you know what I mean. So I've got to go to bed at 21:00 just to unwind myself down." (personal experience)	n/a	5 (19%)
Already reduce time in bed, & advocate it	"I try to spend as little time as possible in bed." (personal experience)	n/a	3 (12%)

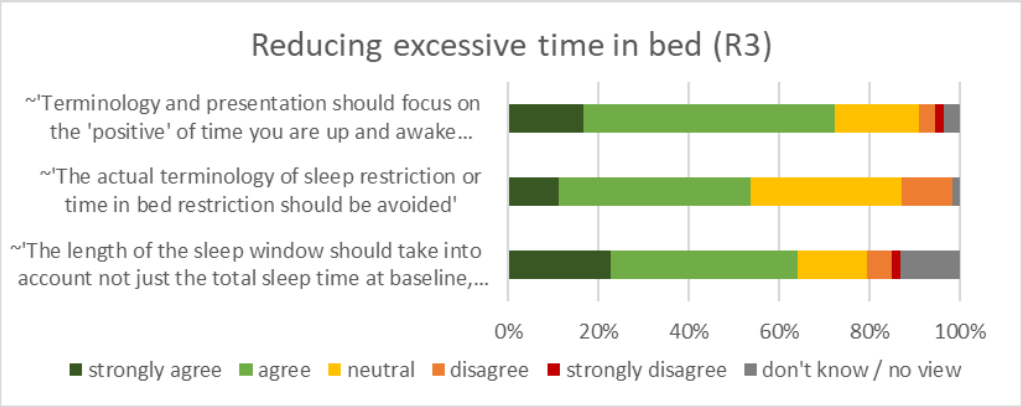

Broad intervention component area ratings, Round 1
SLEEP RESTRICTION THERAPY
0 10 20 30 40 50 60 70 80 90 100
very appropriate
appropriate
neutral
don't know
inappropriate


Intervention components where there is consensus, ratings of importance to include (Round 2)
if hypersomnia (e.g. over 9hrs), work on reducing to 8hrs*
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
very important
important
neutral
not important
better NOT to include


Approaches to time in bed restriction, ratings of agreement (R2)
use sleep compression instead of sleep restriction
use adapted sleep restriction with a longer minimum sleep window
do not use any version of time in bed restriction
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
strongly agree
agree
neutral
disagree
strongly disagree


How long should the minimum sleep window be? (number of votes) (R2)
20
15
10
5
0
5.5hrs
6hrs
6.5hrs
7hrs
7.5hrs
8hrs
abstain...


How long should the minimum sleep window be? (number of votes) (R3)
20
15
10
5
0
5.5hrs
6hrs
6.5hrs
7hrs
7.5hrs
8hrs
don't know / no view...
abstained
better NOT to use...

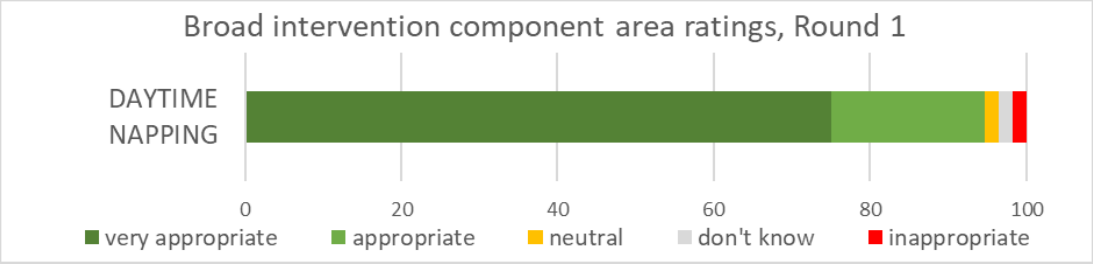


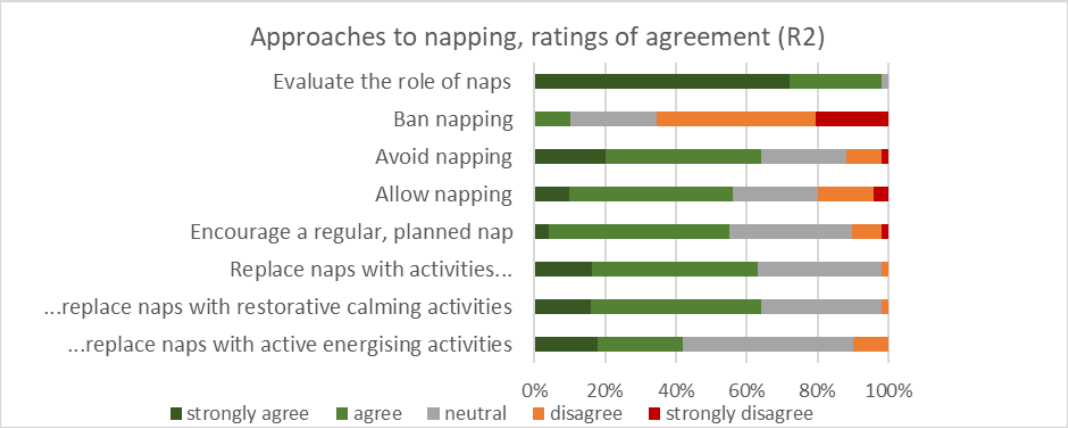
Although sleep restriction was relatively highly endorsed during round 1 (52%=very appropriate, 83%=appropriate or very appropriate) ratings, views diverged by round 2 (only 62% suggesting to use some form of time in bed restriction). In round 3 a large minority selected the option 'don't know / no view' (33%) when this option was offered, or abstained (4%), revealing then a larger majority of those with a view endorsing some form of time in bed restriction (91% / 31) and 8% / 3 suggesting it was better not to use time in bed restriction.

In the final stage participants with personal experience asked together about 'Reducing excess time in bed and avoiding napping', see below.

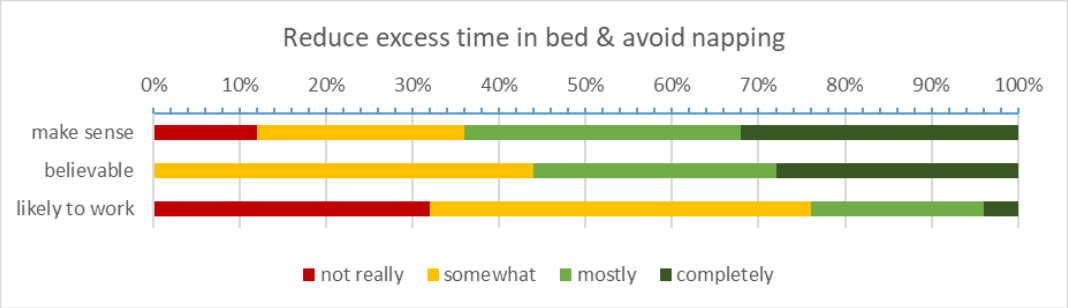
Napping

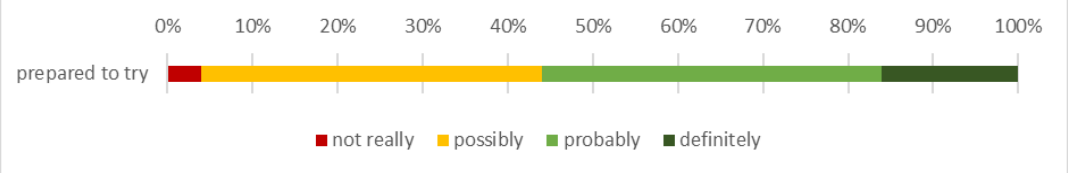
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Allow napping	"Education about pros and cons, when is best or not, and strategies to integrate this into a sustainable routine if the person needs or likes to nap" (MH OT) "Avoiding / reducing napping: would probably exacerbate" (personal experience)	24 (43%)	3 (12%)
Avoid napping	"Avoiding them where possible...!" (sleep & MH researcher) "Ban it!" (sleep OT CBTi practitioner)	19 (34%)	2 (8%)
Evaluate naps	"It depends why the person is napping." (MH OT) "How often, what times, how long, do they feel refreshed, do they try to resist and what happens if they do." (psychiatrist)	27 (48%	4 (15%)
Nap duration	"naps are ok if only 15-20 minutes" (sleep OT)	18 (32%)	2 (8%)
Nap timing	"What time does it occur - the later the more damaging it is." (sleep specialist psychiatrist)	11 (20%)	0 (0%)
Replace naps with activities	"engage in physical activity and meaningful/productive activities rather than sleeping to promote engagement." (sleep OT) "Energising activities particularly important in hypersomnia population" (sleep & MH researcher) "I think you need encouragement for that sometimes because you get [inaudible] very tired and unless you've got somebody in the house to say, let's go for a walk or [inaudible] and if you haven't got that then text reminders to encourage you" (personal experience)	14 (25%)	2 (8%)
Schedule naps	"Scheduled napping may be helpful in some cases" (sleep & MH researcher) "nap to be taken 7-9hrs after habitual wake time in the typical circadian dip" (CBTi practitioner)	6 (11%)	0 (0%)

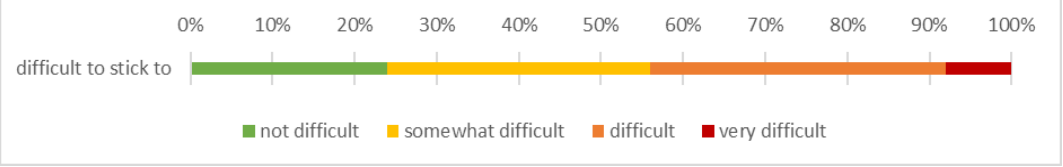


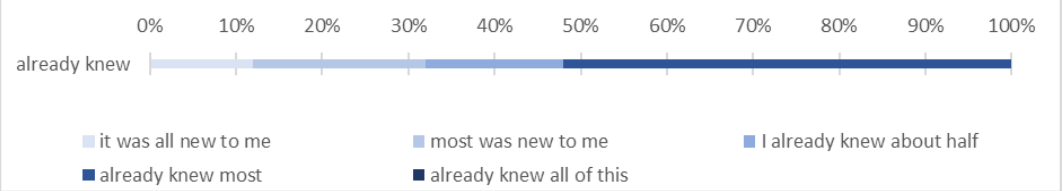


Final stage, views from participants with personal experience:









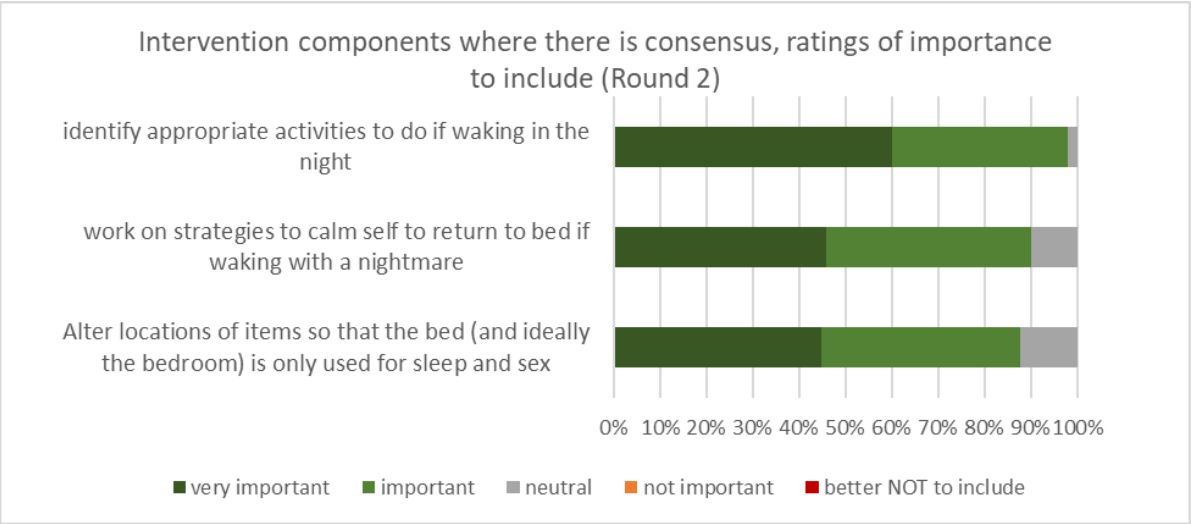
(Reducing excess time in bed & avoiding napping, explained in terms of:
Sleep pressure is the drive to sleep
which builds up more the longer you have been awake.
Example (diagram) - reducing 12 hrs sleep window (10pm-10am) down to 9 hrs (12midnight - 9am)
Daytime naps reduce sleep pressure (balloon analogy)
• Avoid naps
• 1 short nap (under 30 min)
• Not nap late in day
Explore the reasons people have for napping
Explore activities to replace naps with)

Stimulus control, and managing awakenings

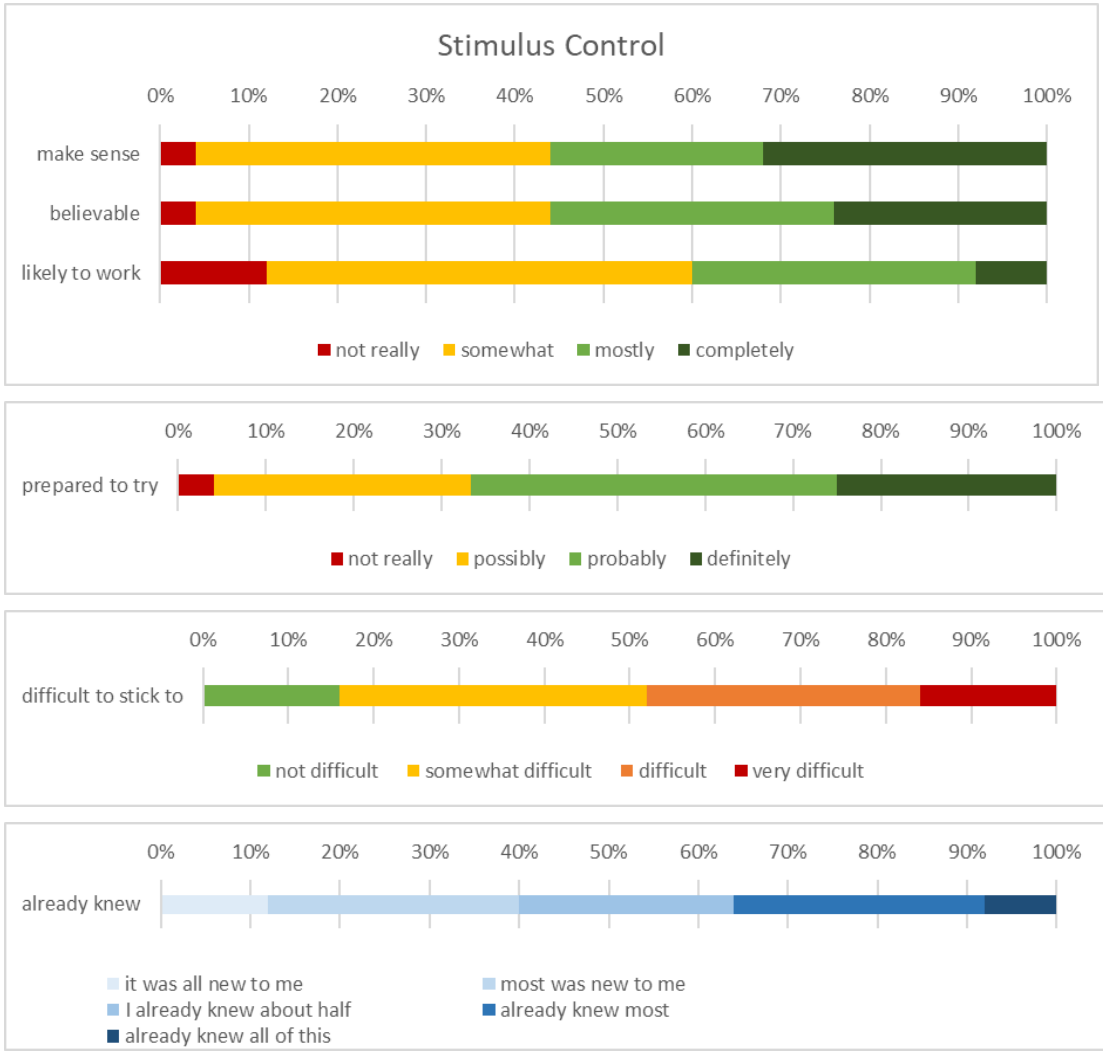
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Avoid non-sleep activities in bed / bedroom	"Modify to remove stimuli - like TV/computers etc... and make environment for sleeping and sex only" (MH OT) "…where would they go. Is bed in same room. Can you set up separate zone etc." (sleep & MH clinician researcher)" "Respondent A: People say you shouldn't have a television in the bedroom. Respondent B: Yes, yes, it's that unnatural… Respondent C: You shouldn't have anything electronic in the bedroom." (personal experience) "Like only go in your bedroom to sleep, that's been quite helpful for me actually." (personal experience)	28 (50%)	13 (50%)
Use 'the 15-minute rule' or similar	"I think it would be a bit harsh to set 15 minutes, because if someone took 20 minutes regularly, I wouldn't be upset with that. (sleep & MH researcher) "So if you've been in bed for a couple of hours its better to get out of bed and do an activity" (MH OT) "I recommend if SRT is not used and stimulus control therapy is used there is still daily monitoring (sleep diary)." (sleep OT CBTi practitioner)	8 (14%)	0 (0%)
	Some participants who deliver CBTi suggest using the 15-minute rule unmodified as a part of stimulus control to work with sleep restriction to establish the bed-sleep association, some who worked in mental health suggested milder versions, longer than 15 minutes or depending how the person is feeling in bed.		
Bad experience using 'the 15-minute rule' as self-help advice	"It wakes you up." "Up, down, up, down, up, down. I find that if I just lie there and don't move and don't do anything whether I sleep or not and I stay like that until about eight o'clock in the morning, I feel a lot more refreshed than if I was to go to bed, keep getting up, sitting up, going out of my room and going doing this." "you're going to disturb other people in the house" "Your body needs that rest even though you're not sleeping your body needs that rest."	n/a	8 (31%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	"You start finding something to do then, don't you, and then get preoccupied with what you're doing and…" "Then I don't get any sleep." (personal experience)		
	Very many participants with personal experience separately raised this from direct personal experience, it was brought up in 4 out of 5 of the focus group discussions. No-one replied in these discussions describing a good experience when attempting to use the 15-minute rule. Professionals emphasised that stimulus control still restricts sleep and requires support and monitoring, but it sounded like these participants had been attempting to follow this based on one off advice.		

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Address activities to do if you awaken in the night	"not using screens, not eating when you get up" (sleep & MH researcher) "move to quiet room with quiet activity until sleepy." (sleep & MH researcher) "so, if you're thinking once you got up good let me read a technical journal so that I get sleepy, I go to my patient 'ah ha! there's sleep effort again!' […] so the first rule is 'get out of bed and do something fun'" (CBT-i practitioner) "So I think having a lot of activity and things they enjoy doing that are really set up for them in that environment without a lot of thought involved." (sleep OT CBTi practitioner)	9 (16%)	0 (0%)
	Views differed regarding what types of activities are appropriate to do if awakening in the night and the best way to choose these, although participants agreed this should be addressed (see graph below).		
Provide education on awakenings being normal	"What is normal sleep - many people I've assessed actually sleep fairly well but don't realise it's normal to wake several times per night and go straight back to sleep again" (psychiatrist)	3 (5%)	0 (0%)



Final stage, views from participants with personal experience:



(Stimulus Control was explained in terms of:

Avoid doing other non-sleep activities in bed (e.g., reading,

phone, TV)

Reduces association of bed with wakefulness

Increases association of bed with falling asleep

Bed then acts as a 'cue' to the brain & body to fall asleep

• If not asleep after a set period (often 15 minutes) get up again

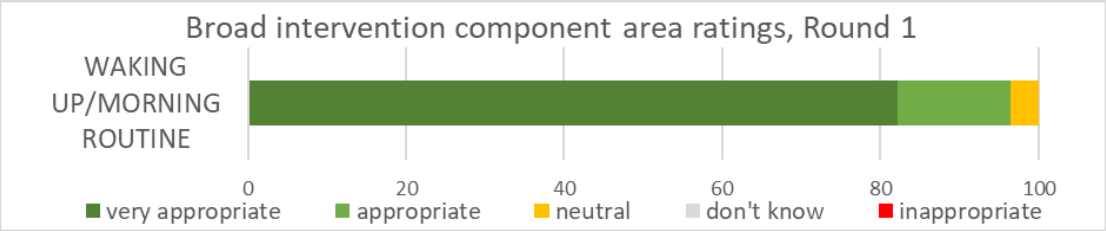
• Get into bed only when feeling sleepy

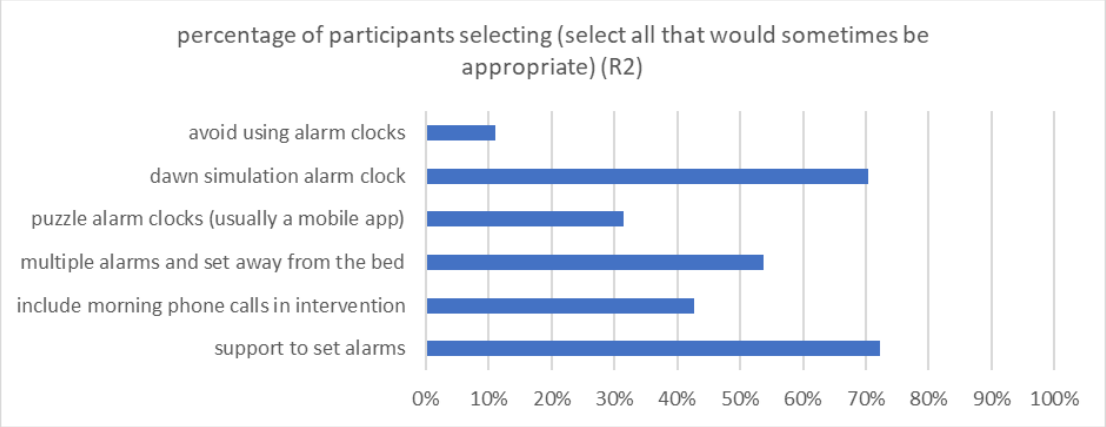
• If awakening in the night, get out of bed and do something until feeling sleepy again (explore and find suitable activities))

Morning routine

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Address type of activities	"Activities that facilitate waking up and boosting energy. Ideally including light exposure." (sleep & MH clinician researcher) "And get out of the bedroom as soon as they have risen from bed." (sleep specialist psychiatrist) "…also with motivation and just knowing they have that consistent role of things they do, and can go into more autopilot in the morning" (sleep OT CBTi practitioner) "a planned, pleasurable, meaningful activity" (MH OT)	17 (30%)	n/a
	The types of activities suggested were quite consistent and included energising activities, ideally going out of the house, or having light exposure, incorporating social contact or concrete plans early in the day if possible. Crucially, getting out of bed. Some discussed having a set morning routine of the same activities, and preparing for the morning, to make the morning easier once it comes.		
Use of alarms	"Assisting clients with setting up an alarm on their phone etc if they do not know how" (sleep & MH clinician researcher) "…I say to [my friend], can you ring me and make sure, you know, if I meet her in the morning" (personal experience) "Respondent A: It would be okay for it to be in the room, but, like, far away, so I can't press the button so that I can go back to sleep. Facilitator: Okay. So that thing about alarms on the other side of the room, you didn't think that was a bit much? Repondent B: No, that's a good idea. Respondent A: Good idea. Respondent C: Yeah" (personal experience)	20 (36%)	10 (38%)
Dawn simulator alarms	"Dawn simulation with light and sound will support the circadian system and sleep structure, including the microbiome" (MH & circadian rhythm researcher) "I'm not worried they are harmful, more the unnecessary cost. I'm not convinced they are so very effective" (sleep specialist psychiatrist) "It might set you into a routine so you don't need it by the end of it, so you might just wake up on your own…" (personal experience) "So, it's like a brightness, isn't it, when you first wake up in the morning, instead of waking up with your blinds open and it's raining, you get a bright light and it'll make you feel better." (personal experience)	6 (11%)	9 (35%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Education on sleep inertia	"Pts needs to understand that first 10-30 mins may involve sleep inertia and as such should not use this fatigue feeling to gauge how well they slept." (CBTi practitioner)	4 (7%)	0 (0%)
Experience of struggle with waking	"…it wouldn't always wake me because I would be in such a deep sleep that it wouldn't wake me." (personal experience) "Because I struggle to wake up. Like I struggle to get to sleep and then when I'm supposed to wake up I don't wake up, not even for alarms and stuff." (personal experience)	n/a	8 (31%)





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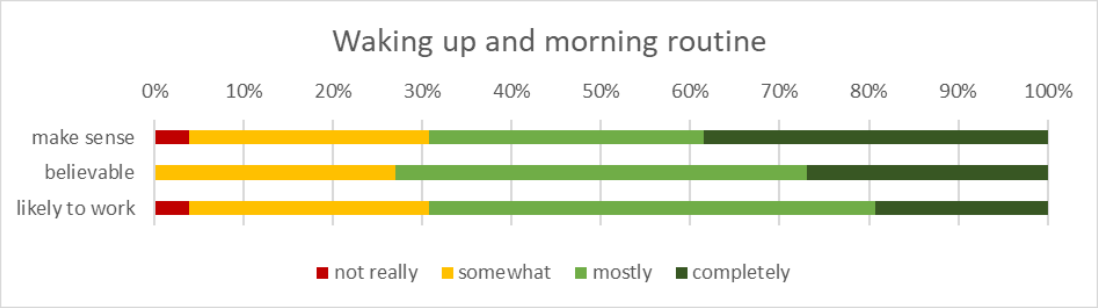
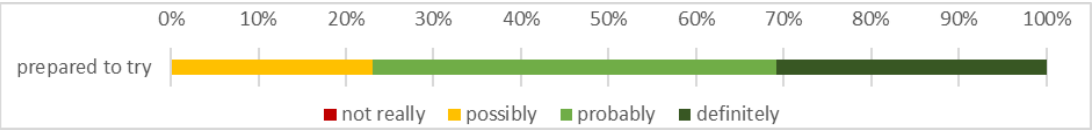
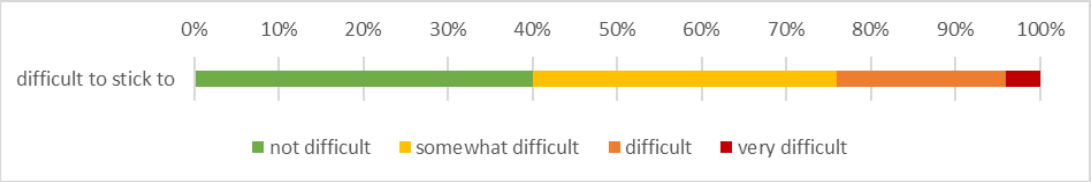
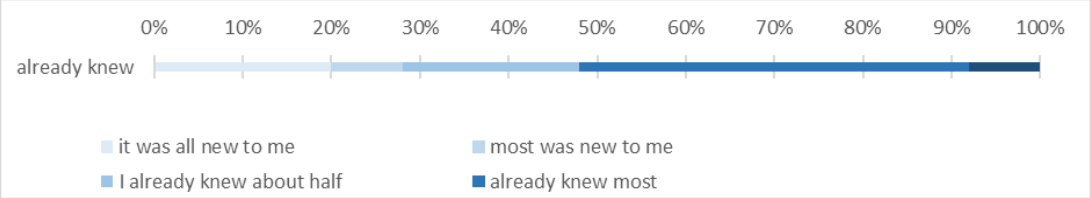




