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LIGHT THERAPY: THERAPEUTIC POTENTIAL
FOR THE MANAGEMENT OF DEPRESSION IN
PRIMARY CARE

JACQUELINE WALSH

A thesis submitted in partial fulfilment of the requirements of
the University of Kent and the University of Greenwich for
the Degree of Master of Philosophy

March 2018

DECLARATION

I certify that this work has not been accepted in substance for any degree, and is not concurrently being submitted for any degree other than that of Master of Philosophy being studied at the Universities of Greenwich and Kent. I also declare that this work is the result of my own investigations except where otherwise identified by references and that I have not plagiarised the work of others.

Jacqueline Walsh

Dr Sarah Corlett

Dr Gurprit Lall

ACKNOWLEDGEMENTS

Firstly, I would like to express my sincere gratitude to Dr Sarah Corlett for her commitment, motivation and kindness during my study. My thanks also to Dr Gurprit Lall for his guidance and efforts throughout. Their tremendous contribution of time and advice has made my experience a rewarding one which, ultimately, would not have come to fruition without their unwavering support.

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ABSTRACT

The management of depression utilises both pharmacological and non-pharmacological strategies. A recent meta-analysis has demonstrated that light therapy (LT) is effective in the treatment of non-seasonal depression (NSAD). However, there is a paucity of evidence exploring its effectiveness in those using LT in their own homes. The aim of this thesis is to design a randomised controlled trial to test the effectiveness of LT in Primary Care.

A literature search was conducted from which options for key aspects of the study design were identified. This included eligibility criteria, duration of study, time of day and duration of light therapy use, feasibility of monitoring requirements and timing of saliva samples, perceived effectiveness of LT, and preference for the appearance of the LT device including both its size and the colour of light. Exploratory qualitative studies were undertaken, with stake-holders (GPs and the general public) to explore their awareness of LT, their views and opinions on the effectiveness, safety and feasibility of LT in the management of depression, and the aspects described above of the proposed study protocol. Strategies for recruitment of participants and use of incentives were also explored.

Thirteen people, with experience of depression, participated in two focus group discussions. Awareness of the use of LT was mostly in relation to treatment of Seasonal Affective Disorder (SAD). No-one had used LT themselves, although some knew of others who had tried it. Generally, it was perceived as being suitable as an adjuvant therapy. It was considered to be safe as it was 'natural' and had an 'external action', although misconceptions relating to tanning of the skin were held. Participants considered that the study design would be feasible to adhere to. Their preferred device distributed the brightest white light. However, they were open to using red light if they were told it would work. Participants suggested recruitment via routes other than through the GP, and advised that financial incentives to take part in the study were not required. They perceived participation in a trial as being a reward in itself.

Five interviews were carried out with GPs. Most related LT use to treatment of SAD and were cautiously optimistic in their expectations of its effectiveness in NSAD, although all emphasised that there was currently a lack of evidence to support its use for this indication. They had negligible concerns regarding its safety. There was a clear need for something to offer patients with mild depression who had persistent symptoms and it was thought that, if the evidence was there to

support it, light therapy could fill this need. The GPs main concern regarding the proposed study was maintaining confidentiality of participants and that participants themselves would not be able to adhere to the LT regimen. They were supportive of the proposed study and were happy to support recruitment into it.

As a result of these exploratory studies a trial protocol was developed. The procedure for recruitment of participants, eligibility criteria, LT dosing regimen, and choice of placebo were all influenced by this approach. Feedback from the focus group also lead to additional information, for example relating to side-effects, and effectiveness of different light therapy colours being added to the Patient Information leaflets. The study has been submitted to, and received approval from, NHS Research Ethics Committee and the relevant NHS Research Governance approval has been granted.

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List of Abbreviations

5-HT	5-hydroxytryptamine
BNF	British National Formulary
CCG	Clinical Commissioning Group
CBT	Cognitive behavioural therapy
DLMO	Dim light melatonin onset
GP	General Practitioners
GSS	Global seasonality score
HCP	Health Care Professional
IPAQ	International Physical Activity Questionnaire
ipRGCs	Intrinsically-photoreceptive retinal ganglion cells
LT	Light therapy
MRC	Medical Research Council
ND	Neutral density
NICE	The National Institute for Health and Care Excellence
NIF	Non-image forming
NHS	National Health Service
NRES	National Research Ethics Service
NSAD	Nonseasonal Affective Disorder
PHQ-9	Patient Health Questionnaire-9
PIL	Participant information leaflet
QALY	Quality-adjusted life-year
Qof	Quality and outcomes framework
RCGP	Royal College of GPs
RCT	Randomised controlled trial
SAD	Seasonal Affective Disorder
SAFTEE-SR	Systematic Assessment for Treatment Emergent Effects
SCN	Suprachiasmatic nucleus
SF-36	Short Form 36

SIGH-SAD-SR Structured Interview Guide for the Hamilton Depression Rating Scale – Seasonal Affective Disorder version Self-rating scale

SPAQ Seasonal Pattern Assessment Questionnaire

SSRIs Selective serotonergic reuptake inhibitors

TBI Traumatic brain injury

Chapter ONE

Introduction

1.1 Background

Globally depression is the single largest contributor to disability and it is estimated that more than 300 million people worldwide have the condition. Symptoms typically include persistent low mood, loss of interest and enjoyment, sleep and appetite changes, guilt or self-criticism, poor concentration, and reduced energy. The impact of mood on the affected person can vary in severity and duration. Symptoms may persist for months or even years. Accuracy of diagnosis is critical for effective management, which includes a clinical assessment of the patients' cognitive and functional abilities, their previous history, the duration of the current episode and the number and severity of symptoms. Two widely accepted classification systems are used within psychiatry to categorise and define depression; these are the DSM-V and ICD-10 (The Diagnostic and Statistical Manual of Mental Disorders and the International Classification of Disease, respectively) criteria. DSM-V includes detailed diagnostic criteria for all types of depression including seasonal affective disorder (SAD), a type of depression where a person's symptoms typically demonstrate seasonal variation largely influenced by exposure to daylight. For diagnosis DSM-V differs from ICD-10 in that people need to score 5 out of 9 symptoms, rather than 4 out of 10, over a two-week period for a diagnosis of mild depression. At least one of the five should be depressed mood or loss of interest or pleasure in activities. Other symptoms may include weight loss, inability to sleep, psychomotor agitation, fatigue, feelings of worthlessness or inappropriate guilt, reduced ability to concentrate or suicidal ideation.

Screening questionnaires have been recommended as a tool to aid diagnosis and classify the condition as mild, moderate or severe. It is estimated that depression affects 5% to 10% of patients in the primary care setting in the UK (World Health Organization, 2017).

Whilst both DSM-V and ICD-10 are widely recognised the National Institute for Health and Care Excellence have based their latest clinical guidelines for the management of depression on DSM-V.

NICE recommend a framework involving a stepped care approach to treat and manage people suffering with the symptoms of depression. This is reproduced in the box below.

Box 1: Stepped care model for management of depression. (NICE, 2009)

Focus of the intervention	Nature of the intervention
Step 4: Severe and complex depression; risk to life; severe self-neglect	Medication, high-intensity psychological interventions, electroconvulsive therapy, crisis service, combined treatments, multiprofessional and inpatient care
Step 3: Persistent subthreshold depressive symptoms or mild to moderate depression with inadequate response to initial interventions; moderate and severe depression	Medication, high-intensity psychological interventions, combined treatments, collaborative care ^[b] and referral for further assessment and interventions
Step 2: Persistent subthreshold depressive symptoms; mild to moderate depression	Low-intensity psychosocial interventions, psychological interventions, medication and referral for further assessment and interventions
Step 1: All known and suspected presentations of depression	Assessment, support, psychoeducation, active monitoring and referral for further assessment and interventions

The stepped approach aims to provide patients with treatment tailored to their individual need with the least invasive intervention provided as a first approach. A number of non-pharmacological interventions are recommended as part of this guideline including psychoeducation, psychosocial and psychological interventions, for example cognitive behavioural therapy. NICE currently do not recommend light therapy as a treatment for depression.

Medication should be considered for those presenting with moderate or severe depression, or those with mild depressive symptoms that have been present for a least 2 years, or for those with mild depression that persists after other intervention.

LT involves exposure to artificial light, either full spectrum or a specific wavelength, using a light box. Typically, the light box would be used for a defined duration at a specific time of day. Bright white light boxes emit 10,000 lux at about 35cm or an arms length's distance. Whilst LT is generally regarded as safe it is not recommended in those that have a history or current diagnosis of psychosis, light-induced migraine or epilepsy, traumatic brain injury, retinal blindness, cataracts, retinal diseases of the eye or glaucoma. Light boxes are not available on the NHS but can be purchased for £50 - £150.

LT has been used as a tool in the treatment of Seasonal Affective Disorder (SAD) (Terman and Terman, 2005). Its use in non-seasonal depression has been limited with several studies demonstrating a range of clinical outcomes, from 50% remission rate to no clinical benefit. However, a Cochrane meta-analysis concluded that the use of bright light boxes does present evidence of therapeutic benefit in the treatment of non-seasonal depression (Tuunainen et al., 2004). The majority of trials demonstrating such effects have been undertaken in hospitalised patients with strict clinical control over the environment, both physical and social. There is a paucity of evidence to support the use of LT in Primary Care, where patients' home environments are likely to be less tightly controlled. Currently, the lack of evidence to support the use of LT in Primary Care for the treatment of depression restricts its prescriptive use in General Practice.

Designing a study to determine the effectiveness of LT in this patient population is challenging as it is recognised that the result may be dependent upon a number of inter-connecting variables. Questions in relation to the acceptability of LT as a treatment for depression, recruitment optimisation, appropriate placebo controls and other feasibility measures would have to be considered for a study such as this. The context of the study, both its focus on Primary Care, the availability of other non-pharmacological treatments within the local health service, the 'normal' management of non-seasonal depression, and the nature and severity of the participants' condition, need careful consideration. These factors would therefore also need to be accounted for in the design of a study exploring the impact of LT on depression. A phased approach to the development of the study protocol, in line with the recommendations of the MRCs framework for the design and evaluation of complex interventions to improve health (Medical Research Council, 2000; 2008), is appropriate.

A broad based literature review was conducted to inform the following aspects of the study design, inclusion/exclusion criteria, including severity of depression; recruitment setting; measurement scales for depression, quality of life, adverse effects and outcome expectancy; measurement of physical activity and sleep quality and duration; adherence to LT treatment, biochemical measurements; light box design, timing and instructions for use; LT colour, intensity and duration of treatment, follow up. The detailed results of the literature review are not reported within this thesis. However, the findings have informed the design of the proposed protocol.

An example of a literature review, conducted as part of the preparatory work for this thesis can be seen in Chapter Two which provides a review of the use of LT in the management of affective disorders. The work presented in this chapter was published in *ChronoPhysiology and Therapy*. As the first author, I conducted the literature searches, reviewed the contribution of co-authors, synthesised all sections into the final manuscript, compiled responses to the reviewers, and proofread the final published paper. My colleague (Lynsey Atkinson contributed specifically to the section on light input into the circadian clock). The supervisory team (GL and SC) reviewed and commented on early versions and read and approved the final paper.

As this is a complex medical intervention modelling to help define variants, testing the acceptability of the proposed components to participants was necessary. Focus groups were carried out with the general public to consider and place into context the local characteristics of the participants of interest, their views and attitudes towards LT and to explore enablers and barriers to their participation in the proposed study. The results from the focus groups are presented in Chapter Three. Similarly, it was deemed essential that the attitudes and opinions of General Practitioners were also explored to ensure that the trial design could be optimised, particularly with respect to recruitment. Therefore, interviews were conducted with GPs within the local area and the results of these are presented in Chapter Four.

Chapter Five, presents the protocol and associated appendices that were submitted to the National Health Services Research Ethics Committee for approval. Permission to undertake the study was granted in April 2015 (Appendix 18). Local governance approvals were also obtained.

A summary of the main findings of this work is detailed in Chapter Six.

1.2 Aims and Objectives

The aim of this thesis was to develop a protocol to explore the feasibility of using LT in primary care for patients with non-seasonal depression.

Objectives

- To review how circadian rhythms can contribute to depression and the theoretical basis for how LT can modify these rhythms to improve mood.
- To explore the general public's awareness of the use of LT for the treatment of depression, their expectations for its effectiveness and any concerns regarding its use.
- To ascertain the general public's opinions on the proposed LT study; specifically, their views on recruitment methods, the type of LT device, the duration of use and feasibility of salivary sampling and Actiwatch™ use.
- To explore GPs' awareness, views of effectiveness and concerns surrounding LT.
- To ascertain the views of GPs regarding the proposed LT study in inform the research design.
- To design an exploratory study based on the findings of the research.
- To gain the necessary approvals (NHS Ethics and research governance) to undertake the exploratory study.

CHAPTER TWO

An Insight into Light as a Chronobiological Therapy in Affective Disorders

2.1 Abstract

The field of chronobiology has vastly expanded over the past few decades bringing together research from the fields of circadian rhythms and sleep. The importance of the environmental day-night cycle on our health is becoming increasingly evident as we evolve into a 24-hour society. Reducing or changing sleep times against our natural instincts to rest at night has a detrimental impact on our wellbeing. The mammalian circadian clock, termed the suprachiasmatic nucleus (SCN), is responsible for synchronising our behavioural and physiological outputs to the environment. It utilises light transduced by specialised retinal photoreceptors as its cue to set internal rhythms to be in phase with the light-dark cycle. Misalignment of these outputs results in symptoms such as altered/ disturbed sleep patterns, changes in mood, physical and mental exhaustion; symptoms shared by many affective clinical disorders. Key links to circadian abnormalities have been found in a number of disorders such as SAD, non-seasonal depression and bipolar affective disorder. Furthermore, therapies developed through chronobiological research have shown to be beneficial in the treatment of these conditions. In this article we discuss the impact of circadian research on the management of affective disorders, giving evidence of how a misaligned circadian system may be a contributor to the symptoms of depression and how moderating circadian rhythms with LT benefits patients.

2.2 Introduction

Chronobiology is a vastly expanding field of research, incorporating both areas of circadian rhythms and sleep. Over the last decade these two disciplines have become increasingly integrated, resulting in a better understanding of mechanisms that underpin both our physiological and behavioural daily routines. Consequently, these emerging principles are now being translated into the clinical setting and are proving to be fundamental; as the importance of both circadian rhythms and sleep in the preservation of human health is unravelled.

Through evolution, the environmental day- night cycle has been the predominant cue to which organisms have adapted their behaviour. Humans have evolved into a diurnal species, preferring to sleep at night and restrict activity to the day. This daily pattern in synchronisation has held true for centuries; however modern society has begun to break away from this norm. With the advent of a

'24-hour' society we find ourselves paying less attention to our natural instincts to rest and rather favour socialising and working. Remarkably, many individuals turn to stimulants to prolong daily 'active' duration in the pursuit of maximising 'awake' efficiency. However, continually reducing the duration of rest or sleep is likely to be a key contributor to the 'burnout' phenomenon, manifesting as extreme tiredness, mental exhaustion and low mood. Thus, this cultural drift in day-night activity impacts negatively on our overall psychological well-being and health.

The synchronisation of our daily behaviour to the environmental day- night cycle is governed by an inherent biological clock that integrates light cues and our social signals to generate a harmonic balance with internal physiology and the outside world. However, a misalignment in such a system due to either a self-driven motivation or a clinical disorder can result in ill health (Baron and Reid, 2014). Recently, it has been shown that some of the characteristic symptoms of natural aging, for instance abnormal sleep patterns are likely to be a result of a circadian desynchronization (Farajnia et al., 2014). Complex neurological conditions such as affective disorders also share common symptoms that are suggestive of a deficit in circadian regulation. Treatments that are aimed at realigning or stabilising physiological synchronicity with the environment have proven beneficial in SAD, non-seasonal depression and bi-polar affective disorders (Asarnow et al., 2014). In this article, we discuss and highlight the importance of chronobiology in affective disorders. In addition, we aim to show the impact of therapies devised from our current understanding of circadian biology to treat these conditions and their beneficial effect on patients.

2.3 The Master Clock and Circadian Entrainment

Mammals possess a master neuronal circadian pacemaker, the suprachiasmatic nucleus (SCN) that is situated within the anterior hypothalamus, beneath the third ventricle and above the optic chiasm (Ralph and Lehman, 1991). The SCN receives direct photic input from the eyes via the retinohypothalamic tract; providing vital information about the environmental day- night cycle. In addition, the SCN is also innervated by projections from the intergeniculate leaflet and raphe nucleus; which relay non-photoc information such as social and behavioural cues to the clock.

Neurons of the SCN are endogenously rhythmic (Brown and Piggins, 2007). These cells express circadian oscillations in both molecular gene expression of specific clock genes and in cellular electrical excitation (Brown and Piggins, 2007; Reppert and Weaver, 2001). It is these rhythms that align themselves in response to photic and non-photoc information received from afferent inputs. For instance, under a typical day-night cycle the SCN displays increased electrical excitation during

the day relative to the night (Shibata et al., 1982). It is these outputs that will in turn provide a timing cue for other physiological systems, such as those governing sleep.

For humans, this synchronisation presents itself through our preference to be active during the day and asleep at night. In addition, such synchronisation can be modified by other neuronal systems governed by behavioural stimuli, such as social activities, meal times and exercise. The incorporation of these behavioural signals and the light-dark cycle provides ultimate entrainment of an individual. For the purpose of this review we will focus on aspects of circadian entrainment that have been identified to contribute to the mood disorders discussed in subsequent sections. For a detailed review on entrainment mechanisms (Lall et al., 2012).

2.4 Light input to the Circadian Clock

In mammals light information enters the physiological system exclusively via the eyes (Foster, 1998). This ocular detection of ambient light intensity, or irradiance, performs a significant role in circadian entrainment in addition to image-forming vision (Lucas and Foster, 1999). When light reaches the retina three classes of photoreceptor cells, rods, cones and intrinsically-photoreceptive retinal ganglion cells (ipRGCs), decode and communicate photic information for further processing. For the purpose of visualisation, rod and cone photoreceptors provide the core translational pathway; however, the task of circadian photo-entrainment has been largely attributed to the subset of retinal ganglion cells possessing the novel photopigment melanopsin, the ipRGCs. For a detailed review on photoreceptor contribution to circadian entrainment see Lucas et al., 2012.