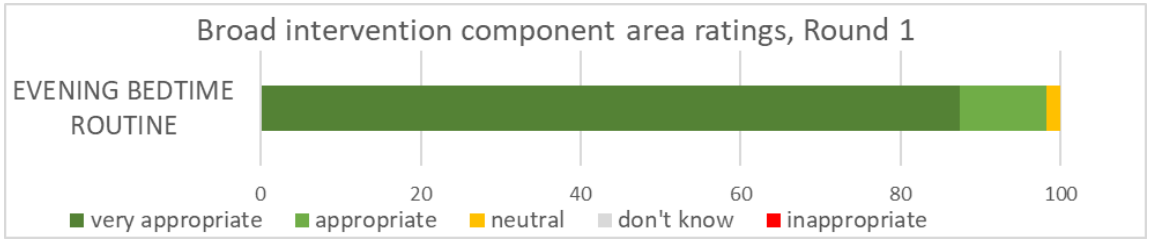


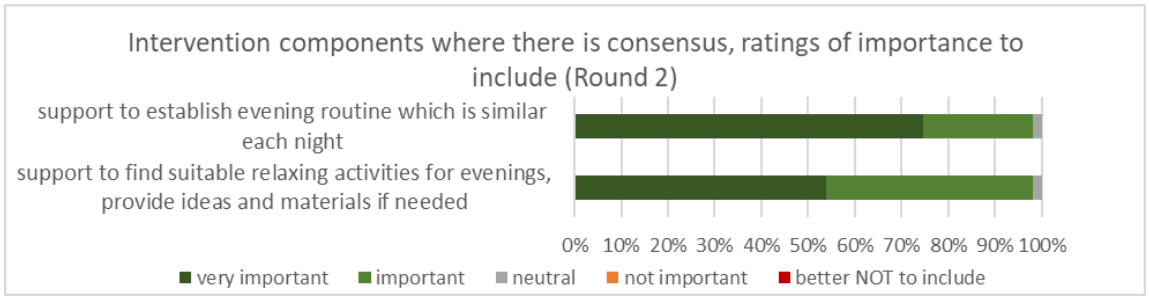


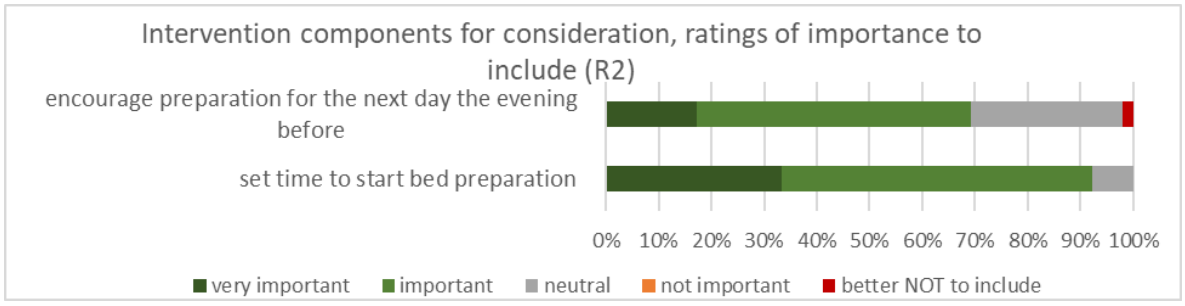
Evening routine

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Evening wind-down activities, lower stimulus	"A buffer zone 30-60 minutes prior to bedtime to decrease arousal" (sleep OT CBT-i practitioner) "having a wind down - similar every evening, calming relaxing routines" (sleep OT) "…some people find structured relaxation stressful. maybe they could be in a passive activity rather than relaxation" (MH OT) "It's a very passive activity isn't it [formal] relaxation whereas if you do something like having a bath listening to music, creating scent in your room, doing the knot tying, or whatever you want to do, that is more occupational of an intervention maybe" (MH OT) "Sometimes I get to sleep by watching YouTube on my phone, with my eyes straining on the small screen, I actually get some sleep eventually." (personal experience) "I used to listen to music to help sleep; that worked for about a month or so, but then it just stopped working and it didn't work any more." (personal experience)	27 (48%)	13 (26%)
Preparation for bed before wind-down	"Brush teeth and get ready for bed before wind down so that when bedtime comes pt can be ready to go straight to bed" (CBT-i practitioner) "otherwise you go into the bathroom and is a really bright light" (sleep & MH researcher)	3 (5%)	0 (0%)
Prepare for the next day - if relevant	"Getting a chance to work out a plan for the next day" (sleep OT CBT-i practitioner) "the value of this will probably vary between individuals. For some people, thinking about the following day may increase arousal levels" (sleep OT) "…not everyone finds this an important thing to do. For those who would benefit and want to do it, it is very important" (sleep OT)	6 (11%)	0 (0%)

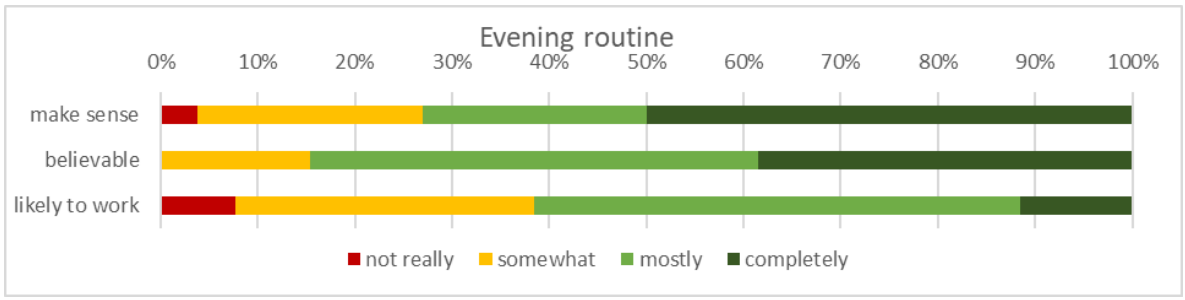
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Support to find suitable activities	"…try to make it a quality time for them, especially if staying up much late than usual, don't want it to feel like a punishment, it's got to feel like a really nice time. I throw out lots of ideas but leave it to them to decide." (sleep OT CBT-I practitioner) "Provision of materials that they could try out for winding down - e.g., art and craft materials, puzzles, books, comics, podcasts, […] may usually be unable to afford these things or lack motivation to look for them on their own at first." (sleep & MH clinician researcher)	7 (12%)	0 (0%)
Get ready for bed alarm	"a cue to start bedtime routine" (circadian rhythm researcher) "I set my alarm to say that I need to go to bed at 10am, what I got into that routine I did sleep for longer than 2 hours, its hard to keep the routine." (personal experience)	2 (4%)	1 (4%)







Final stage, views from participants with personal experience:


Evening routine
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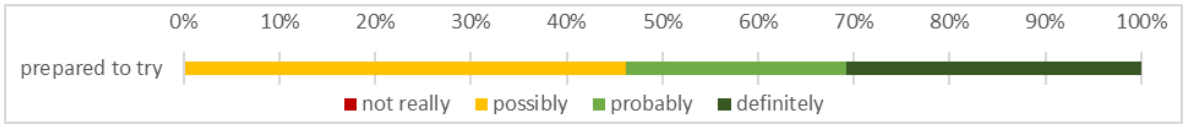
mostly
completely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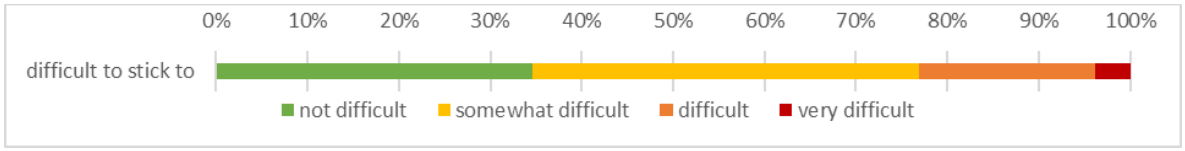
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difficult
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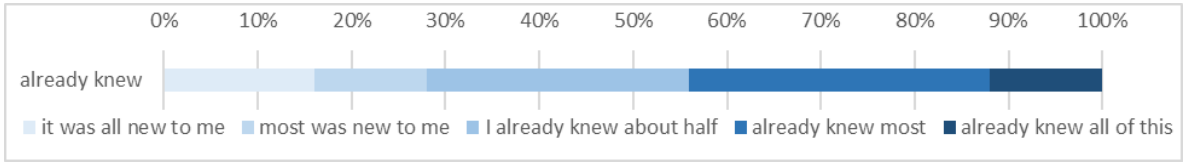
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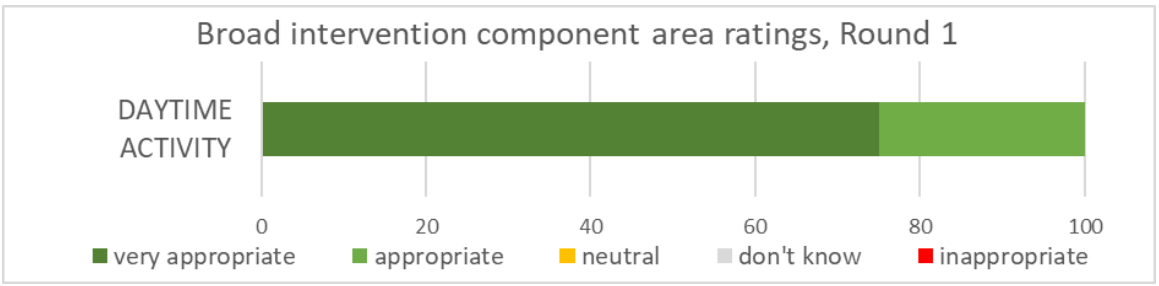
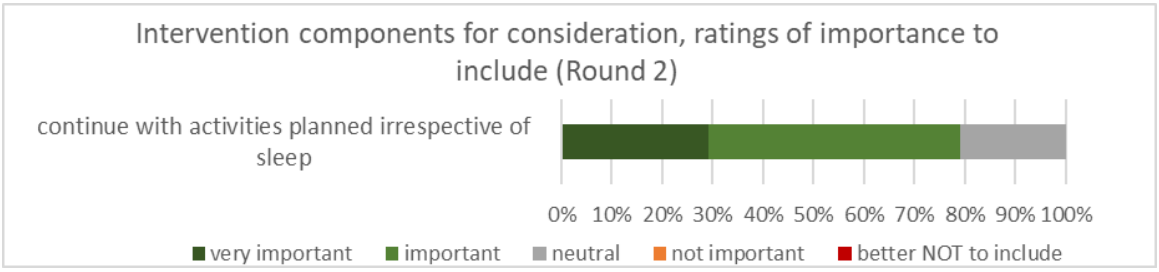
70%
80%
90%
100%
already knew
it was all new to me
most was new to me
I already knew about half
already knew most
already knew all of this

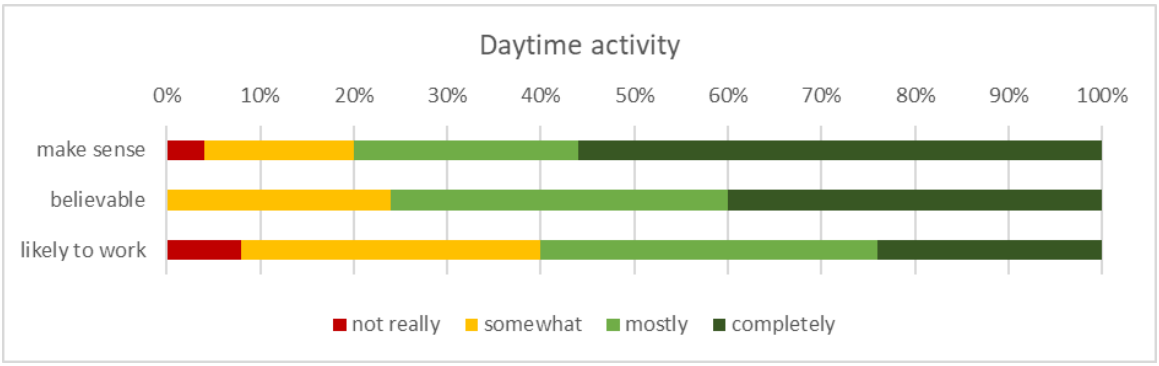
Daytime activity

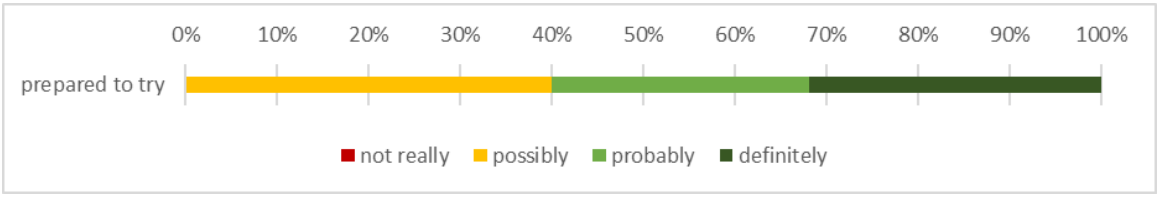
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Increasing amount of activity	"many patients v lonely, and sleep because they are bored /nothing to do- good to encourage social activities" (sleep & MH researcher) "Fill the day with interests and exercise." (personal experience)	28 (50%)	16 (62%)
Address activity type	"Meaningful activities, relaxation activities, mix of ADLs, time outside, time doing physical activity, social contact" (sleep OT)	52 (93%)	18 (69%)
Address activity timing	"Level of activity and pattern of activity - looking at the time of day that activity occurs - impact that this has on light exposure - impact that activity can have on clock - is it periodic - will it impact ability to fall asleep" (circadian rhythm researcher) "And having something to work with to highlight which ones are daytime and nighttime activities." (personal experience)	20 (36%)	8 (31%)
Scheduling activities	"scheduling of activities, especially with commitments to others (e.g., meet a friend for coffee each morning)really helps" (CBT-i practitioner) "Use of a wall calendar to prompt them to remember their plan for that day to encourage them to get going purposefully." (MH OT)	23 (41%)	17 (65%)
Routines and habit formation	"Regularity of routines (including meal timing, walks, social interaction etc.) to strengthen circadian rhythm" (MH & sleep researcher)	16 (28%)	3 (12%)
Meaning, satisfaction and enjoyment	"Meaningful activities - if activity is replacing time in bed trying to sleep then those activities should be valued and useful in working toward a valued "future self"" (sleep OT CBTi practitioner) "Satisfaction, isn't it. If you're doing things for yourself all the time it's not; whereas if you're doing something that's worthwhile and contributing – I think most people want to contribute." (personal experience)	21 (38%)	7 (27%)
Support to find and plan activities	"Very explicitly planning activities, checking in on what was helpful and what wasn't done, creatively brainstorming things to increase activity and light exposure" (sleep & MH researcher) "[If its not scheduled it will] …give people a chance to think and talk themselves out of doing it. […] If it's more vague it's not definitely going to happen, is it?" (personal experience)	9 (16%)	5 (19%)

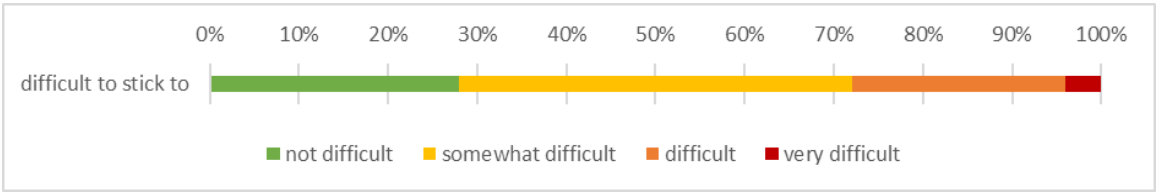


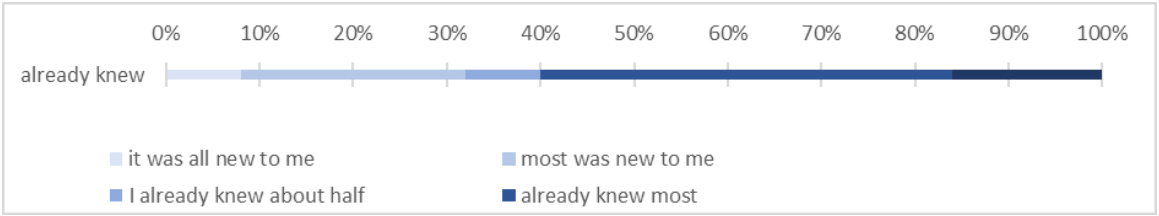


Final stage, views from participants with personal experience:









Explained in terms of:

Physical activity -more tired - sleep better

Mentally active tasks -feel alert - less naps

Outdoor activities improve light exposure Moving stressful activities away from bedtime

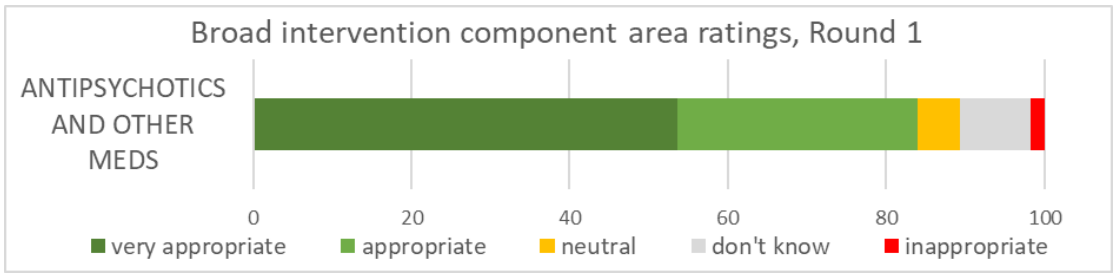
Regular meal times to structure the day (& not eating too late)

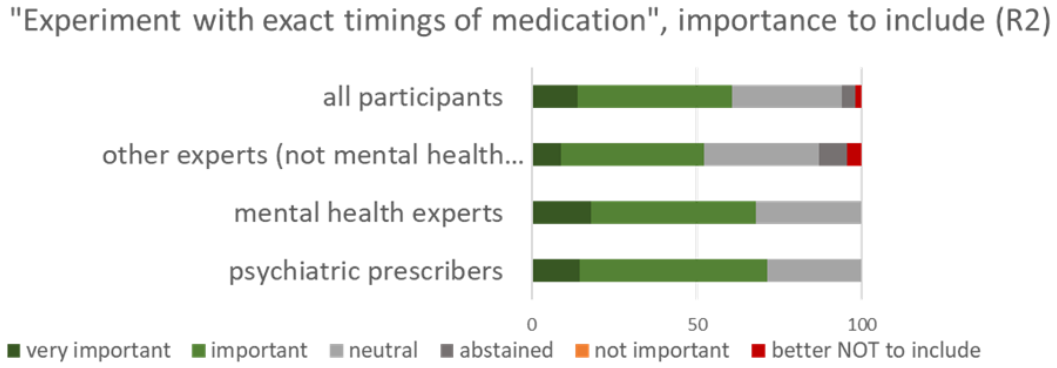
Might involve: • choosing activities • setting graded goals • Scheduling • involving friends & family

(images of paper and electronic diaries)

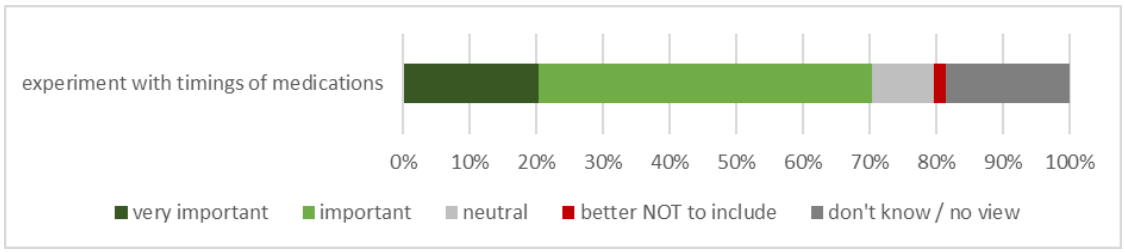
Addressing medications

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Consider side effects	"Antipsychotics may improve and extend sleep appropriately. There are some without significant insomnia for whom APs may cause hypersomnia" (sleep specialist psychiatrist) "some people seem to be sedated where others aren't at all." (MH OT) "Facilitator: Tablets? In what way? Respondent A: They can make you either too tired or to hyper. Respondent B: They can paralyse your body and not turn off your mind. Respondent C: Or they can sedate you so you're not as active during the day. Respondent A: So you're just a cabbage basically, aren't you, for 90 per cent of the week." (personal experience)	8 (14%)	8 (31%)
Addressing timing of prescribed medications	"correct timing eg mane or nocte" (psychiatrist) "understand side effects of medication, timing of intake, and why they are prescribed at certain times of day and not others, promote adherence to routine" (sleep OT) "Where medication is at odds with the sleep window this is important, but I would always recommend doing this work in liaison with the prescriber" (sleep & MH clinician researcher) "Consider medication timing as part of evening routine." (sleep specialist psychiatrist) "what time do you take them, do you get a hangover in the mornings?" (psychiatrist) "Well, I know there are certain medications that you're meant to be taking earlier rather than later because they will help you sleep, but sleep too much. So, if you took it say at ten o'clock at night you might be still in bed at ten o'clock in the morning. So, it's advisable to take it say at six o'clock in the evening. Things like that that could really make a difference." (personal experience)	19 (34%)	3 (12%)
MDT approach	See below: 7. Implementation considerations MDT approach within intervention, MDT approach to medication.		


Broad intervention component area ratings, Round 1
ANTIPSYCHOTICS AND OTHER MEDS
0
20
40
60
80
100
very appropriate
appropriate
neutral
don't know
inappropriate


"Experiment with exact timings of medication", importance to include (R2)
all participants
other experts (not mental health...
mental health experts
psychiatric prescribers
0
50
100
very important
important
neutral
abstained
not important
better NOT to include

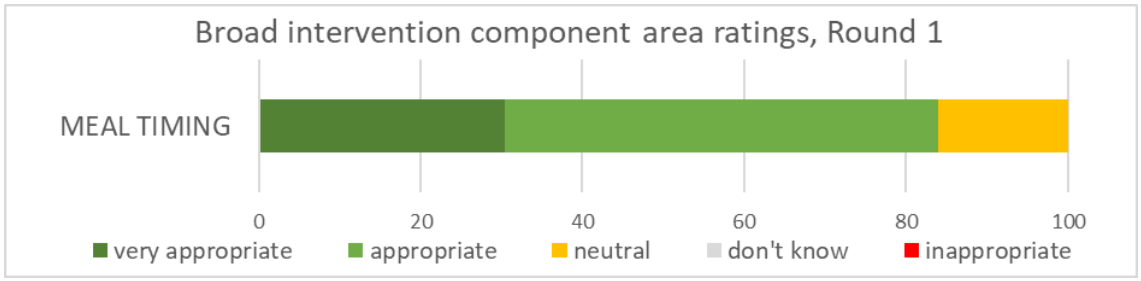
Round 3:

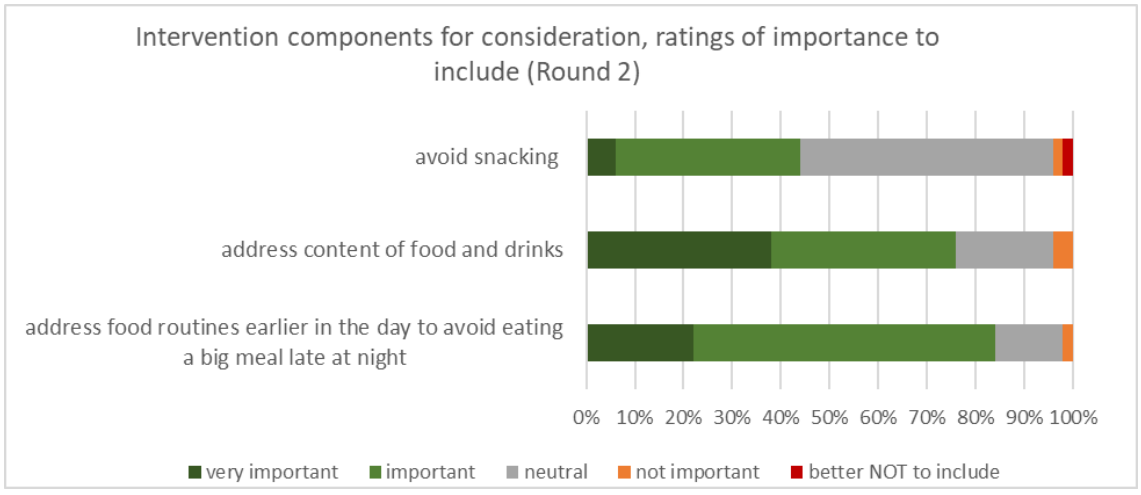

experiment with timings of medications
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
very important
important
neutral
better NOT to include
don't know / no view

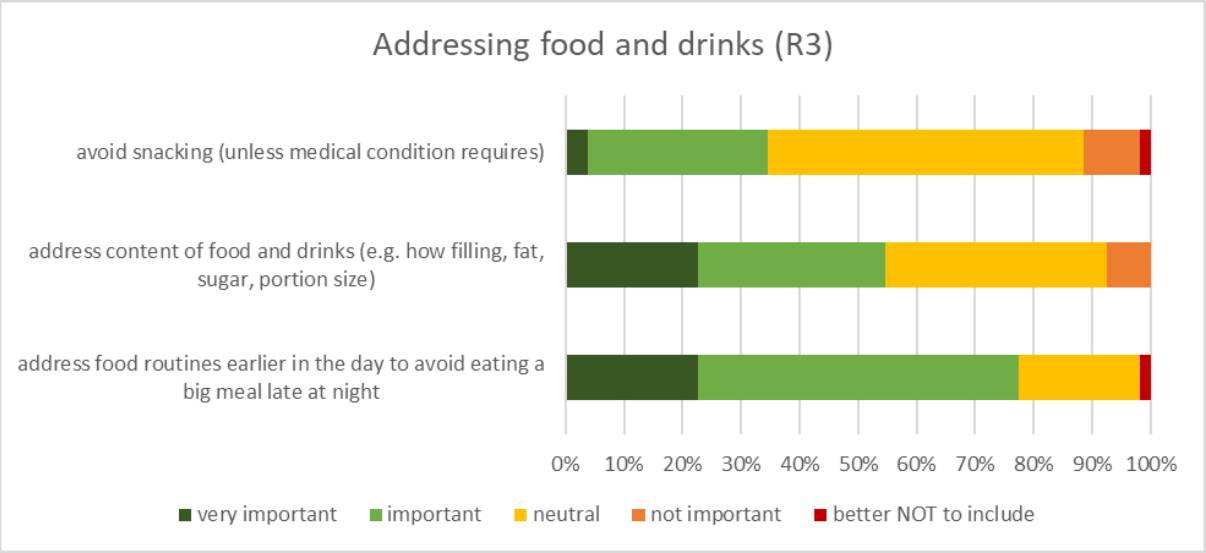
Addressing food and drink

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Consider food and drink timing	"timing of meals to help add structure and pattern to the day which may be chaotic because of the current difficulties with sleep." (MH OT)	49 (88%)	4 (15%)
Address avoiding late eating	"…not too much food too close to bedtime." (sleep OT CBTi practitioner) "A light snack 1-1.5hrs before bed is great marker and prevent hunger in middle of night. Pt should avoid heavy foods close to bedtime" (CBTi practitioner)	25 (45%)	1 (4%)
Address skills and / or routines around meals	"Also elements of how to integrate this into a routine of ensuring the appropriate resources are available, and the person has the skills, to prepare meals on time and budget (i.e. not realising there is no food and going for a late takeaway on a regular basis)" (MH OT) "…increasing awareness and reinforcing planning which is consistent with having adequate time for sleep […] includes have decent food in the fridge and time set aside" (sleep OT)	15 (27%)	0 (0%)
Night eating	"If someone isn't sleeping well it is not unusual for them to be hungry in the middle of the night. If they must eat, then high tryptophan lowish glycaemic index food may be helpful. Half a banana for example." (sleep OT CBTi practitioner) "[Night eating] has not been the key part of the clinical formulation for any client that I've met with insomnia and psychosis." (sleep & MH clinician researcher) "I don't… encounter it because I don't do it myself and a keep forgetting to ask people about it, so that's a shortcoming in me, I'm sorry I should ask more." (sleep specialist psychiatrist) "night eating needs to be addressed in the context of culture. some cultures have emphasis on night meals vs day meals and also seasons for example during muslim fasting month of Ramadan night eating becomes a social norm." (sleep OT) "What I find is…I have broken sleep. I go to bed about 11 o'clock, every two hours, I mean, it's like clockwork, what I find is if I go down and have a half a banana or a banana, I eat something, I comfort eat in the middle of the night [inaudible] send me to sleep…and now I have a weight problem" (personal experience)	18 (31%)	1 (4%)
	Participants varied between feeling this was very common to being slightly surprised when it was raised (Round 2 onwards). One participant admitted feeling it is probably common but not having been asking about it.		