Light-evoked innervation from the combined actions of all classes of photoreceptor are signalled directly to the SCN via multisynaptic circuitry of the retino-hypothalamic tract to drive non-image forming (NIF) responses of circadian photoentrainment, pupillary light reflex, pineal melatonin suppression and sleep propensity (Guler et al., 2008; Lall et al., 2010; Peirson et al., 2009). However, the communicated photic information is not defined simply by duration of light, as retinal sensitivity is subject to irradiance and spectral composition (Lucas et al., 2012; Enezi et al., 2011). It has been shown experimentally that the rod class of photoreceptor has the greatest sensitivity to light with very low illumination still able to contribute to photoentrainment in the absence of other NIF responses (Lall et al., 2010; Altimus et al., 2010; Butler and Silver, 2011). Under higher levels of irradiance cones play a greater role in retinal decoding and in turn, NIF responses but essentially the melanopsin-containing ipRGCs provide the greatest contribution (Lall et al., 2010). Further, photoreceptor sensitivity has been demonstrated to vary according to wavelength of light (Enezi et

al., 2011). For melanopsin, peak sensitivity occurs, around 480 nm, suggesting lighting within the blue spectral range as being optimal for eliciting entraining photic cues (Hattar et al., 2003; Lucas et al., 2001; Rollag et al., 2003). Despite this class of photoreceptor being maximally sensitive to light and able to integrate ambient light levels throughout the duration of an entire day, it possesses very low sensitivity, requiring bright light for optimal signalling. Together, this has formed the basis of LT treatments typically comprising of bright white or blue lights which are given during the day with the sole purpose of activating the melanopsin system and increasing photic signalling to the circadian clock. Thus, increasing the day light signal to, in turn, drive circadian synchronisation (entrainment).

2.5 Light as a Therapeutic Tool

A desynchronised circadian system results in significant changes in mood and sleep, such as those acutely experienced during jetlag. However, it is the presence of light that is able to drive the resynchronisation of these systems through the SCN. Hence, this knowledge and understanding of the circadian system has led to the use of light in the treatment of psychiatric conditions that show symptoms of a destabilised clock. Bright bursts of light can act as strong signals to the SCN thereby reinforcing day light presence. Early controlled studies using bright light as a therapeutic tool for three hours in the morning and in the evening during the winter months proved an effective treatment of SAD 'winter blues'; with the light stimulus acting to elongate the amount of daylight available throughout the day (Terman and Terman, 2005).

Initially, light treatments for longer durations at lower intensities (approximately 2,500lux) were shown to be effective in eliciting an antidepressant response. However, increasing light intensity to 10,000lux for 30-40 minutes yielded comparable remission rates in subsequent SAD studies (Magnusson and Kristbjarnarson, 1991; Terman et al., 1990). In addition to intensity, spectral composition of light may be important. Typically, polychromatic 'white light' has shown greatest efficacy (Terman and Terman, 2005). However, following the discovery of melanopsin, light stimuli shifted towards the blue spectrum, may be beneficial in achieving greater potency (Meesters et al., 2011).

Adverse effects associated with light treatment are minimal. Several studies describe mild visual disturbances including eyestrain and photophobia (Terman and Terman, 2005). Agitation, headaches and eye irritations are reported across affective disorder trials. In a review of non-seasonal LT trials, the frequency of these symptoms was not shown to be significantly different from the control groups (Tuunainen et al., 2004). In terms of ocular safety, a study of long-term exposure to light

treatment did not reveal ophthalmological problems in participants (Even et al., 2008; Gallin et al., 1995). Overall LT is considered well tolerated, safe and presents with a convincing risk-to-benefit ratio (Even et al., 2008).

2.6 Chronotherapeutics and Affective Disorders

Over the last few decades both research into mammalian circadian rhythms and sleep has been rapidly progressing; with a gathering wealth of knowledge in the basic understanding of mechanisms that underlie each process. More recently, the realisation of the importance of these findings in human health has been brought to the forefront. For example, the association between changes in various circadian rhythms and the occurrence of mood disorders has been extensively documented. Specifically, abnormalities in patterns in biochemical, neuroendocrine, physiological and behavioural outputs have been widely observed in patients suffering from affective disorders (Germain and Kupfer, 2008). In this section we will focus on the chronobiological significance and impact of light on seasonal, non-seasonal and bipolar affective disorders.

2.7 Seasonal affective disorder (SAD)

SAD is a clinical subtype of major depression first defined in a seminal report by the Rosenthal group in 1984 (Rosenthal et al., 1984). SAD or winter depression, presents in patients during the autumn and winter months with symptoms such as severe changes in mood, energy and appetite (Miller, 2005). The seasonal dependence of SAD is strongly correlated with the decrease in daylight hours during symptomatic months. Conversely, as the day length increases, these symptoms are attenuated, leading to remission in the summer. The underlying mechanisms driving SAD have been associated with a deficit of the circadian system to adapt to the changing environment, predominately the light-dark cycle. The precise workings remain unclear; however, a number of key candidates or pathways have been proposed centring on the desynchronisation of internal circadian driven physiology with the external environment.

In the first instance, changes in hormonal rhythms have been linked to SAD onset; of particular interest is the hormone melatonin, referred to as the 'sleep hormone'. Melatonin levels typically rise at night and nadir during the day. The majority of circulating melatonin is produced by the pineal gland. The rhythmic profiling of melatonin is regulated, in part, by the light-dark cycle, as light acts to suppress production, thus driving the cyclic nature of this hormone (Pandi-Perumal et al., 2008). More significantly, the onset in expression of melatonin provides a strong biomarker for

assessing circadian synchronisation (Pandi-Perumal et al., 2006). Dim light melatonin onset (DLMO) is a useful indicator obtained by collection of sequential blood or saliva samples every thirty to sixty minutes, from early evening until bedtime, under dim light conditions. This marker provides an excellent output of internal physiological entrainment when correlated to the environmental light-dark and sleep cycles (Hickie and Rogers, 2011).

Sufferers of SAD exhibit a number of traits linked to this defined melatonin rhythm. Affected patients have been shown to express a delay in the DLMO coupled with a lengthened nocturnal and elevated secretion profile during the winter (Rice et al., 1995; Lewy et al., 1987; Wehr et al., 2001; Danilenko et al., 1994). Due to the responsiveness of melatonin secretion to light, one of the major treatment strategies for SAD has centred on using light as a therapeutic agent. Bright light presented to patients during the morning or both morning and afternoon for around 3 hours resulted in significant remission rates in SAD individuals (Terman and Terman, 2005; Rosenthal et al., 1984). The positive impact of light in the treatment of SAD is clear, however its mode of action through adjustment of DLMO is still debatable; thus, the antidepressant efficacy of LT cannot be defined by its effect on melatonin secretions alone (Rice et al., 1995; Murphy et al., 1993; Partonen et al., 1997). To this end, it has been proposed that light acts by resetting key internal rhythms governed by the circadian clock, thus realigning physiological phase to the environment (Lewy et al., 1987; Lewy, 2009).

In addition to melatonin, the neurotransmitter serotonin, 5-hydroxytryptamine (5-HT), has been associated with modulation of behaviour, emotion and circadian rhythms (Pail et al., 2011). Interestingly, hypothalamic serotonin concentrations investigated in post-mortem samples revealed a distinctive seasonal pattern, with lower levels of serotonin detectable in the winter (Carlsson et al., 1980). In addition, there is a higher degradation of serotonin associated with light environments characteristic of winter months, and an amplified rate of serotonin production in direct response to bright sunlight (Lambert et al., 2002). Further, reduced brain serotonin levels share many similarities to SAD for instance, carbohydrate craving, hyperphagia, hypersomnia and attenuated melatonin levels (Miller, 2005). The role of serotonin in SAD is, however, uncertain. Acute reduction in serotonin levels in SAD patients remitting during the summer months has been shown to force sufferers into depressive relapse (Neumeister et al., 1998; Neumeister et al., 1998c; Lam et al., 1996). However, there is variability in the data with other groups showing little or no effect (Neumeister et al., 1998b; Lam et al., 2000). Depressive severities in SAD patients are also unaffected by indirect depletion of serotonin levels (Neumeister et al., 1997; Partonen and Lonnqvist, 1998). Together, these findings call into question the role and specificity of a disrupted serotonergic drive. Interestingly, SAD patients treated with pharmacological agents that increase

serotonin together with light treatments did not respond significantly more than those using light alone, however relapse rates in those taking the combination were slower (McGrath et al., 1990).

2.8 Non-seasonal Depression

The association between non-seasonal depression and chronobiology is one that is not made very often by clinicians or patients; however, there is gathering evidence that has strengthened the link between circadian disruptions and the characteristic symptoms of non-seasonal depression. These include delayed sleep onset, non-restful sleep, early morning waking, daytime fatigue, and diurnal mood variation (Germain and Kupfer, 2008). Typical treatments have predominantly focused on pharmacological interventions mainly targeting the serotonergic pathways. The most commonly used are selective serotonergic reuptake inhibitors (SSRIs) acting to increase endogenous levels of serotonin.