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Consider food and drink content	"Avoiding heavy / spicy meals late at night" (sleep OT) "a nice breakfast as something to look forward to on getting out of bed can be successful." (sleep & MH researcher) "at the same time, OT should not be the one main one assessing a person's diet for nutritional content and calories" (sleep OT)	28 (50%)	6 (23%)







Addressing substance use

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Substance use	"[work on reducing] use of substances (especially cannabis and alcohol) to aid sleep." (sleep specialist psychiatrist) "[Circumstances to exclude for drug use] An example of a hard core amphetamine use who would stay awake for 4 days then just crash […] so if drugs are one of the main determinants of your sleep then that would have to change first" (MH OT) "I think cannabis would be alright if you're given the right dose. That's more natural than any of this crap they give you." (personal experience)	18 (32%)	5 (19%)
Alcohol	"Substances especially alcohol very important. Alcohol disrupts sleep physiologically (the need to urinate) and even on slight withdrawal (few units) heightens anxiety which when awoken in the night or morning can prevent a return to sleep" (psychiatrist) "…reduce or eliminate alcohol entirely when in active treatment because drinking at night increases sleepiness and is counterproductive to maintaining a later bedtime" (CBTi practitioner)	12 (21%)	2 (8%)
Caffeine	"Priority in terms of food/drink content is caffeine, especially if the person may not realise caffeine content of certain food/drinks." (MH & sleep researcher) "… adjust this to the patient as some are rapid metabolisers" (psychiatrist) "…cannot be one rule for all." (MH OT)	24 (43%)	5 (19%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	"Caffeine has a 6-8 hour half life. It should therefore be stopped by 2pm for most people" (sleep OT CBTi practitioner) "…after e.g., 6 p.m" (MH & circadian rhythm researcher)		
Nicotine	"smoking, is best avoided as it can act as a reward or reinforcement for waking." (sleep OT CBTi practitioner) "no heavy meals/alcohol/smoking late at night" (MH OT) "very hard to reduce smoking" (MH OT) "maybe have cigarette and alcohol intake [on the initial assessment] but explain that this isn't to police what they drink and smoke" (MH OT) "Respondent A: I've stopped smoking an hour before I go bed. Respondent B: That's something I couldn't do." (personal experience) "I tell you what I do do in bed when I can't fall asleep, smoke. […]Which that keeps me awake even longer […] if I've done that half the night then I'm shattered." (personal experience)	9 (16%)	4 (15%)

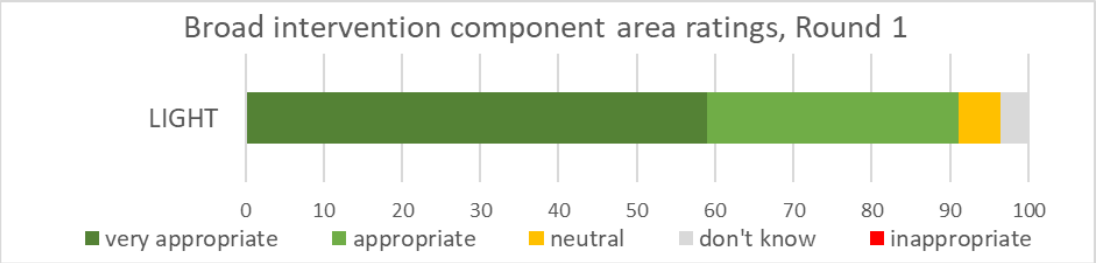
Light Exposure

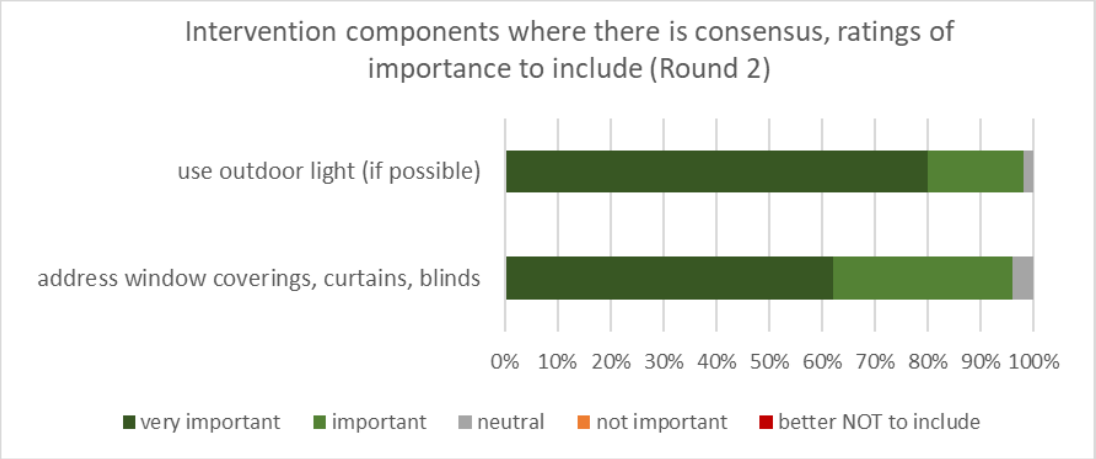
Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
Modifying light exposure			49 (88%)	21 (81%)
Timing of modifications to light	Morning light exposure	"Getting morning exposure to daylight is the key to entrainment" (sleep OT CBTi practitioner)	18 (32%)	1 (4%)
	Daytime light exposure	"Daytime light exposure because of improving sleep quality, more deep sleep, less fragmentation, less sleepy at waking up" (circadian rhythm researcher) "I think its better to be out. I tend to start sleeping if its dark" (personal experience)	11 (20%)	10 (38%)
	Increasing evening light	"for earlier sleep bright light early morning, for later bright light in the evening - even better if linked with exercise" (sleep OT CBTi practitioner)	2 (4%)	0 (0%)

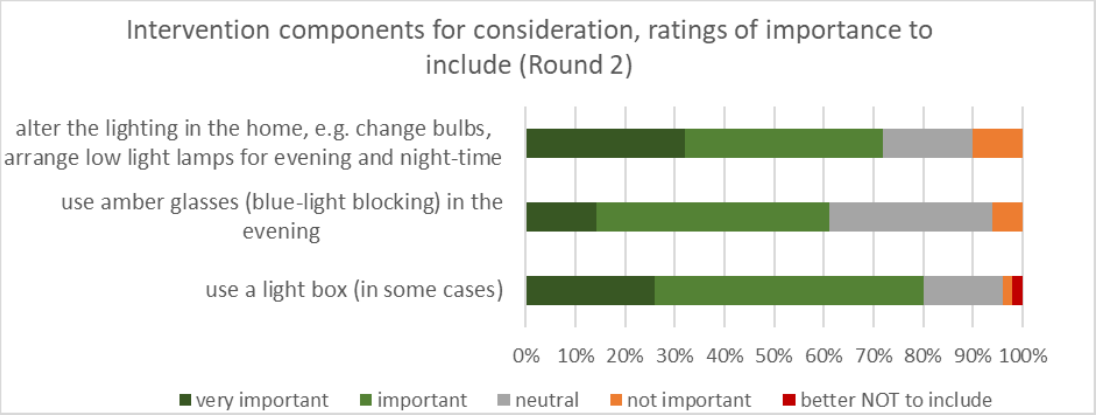
Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
	Reducing evening light exposure	"7pm it is fine to have whatever light […] into evening and it is before you are going to sleep, this is when it is really important as it allows the melatonin" (MH & circadian rhythm researcher) "…a lot of effort for minimal benefit. The evidence that evening light is detrimental is equivocal at best. I would just focus on morning light..." (sleep specialist psychiatrist) "Respondent A: …if you keep looking at your phone light, it's been scientifically proven, that light on your phone, it's called blue something, I can't remember the full name of it but it keeps you awake. Facilitator: What do you all think about that? Do you all have your phones in bed with you or a computer in bed? Respondent A: I've got laptops everyone does. Respondent B: I leave my phone switched on but I don't use the phone, but if I did use my phone before I went to bed, I could still sleep." (personal experience)	29 (52%)	15 (57%)
	Reducing light at night	"Quiet, dark, cool bedroom." (CBTi practitioner) "black out curtains" (MH OT) "Have safe alternative for night trip to bathroom etc rather than full lights on." (sleep OT) "I've got eye patches at home […] I've got to be in complete dark." (personal experience) "That 'cut out all the light', I can't sleep like that, I have got to have the lobby light on […] never been able to sleep without the light on." (personal experience)	30 (54%)	11 (42%)

Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
Method to modify light	Light box	"during winter, could use SAD lamp for 30 minutes after waking if it is still dark" (sleep & MH researcher) "I'm not opposed to light boxes, its harder to get them, whose paying for them etc." (CBTi practitioner)	15 (27%)	15 (57%)
	Light visor	"use of light mask?" (sleep OT CBTi practitioner)	1 (2%)	0 (0)%)
	Blue-blockers / amber glasses	"high effect sizes in the few studies undertaken in dark therapy […] definitely many people with sleep problems report very dramatic changes in sleep" (MH & sleep clinician researcher) "I prefer to lower intensity more than filtering out specific colours. So, I am more in favor of lowering environmental light" (circadian rhythm researcher) "…number of pts willing to try it [amber glasses] was too few" (sleep specialist psychiatrist) "Respondent A: Yeah, I think they'd be all right. Respondent B: Just for a couple of hours at nighttime… Facilitator: Yeah. You wouldn't be worried about what they look like particularly? Respondent C: No, because you'd be in the house anyway. Respondent D: I don't like wearing sunglasses or anything. […] Just irritate me. Facilitator: Mmm. Oh, like, what it feels like on your face? Respondent D: Mmm." (personal experience)	6 (11%)	4 (15%)
	Modifying light in the home & bedroom	"Indoor light is often very low and not bright enough, irrespective of window covering. Only if you sit next to the window or with very large windows [so] I am more in favour of using light boxes than addressing window coverings." (circadian rhythm researcher) "[should address] Light environment - lighting, windows (access to natural light), where spend the majority of time, electronic devices" (circadian rhythm researcher) "Respondent A: I suppose that could work, yeah; because I normally sit in the dark, all, like, in a darkened room; so, I could try opening the curtains more, try and lighten the place up a bit. […] Respondent B: I do the same, keep the blinds shut so it just feels like the outside isn't there." (personal experience)	28 (50%)	6 (23%)
	Using outdoor light / natural light	"lack of exposure to daylight seems to be a significant issue for many people with psychotic disorders" (psychiatrist) "Ideally, the person should just get outside. In cases where that is difficult use of a light box is a possibility" (sleep OT CBTi practitioner)	29 (52%)	0 (0%)

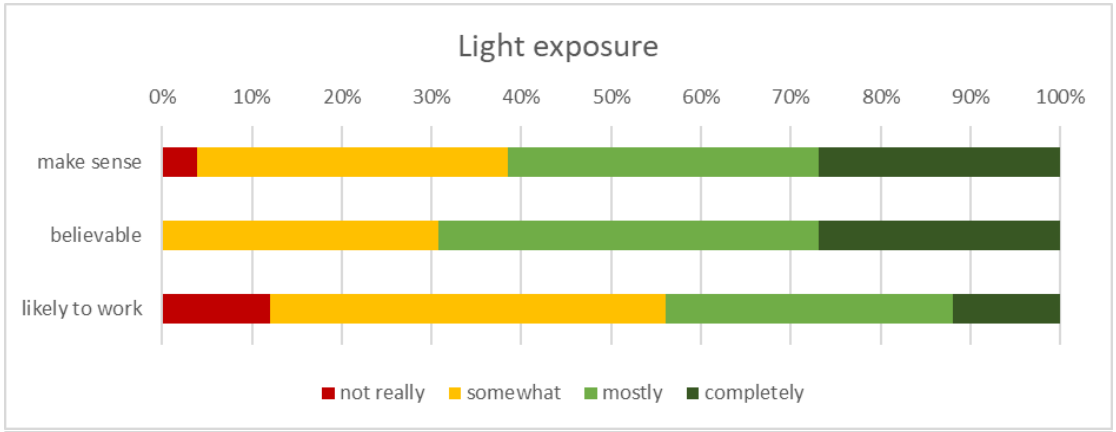
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Season is important	"UK is relatively far north and has significant seasonal differences in the number of hours of daylight per day" (sleep OT CBTi practitioner) "anchor point in the morning […] will probably change with season. if [sleep duration] is long, is it also long in the summer?" (circadian rhythm & MH researcher) "I go into hibernation when it's winter and want to have summer/spring for light mornings as I feel happier." (personal experience)	12 (21%)	4 (15%)
Embedding light in activity / occupation	"More activity outdoors to reduce social isolation" (sleep & MH clinician researcher) "Also, if people are getting more daylight exposure, they are likely to do so by acting in ways that would be beneficial for other reasons (eg. benefits of leaving the house or light exercise)" (psychiatrist) "[dog walking] Routine and daylight so you get multiple things." (personal experience)	8 (14%)	1 (4%)
Education regarding light, circadian rhythm and mood	"I explain it to people in terms of evolution, that we are day-active animals, humans are not nocturnal, so seeing light makes us want to be alert and awake." (sleep & MH clinician researcher) "empower them to take charge of light exposure" (circadian rhythm & MH researcher) "actually the thing is most people respond best to is not the circadian rhythm or the vit D, its that daylight is as effective as antidepressants […] it's a better incentive for ppl." (sleep OT CBTi practitioner)	27 (48%)	0 (0%)
Low expectation of efficacy regarding light	"Don't think I'm affected by circadian rhythm very much." (personal experience) "I'm going to be honest with you, what I've noticed is all this stuff with light and all that, yes, it does affect other people differently but if you've got insomnia because of mental health problems, whether it's light or dark […] it doesn't matter what colour it is outside your eyes, you're not going to sleep." (personal experience)	0 (0%)	10 (38%)
Acute alerting effects of light	"not bright light right up till bed […]so can wind down and feel like its evening" (sleep OT) "The basic research is very convincing that light is activating and sleep-disturbing […] It is also true that the clinical studies are few and with low *n* for the time being" (MH & sleep clinician researcher)	4 (7%)	1 (4%)

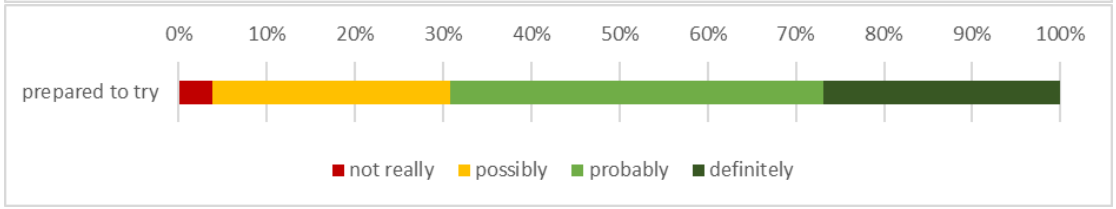

Broad intervention component area ratings, Round 1
LIGHT
0
10
20
30
40
50
60
70
80
90
100
very appropriate
appropriate
neutral
don't know
inappropriate

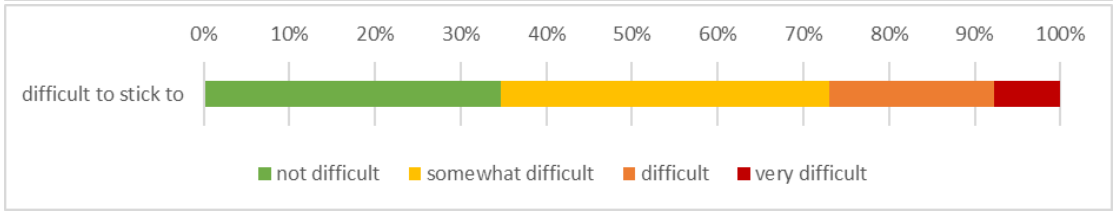

Intervention components where there is consensus, ratings of importance to include (Round 2)
use outdoor light (if possible)
address window coverings, curtains, blinds
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
very important
important
neutral
not important
better NOT to include

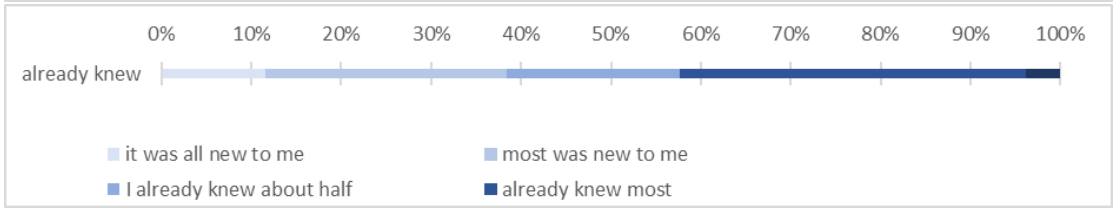

Intervention components for consideration, ratings of importance to include (Round 2)
alter the lighting in the home, e.g. change bulbs, arrange low light lamps for evening and night-time
use amber glasses (blue-light blocking) in the evening
use a light box (in some cases)
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
very important
important
neutral
not important
better NOT to include

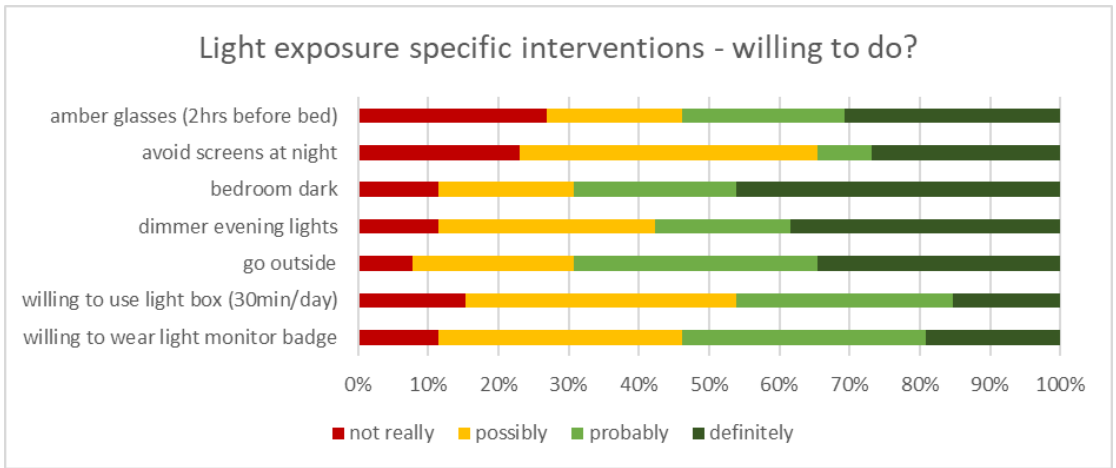
Final stage, views from participants with personal experience:











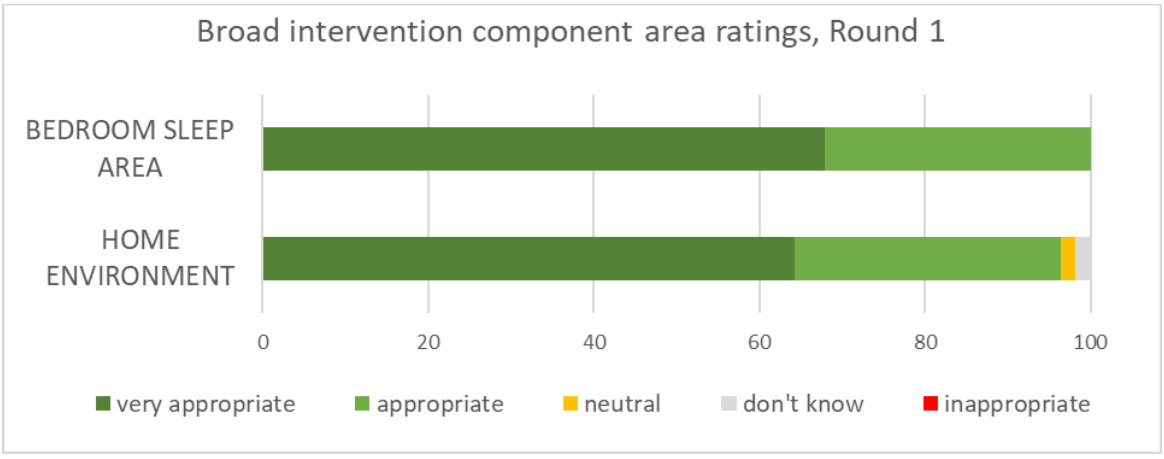
This is the component people knew least about. Whilst some were enthusiastic about light modification others felt it would not work. Awareness of the non-visual effects of light was poor. Unsurprisingly the avoiding screens at night was not popular.

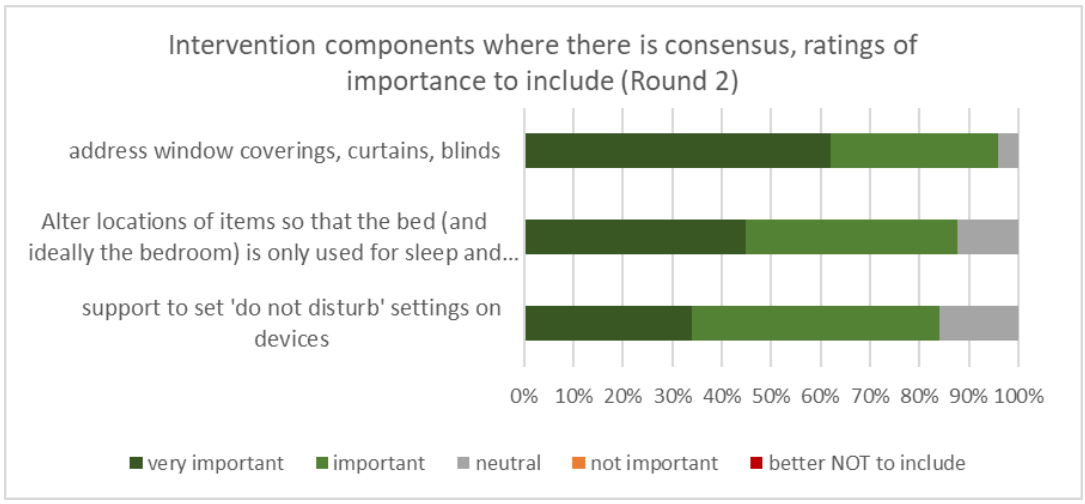
Environmental assessment and intervention

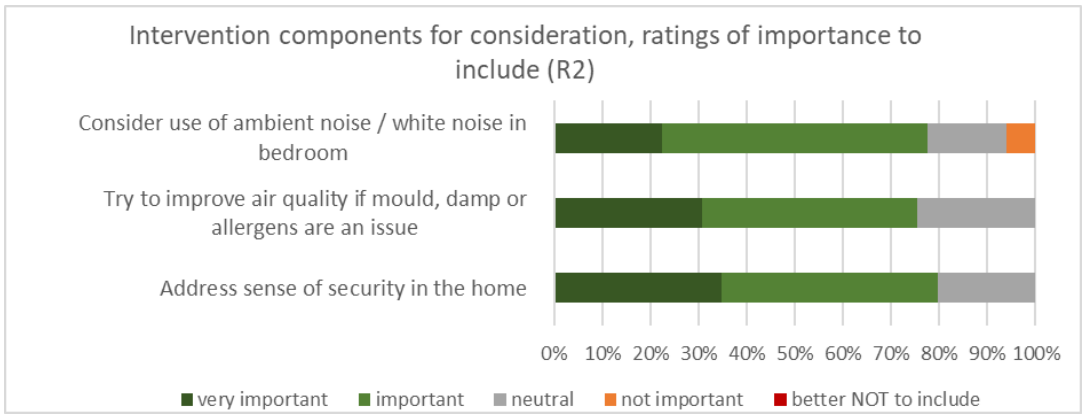
Recommendation or issue raised		Data excerpts	professionals n= (%)	personal exp. n= (%)
Home environment	Home environment		54 (96%)	18 (65%)
	Bed or sleeping surface	"whether they have a comfortable bed/ pillows/ covers/ curtains" (sleep & MH researcher) "do they have a bed and do they use it" (psychiatrist)	23 (41%)	0 (0%)
	Bedroom / bed not for non-sleep activities	"Creating/keeping a dedicated sleeping space" (sleep OT) "Is bed in same room. Can you set up separate zone etc." (sleep & MH clinician researcher) "That's what beds are for anyway, just to sleep." (personal experience) " [I know about] not going on phones in bed, or watching TV where you lay in bed, and stuff like that. […] I do it all the time." (personal experience)	28 (50%)	13 (50%)
	Having other useable rooms	"many of our patients live in cramped conditions and have to multi-purpose their bedrooms" (MH OT) "A person may have neglected all areas but bedroom" (MH OT)	6 (11%)	0 (0%)
	Noise in the bedroom	"noisy neighbours" (sleep & MH researcher) "white noise […]something that negates outside noise." (sleep OT) "ear plugs needed?" (sleep & MH clinician researcher) "earplugs […] may also block smoke alarm signals […] ideally noise should be stopped at the source, tho' this is not always easy." (sleep OT) "Sleep spindles are believed to be protective of sleep disruption by noise. [People with schizophrenia] are thought to have fewer and may be more vulnerable. Therefore a quiet environment is particular critical" (sleep OT)	34 (61%)	0 (0%)
	Temperature in the bedroom	"comfortable temp - cooler at night" (MH OT) "bedroom too hot = difficult to sleep; but bed cosy = easier to sleep" (sleep OT)	36 (64%)	1 (4%)

	Air quality	"airing room" (MH OT) "mould - damp - allergens (blocked nose at night)" (sleep consultant) "I imagine air quality might be the hardest of these variables to address with limited financial resources" (MH OT)	7 (12%)	0 (0%)
	Sensory factors	"colour of furnishings and walls / calm vs hectic" (sleep consultant) "possibly also general clutter, safety, comfort, being a nice space to settle into for sleep." (sleep OT) "ask about how they feel about the environment, the pyjamas, the sensory qualities of the room" (sleep OT) "Suspect this is a much less important factor to prioritise for most clients, but could be important for a minority." (sleep researcher)	29 (52%)	1 (4%)
	Pets in the bedroom	"Not pets in bed" (CBTi practitioner)	9 (16%)	0 (0%)
	Home environment intervention	"Floor should be clear to prevent falls" (sleep OT) "Function and tidiness to allow visitors" (sleep & MH researcher) "options to change bed/environment to improve sleep pattern may be limited due to financial constraints" (sleep OT CBTi practitioner) See also '3. The Assessment - Format and Manner of the assessment - Rapport', rapport required for home assessment	13 (23%)	7 (27%)
	Feeling safe in the home	Do they feel the environment is safe? (sleep specialist psychiatrist) "Home security. Police advice. Reduce anxiety." (MH OT)	14 (25%)	1 (4%)
Social environment & context	Social environment & context		44 (79%)	17 (65%)
	Social environment in the home	"consider the older person who lives in a child's house, and how they go to sleep early because they don't want to disturb the others. They're not sleepy at 8:00 pm but just want to get out of the way." (sleep OT) "Assess bed partner issues" (CBTi practitioner) "…for example the person might live with several noisy siblings or family members and chose to stay up all night when it is quiet as a result" (MH OT)	12 (21%)	1 (4%)