Having established commonalities in symptoms with SAD, the effectiveness of light treatment in non-seasonal depression has been investigated. Interestingly, therapeutic use of light in non-seasonal individuals has shown optimal results at high intensities (>2,500lux) scheduled between 30 minutes and 2 hours; a similar effect size to that observed in SAD patients (Tuunainen et al., 2004; Golden et al., 2005). Further, the combination of light regimens with antidepressant compounds such as, imipramine, sertraline and citalopram have shown to significantly improve mood with faster response rates than an antidepressant only control group (Holsboer-Trachsler et al., 1994; Martiny et al., 2005; Beauchemin and Hays, 1997; Loving et al, 2002; Benedetti and Terman, 2013). In addition, melatonin levels have also been found to show significant differences in patients with non-seasonal major depression, when compared with healthy individuals (Buckley and Schatzberg, 2010). Due to the very nature of non-seasonal depression and its multifactorial causes and symptoms, a clear chronobiological light driven treatment regime would be difficult to apply. However, it is likely that some patients may benefit from those interventions that target specific circadian related symptoms, if nothing else, to alleviate those specifically from their suffering.

2.9 Bipolar affective disorder

Bipolar affective disorder presents with a complex aetiology ranging from unpredictable alternating mood states, typically between depression and normal affect or depression and manic state (Deltito et al., 1991). In general, behavioural therapies are used with caution in this population due to the unstable and temperamental nature of the disorder. However, patients have been found to respond to light treatments in a similar manner observed in a non-seasonal depressive group (Pail et al., 2011; Deltito et al., 1991). Chronotherapeutic strategies have included sleep deprivation in combination with light treatments to good effect with a rapid antidepressant response observed, within 48 hours in some cases, which were sustained for a noteworthy 7 weeks (Wu et al., 2009; Benedetti et al., 2005). However, LT in this population can result in a switch to manic or hypomania in response to treatment (Golden et al., 2005). Currently, pharmacological interventions show the greatest promise in the treatment of bipolar affective disorder, but therapies centred on strengthening circadian physiological and behavioural output are showing promise.

2.10 Pharmacological interventions

A range of pharmacological agents have been utilised in the management of affective disorders; employing direct or indirect chronobiotic properties. Lithium, a mainstay psychopharmacological treatment in bipolar disorder, is known to consistently alter circadian phase of an individual (Klemfuss, 1992). Melatonin formulations, such as Circadin, and melatonin analogues, including Ramelteon and Tasimelteon are found to be effective treatments in a range of insomnia disorders, but have not been studied extensively as antidepressant agents (Lemoine and Zisapel, 2012; Kawabe et al., 2014; Hardeland, 2009).

Selective serotonin reuptake inhibitors (SSRIs) are widely used as first line treatments in clinical practice for the treatment of SAD and non-seasonal depression (NICE, 2009). The precise mechanism of action is debatable, but SSRIs influence the serotonergic system to improve overall mood (Coplan et al., 2014). Interestingly, SSRIs have been found to alter circadian rhythms at both cellular and behavioural levels (Sprouse et al., 2006; Westrich et al., 2013). Hence, it is likely that some of the positive effects of SSRIs are through their regulation of the circadian system.

However, SSRIs commonly present with serious adverse effects including reported gastro-intestinal effects, weight changes, sexual dysfunction and sleep disturbances (BNF). Indeed, recent media attention has highlighted previously unrecognized side effects of SSRI use during pregnancy causing birth defects during development in utero (Kepser and Homberg, 2014). Moreover, SSRIs have a

slow onset of action consisting of two to eight weeks, or greater, in achieving detectable therapeutic response. Consequently, it is not surprising that the adherence of patients to SSRIs is poor, with a recent study reporting 40-50% failure during the maintenance period of treatment (Lopez-Torres et al., 2013).

Recently, a novel dual melatonergic and specific serotonergic antidepressant Agomelatine (Valdoxan) has shown potential in SAD patients (Pjrek et al., 2007). This compound aims to address both the abnormalities in the DLMO and the decrease in serotonin levels found in SAD. Agomelatine has been observed to demonstrate a rapid onset of action, effective symptomatic alleviation and offer a lower risk of relapse or discontinuation of symptoms in non-seasonal depressive individuals when compared to either a comparator or placebo (Gorwood, 2010).

2.11 Concluding Remarks

Research into circadian rhythms and sleep has opened up a whole new avenue in our understanding of several clinical conditions. Of these, affective disorders appear to have aspects of circadian dysfunction that are clearly presented in their symptoms. However, the treatment regimes are not so clear-cut. Pharmacological interventions show potency, but can be hindered by undesirable side effects. Conversely, the use of light as a therapeutic aid shows promise coupled with potentially minimal or no unwanted side effects. It is imperative that we continue to work on optimising such chronobiological interventions so as to fully realise their analeptic potential.

CHAPTER THREE

Focus Groups with Members of the General Public

3.1 Introduction

This chapter introduces the first in a series of research chapters which aim to inform the design of a future randomised controlled trial. Following the review of the current literature to support the use of LT for the treatment of depression in Primary Care (Chapter Two), a paucity of data was identified and a need therefore to conduct further clinical investigation to determine the benefit or otherwise of this intervention. As described in the Medical Research Council's seminal work *Developing and Evaluating Complex Interventions* (2000; 2008), the early phases of piloting, when investigating a complex intervention, is paramount for successful implementation and evaluation of an outcome. With this in mind, a series of studies were designed to fully investigate the major components of a future exploratory trial, including engagement with potential trial participants. Within this chapter, the results from focus groups with volunteers recruited from the general public who had experience of depression and reflected the target sample for a future exploratory trial, are presented.

3.2 Aims and Objectives

The aim of this research was to obtain the views of members of the general public on the use of LT for the treatment of depression. The objectives were:

- A. To explore the participants' awareness, expectations of effectiveness and concerns surrounding LT use for depression.
- B. To ascertain the focus group members' opinions of the proposed exploratory LT pilot trial, including: study setting, the type of LT device, the duration of use, and feasibility of salivary sampling and Actiwatch use.
- C. To determine the participants' opinions regarding the proposed recruitment strategies; identifying and recruiting potential participants.

3.3 Ethical approval

Ethical approval was obtained for this study from the Medway School of Pharmacy Research Ethics Committee (Appendix 1). An Information leaflet (Appendix 5) which explained the study objectives and described what the members should expect to do as participants within the focus group was provided to each potential member prior to the focus group, and written consent (Appendix 6)

obtained before the focus group commenced. An incentive in the form of a £20 gift voucher was offered to each participant, as well as their travel expenses.

3.4 Declaration

This research was completed by myself (primary researcher) and supervised by Dr Sarah Corlett (primary supervisor). The primary researcher and supervisor undertook the design and development of the protocol and together conducted the focus groups (Moderated by SC, observed by JW). The transcripts were produced and analysed by the researcher and confirmed with the supervisor.

3.5 Sampling strategy and study recruitment

Due to time and resource constraints, this study intended to recruit a sample of 12-20 volunteers, with a view of hosting two focus groups, recruited with the following criteria:

Inclusion criteria

- Aged 18 – 64 years old (Age range cut off in order to limit variation of response to treatment. There is a documented decline in photoreception in the elderly as seen in Turner and Mainster, 2008).
- Any history of, or current diagnosis of depression

Exclusion criteria

- Historic or current diagnosis of: psychosis, bipolar disorder, Parkinson's, dementia or Alzheimer's disease.

A poster advertising the focus groups was designed (Appendix 3) and circulated via local mental health charities and support groups. Local charities and support groups, identified through internet searches, advertisements in local media and word-of-mouth, were contacted via telephone and/or email by the researcher for their assistance in disseminating the advert. Print and electronic copies of the advert were provided, as well as a visit from the researcher to promote the study, when requested. Those who expressed interest in the study were provided, via e-mail or post, a participant information leaflet (Appendix 5), a contact information and demographics form

(appendix 4) and consent form (Appendix 6). Participants were informed of the focus group details by letter or e-mail, as indicated by their stated preferred method of contact, where inclusion and exclusion criteria for the study were met (Appendix 8). A letter or e-mail was also sent to those who had not been selected, based on their responses to questions regarding the study criteria, to thank them for volunteering (Appendix 9).

3.6 Focus group topic guide development

The findings of published studies, were used to inform and guide the development of the topic guide designed for the focus groups of this study (Appendix 7). The topic guide explored the following topics: Awareness or experience of LT use for depression, expectations of LT, safety of LT use, the feasibility of LT use and the feasibility of a proposed pilot trial investigating the potential use of LT for depression. During the course of the focus group, the moderator would introduce a topic from the guide, often formed as a question, and, firstly, allow open discussion related to the topic by the group. This was followed by a funnelling questioning technique whereby the moderator would follow the open question, or topic, with a series of closed and probing questions, in the attempt to fully explore and clarify the groups' or individuals' responses, with some pre-empted prompts included within the topic guide to aid the moderator.

3.7 Conduct of the focus groups

Two focus groups, each lasting one hour, were held at Medway School of Pharmacy in a private teaching room for this study. It was designed with one session scheduled in the evening and one during the day, both offering light refreshments, in attempt to accommodate the schedules of potential focus group volunteers. Two researchers attended each group. One researcher acted as moderator with the role of leading the group discussion using the topic guide, probing individual members of the group to gain opinions, and encouraging group discussion. The second researcher has the responsibility of taking field notes during the course of the focus groups. These field notes were to aid analysis of the eventual transcripts of the focus group by describing details that would not be captured in audio recordings alone. The groups were audio recorded using two digital devices, placed on different sides of the table so to aid transcription if conversations were too low to be detected on one device alone.

At each focus group, prior to recording, the researchers welcomed participants to the group, explained again the reason for the discussion group and asked if they had any questions or queries.

Additionally, the moderator confirmed that each individual still wished to participate. It was explained to the members of the group that the interview would be recorded, and transcribed verbatim. Participants contributions would be anonymised at transcription to maintain confidentiality. The recording began once the members of the focus group indicated that they had fully understood this information and had no further questions.

A number of print outs, approved by the ethics committee, were used as tools throughout the discussion in order to aid explanation of different elements of the proposed future study. The first of these tools was a pack of questionnaires that represented the potential recruitment pack. The second was a guide to the equipment to be used during the potential pilot trial including the Actiwatch™ and LT Devices. A copy of each can be found in appendices 23. For each of these print outs, the physical equipment was also shown to participants in order to gain as accurate an opinion as possible.

3.8 Data analysis

Interviews were audio-recorded and transcribed verbatim by the primary researcher and double checked by the primary supervisor to ensure transcript accuracy. Audio files and transcripts were saved onto a password protected University computer accessible only by the research team. File names were edited and transcript contents were anonymised of all potentially identifiable features.

Framework analysis was chosen as the method of qualitative data analysis for this study. This specific approach was developed within the field of applied policy (Ritchie and Spencer, 1993) but has been shown to be useful with a growth in use of this data analysis technique within a range of qualitative focused research (Gale et al., 2013). This method was chosen by the research team as it observes the relevance of previous literature and observations, of which there has been much published, for the use of LT for the management of mental health issues, via its deductive strategy, stemming from a pre-agreed set of aims and objectives (Pope et al., 2000) determined by the researcher. Other advantages of this technique include the allowance of emergent themes sequentially or subsequent to analysis, as well as the relatively time-friendly nature of its approach. There are five stages to the framework analysis approach, as described by Ritchie and Spencer; these are respectively: Familiarisation, identifying a thematic framework, indexing, charting and mapping, and interpretation.

Familiarisations, or immersion of the researcher into the raw data collected, was achieved listening to the digital recording of the interview and production/review of the transcripts generated by the

process of the analysis. Familiarisation with the audio and texts allowed for the initial identification of key issues, concepts, topics and themes which, in combination with the pre-set aims and objectives as described above, were subsequently developed into labels, or more accurately 'codes'. These codes described the overall themes of the raw data, and thus developed a thematic framework. Verbatim quotations and sections of the raw data were then indexed and chartered in accordance to the themes identified in this framework, facilitated by QSR International's NVivo 10 qualitative data analysis Software. These analyses were completed sequentially as interviews were performed. Mapping and interpretation involved the process of explaining the outcomes and findings of the research, involving both the originally agreed research aims and objectives, as well as emergent themes from the data itself, and therefore this stage took place after the final interview had been analysed. Verbatim quotations and excerpts were used to strengthen these interpretations on presentations of the findings of this research study.

3.9 Findings

Two focus groups were conducted within October 2013, both lasting one hour. There were 13 focus group members in total: seven participants in the evening focus group (1 male, 6 females) and six in the afternoon group (1 male, 5 females). Ages of the participants ranged from 31 to 62.

3.9.1 Emergent themes

Five principal themes were identified, namely: awareness, expectations, feasibility, safety, and attitudes. These were further divided in subcategories, as seen in Appendix 16, and discussed in detail in the following sections as the findings of this study.

Each theme will be explored and supported by quotations and excerpts taken from the focus group transcripts and/or field notes. Where appropriate, the counts of focus group members with certain opinions or views may be shared with a view to provide context only, as opposed to attempting to quantify or validate the opinion in this manner as the number of members involved would not substantiate this approach.

3.9.2 Theme 1: Awareness

The findings of this study regarding the members' awareness of LT could be categorised as being through either experience of the therapy (by a third party known to them) or via knowledge they could recall and shared within the group discussions.

There was a lack of direct personal experience of LT, with no participants reporting the use of a LT device. One member had discussed LT within one of their support meetings,

"... the (location) group discussed it at our meeting [] last week our monthly meeting..." FGA3

but this had not lead them to try the treatment themselves.

During the course of one focus group, a member revealed that they used a dawn simulation device in the form of an alarm clock:

"I've got one of those alarm clocks and [] it's really nice. You don't wake up in the dark and it's a sunset [type] as well. So, you go to sleep with the sunset [too]. It's really nice... it helps." FGA4

On further exploration of this with the participant, they had not considered this light alarm clock a form of LT and therefore had not spoken about it earlier when asked about experience.

Furthermore, the participant seemed unsure and reluctant to consider it LT.

"[] don't know [] if it is the same sort of light. Is it?" FGA4

Despite the group members' lack of personal experience, they were, however, able to recount others they know who had used LT for their depression symptoms.

"I know that in my group, for example, we've discussed [it and] people have said (talked about)... experiences of it (LT)" FGA6

"... I do know someone that does have one (a LT device) and she does get a lot out of it [] and I've asked to borrow it and she said "nope it's mine"." FGA6

"... I do know someone who used one but she lives in a basement so she thinks she needs it... but then she's got so many problems anyway... she's still you know a mess but [] she continues to use it so, maybe it is doing something for her but [] I think she's still very depressed." FGA5

Awareness of LT through experience was very limited. This, was surprising particularly as LT devices are easily accessible, when compared to other forms of treatments for depressions such as obtaining a prescription from the GP for pharmacological treatments or enduring long waiting lists to access psychological interventions. This may suggest that LT was not used as it was perceived as not being effective. However, some participants clearly had an understanding of the mode of action of LT, explaining its effect on sleep hormone melatonin and on the circadian system in a lay manner:

"... your body thinks it's got light and all the melatonin" FGA5

"Simulates daytime" FGA5

"... it could be that it's different spectrums?" FGB3

Certainly, this understanding was most coherent and tangible when spoken about in relation to SAD as the indication.

Even in these cases, there was a desire to learn more of the scientific basis behind the therapy. The majority of participants provided little or no comment to demonstrate their knowledge of the device features important to its action, including the light colour.

“I think I’d want to know a bit more about the science of [LT]...” FGB3

“It’s just a normal light bulb, I think.” FGA4

“Does it necessarily have to be bright?” FGB1

“I don’t think I would, I wouldn’t believe in it... [it] doesn’t look very bright.” FGB3

As discussed previously, none of the participants had reported personal use of LT, but were, however, aware of its current home use of the treatment of depression symptoms. This knowledge of current use is somewhat dampened by their lack of personal experience, but also as described above, there was a lack of awareness of other types of LT, in this case the dawn simulation alarm clock, which could lead to an under reporting of the therapy’s use by the group.

“[I] don’t know [] if it is the same sort of light. Is it?” FGA4

Knowledge of LT’s indications for use were discussed by the group. Predictably, SAD was identified most often when discussing LT use:

“...members (of the support group the participant attends) had heard of it mostly in relation to [] seasonal Affective Disorder...” FGA3

“... I do get affected by the [] environment and daytime light and [] different times of the year.” FGB2

This was further substantiated by participants in one group who had heard of LT use in countries which experience long dark winters with little to no sunlight at certain times of the year.

“... in Alaska I think, certain parts of Alaska, they actually give them (LT devices) out... they do it [] a certain time of the day, every day and that keeps that [] depression at bay.” FGA7

“... in northern parts of Sweden and Norway.” FGA6

Insomnia was also identified by the group as an indication of LT that would be beneficial:

“I’m interested in if [LT] might help with insomnia in winter because of, you know like, your body thinks it’s got light and all the melatonin” FGA5

However, non-seasonal depression, was not immediately discussed as a possible indication for LT, and when this was suggested to the group, it was met with mild confusion both in terms of its possible mode of action and the feasibility of using a LT device all year round.

“The one thing I’m not clear about... [SAD is] quite separate... because obviously there’s a theory that people use it this time of year (winter) but, if it’s the middle of the summer [and] you’re feeling depressed, you go to the doctors they’ll still ... give you the lamp?” FGA7

“... in the summer and you wake up and it is lovely and sunny, would you [] have to sit in front of this lamp?” FGA6

This runs contrary the emerging clinical evidence of the past 10 years supporting the use of LT in the case of non-seasonal, as well as seasonal, depression. Evidently, this is not the information that had been available explicitly to these members of the public, and perhaps the public at large.

Details regarding the LT itself, including aspects of the treatment such as duration, timing, and length of treatment were not known to any of the participants. There was a general lack of

awareness as to how to use LT with many questions being asked to the researchers during the discussion and sharing their misconceptions previously held before attending the focus group.

"... can you do anything while you're sitting with the light box?" FGB3

"Can you put sun glasses on? You've got to have the full [power]" FGA6

"Do you have to look at it or can you just sit next to it?" FGA1

"I'll admit I was imagining it more when you get home in the evening, the dark evening." FG6

The groups' sources of information or knowledge of LT were mostly from support group meetings and from advertising information for light boxes sold on the market. One participant knew about clinical studies that supported LT use. There was a lack of depth to the knowledge of even the most informed participant. Their knowledge of LT (LT) could be most effectively summarised as an awareness of the existence of LT and that it is currently being used and/or is available.