	Support from friends, family and carers	"support person to identify network of friends family who can support them to keep up new activities/do activities with" (MH OT) "Would need help from family member / friend. But would give it a go with help." (personal experience) "Involving family may not be helpful for independent. Friends may not want to get involved." (personal experience)	16 (28%)	11 (42%)
	Social commitments	"scheduling of activities, especially with commitments to others (e.g., meet a friend for coffee each morning) really helps." (CBTi practitioner) "Initial interview will establish shift patterns, school hols, split parenting routines and other factors that may vary from week to week" (MH OT)	13 (23%)	5 (19%)
	Peer support	"Group sessions, led by appropriate staff, may provide some valuable peer support for patients and address this" (sleep OT CBTi therapist) "Group treatment can be highly effective to make changes" (sleep OT) "Groups exclude people with poor transport and chaotic people" (MH OT)	18 (32%)	0 (0%)
	Loneliness	"many patients v lonely, and sleep because they are bored /nothing to do- good to encourage social activities" (MH & sleep researcher)	4 (7%)	0 (0%)
	Cultural factors	"Incorporating cultural needs - such as Ramadan, Kosher meal restrictions" (MH OT) "Western culture may over-value an uninterrupted night of sleep, as opposed to two phases of sleep at night" (sleep OT)	6 (11%)	1 (4%)



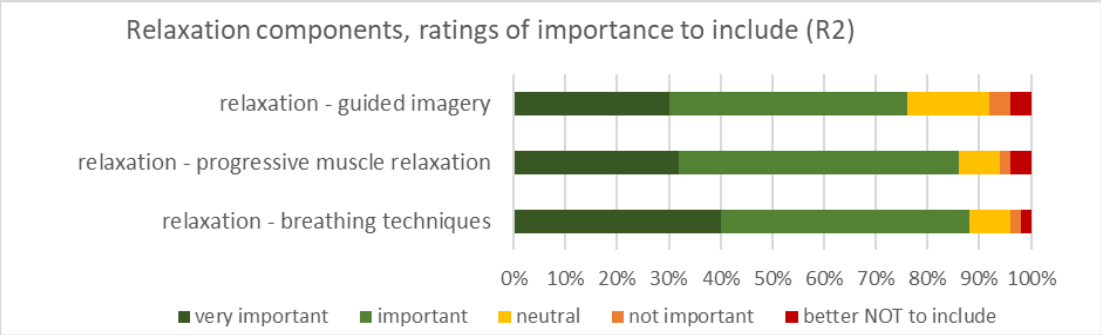

Intervention components where there is consensus, ratings of importance to include (Round 2)
address window coverings, curtains, blinds
Alter locations of items so that the bed (and ideally the bedroom) is only used for sleep and...
support to set 'do not disturb' settings on devices
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
very important
important
neutral
not important
better NOT to include

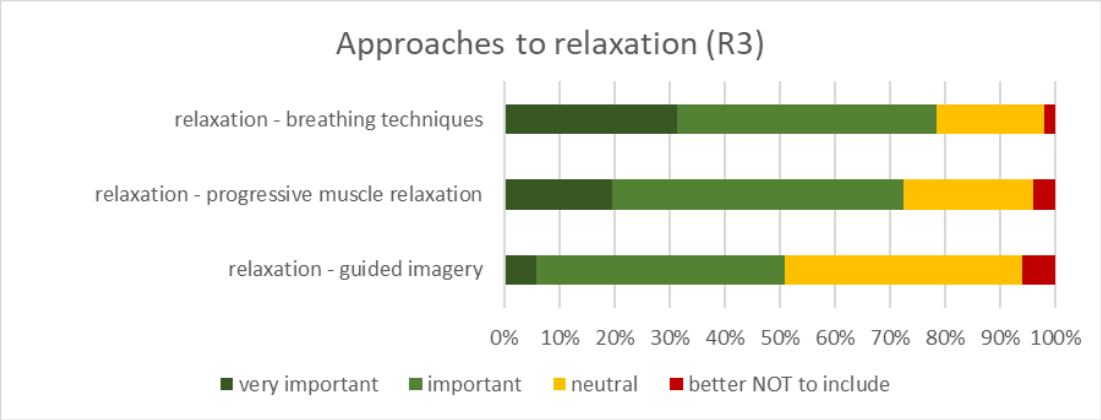

Intervention components for consideration, ratings of importance to include (R2)
Consider use of ambient noise / white noise in bedroom
Try to improve air quality if mould, damp or allergens are an issue
Address sense of security in the home
0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
very important
important
neutral
not important
better NOT to include

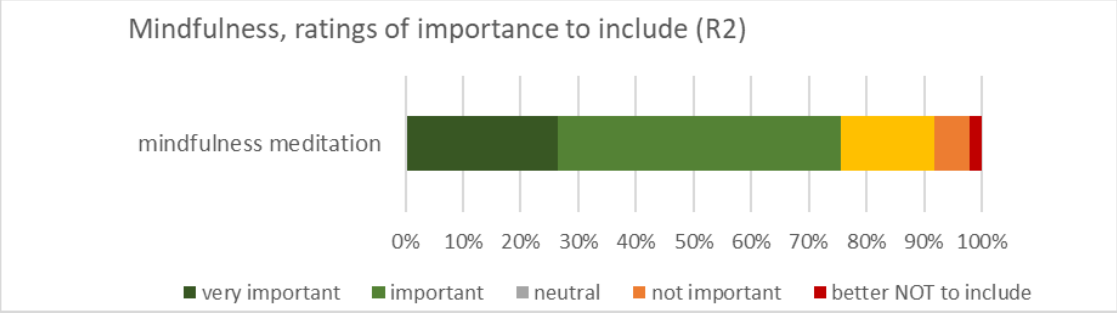
Relaxation and / or mindfulness

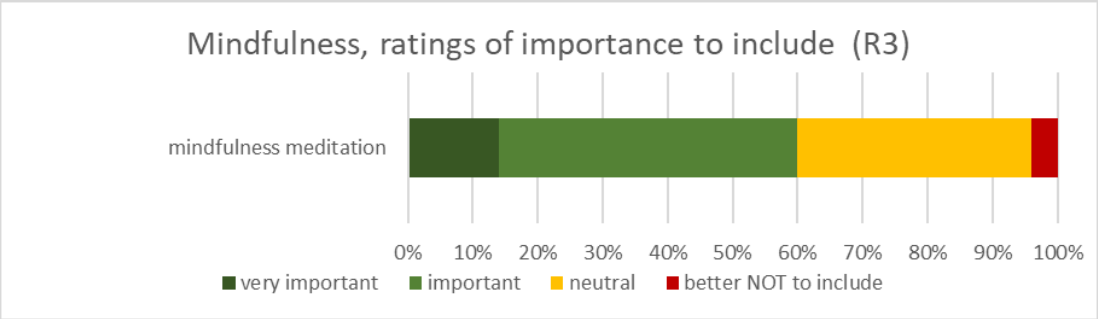
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Mindfulness and relaxation were often brought up together, sometimes interchangeably by participants. This is not to say that all that these participants all thought they were equivalent, but some saw them as interchangeable within a sleep intervention.		46 (82%)	13 (50%)
Relaxation techniques	"Individual responses to each of these relaxation strategies can vary significantly" (sleep OT) "offer a selection for person to trial" (MH OT) "a body-based relaxation technique (yoga, progressive muscle relaxation) may be preferred over a purely "mindful" approach." (sleep OT CBTi practitioner) "I would see these things as an additional adjunctives rather than prioritised within the intervention." (sleep & MH researcher) "practice this during the day for several weeks, until they have built up their skill level, before introducing into a bedtime routine" (sleep OT CBTi practitioner) "definitely in the daytime, I wouldn't use it as a strategy to help you fall asleep." (sleep OT CBTi practitioner) "I do not favour using any kind of relaxation routine (such as PMR) in bed - especially if it involves a recording." (sleep OT CBTi practitioner) "…when you're in that panic, when you're in that state of, like, anxiety […] struggling to breathe, just take a minute to just sit down and feel what's around you and listen to different sounds, and just focus on that." (personal experience) "I find that it's just another thing that I'm thinking about, and that keeps me well awake." (personal experience)	45 (80%)	13 (50%)
Breathing techniques	"concentrate on breathing when in bed" (circadian rhythm & MH researcher) "Perhaps try breathing exercise as the main [approach]" (sleep & MH clinician researcher)	21 (38%)	0 (0%)
Mindfulness meditation	"Relaxation techniques (muscle relaxation, guided visualisation, mindfulness, breathing etc.)" (sleep researcher) "for me mindfulness meditation you cant really separate that from breathing techniques. […] Mindfulness again its not necessarily about producing sleep is it…" (MH OT)	17 (30%)	7 (27%)

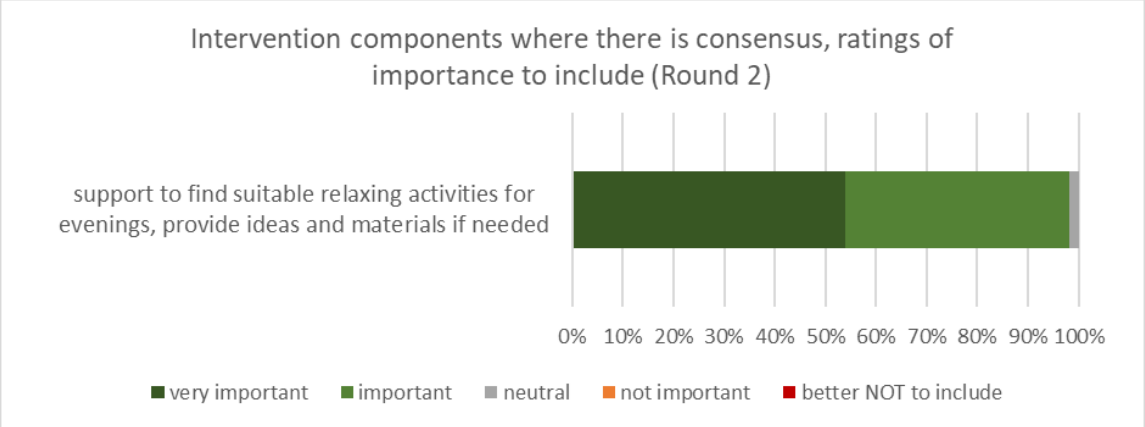
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	"Mindfulness is not about relaxation, that's a misunderstanding, anything you get out of mindfulness that moves you in the direction you thought you might want to go in is a side effect, the main effect is being present, and getting good at feeling what you're feeling" (CBTi practitioner) "Oh, yes, it's really good. It helps me relax but it's not supposed to send you to sleep but it always sends me to sleep." (personal experience)		







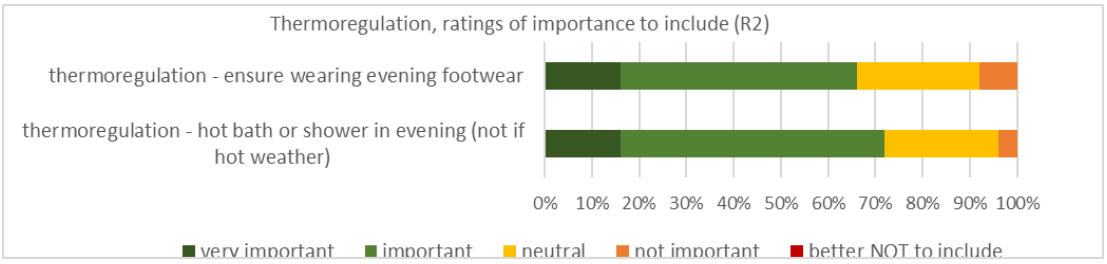




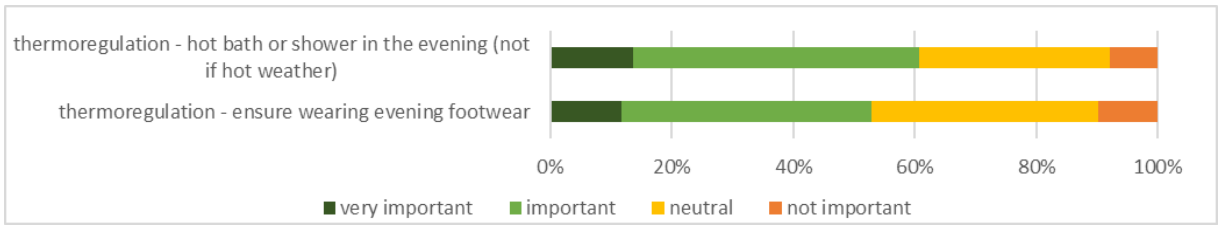
Thermoregulation

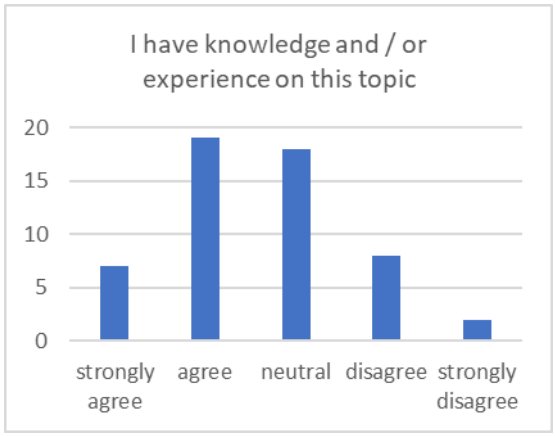
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Thermoregulation	"lower the bedroom temperature, open the window wide for 20 min and allow fresh air to come in before going into bed" (circadian rhythm & MH researcher)	34 (64%)	7 (27%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	"With regards to bedding, it could also be considered in the sense of thermoregulation - e.g., using thinner sheets if they get hot easily in bed." (sleep & MH clinician researcher) "The effects of cold feet are underestimated and very simple to address. However it is important to warm the feet PRIOR to going to bed." (circadian rhythm researcher) "Cold feet prevent vasodilation and impair drop in core body temperature which inhibits or at minimum delays sleep. This is a very well evidenced effect." (sleep OT) "The evidence for wearing warm footwear is not strong" (sleep specialist psychiatrist) "Clearly if this is an issue for some clients it should be addressed, but for many I suspect it could take away time from other aspects of the intervention" (sleep & MH clinician researcher) "timing of shower or bath (makes a difference to sleep onset) […]not 'hot' bath or shower; instead, say warm (avoid really hot or really cold)" (sleep OT) "Less convinced by evidence on hot bath/shower, but could be suggested as part of establishing an evening routine if the client felt a bath/shower worked well for them." (sleep researcher) "It could be mentioned that having an evening soak in the bath may be helpful in inducing sleep" (personal experience)		



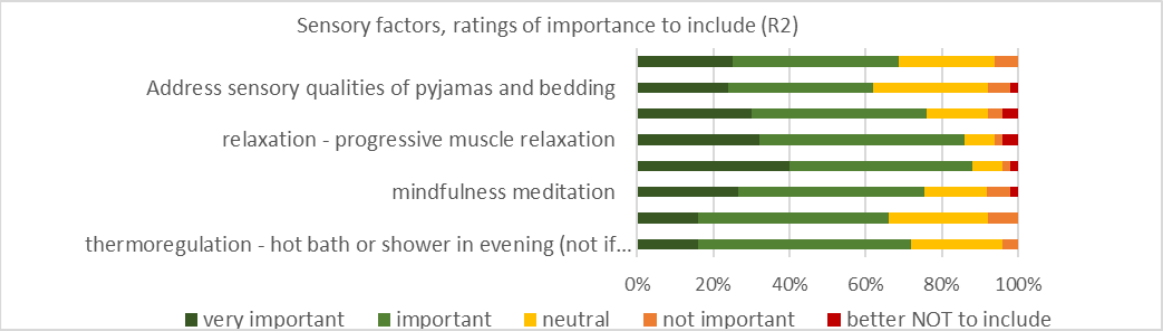
Round 3:


thermoregulation - hot bath or shower in the evening (not if hot weather)
thermoregulation - ensure wearing evening footwear
0%
20%
40%
60%
80%
100%
very important
important
neutral
not important


I have knowledge and / or experience on this topic
20
15
10
5
0
strongly agree
agree
neutral
disagree
strongly disagree

Addressing sensory factors

For qualitative content see above in 'sensory factors', under Environmental assessment and intervention. Sensory factors were mostly related to the bedroom, but also to nightclothes.



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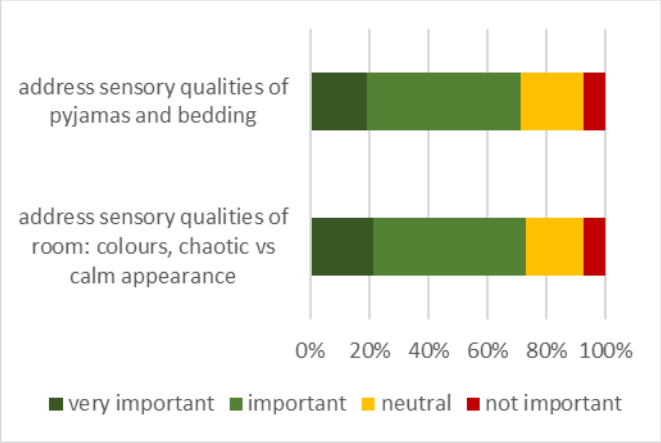
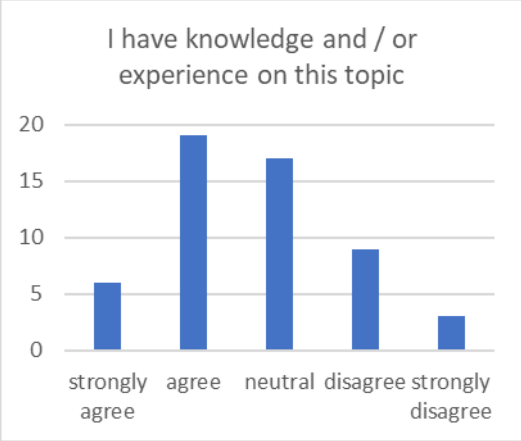
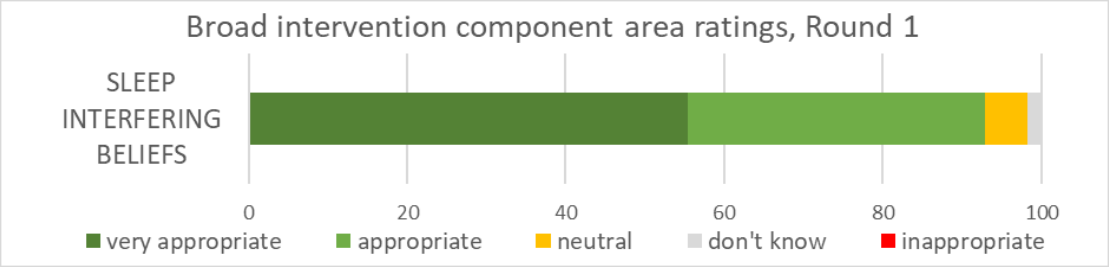


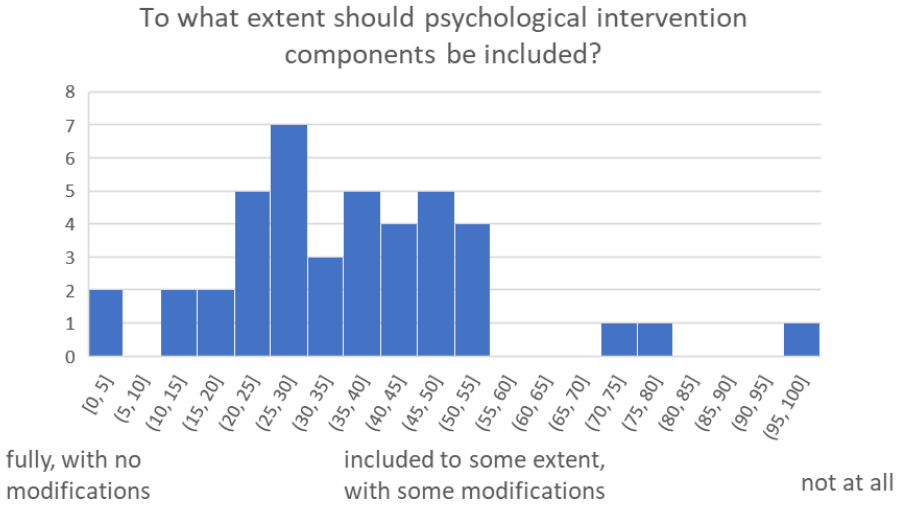


Cognitive or psychological approaches

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Cognitive or psychological approaches	"factors over which there is no control. It may be necessary to think about how to manage thoughts about such things (there is no point getting angry about trains on the line at the end of the garden which was there before you moved in the house)" (sleep OT CBTi practitioner) "Book to write worries in if needed" (MH OT) "Putting the day to rest, eg. wind down, worry management" (sleep & MH clinician researcher) "Thought records, downward arrow techniques, reviewing evidence, worry time, mindfulness, testing of safety behaviors" (CBTi practitioner) "From my standpoint, I might touch on it, but if that's someone's main problem I might refer to a psychologist or a MH clinician, its not that I don't address it but if that's their main thing - and the CBTi I've learned is not so much focused on the cognitive components, its more SR, routines" (sleep OT) "the only reason to use cognitive technique is to get the person on board to do what they need to do" (CBTi practitioner) "I honestly think every patient should receive some cognitive input, at minimum around helping them to drop the struggle, which perpetuates insomnia and around activating the PNS." (sleep OT CBTi practitioner) "I feel using cognitive techniques in addressing dysfunctional sleep beliefs is within OT scope" (sleep OT CBTi practitioner) "and the psychologist said to me instead of worrying about everything all day, choose a time, say it's like five o'clock, and for that hour you can think about it through that hour, and then the rest of the day you forget about it. […] But it's not that easy." (personal experience) "I'm not sure about that because is it, kind of, like counselling? […] If it's going to mean I have to talk about things that might upset me then that's not going to be a good thing…" (personal experience)	35 (62%)	5 (19%)
Psychological approaches better dealt with by	"if you are going too far down the CBT route you should probably be using psychological therapists." (MH OT)		

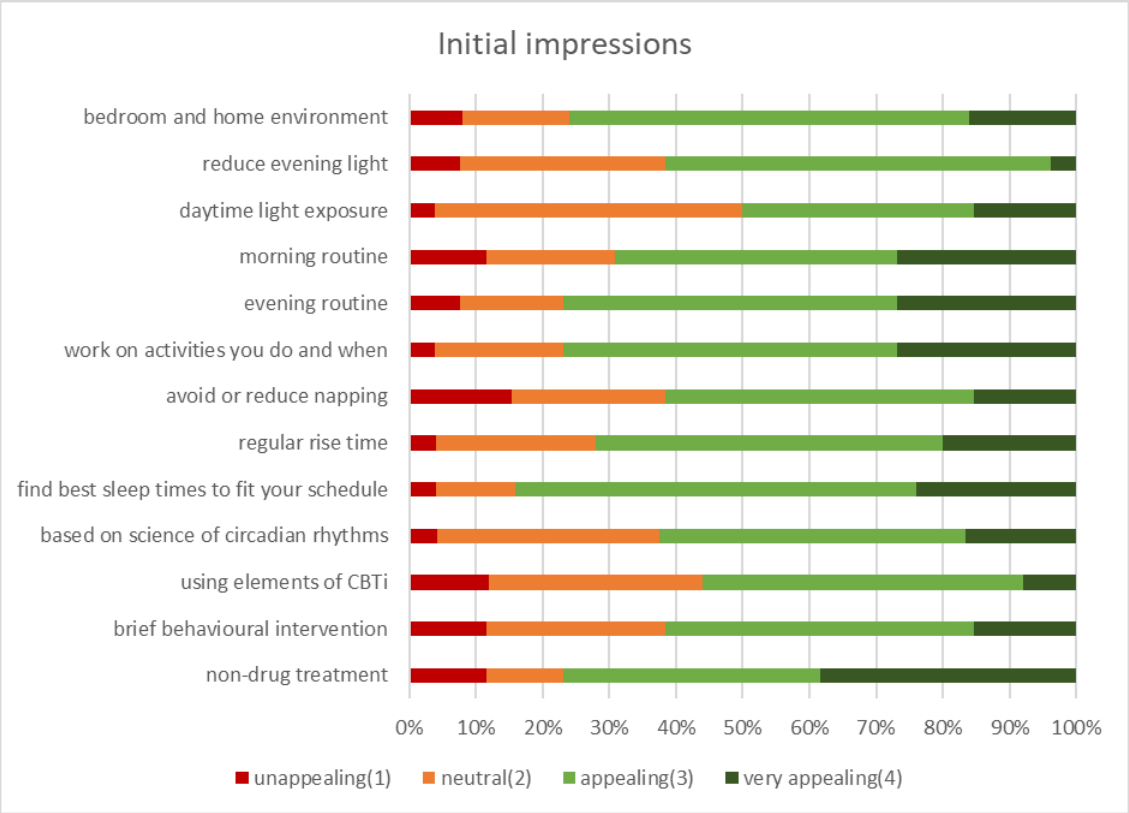
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
psychological therapist	"If more cognitive approaches are needed, refer to a psychologist. You do not need to have all expertise in one hand." (circadian rhythm & MH researcher)		





It is acknowledged in hindsight that there may be a social desirability bias in responses to this question as it was posed partly in relation to points made about the skills and professional remit of OTs. There may have been a bias toward rating higher toward inclusion in order to reflect positively on the skills of OTs, a group of which the researcher and many participants in the study are members, rather than ratings reflecting the ideal format for inclusion within this particular intervention.

Intervention components and intervention descriptions - Final stage, views from participants with personal experience:



4. Personalisation

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
The goals of the intervention should be individually determined	"ask them to write down their key concerns about their sleep" (sleep & MH researcher) "what is the one thing you want to change most of all, and why…" (OT CBTi therapist) "For me naps depend on whether patient wants to be a napper when Tx is done" (CBTi therapist) "…and why should you make them mainstream" (circadian rhythm & MH researcher) "flexibility for individual patients' interests and preferences" (psychiatrist) "what (if anything) they feel they can/wish to change." (MH OT) "I think it's really difficult to say, this is the way everybody will… Because people have different sleeping patterns, they have different interests" (personal experience) "go through everyone's list and say which of these is most important to you? Right, we'll do the intervention on that. A tailored personalised…" (personal experience)	22 (%)	3 (%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	Although some advocated a fairly standardised protocol, there was always some degree of flexibility in aims advocated. Flexibility ranged from fairly limited: such as personalising target sleep onset and offset times, to much more wide ranging flexibility in aims. CBTi therapists were less likely to be flexible about avoiding or banning naps, other participants views varied more regarding sleep schedule and naps.		
The methods of intervention should be personalised	"Some individuals may be more sensitive to light than others" (OT CBTi therapist) "what is done first will depend to a great extent on the person." (OT CBTi therapist) "Individual responses to each of these relaxation strategies can vary significantly" (OT sleep researcher) "But if you have somebody with a severe delay […] I never [sleep] restrict those people" (CBTi therapist) "some people may be able to maintain more irregularity and maintain progress towards good sleep than others." (MH OT) "Chair: You don't think it [relaxation] has to be like, it should be used with everyone? Respondent A: No. Respondent B: No. Everyone's different." (personal experience) "We're all unique and we all do it different ways." (carer / significant other) "There's never going to be an intervention that's right for everybody." (carer / significant other)	38 (68%)	9 (35%)
	Sometimes personalisation was advocated around sleep schedule. Occasionally personalisation was described around light. Very commonly personalisation was advocated around relaxation, mindfulness, and sensory approaches. Reasons for personalising included around individual client preferences, and around different sleep problem phenotypes.		
Limits to personalisation	"while individuals will vary, it is not practical formally to offer a range of techniques when there are so many other things to do" (OT CBTi clinician) "it is also an issue of whether one is sacrificing time on another aspect of the intervention by including it" (sleep & MH clinical psychologist) "standard forms like ISI, GAD and PHQ, I think doing those is really helpful to start a conversation if you are a bit unsure" (sleep OT clinician) "I would have thought the level of structure required may depend on the clinician's expertise and confidence, therefore, needs some flexibility across different levels of expertise in how the assessment is performed. That said, I would have thought it needs to be fairly structured across	10 (18%)	0 (0%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	the board to be consistent in gathering information on what are determined the important areas" (MH OT)		
	Increasing personalisation although desirable in principle, was acknowledged as potentially increasing the length of the intervention or the assessment, as well as increasing training and experience demands on the therapist. This could impact on the confidence of the therapist in delivery, which may impact outcomes (see code below).		
Other areas in which personalisation was discussed	See also content relating to personalisation in the following areas and sections: Accommodating differences in: occupations and interests, social environment and context, cultural factors, home environment Considering the impact of differences in: light sensitivity, caffeine sensitivity, and medication side effects, individual responses to relaxation, sensory factors and thermoregulatory input Choices in format for activity and sleep diary discussed.		