"... the (location) group discussed it at our meeting [] last week our monthly meeting..." FGA3

"... apparently Phillips have come out with a new range of LED type ones that are [] very very expensive that are meant to be the best. So, we have had a discussion and Maplin's, for example, sells something (a light lamp) for about forty quid." FGA6

"... studies [have] shown that it does work to that degree, but I don't think that it would eliminate [] the whole of depression" FGA7

Awareness of LT was perceived to be dependent upon an individual's age.

"... a few of the older members had never heard of it, and a few of the younger members had heard of it..." FGA3

There is a relative ease of access to LT as a treatment due to wide availability of brands and models on the market, and no barriers to access the treatment by a Health Care Professional (HCP).

However, with some models costing upwards of £200 the expense of the treatment was highlighted as a barrier to those who may be willing to try the treatment for their depression but whom could not afford it. There is currently no funding available to support such measures on the NHS.

“... but we are all put off by the fact that they’re very expensive...” FGA3

3.9.3 Theme 2: Effectiveness

Reports of the effectiveness of LT from the groups were limited, and primarily from third party sources. These accounts were mixed in terms of the level of success experienced with LT:

“... I do know someone that does have one (a LT device) and she does get a lot out of it...” FGA6

“... I do know someone who used one but she lives in a basement so she thinks she needs it ... she’s still [] a mess but [] she continues to use it so, maybe it is doing something for her but [] I think she’s still very depressed.” FGA5

Therefore, it was primarily the participants’ expectations of LT that were key to their overall opinion of the therapy’s effectiveness, rather than experience.

From the offset, some of the participants had a relatively positive expectation of LT’s effectiveness with one citing clinical evidence as their source:

“... studies [have] shown that it does work to that degree...” FGA7

However, most participants were unsure of its potential effectiveness.

“... I don’t think that it would eliminate [] the whole of depression because [depression] is made up of a lot of different things for a lot of people.” FGA7

The participants' confidence in the treatment appeared in some cases to be dependent on how the questions were phrased in relation to its effectiveness. When asked if they believed LT would alleviate their symptoms, they were relatively positive in their responses and seemed cautiously optimistic. However, when asked if they felt confident LT would eliminate their symptoms, unanimously the groups were opposed to this proposal. This perhaps reflects their experience of managing their depression and acknowledges how challenging overcoming the symptoms with treatment can be.

The credibility of LT use in depression appeared highest when participants linked their experience of onset of depression symptoms within the winter months – noting lack of light being the culprit for these symptoms and linking this strongly to the mode of action of LT by replacing the light stimulus artificially.

“I think it’s been difficult this year because it’s [been] such a hot sunny nice summer and all of a sudden it’s, well it feels all of a sudden to me, I don’t know, just black and dark. And, when you work in London and ... you go to work in the dark, you come home in the dark, you have no natural light in your office.” FGA3

Moreover, when asked if the group found the action of LT to be logical, the response was very positive, generally, and also specifically with regards its use at certain times of years (Winter) and times of day (morning) for most participants.

“...on a positive note though, [] in my experience, that (the morning) is when you feel the lowest.” FGB3

Overall, the participants were willing to recommend the use of LT for the treatment of depression with their current knowledge and expectation of effectiveness.

“I could think of a number of people I know to benefit by it.” FGB2

Despite this apparent optimism for LT's credibility as a treatment for depression, there was evidence of limits to this belief in LT's effects.

With the participants' association of LT's credibility with SAD and their experience of depression symptoms with the changing seasons of the year, there was a somewhat foreseeable confusion when LT was subsequently discussed in the context of its use in nonseasonal depression cases.

"The one thing I'm not clear about, [] it's seasonal affective disorder. [SAD is] quite separate... because obviously there's a theory that people use it this time of year (winter) but, if it's the middle of the summer [and] you're feeling depressed, you go to the doctors they'll still ... give you the lamp right?" FGA7

The use of LT for this indication was not a prescription the participants could easily empathise with, or understand the logic of its use here, for this reason.

"... in the summer and you wake up and it is lovely and sunny, would you [] have to sit in front of this lamp?" FGA6

The groups' disagreement with the use of LT for nonseasonal depression, however, was upheld by all except one participant who was able to see how LT could be of benefit all year round for this diagnosis.

"Then again, there's times when it's like ninety degrees and I've [] got the curtains closed and I've got the [blankets] over my head because I'm depressed... You don't want to face the outside, you can get that low you... don't want to face [the] outside world. So, I'd rather sit in front of a lamp and get my [therapy]... so there's both sides really" FGA7

The level of credibility LT seemed to manifest within the group was, again, confronted with the majority of the participants expressing that they would refuse to use LT as a monotherapy for their

symptoms. Most stated that they would only be comfortable applying LT as an additional treatment to their current regimen, conveying either their scepticism in its potential effects or their experience of the difficulty in finding an effective treatment for depression. The positive expectations, as described earlier, were not robust enough to support unrestrained lone use of LT for the management of symptoms for the participants, at least initially.

“Yeah, I think that I would always have to do something alongside it... like CBT or something alongside it.” FGA1

“... I don't think I'd ever really be able to think that I could not take [antidepressants] at all... I would just see [LT] as like [] an extra support, a bit like when you go counselling as well as taking medication... not initially anyway I don't think...” FGB2

Also explored during the discussion was the groups' expectations of different colours, or wavelengths, used in LT treatment and their expectation of its overall effect in depression. Although the participants shared their views and opinions of the different colours of LT, it appeared that none of them were either aware that different colours or wavelengths of light may affect its effectiveness.

“Does it work with different colours though? What, how does it work?” FGA3

The majority seemed unconvinced that colour of light was important, with some going as far as to suggest that any involvement of colour to the antidepressant effect experienced by a patient would be a placebo effect.

“Would it actually make a difference what colour it is?” FGB1

“It's a state of mind isn't it? I mean, does it matter what colour it is: blue red grey.” FGB4

The majority were amenable, however, to the idea of coloured LT and were willing to accept the treatment if it were available and they were told that it would work; showing no adversity to using the alternative therapy.

“If you’ve a scientifically proven that, yes, this LT will help you [that] doesn’t necessarily got to be bright white or anything.” FGB1

Only one participant expressed a preference for the coloured LT, however, this was not due to a belief that it would be more effective but because they were afraid of the adverse effect of the “bright” white LT:

“I’d probably go along with [a] coloured one, or something like that, because [the] bright one (LTD) would be [] too powerful on the eyes anyway.” FGB1

When asked about their expectations of the colour associated with LT generally, interestingly two themes emerged. Participants expected the most effective colour to emulate sunlight. This is, in one way, a positive response as it illustrates a consistent link between the LT and its mode of action. However, some participants, when elaborating on this, went further to describe sunlight to be yellow in colour, as opposed to white light. The short wavelengths, perceived by the eye within yellow to red section of the colour spectrum, have no measurable effect on the non-image forming functions of the circadian system and is in fact often used as a placebo in LT experimental trials (ref).

“... more like the sun” FGA7

“... I would imagine it to be more of a yellow.” FGA6

Along with this expectation of the colour of light to replicate that of sunlight, they also seem to have expectations regarding the purpose of the colour. The groups repeatedly refer to the coloured LT as being calming or relaxing for the patient using the treatment.

"... all the colours would be calming and [I'd] probably just go back to bed." FGA1

"...meant to be relaxing..." FGA6

"I don't think it could be very relaxing (referring to red colour therapy)." FGB6

There is no evidence that the use of specific wavelengths to activate photoreceptors has additional relaxing effects as described within the focus groups. This perception is misleading. Additionally, different colours of light were associated with certain emotions; blue was associated with feeling sad and orange with happiness:

"Could be sad – blue?" FGA4

"Orange is supposed to be a cheerful colour..." FGA5

There is no scientific basis to support these beliefs. This could therefore lead some patients, when using coloured LT to have different expectations of the outcomes of their treatment, which may affect their adherence to it. Exploring an individual's expectations with them prior to initiating treatment would therefore be recommended.

The groups were prompted to discuss their expectations of specific colours posed to them by the moderator. The colours presented can be categorised as either active, meaning this colour would have an effect on the circadian system resulting in the proposed antidepressant effect being investigated, or inactive/placebo which has no, to a negligible, effect. Active colours discussed were white and blue light. White light was received very positively and seemed acceptable to the group, even over other colours in some cases.

" [The white LTD] would wake my brain up that way, whereas, all the colours would be calming and probably just go back to bed." FGA1

Blue light, although received mostly positively by the participants, had some hesitations with the colour being used as treatment, associating it with sadness as expressed earlier.

“... I think so, [the] most effective would be like sun or blue something mixed because this is bringing some... calmness for yourselves.” FGA2

“Could be sad – blue?” FGA4

The placebo or inactive colours of LT, including colours ranging from yellow to red, had the most surprising response as many felt that yellow and orange would be something they would expect, or predict to be effective.

“... I would imagine it to be more of a yellow.” FGA6

“Orange is supposed to be a cheerful colour, so maybe yellowy orange?” FGA5

Furthermore, despite having many misgivings regarding using red light for the LT, which by far received the most resistance in terms of both usability and expectation of effectiveness, there were some participants who would accept it as a treatment if they were told it would help their symptoms.