5. Format, structure and pragmatic considerations

Personalisation and complexity vs simplicity to deliver

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Personalisation	See section 1. Personalisation, final sub-topic "limits to personalisation". A tension was identified between the need to personalise the intervention, and to make it simple enough to be delivered confidently and not confusing to therapist or client (see also below 6. Therapeutic Approach and therapist factors, which discusses confidence, knowledge and skills required to deliver the therapy.)		
Keep it simple	"rules of thumb are important in a program and I like the idea of general guidelines since in the real world we have little time to 'customise' everything" (sleep OT) "The protocol should fit onto an easily legible A4 format sheet, and only one!" (sleep specialist psychiatrist) "There is a huge amount here, and potentially daunting for non-sleep-experts. Therefore keep it really simple, modular" (sleep specialist psychiatrist) "I guess you have to limit it somehow, but sleep involves EVERYTHING. […] you can't focus on everything really" (sleep OT) "…what is the one thing you want to change most of all, and why is that most important thing for you to change now, because we probably wouldn't look at trying to do the whole thing, it would just be change one thing at a time." (sleep OT CBTi practitioner)	22 (39%)	0 (0%)

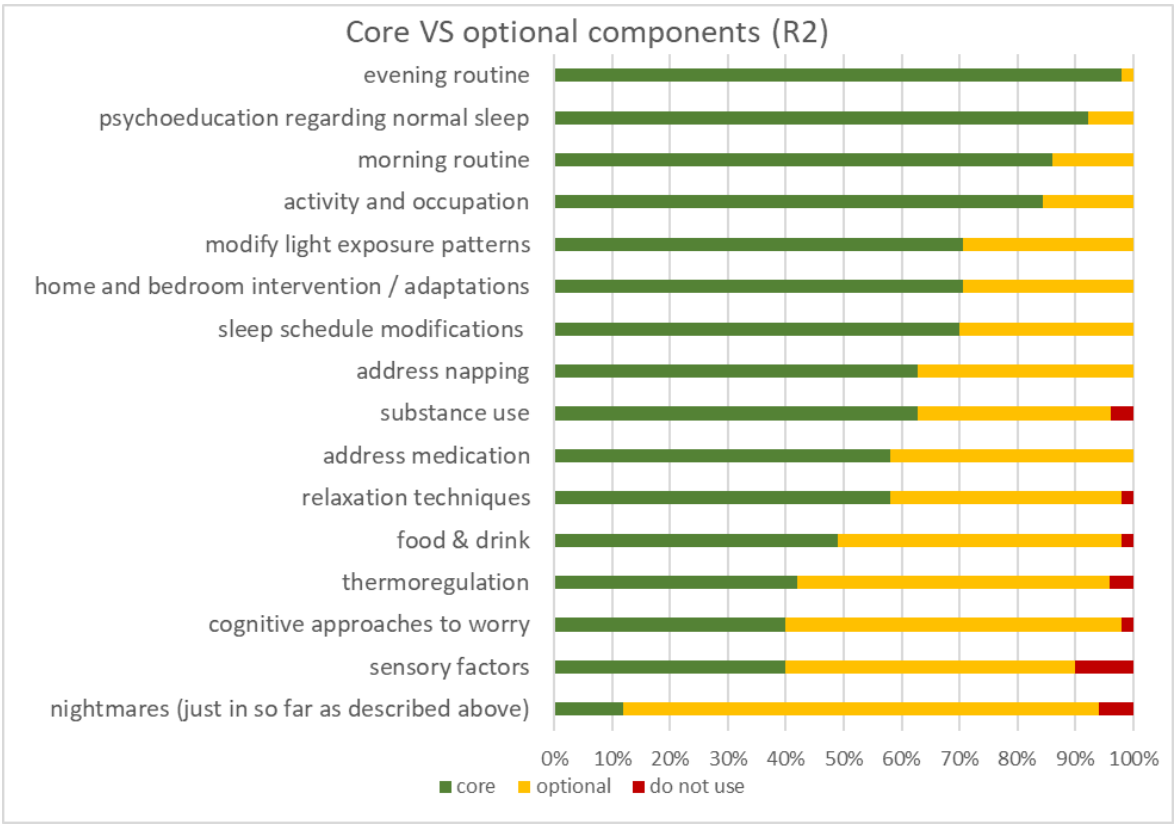
Format of intervention and assessment materials

See also section 2. The Assessment, for discussion of diary options to suit different individuals technological literacy and preferences, and use of technology in passive monitoring of sleep, activity and light.

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Format options & literacy	"Some patients have poor concentration [and / or literacy need to vary teaching approaches/information sources" (MH OT) "Large print and check readability and understanding of written content" (sleep & MH clinician researcher)	4 (7%)	0 (0%)
Use of technology in delivery of the intervention	"a smartphone app for use alongside the intervention and to carry on the techniques after the intervention period ends?" (MH researcher) "In terms of high tech or low tech, I think people should be given an option." (sleep OT) "Signposting to websites, apps, pod casts, books etc" (MH OT) " Facilitator: Some people said about like therapists could call people or text people… Respondent A: Yeah. Respondent B: Yeah Facilitator: …at certain times. Respondent B: I'd prefer the text at certain times, myself. Facilitator: Yeah. If we had like an automated texting system that we could set them all in advance, would that be as good as a real therapist texting you? Respondent B: Erm, I think…Yeah, I think it would, to be honest. Respondent C: Yeah, I think it would. Yeah." (personal experience)	24 (43%)	9 (35%)

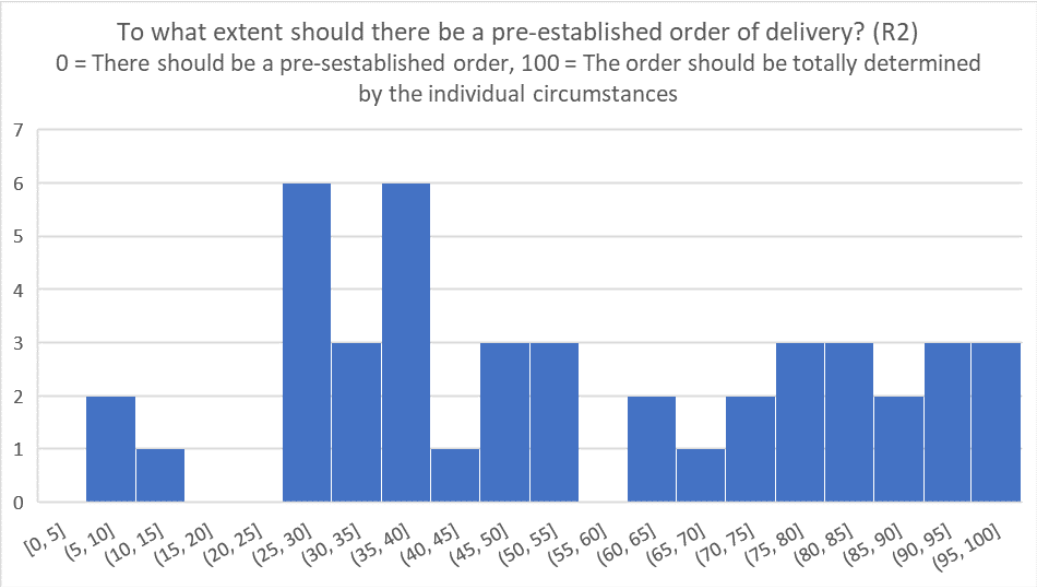
Core vs optional components

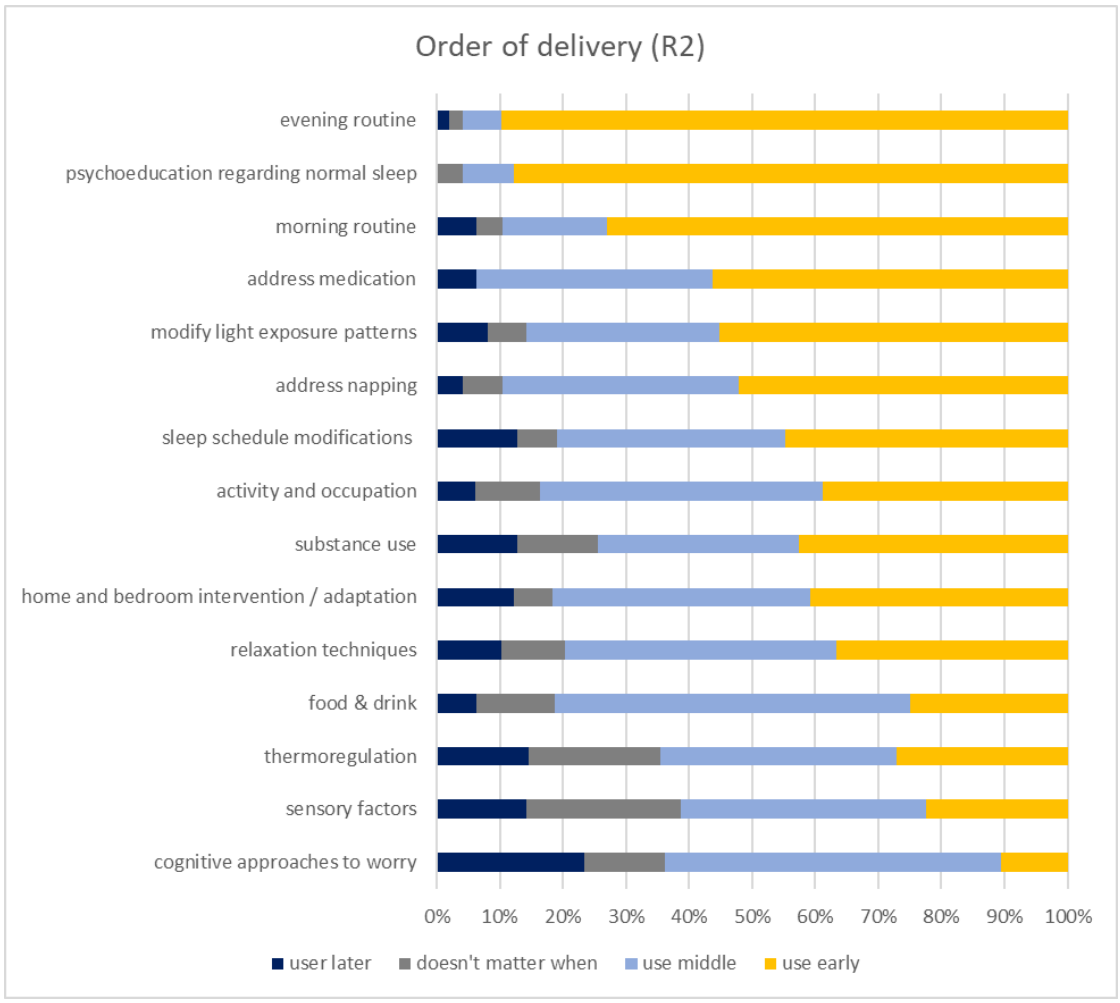
Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Core vs optional components	"Yes so for a lot of ppl if they can stick to SRT and stimulus control, I find they are sleeping through 85% of the time, for some there are sensitive people, or the temp in the room is high, caffeine at night, those things you are going to have to address. For the most part the core sleep behaviours take care of it." (sleep OT CBTi practitioner) "If the effects of modifying light environment causes deactivation instantly and alters sleep very much- this will make some other interventions less necessary […] that might still be necessary for some." (circadian rhythm & MH clinician researcher) "Everything needs to be covered, it is just a case of when" (MH OT) "I feel the 'core' (apply to everyone, cover at the beginning and middle) and 'optional' (applies to some individuals, cover towards middle and end) makes sense […] makes it more manageable for the clinician, and also patient." (sleep specialist psychiatrist)	9 (16%)	0 (0%)



Order of delivery

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Order of delivery	"Focus on establishing sleep schedule (supported by evening routine and light exposure) to anchor circadian rhythm and improve sleep efficiency first. Then add in other components as sleep efficiency and sleep timing stability are improving." (sleep researcher) "Although I would not think that relaxation is the solution for many people, it would make sense to start early on it as it takes time to learn." (sleep OT) "psychoeducation would usually be first, but then rest of it probably relies on what is going on for that person" (sleep & MH researcher "it is all important, should almost all be delivered early on and repeated often!!" (sleep specialist psychiatrist) "While I might tend toward a set order, I would also want to be listening first to what the patient experiences as the critical sleep issues..because developing a good therapeutic relationship will expand trust and motivation leading to treatment success." (sleep OT) "'The order will depend on the complaint and the baseline pattern […] open to changes according to what the client sees as manageable concurrently and what is a 'no-no' for the client." (circadian rhythm & MH researcher) "If all interventions are given at once, the learning for patients about the effects is confounded." (circadian rhythm & MH clinician researcher)	15 (27%)	0 (0%)




Order of delivery (R2)
evening routine
psychoeducation regarding normal sleep
morning routine
address medication
modify light exposure patterns
address napping
sleep schedule modifications
activity and occupation
substance use
home and bedroom intervention / adaptation
relaxation techniques
food & drink
thermoregulation
sensory factors
cognitive approaches to worry
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%
user later
doesn't matter when
use middle
use early

Follow-up and ending of therapy

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Maintenance plan	"Try to work out how they can remember the steps that are involved, because it's really easy to go back to old habits. Whether you have it in a written form, or you could do a chat about what's important and what their goals are and actually record something for them" (sleep OT). "Having clear goals and behavioural plans to take forward, tools to self monitor improvements" (MH OT) "Go through a relapse prevention form and write down all the things that worked for that person so they have it to refer back to. Teach them what you are doing and why so they take that with them and don't just do the intervention but once done know how to do it themselves" (sleep OT CBTi practitioner) "Positive sleep maintenance plan (as opposed to relapse prevention plan)" (MH OT)	23 (41%)	0 (0%)
	See also 7. Implementation considerations, MDT approach within the intervention, MDT involvement in maintenance.		
Follow-up / tapering of ending	"Maybe a follow up review 6 months or so after the intervention to review progress" (psychiatrist) "support group, either online or in person" (sleep OT) "Follow up visits. Mobile-phone app for long term recording/routine maintenance." (circadian rhythm & MH clinician researcher) "Arrange follow-ups after the therapy at short and longer term intervals if possible" (MH OT) "Invite them three time a year for a special event and inform about new developments in therapy" (circadian rhythm & MH researcher)	40 (71%)	0 (0%)

6. Therapeutic approach and therapist factors

Therapeutic approach, therapist attitude & manner

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
An educational approach	"Education regarding the impact of being in bed too long" (sleep OT) "Why drugs such as benzos or alcohol don't work" (psychiatrist) "role of the biological clock, light and darkness" (MH & circadian rhythm researcher) "Information about sleep & good sleep practices" (sleep & MH researcher) "Sleep psychoeducation (in contrast to e.g., standard insomnia treatment, where often people know a lot already!)" (sleep & MH researcher)	34 (61%)	0 (0%)
	Education is also discussed specifically in relation to light, circadian rhythm, and regular rise time (above), and prior knowledge in these areas was rated as low by people with personal experience, as well as confidence that these approaches would work.		
Education re: normal sleep	"What is normal sleep - many people I've assessed actually sleep fairly well but don't realise it's normal to wake several times per night and go straight back to sleep again" (psychiatrist) "…helping people understand sleep and their sleep systems and why some of their beliefs are not accurate is a huge factor in their motivation to change their sleep behaviours." (sleep OT CBTi practitioner)	22 (39%)	0 (0%)
Normalising	"normalising information on the variability of sleep for everyone" (sleep & MH researcher) "Yes I think people can say that nightmares = going mad, but it might just be that your processing some stuff. […] [psychoeducation] include nightmares and role in processing memories." (clinical psychologist)	8 (14%)	0 (0%)
Experimentation	"Encourage patients to see patterns (e.g., late wake time one day leads to poorer sleep and insomnia that night). Obtain baseline sleep diary or passive monitoring data, and review together with patient, to gain insight into schedule." (sleep specialist psychiatrist) "…behavioural experiments with light in sessions (e.g., going outside and seeing how much that improves alertness/mood)" (sleep & MH researcher)	5 (9%)	0 (0%)
Benefits of change, motivational	"The benefits of it and link it to each person's goal achievement." (MH OT)	11 (20%)	0 (0%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
interviewing approach	"changing the view upon how time spend is a starting point" (sleep & MH researcher) "Motivational interviewing for following through with treatment" (sleep & MH clinician researcher)		

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Therapeutic rapport & listening	"instilling hope for change will be an important part of building the rapport" (MH OT) "must emphasize good connection/good relation with the patient" (MH & circadian rhythm clinician researcher)	5 (9%)	0 (0%)
Rapport required before home assessment	"I don't like strangers so interaction in the community first would be necessary" (personal experience) "Too intrusive if it is a social worker. Social workers coming to your house are very judgemental - who would be doing the assessment and what does it entail." (personal experience)	0 (0%)	6 (23%)

Therapist knowledge, skills & confidence

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Therapist confidence in delivering the intervention	"a lot of people say to me 'if it wasn't for how sure you were I couldn't have done this', so one think I always say […] is, never blink" (CBTi practitioner) "Well usually I say that I know in practice for many patients this works so probably for you it will as well. So just go out and try it." (sleep specialist psychiatrist) "Encourage client that CBTi is well evidenced and researched to help people with insomnia." (sleep OT) "I would have thought the level of structure required may depend on the clinician's expertise and confidence, therefore, needs some flexibility across different levels of expertise in how the assessment is performed. That said, I would have thought it needs to be fairly structured across the board to be consistent in gathering information on what are determined the important areas" (MH OT)	5 (9%)	n/a
Relationship to OT role & skills	"where others have specific, maybe psychology training or something far above what we have, we have those practical problem solving skills, its natural for us to look at ways to managing difficult activities in an easier way, and learning a new skill, its repetition, routine" (sleep OT CBTi practitioner) "Alternatives to looking at screens in the evening. This is something I struggle with in patients who don't like reading, and OTs may be in a good position to explore this." (psychiatrist) "Barriers: OTs aren't aware it is in their domain, poor training of OT, not enough research" (sleep OT)	21 (38%)	n/a

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
	" [Difficulties you would foresee with OTs delivering this] None. However in previous role it was clearly seen as the role of psychologists" (MH OT) "[Difficulties you would foresee with OTs delivering this] Specialist therapy skills, unless training received. Eg. Socratic questioning, gentle cognitive restructuring, imagery rehearsal" (sleep & MH clinician researcher) "you know how to be an OT, this is just an extension of what you already do […] sleep interventions. Its just extending OT to the 24hr day" (sleep OT)		
Generic working barrier to OT interventions	"Occupational therapists who are working generically in the community are struggling to carry out occupational therapy interventions […] When testing the intervention I suggest targeting those occupational therapists who are already employed to provide occupational therapy interventions" (MH OT)	3 (5%)	n/a

7. Implementation considerations

Reaching referrals

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
Reaching referrals	"MDT colleagues would not routinely consider sleep disturbance as an occupational issue" (MH OT) "The biggest obstacle may be convincing the other professionals that this belongs in the OT treatment plan and is not left only to MDs/meds or psychologists" (sleep OT) "a) Provide specific services addressing sleep. […] b) Provide a basic toolkit to professionals (so every team has someone with at least a basic knowledge of assessing and treating sleep in psychosis)" (sleep specialist psychiatrist) "Include sleep questions in all assessments, ask the question (most people think it's about not enough sleep). Highlight the impact of poor sleep?" (MH OT) "an advantage as OTs as when ppl are asked by the Dr to see a psychologist they might say 'no theres nothing wrong with me I'm not crazy', but when its do you want to work with the OT, they might be able to suggest some ways to help you, they say 'sure'. […] its not really a therapy group […] focus on education." (sleep OT) "clients were more than willing to go into detail of their sleep problems and could very well pinpoint the problem" (circadian rhythm & MH researcher)	35 (56%)	0 (0%)

MDT approach within intervention

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
MDT knowledge & attitude	"Changing the cultures of CMHTs to look at people's quality of life, not just preventing/treating illness and making sure people comply with medication - big ask perhaps" (MH OT) "Mental health professionals often view sleep problems as epiphenomena or symptoms associated with other diagnoses" (sleep OT) "the social workers and occupational therapists, rather than the doctors were aware of the sleep disturbances but helpless in doing anything about it, because they were not having access to information and tools." (circadian rhythm & MH researcher) "Is sleep classed as a mental health? […] …so why doesn't my psychiatrist treat me for insomnia? He won't give me sleeping tablets. He won't give me melatonin. He just treats me for this psychosis which I haven't had for three years." (personal experience)	18 (32%)	3 (12%)

Recommendation or issue raised	Data excerpts	professionals n= (%)	personal exp. n= (%)
MDT approach to intervention	"I have worked in multiple CMHTs. The difficulty is getting consistent and regular staff input to support the patients as they go through the process." (sleep specialist psychiatrist) "this needs to be generic to rehabilitation and not specific to OT" (sleep OT) "Involvement of carers and support workers" (sleep & MH clinician researcher) "addressing food and drink content […] people have complex medical issues and their diet (including fluid intake) should be carefully managed [not by OT but by dieticians] (sleep OT) "Another example is having a dual diagnosis specialist who understands the role of drug use in sleep." (sleep specialist psychiatrist)	36 (64%)	1 (4%)
MDT approach to medication	"In order to optimise outcomes, the team will need to work together to treat sleep. This will therefore require prescribers (usually psychiatrists) who understand sleep and the effect of different	25 (45%)	1 (4%)

	psychotropics on sleep, and work with the OT to optimise this." (sleep specialist psychiatrist) "Medication changes tend to pose some difficulties with determining whether a sleep strategy is working or not" (sleep & MH clinician researcher) "napping is sometimes unavoidable due to medication, coordination between [C]MHT and OT important" (personal experience)		
MDT approach to maintenance	"Engaging the person's social and other professional support network to continue any required prompting" (MH OT) "Info for the usual clinicians on what has been covered in therapy, with resources to point the patient to if problems recur" (psychiatrist)	9 (16%)	0 (0%)

S2 Survey. Round 1 survey questions

questions extracted from Select Survey

Round 1:

Page 3

About you

3. What is your name?

4. What is your job title / role / position?

5. Are you predominantly a clinician or researcher?
   - ◯ predominantly a clinician
   - ◯ predominantly a researcher
   - ◯ pretty much equally split, clinical academic

6. What groups do you work with or study?

   Select all those you regularly work with:
   - ☐ general population / healthy adults
   - ☐ depression (seasonal or non-seasonal)
   - ☐ bipolar
   - ☐ psychosis
   - ☐ personality disorder
   - ☐ anxiety disorders and phobias
   - ☐ sleep disorders - insomnia
   - ☐ sleep disorders - parasomnias and sleep disordered breathing
   - ☐ sleep disorders - circadian rhythm
   - ☐ neurodegenerative disorders
   - ☐ Other, please specify

7. **Your expertise**:
   We would like to identify the nature of your knowledge and experience, you could include information about the focus of the majority of your work as it relates to this project, and your professional background (if relevant). Please provide information in whatever way is easiest for you. E.g. If information is already on line you can paste a link to your institutional profile page, LinkedIn page, ResearchGate page, etc, and/or you can write in or paste in information.

   - This does not need to be exhaustive.

- We are **not** weighting responses based on qualifications or experience.
- We will use this information to best target further recruitment to fill in gaps and get a range of expertise within each group.
- We will use this information to help decide which group to include participants in, in cases where they fit into more than one group.

8. Please select which expert group you feel you best fit into:

*

- [ ] Sleep and/or circadian rhythm expert (clinician or researcher)
- [ ] Experienced mental health occupational therapy clinician or researcher
- [ ] Occupational therapist with expertise in sleep
- [ ] Other mental health expert or senior stakeholder
- [ ] I fit equally into two or more of these groups

9. What is the best email address to contact you with the link to complete round 2 and round 3?*

Page 9

Your initial thoughts

This page is to capture your initial thoughts before we start to use any more specific headings which might alter your responses. There will be chance to elaborate on these later if you wish.

15. Do you have any views about what should be covered and how in the pre-intervention assessment?

This is the assessment that would be completed if the intervention were in routine clinical practice. An assessment to inform the therapy. We don't mean any baseline assessments which might be done primarily for the purposes of the research study.

1

2

3

16. Based on your knowledge and experience, what are the main aspects or components are which should be included in the intervention?

1

2

3

4

5

17. Do you have any thoughts about how to best help the service user maintain any improvements after therapy has ended?

1

2

3

Page 10

For all of the free-text questions please feel free not to write in full sentences.

You are free to leave boxes blank if you have no idea or no opinion on that topic.

If you are arranging a phone / skype call (optional) you can leave some or all boxes blank and give verbal feeback on those instead.

Page 11

The assessment

19. We have already determined that passive monitoring of rest-activity patterns will form part of the assessment, and later will form part of the intervention.

Do you have any comments or suggestions regarding this? (for example, how important is this, any drawbacks or challenges, any views about how to best approach this)

20. We have already determined that some form of recording of daytime activity will be invovled in the baseline assessment and later in the intervention.

Do you have any comments or suggestions regarding this? (for example, how important is this, any drawbacks or challenges, any views about how to best approach this)

21. We would ideally like to measure light exposure as part of the assessment and later durign the intervention, but as you may be aware there are methodological challenges in measuring light exposure accurately (devices worn onthe wrist are covered by clothes, devices struggle to account for factors like direction of gaze).

Do you have any comments or suggestions regarding this? (for example, how important is this, any drawbacks or challenges, any views about how to best approach this)

22. Do you have any comments or suggestions regarding technology or tools relating to any of the above (hardware, software, online or paper based)?

23. How long should the baseline assessment period be (roughly)? (i.e. the period within which sleep, and anything else, is measured and assessed before beginning intervention)

- ◯ assessment within first contact
- ◯ 1 week
- ◯ 2 weeks
- ◯ 3 weeks
- ◯ 4 weeks
- ◯ Other, please specify

Possible areas to address

24. How appropriate do you feel it is for the intervention to focus on the following areas:*

	Very Appropriate	Appropriate	Neutral	Inappropriate	Don't know / no view on this
sleep schedule	○	○	○	○	○
meal timing	○	○	○	○	○
daytime napping	○	○	○	○	○
daytime activity	○	○	○	○	○
bedroom / sleep area	○	○	○	○	○
light exposure	○	○	○	○	○
sleep interfering beliefs	○	○	○	○	○
waking up and morning routine	○	○	○	○	○
nightmares	○	○	○	○	○
evening and bedtime routine	○	○	○	○	○
antipsychotics and other medication	○	○	○	○	○
time in bed restriction / sleep restriction therapy	○	○	○	○	○
home environment	○	○	○	○	○

25. Do you feel there is anything missing from this list that you didn't already mention earlier? (response optional)

On the previous page you said:

-
-
-

26. Can you say any more about the reasons you feel it is better NOT to include any of the components you have selected as inappropriate above?

Page 13

27. What should be included in relation to light exposure and why?

Page 14

28. What should be included in relation to daytime activity and why?

Page 15

29. What should be included in relation to waking up and morning routine and why?

Page 16

30. What should be included in relation to evening and bedtime routine and why?

Page 17

31. What should be included in relation to daytime napping and why?

Page 18

32. What should be included in relation to sleep schedule and why?

Page 19

33. What should be included in relation to meal timing and why?

Page 20

34. What should be included in relation to time in bed restriction / sleep restriction therapy and why?

Page 21

35. What should be included in relation to home environment and why?

Page 22

36. What should be included in relation to bedroom / sleep area and why?

Page 23

37. What should be included in relation to nightmares and why?

Page 24

38. What should be included in relation to sleep interfering beliefs and why?

Page 25

39. What should be included in relation to antipsychotics and other medication and why?

Page 26

40. Do you want to add any more detail about what should be included in relation to any of these answers you gave?

-
-
-
-

Page 27

Implementation questions

41. The intervention is aimed at people with schizophrenia spectrum disorders, who have problems with sleep initiation, maintenance, quality or timing.

Do you have any comments regarding for whom within this group the intervention would be most appropriate, or any exclusions you feel would need to be made?

42. (if relevant) What difficulties if any would you foresee with an occupational therapist in your service / in community mental health services you are familiar with delivering this intervention in future?

43. Do you have any comments regarding barriers to the delivery and effectiveness of the intervention, and how to avoid or overcome these?

44. Are you electing to give feedback verbally by phone or skype for this round? This can be general or just on a certain topic or question.

    If so please give contact details and an indication of what days and times are best for you and I will get in touch.

Thank you very much for completing this survey!

I will be in touch with round 2 in late November.

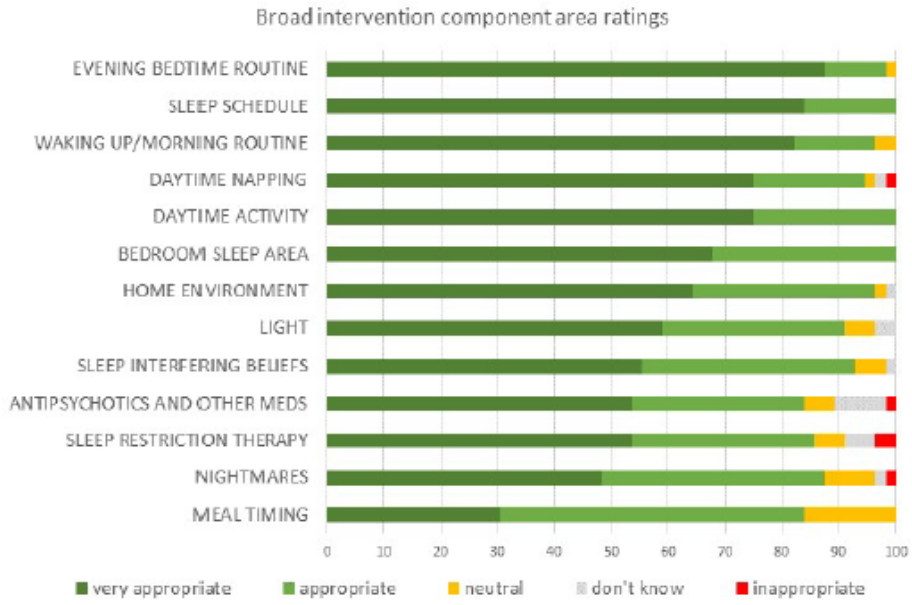
Best Wishes,
Sophie

S3 Survey. Round 2 survey questions

Round 2

Developing an Occupational Therapy intervention to improve sleep in people with schizophrenia spectrum disorders.

Welcome to round 2!



This survey will cover the following areas:

1. the initial assessment
2. the baseline assessment period
3. what should be included within the intervention components
4. which components are 'core' or 'optional'
5. order of componentsWe've put comments boxes throughout, but you needn't write in them all.

It should take you about half an hour, maybe less.
You can save and resume: press the 'save and resume button at the bottom of the page.

1 of 5: The initial assessment

- ◯ strongly agree
- ◯ agree
- ◯ neutral
- ◯ disagree
- ◯ strongly disagree

Assuming that there is limited time to complete the initial assessment, how should we prioritise the following broad areas?

Please rank:

	1st - give most time and effort	2nd	3rd	4th	5th	6th - give least time and effort
impact of problem, motivation to change sleep, expectations of intervention	◯	◯	◯	◯	◯	◯
nature and history of sleep complaint	◯	◯	◯	◯	◯	◯
medical and psychiatric condition	◯	◯	◯	◯	◯	◯
life context (social, occupational, physical, immediate and wider)	◯	◯	◯	◯	◯	◯
values, interests and priorities in life	◯	◯	◯	◯	◯	◯
medication, including client views	◯	◯	◯	◯	◯	◯

In round 1 many of you commented to the effect:
~You need to first identify the type of problem, and the context, to decide what to assess and what intervention to suggest.~

It is agreed that we need to find out the following early on:

is the problem with sleep initiation, broken sleep, unrefreshing sleep, sleep timing, something else
what aspects of sleep does the person want to change (if any?)
personal and social factors which dictate what sleep schedule is needed or desired
is the problem more insomnia or more circadian rhythm disorder (or both, or something else)
If you have anything to add, please write it here:

How important is it to cover the following in the initial assessment?

	very important	important	neutral	not important	better NOT to include
medical co-morbidities / physical illnesses	○	○	○	○	○
mental health condition and symptoms (when ill, when well, current)	○	○	○	○	○
history of sleep complaint	○	○	○	○	○
family history of sleep complaints	○	○	○	○	○
self-report triggers for sleeping difficulties	○	○	○	○	○
assess chronotype / circadian preference (owl or lark)	○	○	○	○	○

It is agreed:
We will screen for sleep disordered breathing, restless leg syndrome, movement disorders and other parasomnias. Many of you mentioned this. Also it would be wrong not to. (Thank you for suggestions regarding screening tools.)

How important is it to cover the following in the initial assessment?

	very important	important	neutral	not important	better NOT to include
social environment (immediate and wider)	○	○	○	○	○
overview of activities and routines	○	○	○	○	○
interests and priorities in waking life	○	○	○	○	○

	very important	important	neutral	not important	better NOT to include
medication(s) (what drug)	○	○	○	○	○
medication timing(s)	○	○	○	○	○
medication dose(s)	○	○	○	○	○
person's view of medications and their role(s)	○	○	○	○	○
person's view of medication's impact on sleep	○	○	○	○	○

	very important	important	neutral	not important	better NOT to include
effect on daytime functioning sleep	○	○	○	○	○
assess motivation to improve sleep	○	○	○	○	○
can the person tolerate intervention without immediate benefit (sleep might be worse initially)?	○	○	○	○	○
what have they already tried?	○	○	○	○	○
what are their expectations and hopes for intervention?	○	○	○	○	○

2 of 5: The baseline assessment period

Better for baseline assessment period to depend on variability of presentation

Better to use a set length of baseline assessment period

(Place a mark on the scale above)

If we vary the length of the baseline assessment period, how much should it vary?

Shortest length	◯ 1 week ◯ 2 weeks ◯ 3 weeks ◯ 4 weeks ◯ 5 weeks ◯ more than 5 weeks
Longest length	◯ 1 week ◯ 2 weeks ◯ 3 weeks ◯ 4 weeks ◯ 5 weeks ◯ more than 5 weeks

If you have anything to add, please write it here:

3 of 5: Intervention components

Evening routine

It is agreed:
encourage to reduce stimulus and have evening wind down time
ensure following sleep hygiene recommendations as far as possible

Please rate:

	very important	important	neutral	not important	better NOT to include
support to establish evening routine which is similar each night	○	○	○	○	○
set time to start bed preparation	○	○	○	○	○
support to find suitable relaxing activities for evenings, provide ideas and materials if needed	○	○	○	○	○
encourage preparation for the next day the evening before	○	○	○	○	○

If you have anything to add, please write it here:

Morning routine

It is agreed:
give psychoeducation on sleep inertia - that sleepiness immediately on waking does not always reflect inadequate quality or amount of sleep
encourage energising activities such as shower, dress, go outside if possible

Please slide:

regular rise time
to anchor the circadian rhythm

could sometimes sleep in to recover sleep debt
if not enough sleep time

(Place a mark on the scale above)

Please slide:

continue with strictly regular rise time
to anchor the circadian rhythm

can afford occasional flexibility once routine is established

(Place a mark on the scale above)

Alarm clocks (select all that would sometimes be appropriate)	☐ support to set alarms ☐ include morning phone calls in intervention ☐ multiple alarms and set away from the bed ☐ puzzle alarm clocks (usually a mobile app) ☐ dawn simulation alarm clock ☐ avoid using alarm clocks

If you have anything to add, please write it here:

Sleep restriction therapy / time in bed restriction / sleep efficiency training.

	strongly agree	agree	neutral	disagree	strongly disagree
do not use any version of time in bed restriction	○	○	○	○	○
use adapted sleep restriction with a longer minimum sleep window	○	○	○	○	○
use sleep compression instead of sleep restriction	○	○	○	○	○

How long should the MINIMUM sleep window be (the shortest that should ever be used in this intervention)?

response optional

○ 5.5hrs ○ 6hrs ○ 6.5hrs ○ 7hrs ○ 7.5hrs ○ 8hrs ○ 8.5hrs ○ 9hrs ○ 9.5hrs ○ 10hrs

If you have anything to add, please write it here:

Napping

It is agreed:
avoid naps too late in the day
avoid longer naps
consider scheduling a nap midday or early afternoon if it is the only way to avoid a nap later in the day
Please rate:

	strongly agree	agree	neutral	disagree	strongly disagree
Allow napping	○	○	○	○	○
Avoid napping	○	○	○	○	○
Ban napping	○	○	○	○	○
Evaluate the role of naps	○	○	○	○	○
Encourage a regular, planned nap	○	○	○	○	○
Replace naps with activities...	○	○	○	○	○
...replace naps with active energising activities	○	○	○	○	○
...replace naps with restorative calming activities	○	○	○	○	○

If you have anything to add, please write it here:

Modifying light exposure

	very important	important	neutral	not important	better NOT to include
use a light box (in some cases)	○	○	○	○	○
use outdoor light (if possible)	○	○	○	○	○
address window coverings, curtains, blinds	○	○	○	○	○
use amber glasses (blue-light blocking) in the evening	○	○	○	○	○
alter the lighting in the home, e.g. change bulbs, arrange low light lamps for evening and night-time	○	○	○	○	○

If you have anything to add, please write it here:

Home assessment and intervention

	very important	important	neutral	not important	better NOT to include
Address sense of security in the home	○	○	○	○	○
Try to improve air quality if mould, damp or allergens are an issue	○	○	○	○	○
Consider use of ambient noise / white noise in bedroom	○	○	○	○	○
Alter locations of items so that the bed (and ideally the bedroom) is only used for sleep and sex	○	○	○	○	○

If you have anything to add, please write it here:

Activity and occupation

	very important	important	neutral	not important	better NOT to include
support to set "do not disturb" settings on devices	○	○	○	○	○
continue with activities planned irrespective of sleep	○	○	○	○	○
identify appropriate activities to do if waking in the night	○	○	○	○	○

If you have anything to add, please write it here:

Food and drink

It is agreed:
More relevant to refer to food and drink than to 'meals'
Psychoeducation on why to avoid large late meals
Don't go to bed hungry either (light snack 1 - 1.5hrs before bed if hunger disturbs sleep)

Please rate

	very important	important	neutral	not important	better NOT to include
address food routines earlier in the day to avoid eating a big meal late at night	○	○	○	○	○
address content of food and drinks	○	○	○	○	○
avoid snacking	○	○	○	○	○

If you have anything to add, please write it here:

Substance use (caffeine, alcohol, nicotine, illicit substances)

It is agreed:
reduce caffeine use, especially late in day
reduce smoking late at night, discourage smoking if awakening in night
psychoeducation on the effect of alcohol on sleep

If you have anything to add, please write it here:

Medication

It is agreed:
ensure taken at correct timing - morning or evening
liaise with prescriber, generally and regarding any sleep affecting side effects (e.g.daytime sedation, hypersalviation)

Please rate:

	very important	important	neutral	not important	better NOT to include
Experiment with altering exact timing of oral medication (e.g. earlier / later in the evening)	○	○	○	○	○

If you have anything to add, please write it here:

Nightmares

Although some of you suggested delivering imagery rehearsal or re-scripting, more respondents felt specialist nightmare intervention was beyond the scope of this intervention.

It is agreed:
nightmares will be assessed, refer or liaise as indicated
psychoeducation to normalise occasional nighmares or bad dreamsSome noted that nightmares may improve through treatment of other sleep problems.

Please rate:

	very important	important	neutral	not important	better NOT to include
work on strategies to calm self to return to bed if waking with a nightmare	○	○	○	○	○
if hypersomnia (e.g. over 9hrs), work on reducing to 8hrs	○	○	○	○	○

If you have anything to add, please write it here:

New components suggested

	very important	important	neutral	not important	better NOT to include
thermoregulation - hot bath or shower in evening (not if hot weather)	○	○	○	○	○
thermoregulation - ensure wearing evening footwear	○	○	○	○	○
mindfulness meditation	○	○	○	○	○
relaxation - breathing techniques	○	○	○	○	○
relaxation - progressive muscle relaxation	○	○	○	○	○
relaxation - guided imagery	○	○	○	○	○
Address sensory qualities of pyjamas and bedding	○	○	○	○	○
Address sensory qualities of room: colours, chaotic vs calm appearance	○	○	○	○	○

If you have anything to add, please write it here:

Cognitive approaches to worry and rumination were suggested, particularly by people trained in CBT for insomnia, but some note not all occupational therapists would be confident in this area.

POINTS FOR:
Usually included within CBT for insomnia.
Worry will be an issue for some clients.
POINTS AGAINST:
Maybe better matched to the skills of psychologists.
Cognitive approaches not as essential within CBT for insomnia as in other forms of CBT.

To what extent should cognitive or psychological approaches be included?

fully, with no modifications	included to some extent, with some modifications	not at all

(Place a mark on the scale above)

If you have anything to add, please write it here:

4 of 5: Core vs optional components

Core componentswould be those which are relevant for only certain cases (for example if reducing napping was an optional component, you might only attempt to reduce napping under certain conditions, such as if a particular complaint was present, or if naps were of a certain type/length/timing)

Please rate:

	core component (always use)	optional component (sometimes use)	do not use
nightmares (just in so far as described above)	○	○	○
relaxation techniques	○	○	○
psychoeducation regarding normal sleep	○	○	○
thermoregulation	○	○	○
sensory factors	○	○	○

	core component (always use)	optional component (sometimes use)	do not use
food & drink	○	○	○
substance use	○	○	○
morning routine	○	○	○
evening routine	○	○	○
address napping	○	○	○
sleep schedule modifications	○	○	○

	core component (always use)	optional component (sometimes use)	do not use
address medication	○	○	○
home and bedroom intervention / adaptations	○	○	○
activity and occupation	○	○	○
modify light exposure patterns	○	○	○
cognitive approaches to worry	○	○	○

5 of 5: Order of delivery

to what extent should there be a pre-established order?

There should be a pre-established order of delivery — The order should be totally determined by the individual circumstances

(Place a mark on the scale above)

Please select:

	should be delivered first / early on	should be delivered around the middle	should be delivered later on / last	doesn't matter when
nightmares (just in so far as described above)	○	○	○	○
relaxation techniques	○	○	○	○
psychoeducation regarding normal sleep	○	○	○	○
thermoregulation	○	○	○	○
sensory factors	○	○	○	○

	should be delivered first / early on	should be delivered around the middle	should be delivered later on / last	doesn't matter when
food & drink	○	○	○	○
substance use	○	○	○	○
morning routine	○	○	○	○
evening routine	○	○	○	○
address napping	○	○	○	○
sleep schedule modifications	○	○	○	○

	should be delivered first / early on	should be delivered around the middle	should be delivered later on	doesn't matter when
address medication	○	○	○	○
home and bedroom intervention / adaptation	○	○	○	○
activity and occupation	○	○	○	○
modify light exposure patterns	○	○	○	○
cognitive approaches to worry	○	○	○	○

If you have anything to add, please write it here:

DONE!

20. We have already determined that some form of recording of daytime activity will be invovled in the baseline assessment and later in the intervention.

Do you have any comments or suggestions regarding this? (for example, how important is this, any drawbacks or challenges, any views about how to best approach this)

21. We would ideally like to measure light exposure as part of the assessment and later durign the intervention, but as you may be aware there are methodological challenges in measuring light exposure accurately (devices worn onthe wrist are covered by clothes, devices struggle to account for factors like direction of gaze).

Do you have any comments or suggestions regarding this? (for example, how important is this, any drawbacks or challenges, any views about how to best approach this)

22. Do you have any comments or suggestions regarding technology or tools relating to any of the above (hardware, software, online or paper based)?

23. How long should the baseline assessment period be (roughly)? (i.e. the period within which sleep, and anything else, is measured and assessed before beginning intervention)

- ◯ assessment within first contact
- ◯ 1 week
- ◯ 2 weeks
- ◯ 3 weeks
- ◯ 4 weeks
- ◯ Other, please specify

Possible areas to address

24. How appropriate do you feel it is for the intervention to focus on the following areas:*

	Very Appropriate	Appropriate	Neutral	Inappropriate	Don't know / no view on this
sleep schedule	○	○	○	○	○
meal timing	○	○	○	○	○
daytime napping	○	○	○	○	○
daytime activity	○	○	○	○	○
bedroom / sleep area	○	○	○	○	○
light exposure	○	○	○	○	○
sleep interfering beliefs	○	○	○	○	○
waking up and morning routine	○	○	○	○	○
nightmares	○	○	○	○	○
evening and bedtime routine	○	○	○	○	○
antipsychotics and other medication	○	○	○	○	○
time in bed restriction / sleep restriction therapy	○	○	○	○	○
home environment	○	○	○	○	○

25. Do you feel there is anything missing from this list that you didn't already mention earlier? (response optional)

On the previous page you said:

·

·

·

26. Can you say any more about the reasons you feel it is better NOT to include any of the components you have selected as inappropriate above?

Page 13

27. What should be included in relation to light exposure and why?

Page 14

28. What should be included in relation to daytime activity and why?

Page 15

29. What should be included in relation to waking up and morning routine and why?

Page 16

30. What should be included in relation to evening and bedtime routine and why?

Page 17

31. What should be included in relation to daytime napping and why?

Page 18

32. What should be included in relation to sleep schedule and why?

Page 19

33. What should be included in relation to meal timing and why?

Page 20

34. What should be included in relation to time in bed restriction / sleep restriction therapy and why?

Page 21

35. What should be included in relation to home environment and why?

Page 22

36. What should be included in relation to bedroom / sleep area and why?

Page 23

37. What should be included in relation to nightmares and why?

Page 24

38. What should be included in relation to sleep interfering beliefs and why?

Page 25

39. What should be included in relation to antipsychotics and other medication and why?

Page 26

40. Do you want to add any more detail about what should be included in relation to any of these answers you gave?

-
-
-
-

Page 27

Implementation questions

41. The intervention is aimed at people with schizophrenia spectrum disorders, who have problems with sleep initiation, maintenance, quality or timing.

Do you have any comments regarding for whom within this group the intervention would be most appropriate, or any exclusions you feel would need to be made?

42. (if relevant) What difficulties if any would you foresee with an occupational therapist in your service / in community mental health services you are familiar with delivering this intervention in future?

43. Do you have any comments regarding barriers to the delivery and effectiveness of the intervention, and how to avoid or overcome these?

Page 28

44. Are you electing to give feedback verbally by phone or skype for this round? This can be general or just on a certain topic or question.

    If so please give contact details and an indication of what days and times are best for you and I will get in touch.

Thank you very much for completing this survey!

I will be in touch with round 2 in late November.

Best Wishes,
Sophie

- We are **not** weighting responses based on qualifications or experience.
- We will use this information to best target further recruitment to fill in gaps and get a range of expertise within each group.
- We will use this information to help decide which group to include participants in, in cases where they fit into more than one group.

8. Please select which expert group you feel you best fit into:

*

- [ ] Sleep and/or circadian rhythm expert (clinician or researcher)
- [ ] Experienced mental health occupational therapy clinician or researcher
- [ ] Occupational therapist with expertise in sleep
- [ ] Other mental health expert or senior stakeholder
- [ ] I fit equally into two or more of these groups

9. What is the best email address to contact you with the link to complete round 2 and round 3?*

Page 9

Your initial thoughts

This page is to capture your initial thoughts before we start to use any more specific headings which might alter your responses. There will be chance to elaborate on these later if you wish.

15. Do you have any views about what should be covered and how in the pre-intervention assessment?

This is the assessment that would be completed if the intervention were in routine clinical practice. An assessment to inform the therapy. We don't mean any baseline assessments which might be done primarily for the purposes of the research study.

1

2

3

16. Based on your knowledge and experience, what are the main aspects or components are which should be included in the intervention?

1

S4 Survey. Round 3 survey questions

Round 3 survey (final round): ask the experts

Welcome to Round 3!
(the final round)

Thanks again for your responses in rounds 1 & 2. They were really great!

A high level of consensus has been reached on some items to include. We are only asking about selected topics. Sometimes re-rating, other times we are exploring further how to address this component. It is always OK if your view has not changed. We are not expecting to reach a consensus on all items.

Paraphrased comment are ~"presented like this"

Items agreed based on round 2 will be presented in green boxes.
Points which we already described as 'agreed' in the last round (agreed from round 1) will be presented in yellow boxes.
Judging consensus was based on ratings of 'importance' and 'agreement', and the extent of votes in the opposite direction. Qualitative comments were also taken into account.

First a summary of where we are up to so far.

This survey will cover:

1. Eligibility (who the intervention is aimed at)
2. Intervention components questions

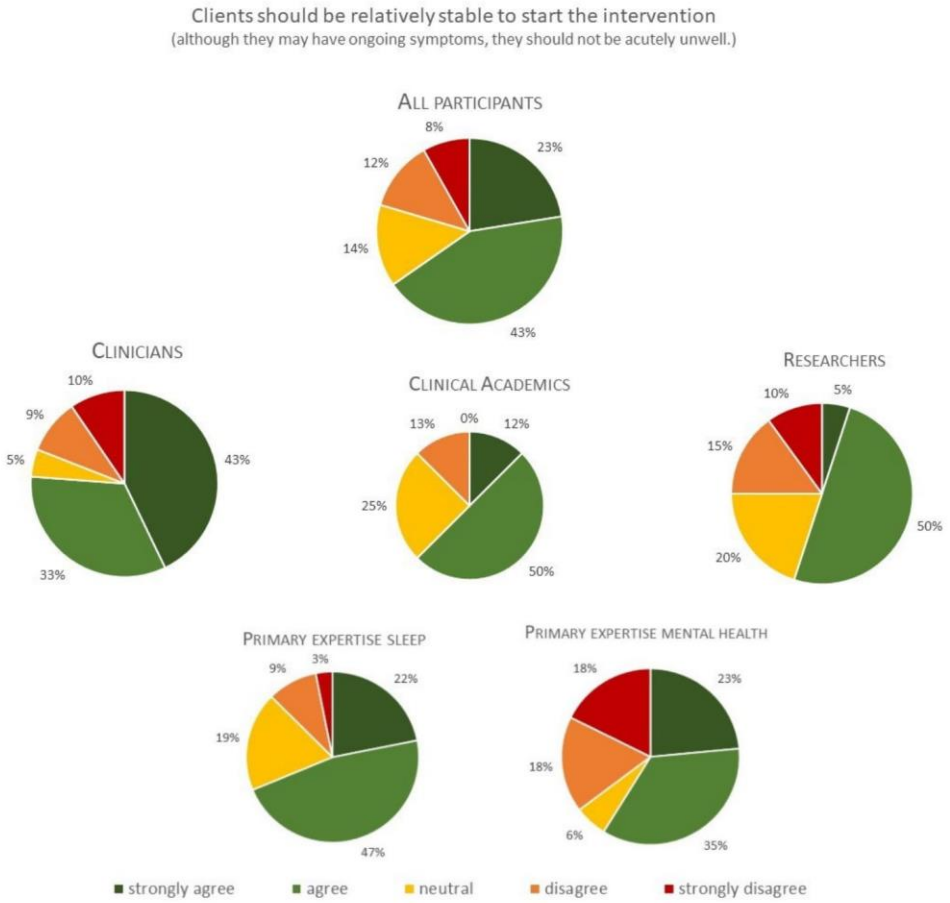
3. OPTIONAL: Additional feedback, comment optionalEND - select gift voucher & contact preferences

It should take you around 30min to complete (longer if you comment on the optional section). You can press 'save and resume' at any time. You will be able to return and read more and edit or add to your response until we close round 3, even after you have pressed 'finish'.

There are many optional comments boxes throughout, you are welcome to write in as many or as few as you want.

1) Eligibility (who is the intervention aimed at)

For background

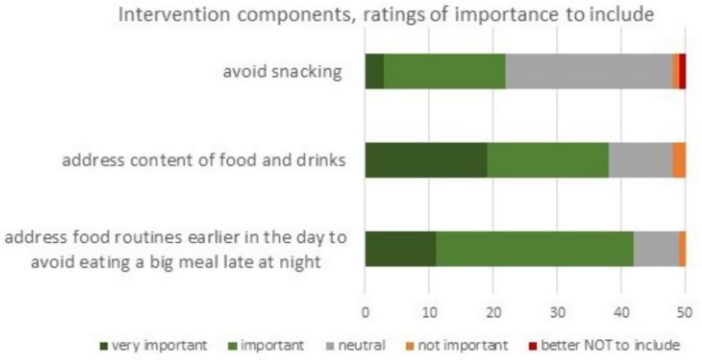


If you have concerns about imposing inclusion criteria or using a clinical assessment to determine whether the client is stable enough to usefully begin the intervention, please can you describe?

- ◯ strongly agree
- ◯ agree
- ◯ neutral
- ◯ disagree
- ◯ strongly disagree
- ◯ don't know / no view on this

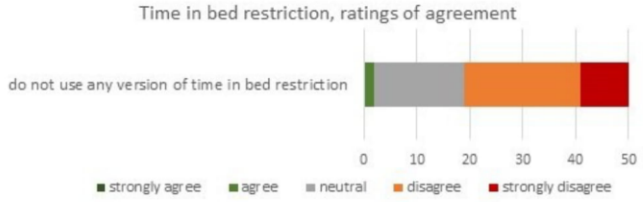
2) Intervention components questions

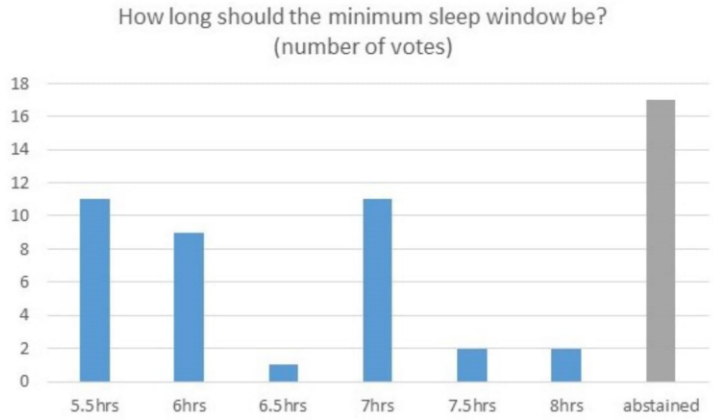
Food & drink
Agreed:Education regarding why to avoid large late meals
Don't go to bed hungry either (light snack 1 - 1.5hrs before bed if hunger disturbs sleep)



	very important	important	neutral	not important	better NOT to include
address food routines earlier in the day to avoid eating a big meal late at night	○	○	○	○	○
address content of food and drinks (e.g. how filling, fat, sugar, portion size)	○	○	○	○	○
avoid snacking (unless medical condition requires)	○	○	○	○	○

Sleep restriction / time in bed restriction / extension of time up and awake





(some felt they often do, others felt they do not).
~"Even a small amount of time in bed restriction may be effective."
~"Limited research on effectiveness in this population."
~"Limited evidence of risk of causing psychosis."
~"In practice the limiting factor may not be contra-indications and risk, but what participants can manage to adhere to."