“Be a bit like blood a bit sort of sombre.” FGA6

“It’s kind of like a dark colour as well.” FGA3

“...in a red [light]... I don’t know. I don’t think I personally would like to sit under a red [light]” FGB6

“I think if I was going to carry something around with me or sit in front of something, I [would] want

it to be a nice experience, not like [that] (referring to red colour therapy).” FGB6

“I think I would one hundred per cent trust if people were telling me [] that [it] was proven to be more effective... I’d even sort of put up with it, red light. If I thought it was [effective].” FGB6

“If it was convincing science.” FGB3

It was clear from these discussions that the participants knew little to no information about coloured LT and were basing these opinions and expectations on their assumptions.

Following this, the participants were given a demonstration of two different types of light boxes in order to ascertain their views regarding the devices’ perceived effectiveness and feasibility of use. Here, considering their comments regarding expectation of effectiveness of the devices (as feasibility of the devices will be discussed in detail in the theme below), the participants’ appeared to chiefly connect the brightness of the device to its perceived effectiveness.

“[I] don’t want to relax [] in the morning. I think that one (pointing to the large LTD) would because the bright light, [] I think would trick my brain more into thinking it’s daylight instead of dark.” FGA1

Their emphasis on brightness as an indicator for effectiveness was instilled further by their uncertainties concerning the second LT device which appeared smaller and less bright, despite being equal to the first device in lux measurement.

“Yeah it doesn’t seems much brighter than a table lamp (laughs) it doesn’t seem to give out that much light” FGA5

“I don’t think I would, I wouldn’t believe in it. This is not it’s not doesn’t look very bright.” FGB3

Size, too, played a part in the participants assessment of the devices’ effectiveness.

“I would’ve thought it would look more like that [indicating large light box] than that [indicating small light box] so I think I’d be quite surprised of how small and dull it seems...” FGB6

“No, I was just going to say that, for me, I’d think the bigger one would feel more.” FGB2

However, the majority of references made to the size of the devices within the transcripts are participants identifying which device they were speaking of, whilst repeatedly returning to its brightness as a major factor for their expectations.

“It’s not always the case though, bigger is best.” FGB1

Lastly, there was one comment made by a participant which implied that the more expensive device would be superior based on the cost or the known brand of the device:

“... apparently Phillips have come out with a new range of LED type ones that are [] very very expensive that are meant to be the best.” FGA6

Only one participant suggested that the cost of the device was related to its effectiveness. Cost has previously been recognised as a barrier to accessing LT treatment.

3.9.4 Theme 3: Safety

The moderator asked the groups to discuss any concerns regarding the safety of using LT. During the course of the groups’ discussion, the participants expressed positive remarks in relation to their belief of LT as natural, and therefore, it was not perceived to be dangerous as a treatment.

“It’s hard to imagine how it could be harmful. Isn’t it?” FGB3

“I’d be much happier [to try LT]... I’ve never taken antidepressants because [although] I’ve been offered them, [I] don’t like the idea of the drugs. So, I’d be much happier to try something that’s not [] going to interfere with my body...” FGB6

This too being supported by the fact that LT is not something taken internally, as you would with a tablet, but instead is something applied externally, further supporting this idea that LT should be safe, in the minds of the participants.

“That’s an external thing” FGB6

However, when asked directly by the moderator to express any concerns they had around using LT, the majority of the participants were able to contribute some issue they had with the safety of LT. The first of the concerns raised by the participants addressed potential contraindications.

“... Is there any medical reasons why you should use it, a light box?” FGA3

Specific contraindications discussed were those who suffer from epilepsy, light-sensitive epilepsy sufferers in particular, and conditions affecting the eye.

“The only way it could be harmful is if you were forced into being epileptic or something like that with bright light... I don’t know medical things.” FGB1

“... eyes and things like that (referring to the proposed exclusion criteria of the study)” FGA4

These were confirmed as contraindication for the treatment and had been included in the exclusion criteria for the proposed LT pilot trial as, even in its current use, LT would not be recommended for the use in these patient populations.

One participant was concerned with the inclusion of bipolar affective disorder within both the exclusion criteria of the present study and the proposed LT pilot trial, querying the reasoning for it as unsafe for this diagnosis.

“...one of my members, she was going to come tonight and then when she read the thing she bipolar [being excluded] -what was the thinking behind that?” FGA3

It was explained that LT can be used in the treatment of bipolar affective disorder and the rationale for excluding these patients from these studies is to focus research in unipolar depression, and limit variation within the sample. Bipolar affective disorder is not a contraindication for LT per se.

Side effects were also cited as safety concerns for the participants. A common side effect discussed in both groups was the fear that using the LT may cause the patient to get a sun tan:

“I feel like I might get a tan.” FGA1

“I’d probably be thinking I’m going to get a tan.” FGB1

This, of course, is not the case but this belief could be problematic to the future uptake of the treatment as it could imply risks of skin cancer, and other adverse effects, caused by sun exposure which are not emulated with the use of LT.

Eye pain was another side effect of concern from the two groups. Eye pain was identified by the groups as a potential side effect when asked about safety concerns but was also a prevalent complaint when an example light box was demonstrated to the group.

“...if you’re light sensitive with your eyes I suppose.” FGB2

“Can you put sun glasses on? You’ve got to have the full [power]” FGA6

Although following the demonstration of the light boxes there was more concern expressed from the group about the brightness of the device and how the therapy could lead to eye problems,

advice regarding the appropriate technique to use from the researchers, including not staring directly at the device and the distance to sit away from the device, alleviated these concerns. In the same vein, heat generated by the device was also highlighted as a concern:

“Doesn’t [It] give out a lot of heat?” FGA4

3.9.5 Theme 4: Attitude

Further to the themes identified via the framework designed prior to the focus groups taking place, the transcripts were analysed for statements that would illustrate the emergent attitudes of the participants towards LT itself, as well as the proposed feasibility trial. When considering LT and its use for depression symptoms, many from the group shared their interest in the novel treatment:

“... it’s certainly something that we’re all interested in.” FGA6

Furthermore, there was an indication that LT was more than just wanted, but needed by this patient group due to the perceived lack of options available, aside from antidepressants.

“I’ll try anything.” FGA5

“...I get very depressed and I get desperate [] to be cured, so if I thought it might work, that would be the most significant factor.” FGA1

This is a positive outcome for a potential LT treatment in Primary Care as there is an expressed necessity for alternatives in this area of mental health, albeit no more so than any alternative treatment to what is currently available.

As discussed previously, LT is viewed positively as a ‘natural’ treatment for depression symptoms:

"I'd be much happier [to try LT]... [I] don't like the idea of the drugs. So, I'd be much happier to try something that's not [] going to interfere with my body..." FGB6

Many of the participants demonstrated an affinity to this type of treatment and voiced that they could envisage themselves using LT alongside other 'natural' treatments such as meditation.

"I think sitting would give me an excuse to sit down in front of [it for] half an hour and chill out and gather my thoughts, [] quite [] like [] meditation really." FGA7

"I use meditation a lot so I will use [it] together with my meditation, probably in the morning." FGA2

This positive attitude towards 'natural' treatments was also emphasised within the group by the contrasting negative sentiments towards antidepressants:

"... I would say, I don't want to take the tablets, I'd much rather do that please and give that a go (referring to LT)." B3

However, it should be noted that this opinion was not shared by all in the group with one participant vocal in her desire to continue antidepressant treatment regardless of the therapy's effect.

"... I don't think I'd ever really be able to think that I could not take [antidepressants] at all... I would just see [LT] as like [] an extra support, a bit like when you go counselling as well as taking medication." FGB2

While the group believes LT to be 'natural', it was still considered to be a medical treatment, rather than just an ordinary light lamp. This was highlighted when the group was shown variations of LT devices and when one was not deemed to be bright enough, they compared it to household lighting and seemed resolute that this could not be a legitimate treatment for this reason.

"... looks like a sort of down lighting [like] you'd have in the kitchen or something." FGB1

"Because that just looks like fluorescent light doesn't it?" FGB3

Finally, when a group was asked if they would recommend LT for a friend suffering with depression symptoms, every participant in the group, despite never using LT in the past, indicated that they would.

"I could think of a number of people I know to benefit by it." FGB2

Although there was a clear desire for an alternative treatment for depression in the group and, moreover, a positive attitude towards many of LT's attributes as a potential treatment in this regard, there were also suggestions of some possible negative attitudes that could effectively act as a barrier to its use.

The first of these likely barriers, which became apparent during the group's discussions, is associated stigma. This stigma applied both to LT use itself but also to the stigma of the diagnosis of depression as a whole. This type of stigma is clearly indicated by the systemic issues experienced in the research and treatment in the mental health field, generally (Corrigan and Watson, 2002).

"there's all this stigma around [Depression], it's still is now..." FGB4

"I don't think I'd worry too much, but I think some people, [] they don't want to phone someone up and say I'm depressed you know? [] You might feel a bit embarrassed." FGB6

With LT use specifically, participants worried that people would notice their use of the LT device and shared their fears of embarrassment.

“... that’s (referring to smaller LT device) handy if you wanted to take it to work, and be subtle... people wouldn’t talk about it so much if you had that on your desk” FGA6

“Looking a bit...weird” FGA5

This stigma could potentially affect uptake of the treatment as LT has features, such as requiring a device that is not as easily concealed as a tablet, which could worsen this experience. Nonetheless, there is seems to be a constant associated stigma across this field regardless of the treatment received by the patient (Corrigan et al., 2014).