The below were suggested. Do you agree?

	strongly agree	agree	neutral	disagree	strongly disagree	don't know / no view on this
~"The length of the sleep window should take into account not just the total sleep time at baseline, but also the length of the time in bed at baseline"	○	○	○	○	○	○
~"The actual terminology of sleep restriction or time in bed restriction should be avoided"	○	○	○	○	○	○
~"Terminology and presentation should focus on the 'positive' of time you are up and awake rather than time you are not in bed."	○	○	○	○	○	○

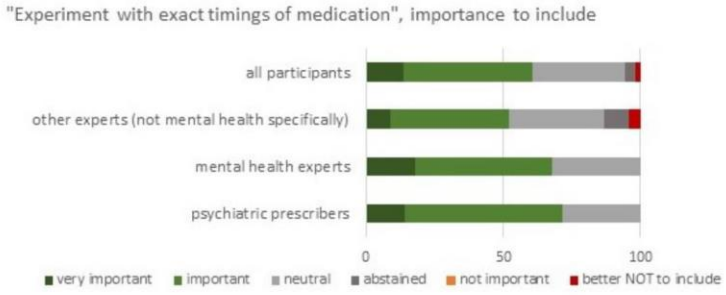
~"People taking anti-psychotics may need to sleep for longer."

How long should the MINIMUM sleep window be (the shortest that should ever be used in this intervention)?

includes options 'don't know / no view on this' and 'do not use'

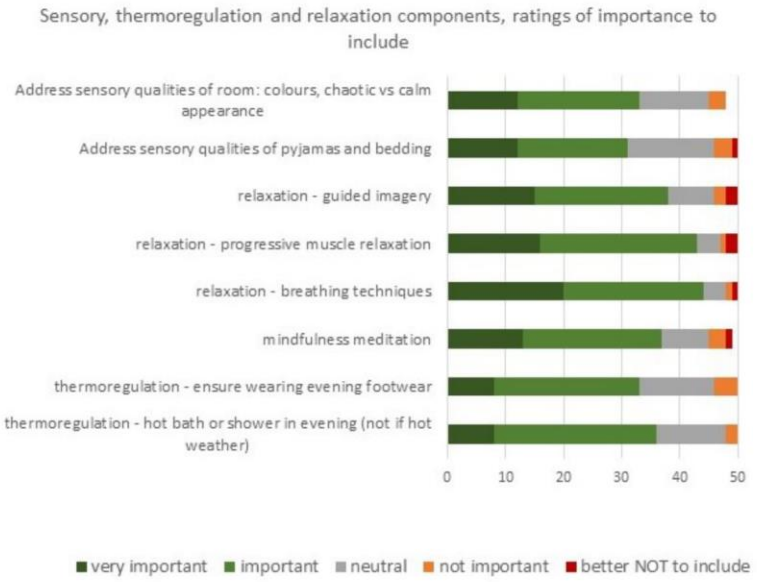
○ 5.5hrs ○ 6hrs ○ 6.5hrs ○ 7hrs ○ 7.5hrs ○ 8hrs ○ longer than 8hrs ○ better NOT to use time in bed restriction ○ don't know / no view on this

Medication
Agreed:ensure taken at correct timing - morning or evening
liaise with prescriber - generally, and regarding any sleep affecting side effects (e.g.daytime sedation, hypersalivation)~"Obtain this information from clinical records in advance if possible"
~"Spend less time discussing a medication if there is no realistic prospect of altering this medication"



◯ very important ◯ important ◯ neutral ◯ not important ◯ better NOT to include
◯ don't know / no view on this

Intervention components still under consideration



Sensory factors

	strongly agree	agree	neutral	disagree	strongly disagree
I have knowledge and / or experience on this topic	◯	◯	◯	◯	◯

	very important	important	neutral	not important	better NOT to include
address sensory qualities of room: colours, chaotic vs calm appearance	○	○	○	○	○
address sensory qualities of pyjamas and bedding	○	○	○	○	○

Thermoregulation
(agreed, discussed without using the word thermoregulation within the home environment component)

	strongly agree	agree	neutral	disagree	strongly disagree
I have knowledge and / or experience on this topic	○	○	○	○	○

	very important	important	neutral	not important	better NOT to include
thermoregulation - ensure wearing evening footwear	○	○	○	○	○
thermoregulation - hot bath or shower in the evening (not if hot weather)	○	○	○	○	○

Relaxation

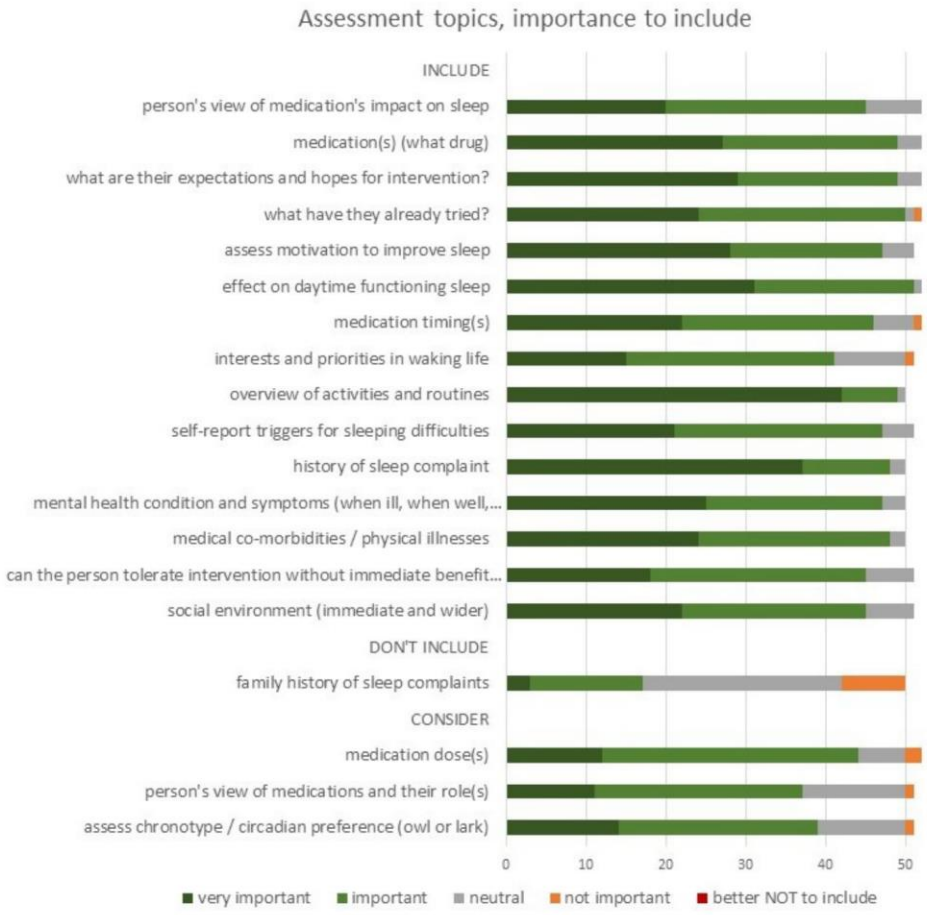
	strongly agree	agree	neutral	disagree	strongly disagree
I have knowledge and / or experience on this topic	○	○	○	○	○

	very important	important	neutral	not important	better NOT to include
relaxation - guided imagery	○	○	○	○	○
relaxation - progressive muscle relaxation	○	○	○	○	○
relaxation - breathing techniques	○	○	○	○	○
mindfulness meditation	○	○	○	○	○

PAGE 3 IS ADDITIONAL FEEDBACK, AND CAN BE SKIPPED OR SKIMMED.
If skipping please proceed to pages 5 & 6.
You can return to this survey later with the same link if you want to look at this another time, you will be able to edit or add to your response until we close round 3, even after you have pressed 'finish'.

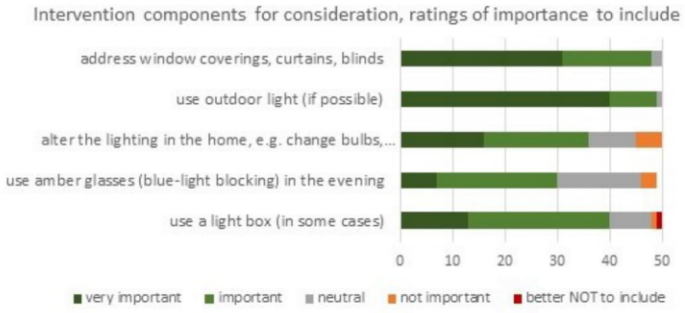
3. Additional feedback, comment optional, can skip

Assessment:
Here are the ratings of importance of the assessment topics:



Also agreed:
As part of assessing food routines we will ask about night eating.
If the person follows a religion we will ask about the timing or prayers or other practices (including fasting if relevant) to be taken into account in relation to routines. (This will form part of the 'overview of activities and routines', but merits its own prompt within the protocol/materials)

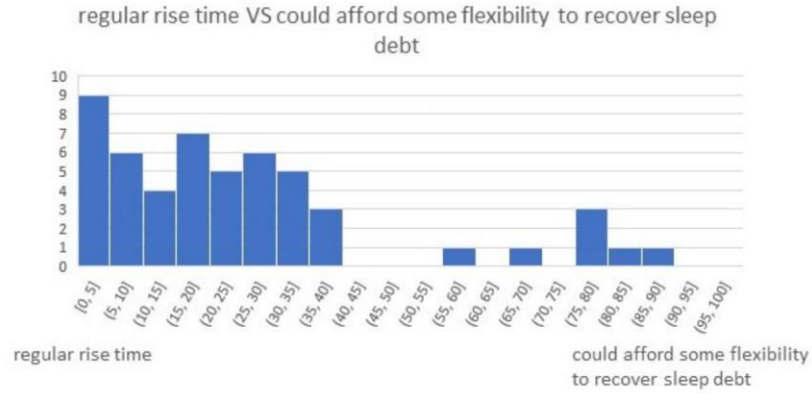
Light exposure:
Increase morning light
Increase daytime light
Outdoor light especially good
Reduce evening light exposure
Incorporate with activity/occupation
Give education and explanation of how light affects circadian rhythm



Address window coverings (e.g. windows and blinds)
Use outdoor light (if possible)

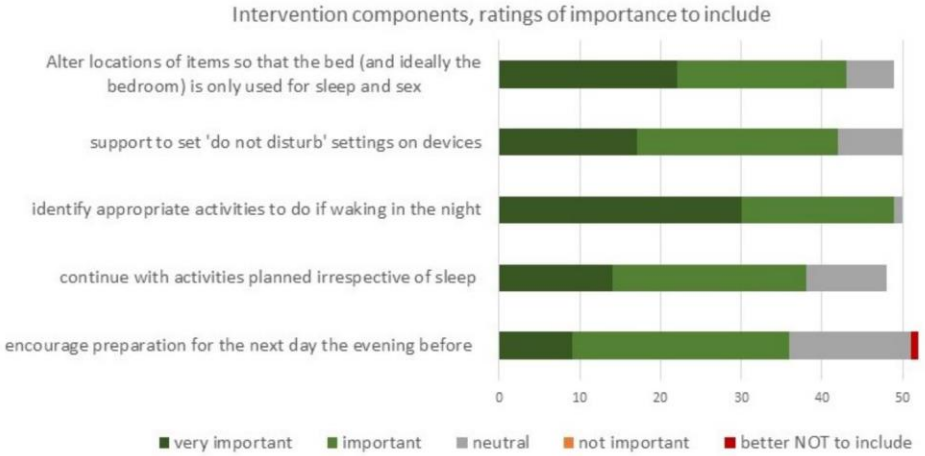
Rise time

Slider questions, ratings at extreme ends of scale indicating stronger opinion



Regularity should be the aim, especially during the intervention.
Regularity should not be at any cost- i.e. if the only way to achieve regular timing is for sleep to be regularly timed but continuously insufficient, it would be better to eventually revert to napping or irregular timing.
If you have any further comments, please write them here:

Activity and occupation:
Encourage daytime exercise / physical activity, to increase sleep pressure
Reviewing activity diary with client may form an intervention in itself
Activity analysis - includes emotional, cognitive and physical stimulating / calming effect of activities, and light exposure during.
Collaborative activity scheduling if required



Alter locations of items so that the bed (and ideally the bedroom) is only used for sleep and sex
Support to set do not disturb setting on devices
Support to find appropriate activities to do if waking in the night

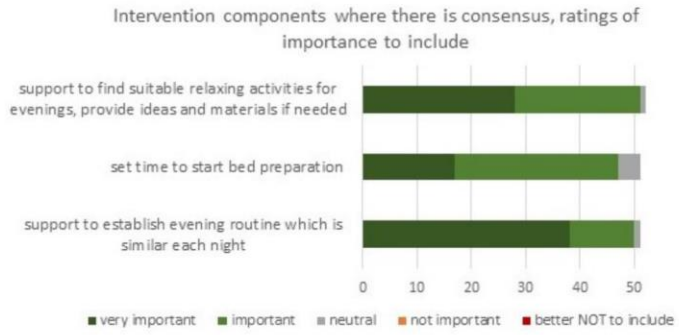
~"(This varies between individuals) preparing for the next day could make some people more anxious"
~"It is easier to get up if things are in place for the morning, e.g. breakfast, clothes, alarm"

Napping:
Avoid naps too late in the day
Avoid longer naps
Consider scheduling a nap midday or early afternoon if it is the only way to avoid a nap later in the day

Evaluate the role of naps
Do not ban naps

Alarms:
If you have any further comments, please write them here:

Evening routine:Encourage to reduce stimulus and have evening wind down time
Ensure following sleep hygiene recommendations as far as possible



Support to establish evening routine which is similar each night
Support to find suitable relaxing activities for evenings, provide ideas and materials if needed
Set time to start bed preparation

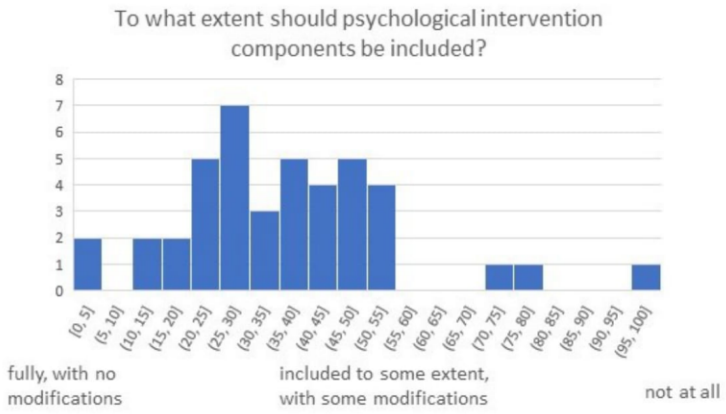
Morning routine:
Include attention to:
Getting dressed
Going outdoors if possible
Increasing light exposure soon after waking
Energising activities to help wake up and get going
Ideally physical activity if possible
Give education on sleep inertia - that sleepiness immediately on waking does not always reflect inadequate quality or amount of sleep

Substance use:
Reduce caffeine use, especially late in day
  Reduce smoking late at night, discourage smoking if awakening in night
  Psychoeducation on the effect of alcohol on sleep
~"Bear in mind individual differences in metabolism and sensitivity to caffeine and other substances"

Home environment:
Home environment will be assessed with client agreement
Explicitly ask where sleep takes place (may not be the bed)
  Consider and address: noise, temperature, other occupants, pets, comfort
  Identify modifications which can be made to improve the above, set goals, offer support
If you have any further comments, please write them here:

Nightmares:
Nightmares will be assessed, refer or liaise as indicated
  Psychoeducation to normalise occasional nightmares or bad dreams
Nightmares may improve through treatment of other sleep problems.

Psychological components:

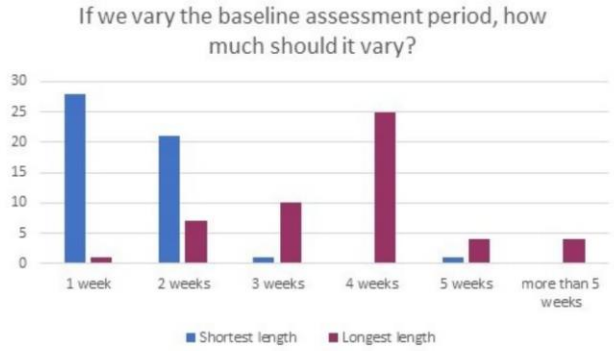


~"There is enough to address in terms of environment, behaviours and routines"
~"Dealing with worry will be very important for some clients"
~"Strategies to manage worry are already relevant to the role of mental health occupational therapists"

4) The baseline period

Please note that a long baseline period would not require constant self-report recording by the participant, only intermittent self-report recording, and constant use of an activity tracking wearable device ("passive monitoring"; the person just wears the device and has to take no action.)

Here is a graph of the votes for proposed shortest and longest length of the baseline period.



If we have a set length of baseline how long should it be?

◯ 1 week ◯ 2 weeks ◯ 3 weeks ◯ 4 weeks ◯ 5 weeks ◯ more than 5 weeks

Better to vary baseline assessment period depending on presentation — Better to use a set length of baseline assessment period

(Place a mark on the scale above)

If you have any other comments relating to the baseline assessment please write them here:

5) Implementation issues

Intervention reach / can the intervention reach the recipients?

In the service you have mentioned above, what percentage of clients on an average practitioners caseload do you think would be suitable for this intervention (as far as you currently understand the intervention will look)?

0% of caseload 50% of caseload 100% of caseload

(Place a mark on the scale above)

(or other comments about what we have said above.)

Inclusion criteria for your reference (as per section 1).

A 'diagnosis based' intervention
(This might include bipolar affective disorder, severe uni-polar depression, personality disorder)
If more relevant for some mental illnesses than others please describe.

Would the intervention require much modification to be applied to people with different diagnoses?

If you have any other comments about this intervention being diagnosis specific VS being offered to people with other diagnoses or other symptoms (now or in future), please write them here:

Next steps
(response optional)

(response optional)

END OF QUESTIONS

Thank you!

You have completed round 3!

Would you like us to contact you about the results by email?	☐ Please send a summary of the results ☐ Please contact me when the results are published ☐ Neither of the above
How do you feel about being contacted in future about this research topic?	◯ I am keen to be contacted ◯ I am OK with being contacted ◯ I prefer not to be contacted
Please select which type of voucher you would like: (You may decline, but we would like to send you this as a small thank you gesture if you will accept.)	◯ Amazon (United Kingdom, France, Germany, Italy, Netherlands, Spain, Turkey, Canada, Mexico, United States, Australia, Brazil, China, India, Japan, Singapore) ◯ IKEA (Australia, Austria, Belgium, Canada, China, Czech republic, Denmark, Finland, France, Germany, Hungary, Italy, Japan, Netherlands, Norway, Poland, Portugal, Russia, Slovakia, Spain, Sweden, Switzerland, United kingdom and USA) ◯ Prezzee digital gift card (Australia) ◯ Argos e-gift card (use in store or online) (UK) ◯ Tesco digital gift card (UK) ◯ 'Love to shop' voucher (by post, UK) ◯ Waterstones gift card (by post, UK)
For Amazon or IKEA please specify country and currency:	_____
For 'Love to shop' or Waterstones please provide a postal address:	_____ _____

S5 Topic Guide. Topic guide for focus groups. Used in stage 4 with participants with relevant personal experience

What aspect of the intervention do you like the sound of the most? (and why)

Was there anything described that you would be worried about trying? (and why)

Was there much where you thought "I / they already do exactly that" (which things?)

What did you think about:

Avoiding non-sleep activities in bed (except sex)

Reducing excess time in bed & avoiding or reduce napping

Increasing daytime light exposure

light boxes getting outdoor light

Reducing evening light exposure

changing lamps / bulbs amber glasses

Sticking to a regular rise time

Does it seem important to do? Would it be achievable / hard?

Changes to wake up and morning routine

Alarm clocks dawn simulation

Daytime activity (type, timing & amount of activity)

How much help would be needed to change routines?

Evening wind-down routine

Do you think this would help?

Any of the other components or elements we haven't discussed just now?

Appendix 6: Supplement to Study D - “Sleep problems and referral intentions in mental health services: service user self-report and staff proxy report surveys”

Appendix A, survey questions

Service user survey:

Do you have sleep problems and to what extent?

- ○ severe sleep problems
- ○ significant sleep problems
- ○ mild sleep problems
- ○ no, I am a good sleeper
- ○ I'm unsure

How frequently are these sleep problems present?

- ○ only occasionally
- ○ some of the time
- ○ most of the time
- ○ always / almost always
- ○ I'm unsure

What type/s of problems? (select all that apply)

- ☐ difficulty getting to sleep
- ☐ difficulty staying asleep / waking in the night
- ☐ poor sleep quality
- ☐ sleeping at the wrong times
- ☐ daytime sleepiness
- ☐ difficulty waking up
- ☐ having too little sleep
- ☐ having too much sleep
- ☐ nightmares
- ☐ sleepwalking
- ☐ restless legs syndrome
- ☐ night eating
- ☐ I have a diagnosis of a sleep related movement disorder
- ☐ I have a diagnosis of obstructive sleep apnoea / sleep disordered breathing
- ☐ it has been suggested that I have sleep apnoea but I haven't been tested

Thinking of the sleep issues you ticked above, how much of a problem are they for you?

On a scale of 1-5 where 5 is a really big problem

- ○ 1 = No problem at all
- ○ 2
- ○ 3
- ○ 4
- ○ 5 = Really big problem

Would you want to be referred for a non-drug sleep intervention involving changes to sleep schedule, light exposure, and daytime occupation/activity if this were available from a mental health occupational therapist?

- ○ definitely
- ○ probably
- ○ maybe
- ○ probably not
- ○ no / highly unlikely

What is the main reason that would make you less likely to want to be referred for sleep treatment? (write brief sentence or word/s)

_____

Are any of these statements true for you? (select all that apply)

- ☐ I don't want to improve my sleep
- ☐ I don't think it is possible to improve my sleep
- ☐ I would like to improve my sleep on my own
- ☐ I would like self-help advice
- ☐ I would like help from a professional to improve my sleep
- ☐ I would like a therapy to help improve my sleep

How much do you agree with these statements?

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I would like to be prescribed a drug for my sleep	○	○	○	○	○
I am already taking a drug for my sleep	○	○	○	○	○
I would like to have a talking-based therapy for my sleep	○	○	○	○	○
I would like to have an activity-based therapy for my sleep	○	○	○	○	○
I would like to have a sleep treatment involving changing my light exposure (light box or natural light, and reducing evening light)	○	○	○	○	○
I would have any type of sleep therapy if it will work	○	○	○	○	○

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not applicable
I need someone to look at what medication I am on and its effect on my sleep	○	○	○	○	○	○
I need someone to look at what time I take my medication and the effect on my sleep	○	○	○	○	○	○
I need treatment to reduce my excessive worry or repetitive thoughts so that I can sleep better	○	○	○	○	○	○
I need help to stop using illicit drugs first before I can start work on improving my sleep	○	○	○	○	○	○
I need treatment for symptoms of psychosis (such as hearing voices or having unusual thoughts) first before I can start work on improving my sleep	○	○	○	○	○	○

If there is anything you want to add about anything above you can write here:

_____

What is your main mental health diagnosis?

- ☐ I don't have a diagnosis
- ☐ I don't know or can't remember what my diagnosis is
- ☐ schizophrenia
- ☐ schizoaffective disorder
- ☐ schizotypal disorder
- ☐ psychosis
- ☐ bipolar affective disorder
- ☐ depression
- ☐ an anxiety disorder
- ☐ post-traumatic stress disorder
- ☐ a personality disorder
- ☐ substance misuse disorder / illicit drug use
- ☐ something not listed above

Please describe:

_____

What is your age?

- ◯ 18-24
- ◯ 25-30
- ◯ 31-40
- ◯ 41-50
- ◯ 51-60
- ◯ 61-70
- ◯ 71-80
- ◯ 80+

What is your gender?

- ◯ female
- ◯ male
- ◯ non-binary / gender fluid / genderqueer / other
- ◯ I prefer to self-describe
- ◯ I prefer not to say

Please choose one option that best describes your ethnic group or background:

- ◯ White English/Welsh/Scottish/Northern Irish/British
- ◯ White Irish
- ◯ White Gypsy or Irish Traveller
- ◯ Any other White background
- ◯ White and Black Caribbean
- ◯ White and Black African
- ◯ White and Asian
- ◯ Any other Mixed/Multiple ethnic background
- ◯ Indian
- ◯ Pakistani
- ◯ Bangladeshi
- ◯ Chinese
- ◯ Any other Asian background
- ◯ African
- ◯ Caribbean
- ◯ Any other Black/African/Caribbean background
- ◯ Arab
- ◯ Any other ethnic group
- ◯ I prefer not to say

I am seen by:

- ◯ Greater Manchester Mental Health NHS Foundation Trust (GMMH)
- ◯ Pennine Care NHS Foundation Trust
- ◯ Neither or the above

Staff survey:

First please write down for your own reference numbers 1 to 5, and beside them the name or initials (any identifier you are comfortable with) of the 5 clients on your caseload who you had contact with most recently.

Don't include any clients you have seen but who aren't on your caseload (for example duty work or mental health act assessments).

◯ Done

What is your profession or job role? (begin typing or select)	◯ clinical psychologist ◯ clinical psychologists trainee ◯ mental health nurse ◯ NHS support staff (clinical) (includes recovery workers, support workers, employment workers, nursing assistants) ◯ occupational therapist ◯ other AHP (includes speech and language, dietician, physiotherapist, art/music/drama therapists) ◯ other junior doctors (e.g. staff grade, locum etc) ◯ other medical trainees (not psychiatry) doctor ◯ psychiatry consultant doctor ◯ psychiatry trainee doctor ◯ social worker ◯ student (other) ◯ student nurse ◯ student OT ◯ student social worker ◯ third sector (non-NHS) qualified staff ◯ third sector (non-NHS) unqualified staff
How many years have you been in your current profession?	_____
How many years have you worked in mental health?	_____
What type of service do you work in?	◯ CMHT ◯ Early Intervention in Psychosis ◯ rehabilitation ◯ acute inpatients ◯ home treatment / crisis team ◯ other specialist service ◯ third sector / non-NHS ◯ none of the above
What organisation do you work in:	◯ GMMH ◯ Pennine Care ◯ Neither of the above ◯ Prefer not to say
How confident do you feel in your ability to identify sleep problems?	◯ very confident ◯ reasonably confident ◯ not very confident ◯ not confident at all
How confident do you feel in your ability to address or improve sleep problems? (on average)	◯ very confident ◯ reasonably confident ◯ not very confident ◯ not confident at all
How much training have you had regarding sleep? (select all that apply)	☐ a lot ☐ some ☐ hardly any ☐ none ☐ I have a sleep related qualification

Please select the MAIN sources of your knowledge:
(select all that apply)

- ☐ my own research
- ☐ general awareness and mainstream media
- ☐ content covered as part of my professional training (pre-qualification)
- ☐ a university / college course about sleep
- ☐ Trust delivered training about sleep
- ☐ a course from another provider

How long have you known each of the 5 clients on the list you have written?

	less than 1 month	1-3 months	over 3 months but less than 6 months	6 months - 1 year	over 1 year
client 1	○	○	○	○	○
client 2	○	○	○	○	○
client 3	○	○	○	○	○
client 4	○	○	○	○	○
client 5	○	○	○	○	○

How frequently do you usually see each of the clients on the list you have written?

	more than weekly	weekly	fortnightly	3 weekly	monthly	2 - 6 monthly	7 monthly - yearly
client 1	○	○	○	○	○	○	○
client 2	○	○	○	○	○	○	○
client 3	○	○	○	○	○	○	○
client 4	○	○	○	○	○	○	○
client 5	○	○	○	○	○	○	○

Now think of client 1 from your list.

Does client 1 have sleep problems and to what extent?

○ severe ○ significant ○ mild ○ no, they are a good sleeper ○ I'm unsure

How frequently are these problems present?

○ only occasionally ○ some of the time ○ most of the time ○ always / almost always
○ I'm unsure

What type/s of problems?

- ☐ difficulty getting to sleep
- ☐ difficulty staying asleep / waking in the night
- ☐ poor sleep quality
- ☐ sleeping at the wrong times
- ☐ daytime sleepiness
- ☐ difficulty waking
- ☐ having too little sleep
- ☐ having too much sleep
- ☐ nightmares
- ☐ sleepwalking
- ☐ restless legs syndrome
- ☐ obstructive sleep apnoea / sleep disordered breathing
- ☐ another sleep related movement disorder
- ☐ night eating
- ☐ I know they have sleep problems but I'm not sure in what respect

What is their main diagnosis?

- ○ depression and/or anxiety
- ○ bipolar affective disorder
- ○ schizophrenia spectrum disorder
- ○ psychosis not otherwise specified
- ○ personality disorder
- ○ substance misuse as primary diagnosis
- ○ none of the above

Would you refer this client for a non-drug sleep intervention involving changes to sleep schedule, light exposure, and daytime occupation/activity if this were available from an occupational therapist in clinical practice?

- ○ definitely
- ○ probably
- ○ maybe
- ○ probably not
- ○ no / highly unlikely

What is the main reason that would make you less likely to refer? (write brief sentence or word/s)

_____

If there is anything you want to add about anything above you can write here:

_____

Now think of client 2 from your list.

Does client 2 have sleep problems and to what extent?

○ severe ○ significant ○ mild ○ no, they are a good sleeper ○ I'm unsure

How frequently are these problems present?

○ only occasionally ○ some of the time ○ most of the time ○ always / almost always
○ I'm unsure

What type/s of problems?

- ☐ difficulty getting to sleep
- ☐ difficulty staying asleep / waking in the night
- ☐ poor sleep quality
- ☐ sleeping at the wrong times
- ☐ daytime sleepiness
- ☐ difficulty waking
- ☐ having too little sleep
- ☐ having too much sleep
- ☐ nightmares
- ☐ sleepwalking
- ☐ restless legs syndrome
- ☐ obstructive sleep apnoea / sleep disordered breathing
- ☐ another sleep related movement disorder
- ☐ night eating
- ☐ I know they have sleep problems but I'm not sure in what respect

What is their main diagnosis?

- ○ depression and/or anxiety
- ○ bipolar affective disorder
- ○ schizophrenia spectrum disorder
- ○ psychosis not otherwise specified
- ○ personality disorder
- ○ substance misuse as primary diagnosis
- ○ none of the above

Would you refer this client for a non-drug sleep intervention involving changes to sleep schedule, light exposure, and daytime occupation/activity if this were available from an occupational therapist in clinical practice?

- ○ definitely
- ○ probably
- ○ maybe
- ○ probably not
- ○ no / highly unlikely

What is the main reason that would make you less likely to refer? (write brief sentence or word/s)

_____

If there is anything you want to add about anything above you can write here:

_____

Now think of client 3 from your list

Does client 3 have sleep problems and to what extent?

○ severe ○ significant ○ mild ○ no, they are a good sleeper ○ I'm unsure

How frequently are these problems present?

○ only occasionally ○ some of the time ○ most of the time ○ always / almost always
○ I'm unsure

What type/s of problems?

- ☐ difficulty getting to sleep
- ☐ difficulty staying asleep / waking in the night
- ☐ poor sleep quality
- ☐ sleeping at the wrong times
- ☐ daytime sleepiness
- ☐ difficulty waking
- ☐ having too little sleep
- ☐ having too much sleep
- ☐ nightmares
- ☐ sleepwalking
- ☐ restless legs syndrome
- ☐ obstructive sleep apnoea / sleep disordered breathing
- ☐ another sleep related movement disorder
- ☐ night eating
- ☐ I know they have sleep problems but I'm not sure in what respect

What is their main diagnosis?

- ○ depression and/or anxiety
- ○ bipolar affective disorder
- ○ schizophrenia spectrum disorder
- ○ psychosis not otherwise specified
- ○ personality disorder
- ○ substance misuse as primary diagnosis
- ○ none of the above

Would you refer this client for a non-drug sleep intervention involving changes to sleep schedule, light exposure, and daytime occupation/activity if this were available from an occupational therapist in clinical practice?

- ○ definitely
- ○ probably
- ○ maybe
- ○ probably not
- ○ no / highly unlikely

What is the main reason that would make you less likely to refer? (write brief sentence or word/s)

_____

If there is anything you want to add about anything above you can write here:

_____

Now think of client 4 from your list

Does client 4 have sleep problems and to what extent?

○ severe ○ significant ○ mild ○ no, they are a good sleeper ○ I'm unsure

How frequently are these problems present?

○ only occasionally ○ some of the time ○ most of the time ○ always / almost always
○ I'm unsure

What type/s of problems?

- ☐ difficulty getting to sleep
- ☐ difficulty staying asleep / waking in the night
- ☐ poor sleep quality
- ☐ sleeping at the wrong times
- ☐ daytime sleepiness
- ☐ difficulty waking
- ☐ having too little sleep
- ☐ having too much sleep
- ☐ nightmares
- ☐ sleepwalking
- ☐ restless legs syndrome
- ☐ obstructive sleep apnoea / sleep disordered breathing
- ☐ another sleep related movement disorder
- ☐ night eating
- ☐ I know they have sleep problems but I'm not sure in what respect

What is their main diagnosis?

- ○ depression and/or anxiety
- ○ bipolar affective disorder
- ○ schizophrenia spectrum disorder
- ○ psychosis not otherwise specified
- ○ personality disorder
- ○ substance misuse as primary diagnosis
- ○ none of the above

Would you refer this client for a non-drug sleep intervention involving changes to sleep schedule, light exposure, and daytime occupation/activity if this were available from an occupational therapist in clinical practice?

- ○ definitely
- ○ probably
- ○ maybe
- ○ probably not
- ○ no / highly unlikely

What is the main reason that would make you less likely to refer? (write brief sentence or word/s)

_____

If there is anything you want to add about anything above you can write here:

_____

Now think of client 5 from your list

Does client 5 have sleep problems and to what extent?

○ severe ○ significant ○ mild ○ no, they are a good sleeper ○ I'm unsure

How frequently are these problems present?

○ only occasionally ○ some of the time ○ most of the time ○ always / almost always
○ I'm unsure

What type/s of problems?

- ☐ difficulty getting to sleep
- ☐ difficulty staying asleep / waking in the night
- ☐ poor sleep quality
- ☐ sleeping at the wrong times
- ☐ daytime sleepiness
- ☐ difficulty waking
- ☐ having too little sleep
- ☐ having too much sleep
- ☐ nightmares
- ☐ sleepwalking
- ☐ restless legs syndrome
- ☐ obstructive sleep apnoea / sleep disordered breathing
- ☐ another sleep related movement disorder
- ☐ night eating
- ☐ I know they have sleep problems but I'm not sure in what respect

What is their main diagnosis?

- ○ depression and/or anxiety
- ○ bipolar affective disorder
- ○ schizophrenia spectrum disorder
- ○ psychosis not otherwise specified
- ○ personality disorder
- ○ substance misuse as primary diagnosis
- ○ none of the above

Would you refer this client for a non-drug sleep intervention involving changes to sleep schedule, light exposure, and daytime occupation/activity if this were available from an occupational therapist in clinical practice?

- ○ definitely
- ○ probably
- ○ maybe
- ○ probably not
- ○ no / highly unlikely

What is the main reason that would make you less likely to refer? (write brief sentence or word/s)

_____

If there is anything you want to add about anything above you can write here:

_____

How many clients on your caseload?
(estimate if you need to)

_____

How many of your clients do you think would be potentially relevant to receive Light-Dark and Activity Rhythm Therapy for sleep (L-DART), irrespective of their diagnosis?
(estimate if you need to)

_____

How many of these potentially relevant clients also have either schizophrenia, schizoaffective disorder, delusional disorder, or schizotypal disorder?
(estimate if you need to)

_____

Appendix B, Business Intelligence sample comparison

Summary demographic data for clients open to Trust #1 on 10/11/20			Service user survey participants				Service users via staff proxy (staff survey)			
Measure	**Total**	**%**		Total	%			Total	%	
Total number of clients	**46058**			190				619		
Primary diagnosis for clients with a diagnosis recorded			**Primary diagnosis for those clients reporting a diagnosis:**				**Primary diagnosis**			
Primary Diagnosis: Schizophreni	3627	18.6%	schizophrenia	83	50.3%		schizophrenia spectrum disorde	199	32.2%	
Primary Diagnosis: Schizoaffecti	756	3.9%	schizoaffective disorder	10	6.1%					
Primary Diagnosis: Other psycho	1340	6.9%	other psychosis diagnosis	16	8.5%		psychosis not otherwise specifie	74	12.0%	
Primary Diagnosis: Bipolar affect	1313	6.7%	bipolar affective disorder	14	13.3%		bipolar affective disorder	53	8.6%	
Primary Diagnosis: Depression /	2719	13.9%	depression / anxiety	22	9.7%		depression / anxiety	102	16.5%	
Primary Diagnosis: Personality d	1287	6.6%	personality disorder	13	7.9%		personality disorder	77	12.4%	
Primary Diagnosis: Other Diagno	8460	43.4%	other, none of the above	7	4.2%		substance misuse disorder	56	9.1%	
total clients with a diagnosis rec	19502		total clients reporting a diagn	165			none of the above	58	9.4%	
Primary Diagnosis: No diagnosis	26556		I don't have a diagnosis	10						
			I don't know / can't remember	6						
			no response	9						
Ethnicity			**Ethnicity:***							
Ethnicity: White British	28685	62.3%	White British	140	77.3%					
Ethnicity: White Other	2086	4.5%	Other white	4	2.2%					
Ethnicity: Asian or Asian British	2916	6.3%	Asian	10	6.3%					
Ethnicity: Black or Black British	1816	3.9%	Black/African/Caribbean	5	2.8%					
Ethnicity: Mixed	1910	4.1%	Mixed	13	7.2%					
Ethnicity: Other Ethnic Group	1291	2.8%	Any other ethnic group	3	1.7%					
Ethnicity: Not stated / not disclo	2726	5.9%	I prefer not to say	6	3.3%					
Ethnicity: Unknown	4628	10.0%								
Gender			**Gender:**							
Gender: Female	26766	58.1%	female	89	48.9%					
Gender: Male	19046	41.4%	male	86	47.2%					
Gender: Not specified	98	0.2%	other*	5	2.8%					
Gender: Not known	148	0.3%	I prefer not to say	2	1.1%					
Age bracket			**Age**							
Age bracket: 18 to 24	6915	15.0%	18-24	11	6.0%					
Age bracket: 25 to 30	6763	14.7%	25-30	19	10.4%					
Age bracket: 31 to 40	9793	21.3%	31-40	39	21.4%					
Age bracket: 41 to 50	6791	14.7%	41-50	52	28.6%					
Age bracket: 51 to 60	6116	13.3%	51-60	42	23.1%					
Age bracket: 61 to 70	3409	7.4%	61-70	16	8.8%					
Age bracket: 71+	6271	13.6%	71+	3	1.7%					

Appendix C, Tables and Figures

Table C1: Service user participants diagnoses, separated by NHS Trust

NHS Trust	personality disorder	PTSD	bipolar	depression / anxiety	other psychosis	schizophrenia	schizoaffective disorder	other	none	no response	Total
Trust #1	11 14.7 %	2 2.7%	10 13.3 %	12 16.0 %	12 16.0 %	17 22.7 %	3 4.0%	3 4.0%	4 5.3%	1 1.3%	75
Trust #2	2 2.0%	0 0.0%	4 4.0%	7 7.1%	4 4.0%	66 66.7 %	7 7.1%	1 1.0%	3 3.0%	5 5.1%	99
Total	13 7.5%	2 1.2%	14 8.0%	19 10.9 %	16 9.2%	83 47.7 %	10 5.7%	4 2.3%	7 4.0%	6 3.4%	174

Table C2: Sleep problems severity service user self-report, separated by diagnosis

Severity of sleep problems	Whole sample	personality disorder	PTSD	bipolar affective disorder	depression / anxiety	other psychosis diagnosis	Schizophrenia	schizoaffective disorder	Other	I don't have a diagnosis	I don't know / can't remember
no, I am a good sleeper	54 28.6 %	0 0.0%	1 50.0 %	0 0.0%	0 0.0%	4 25.05	37 44.6 %	4 40%	0 0.1%	4 40.1 %	3 50%
mild sleep problems	54 28.6 %	1 7.7%	0 0.0%	2 14.3 %	6 27.3 %	4 25.0 %	29 34.9 %	3 30%	2 40.0 %	2 20.0 %	1 16.7 %
significant sleep problems	47 24.9 %	6 46.2 %	1 50.0 %	7 50.0 %	8 36.4 %	5 31.3 %	13 15.7 %	1 10.0 %	1 20.0 %	2 20.0 %	1 16.7 %
severe sleep problems	32 16.9 %	5 38.5 %	0 0.0%	5 35.7 %	8 36.4 %	3 18.8 %	4 4.8%	2 20.0 %	1 20.0 %	2 20.0 %	1 16.7 %
I'm unsure	2 1.05 %	1 7.7%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 20.0 %	0 0.0%	0 0%

Table C3: Sleep problems severity staff report, separated by diagnosis

Severity of sleep problems	Whole sample	bipolar	depression / anxiety	personality disorder	psychosis	schizophrenia	substance misuse	none of the above
no, they are a good sleeper	144 23.3%	13 24.5%	19 18.6%	18 23.4%	14 18.9%	51 25.6%	10 17.9%	19 32.8%
mild	172 27.8%	14 26.4%	42 41.2%	23 29.9%	27 36.5%	41 20.6%	19 33.9%	6 10.3%
significant	194 31.3%	15 28.3%	22 21.6%	26 33.8%	21 28.4%	73 36.7%	20 35.7%	17 29.3%
severe	65 10.5%	8 15.1%	9 8.8%	6 7.8%	9 12.2%	27 13.6%	2 3.6%	4 6.9%
I'm unsure	44 7.1%	3 5.7%	10 9.8%	4 5.2%	3 4.1%	7 3.5%	5 8.9%	12 20.7%

Table C4: Service users in whom staff are unsure if they have sleep problems, are not just those who are new to staff of infrequently seen

How well known	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Number of service users for whom staff selected “I'm unsure” if they have sleep problems (n)	0	2	4	5	2	11	4	7	2	3	1
%	0.00	4.88	9.76	12.20	4.88	26.83	9.76	17.07	4.88	7.32	2.44
Total of sample in this category	8	9	16	40	52	102	115	94	69	52	30
%	1.36	1.53	2.73	6.81	8.86	17.38	19.59	16.01	11.75	8.86	5.11

“How well known” is a composite variable where: How long known “less than 1 month"=0, "1-3 months"=1, "over 3 months but less than 6 months"=2, "6 months - 1 year"=3, "over 1 year"=4. How often seen "7 monthly - yearly"=0, "2 - 6 monthly"=1, "monthly"=2, "3 weekly"=3, "fortnightly"=4, "weekly"=5, "more than weekly"=6

Table C5: Staff referral intentions, separated by diagnosis

	bipolar	depression	none of the above	personality disorder	psychosis not otherwise specified	schizophrenia spectrum disorder	substance misuse as primary diagnosis	Total
definitely	14 26.4%	23 22.6%	7 12.1%	19 24.7%	20 27.07%	42 21.17%	11 19.67%	136 22.07%
probably	10 18.9%	20 19.6%	4 6.9%	16 20.8%	20 27.0%	47 23.6%	17 30.4%	134 21.7%
maybe	5 9.4%	10 9.8%	6 10.3%	9 11.7%	6 8.1%	19 9.6%	6 10.7%	61 9.9%
probably not	6 11.3%	13 12.8%	5 8.6%	7 9.1%	7 9.5%	13 6.5%	6 10.7%	57 9.2%
no / highly unlikely	2 3.8%	6 5.9%	5 8.6%	4 5.2%	3 4.1%	20 10.1%	1 1.8%	41 6.6%
Total	53	102	58	77	74	199	56	619

Table C6: Service user wish to be referred, separated by diagnosis

	personality disorder	PTSD	bipolar affective disorder	depression / anxiety	other psychosis diagnosis	Schizophrenia	Schizoaffective disorder	I don't know / can't remember	other	none	no response	Total
definitely	5 38.5 %	1 100 %	4 28.6 %	8 38.1 %	6 50.0 %	9 19.6 %	2 7.4%	3 100 %	1 25.0 %	2 33.3 %	2 28.6 %	44 33.1 %
probably	4 30.8 %	0 0.0%	6 42.9 %	5 23.8 %	1 8.3%	6 13.0 %	0 0.0%	0 0.0%	1 25.0 %	0 0.00 %	1 14.3 %	24 18.1 %
maybe	3 23.1 %	0 0.0%	2 14.3 %	4 19.1 %	2 16.7 %	4 8.7%	1 4.4%	0 0.0%	1 25.0 %	4 66.7 %	2 28.6 %	23 17.3 %
probably not	1 7.7%	0 0.0%	1 7.1%	3 14.3 %	2 16.7 %	7 15.2 %	0 0.0%	0 0.0%	0 0.0%	0 0.00 %	1 14.3 %	15 11.3 %
no / highly unlikely	0 0.0%	0 0.0%	1 7.1%	1 4.8%	1 8.3%	20 43.5 %	3 6.8%	0 0.0%	1 25.0 %	0 0.00 %	1 14.3 %	27 20.3 %
Total	13	1	14	21	12	46	6	3	4	6	7	133

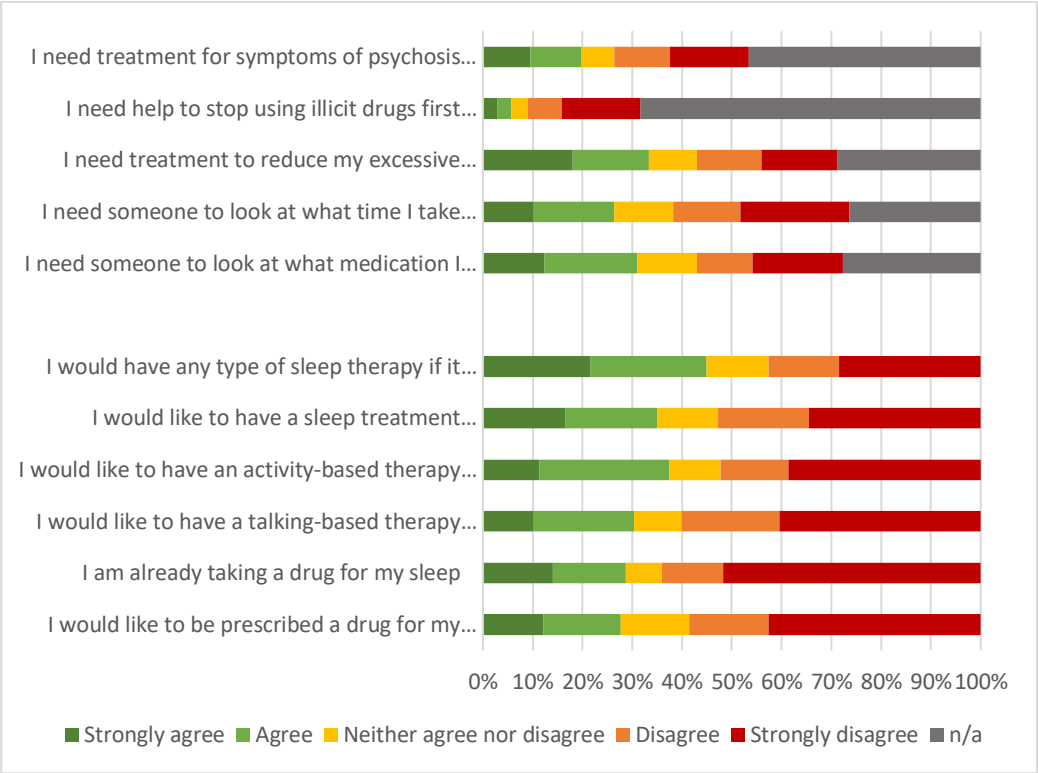


Figure C1: Treatment beliefs and preferences (whole sample)

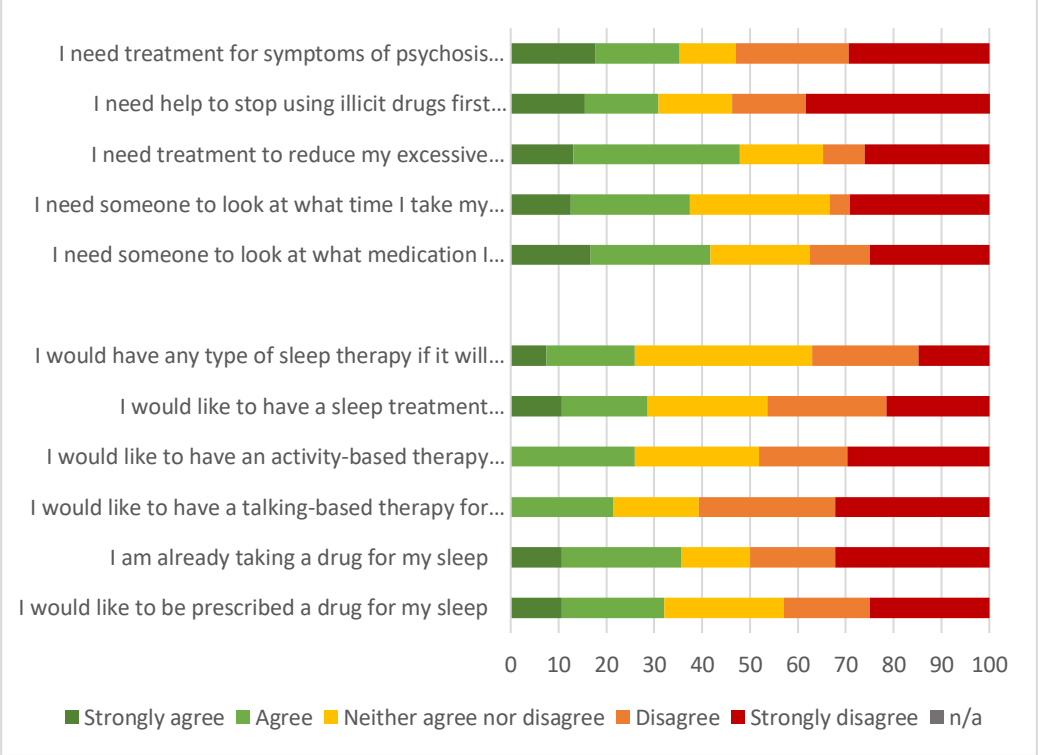


Figure C2: Treatment beliefs and preferences among those who reported significant or severe sleep problems but did not want referral to an intervention like L-DART (maybe, probably not, or definitely not)

Table C7: Qualitative comments on reasons not to want referral

Sentiment / content	example quote(s)	number of instances
Don't need therapy to improve sleep, because sleep is not too bad	"Not too much of an issue" (staff proxy) "I think i'm alright" (service user)	staff = 3 service users = 5
Already have enough other mental health input	"Already have enough engagement with treatments of various kinds" (service user) "Receiving treatment" (service user)	service users = 3
Medication helps with sleep, don't need a sleep therapy	"[medication] it's helping me stay asleep and not have any nightmares." (service user) "Only would like a short term prescription when unable to sleep." (service user) "clozapine helps to sleep." (service user)	service users = 5
Sleep problem expected to resolve without treatment	"As a result of medication withdrawal" (staff) "whether they will get better […] once her psychosis is effectively treated" (staff)	staff = 2
Concern that it wont work	"Probably won't work" (service user) "Nothing can be done about my sleep." (service user)	service users = 4
Just not interested / not motivated	"lack of motivation, doesn't see it is a problem (usual for them)" (staff) "I wouldn't be interested." (service user)	staff = 2 service users = 1
"Engagement"	"if they were willing to engage" (staff)	staff = 5
Current specific barriers to making the required changes / homework	"On-going stimulant misuse" (staff) "Wakes very early for work." (staff) "Recent bereavement" (staff) "Currently NFA" (staff) "would consider in future with more stable mood" (staff) "I have a lot going on at the moment with my mental health. " (service user) "I lead a busy life and I'm not sure I would be able to engage fully in advice offered." (service user)	staff = 6 service users = 3
other concerns where there was only one instance of this content	• rather do on own (service user) • don't like groups (assumes group therapy) (service user) • concern that if sleep is improved underlying mental health condition will not be diagnosed properly (service user) • would want more information first to decide (service user) • would refer if it was evidence based (staff) • would refer if sure service users with substance use wont be excluded (staff)	

Appendix 7: Feasibility study update

The feasibility study received ethics on 13 March 2020 from REC reference 20/NW/0059. It opened to recruitment one year and two months later at its first site on 13/05/2021. Uptake was good and recruitment was completed within half the allowable time, see Figure A below.

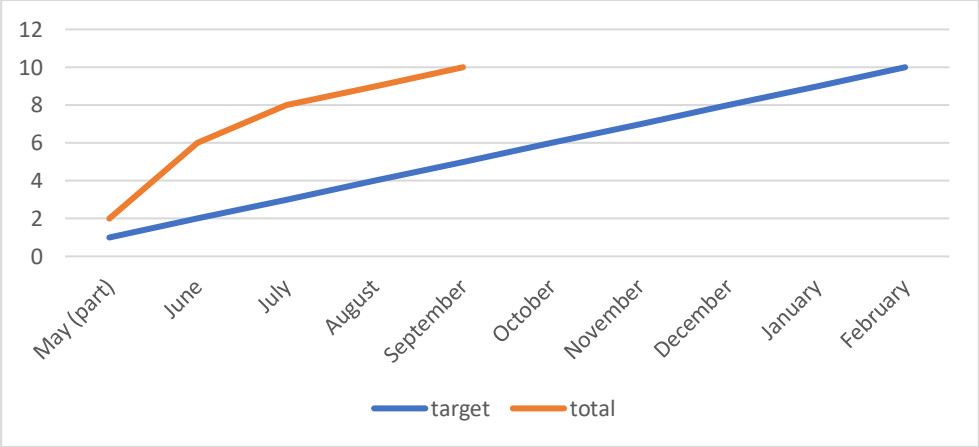


Figure A: Participant recruitment per month (including wait list)

Twenty-eight referrals were received before the study finished filling available places including on the waiting list, a further seven referrals were then received who were placed onto a reserve list. Table A shows the reasons participants declined or were not recruited.

Table A: Reasons people referred did not participate

Reason person referred did not participate	Number of people
Lost contact	4
Declined (total)	6
Declined, no further info	2
Declined due to, don't want to participate in research	1
Declined due to study / therapy is too much contact / too much commitment	3
Ineligible (total)	8
Ineligible due to wrong diagnosis	5
Ineligible, due to another exclusion	2
Unable to understand study info to provide informed consent	1
Patient referred for OSA assessment so clinician withdrew referral to await result	1
Wait list already full at time of referral	7

Table B shows the demographics of the feasibility study participants who have participated or are still participating.

Table B: Demographics of feasibility study participants

Characteristic	**n (%)**	**data completeness**
Total	10	
Gender		100%
Female	2 (20%)	
Male	8 (80%)	
Diagnosis		100%
Schizophrenia	10 (100%)	
Schizoaffective disorder, delusional disorder, schizotypal disorder	0 (0%)	100%
Ethnicity		100%
White British	10 (100%)	
Other	0 (0%)	
Religious status		100%
No formal religion	3 (30%)	
Christian (various denominations)	7 (70%)	
	mean (SD)	
Age	50.4 (8.59)	100%
BMI	30. 58 (4.43)	90% (1=weight out of date on notes, unable to weigh)
Medications		100%
Taking clozapine	4 (40%)	
Taking other oral antipsychotic	5 (50%)	
Anti-psychotic depot	4 (40%)	
Antidepressant	4 (40%)	
Hypnotic	3 (30%)	
Other medications not itemised here included those for blood pressure, thyroid, allergies, painkillers including opiates, anti-histamines, diabetes medications, reflux medications, and medications for psychotropics side effects		

As recruitment was faster than expected participants were seen in two cohorts with a gap in between, to accommodate limited therapist capacity and to ensure participants received the intervention in both summer and winter (relevant due to modifying light exposure and difference in natural light and weather). The first cohort began participation in May-June 2021 and finished in Nov 2021 - Jan 2022, and the second cohort began Dec 2021 - Jan 2022, and their follow-up will end in June - July 2022.