Other aspects of LT that garnered a negative attitude from the group included LT indications and effect. Regarding the former, the negative response was concentrated against its use in non-seasonal depression. The language used to describe their disbelief of this indication was distinctly disapproving, using emotive terminology such as ‘stuck’ to describe how they would feel and disparaging its use in Nonseasonal Affective Disorder (NSAD) by suggesting that patients go and experience the ‘real sun’.

“When you can go and sit in the real sun.” FGA1

“Uh I’m stuck in here” FGA6

Perhaps more worryingly, there were many incidents where the participants described a placebo effect associated with LT, which appear to suggest that this is an established feature of the treatment.

“.. maybe, it’s [] a crutch for her (referring to person using LT), if nothing else it’s a placebo but I don’t actually know if it works for her or not...” FGA5

“... it’s expectations isn’t it? It’s all about expectation level from it (LT)” FGA6

“Somebody might think it’s going to magically cure you.” FGA6

“... even if you’re just like, fooling yourself to an extent to start with...” FGA7

This belief from the outset that, noting still that none of the current participants have used LT previously, LT’s effect is not fully legitimate and relies at least in part in the phenomenon of a placebo effect seems to go beyond that of just poor expectation of effect, but a priori negative attitude.

The attitudes of the groups towards the research into LT and the proposed feasibility study were also informative, specifically considering their attitude that may affect study recruitment. In one of the focus groups, when questioned on how to target potential volunteers for the proposed trial, the participants highlighted a possible conflict. The focus group members considered themselves to be abnormal compared to the greater depression population in their high level of self-motivation - rendering their advice potentially unrepresentative of the target sample who are often characterised by low motivation.

“The only thing is, we’ve all made the effort to come here tonight, so I’m guessing that we’re already pretty motivated. I’m not sure how people [who] wouldn’t like [to] come to this (focus group), if you see what I mean.” FGA1

“... that’s why we’re all here tonight” FGA6

Nevertheless, the participants were able to impart, at least, their personal motivations in an effort to help generate a high rate of recruitment to the future study. A few participants referred their desire to aid research as a key motivator to their participation in a LT trial:

“... really interested in taking part in research that’s going to help other people.” FGA3

However, more participants seemed to indicate that, although they felt it was positive that research

is being done in an area that affects them, they and perhaps others were primarily motivated to try LT for themselves in the hope that it would benefit their condition. This is a particularly strong motivator as previously cost was identified as a possible barrier to trying LT, and therefore the offer of free use of a device would be an attractive incentive to volunteer.

"... not so much to benefit yourself but to benefit others..." FGA6

"... you might not be in that frame of mind..." FGA1

"... but we are all put off by the fact that they're very expensive..." FGA3

There were also substantive attitudes in relation to the possible method of recruitment of volunteers through the general practitioner consultations by the GPs. A surprising number of participants shared their negative attitudes towards GPs in general, chiefly describing a lack of trust in the GP's guidance, effectiveness, and their inclusion within the future study.

"If my doctor said it, [I'd] go away and google it. I would look at reviews." FGA1

"... some people feel [and] are quite negative about GPs, to be polite" FGA6

"... doctors don't tell you about the stuff anyway." FGA1

"You have to find it yourself normally." FGA7

Not all participants felt this way about their practitioner suggesting that recommendation of the treatment by the General Practitioner would be a motivating factor to use the treatment for some.

"Positive for the GP to come out with (offering LT)" B4

"... if the GP was to mention it (the study) there's that feeling of I'm... honoured to do it because the GP said it." FGA6

3.9.6 Theme 5: Feasibility

None of the focus group members had experience of LT and were unaware of how to use it or able to recount its use by others in much detail. In relation to using LT they perceived a financial barrier but thought that light therapies' 'natural' or non-pharmacological qualities might act as a facilitator to its use, particularly when compared to current pharmacological treatments prescribed for depression which can often cause unwanted systemic effects (Joint Formulary Committee, 2013).

"... but we are all put off by the fact that they're very expensive..." FGA3

"I'd be much happier [to try LT]... I've never take antidepressants because, [although] I've been offered them, [I] don't like the idea of the drugs. So, I'd be much happier to try something that's not [] going to interfere with my body..." FGB6

However, when presented with the proposed feasibility trial, along with the treatment details of how LT is to be used within the trial, the groups focussed their discussion on the feasibility of this LT schedule.

The proposed protocol for the feasibility trial, the information for which was provided to the focus group members for discussion, described the use of LT to be completed every morning, for 30-60 minutes, within ten minutes of waking for a six-week period. There was one participant from each group, the two male participants, who were negative regarding the morning use of LT with one of the participants enquiring as to whether evening LT could be as effective as in the morning; presumably hoping that evening use would be an equivalent alternative. This participant went on to explain they had expected it to be an evening treatment, the other participant did not clarify their expectations of the timing.

"Personally, I'd have to get up earlier, which I hate. I hate getting up in the morning as it is and I'd have to get up earlier specially to sit in front of it and that would be quite [difficult] so that's put me off. I'll admit I was imagining it more when you get home in the evening, the dark evening." FGA6

“... I'd have problems setting the alarm.” FGB1

Other members of the group expressed concern for potential user who may be very busy during this time of day, especially those who have children, for instance this participant:

“I've got an eight year old... You know, mornings are just like manic, focusing on them... you know the only way [to complete the LT] would be for me to get up at five before they (the children) wake up or something like that... I don't know [if] that [] would fit in with children...” FGB6

Citing further that, using the therapy within 10 minutes of waking up could also prove to be an obstacle to those potentially following this protocol.

“...it would be quite difficult I think to do [LT] within ten minutes of waking up...” FGB4

Aside from these few comments, the majority of the group reportedly found the morning timing of LT not to be an issue for them personally, with many actually preferring this schedule.

“...on a positive note though, [] in my experience, that (the morning) is when you feel the lowest”

FGB3

“... it might feel like the right thing to do.” FGB3

Overall, there was only minimal resistance to the morning timing of the LT.

Additionally, the duration of LT was among the topics the groups' discussed regarding the scheduling of the LT, as per the protocol. Within the proposed protocol, a guide of 30 to 60 minutes was given, where it was explained to the participants that a fixed duration per day would be eventually finalised for the future feasibility study.

The participants were generally positive about the duration range, making suggestion of what they could do to fill that period of time while using the light device.

“I guess you can like read a book or something” FGB4

“Write...” FGB3

However, the groups were overwhelmingly more in favour of thirty minutes, with some feeling an hour is just too long a time for them to commit to.

“Yeah, I think half an hour would [work].” FGB2

“Nah, an hour? One’s a bit much isn’t it? I think half an hour periods would probably be better” FGA7

“Yeah, I was going to say about half an hour would be probably max.” FGB1

One participant suggested that instead of one longer session of LT of 30-60 minutes, the LT could be used in shorter intervals throughout the day, when (and where) it would be convenient to the patient, to make the treatment more feasible to use and complete. Unfortunately, although there are alternative protocols for the use of LT (ref), there is no current clinical evidence or literature suggesting that this type of ‘interval’ schedule would be an effective intervention for depression symptoms.

“I think it’d [be] easier if you were to have a study... using it at intervals throughout the day because it’s so portable you can just stick it somewhere for ten minutes or whatever, you don’t have to be at home to use it you know” FGA5

Finally, the groups were presented with two different LT devices in order to give comments on their expectations of the devices effectiveness (as discussed above in the effectiveness theme) and their opinions on each on the feasibility of each device. The device designs were chosen purposefully to be different to one another with the view of challenging the participants perceptions. The first device was a large table standing device which emitted a bright white light, and the second was smaller table top device which emitted light at a slightly bluer hue of bright light. Both were similar

in both cost and brightness measured in lux (10,000 lux). Each of the devices were presented, respectively, to the participants of the focus groups and turned on to demonstrate their light for a few seconds each.

In terms of feasibility of the devices, the second and smaller device was the clear favourite for both groups. The chief reason given for their preference was the device's portability and size. This second device runs on batteries, as opposed to the first device which requires to be plugged in for use, as well as being compact and easy to store in their homes.

"... that's (referring to smaller LT device) handy if you wanted to take it to work, and be subtle." FGA6

"It's portable" FGA5

Although the participants saw these qualities as positive and, to their minds, would increase the usability of the device, this may counter intuitively be a problem for the future feasibility study. The device's portability may act as a temptation to use the device on the move, resulting in greater variability of its use. Examples of the comprising behaviours may be the consistency of the distance of the patient from the device, duration of therapy use or use of device during acts that are not recommended (e.g. driving), all of which would not be measurable by the researchers.

"I think it'd [be] easier if you were to have a study with that (the small LTD)... because it's so portable you can just stick it somewhere for ten minutes or whatever, you don't have to be at home to use it, you know...carry it around" FGB5

Furthermore, the participants storing the device out of sight could also result in the loss of a natural cue to use the device each morning. Having a physical cue such as the device next to the bed or at the breakfast table could act as a powerful reminder to use the therapy resulting in better adherence to the intervention.

"The smaller one probably would take up less room and would be less intrusive." FGB1

The first, large standing device would, therefore, be more likely to ensure that treatment is consistent and poor practices do not occur whilst the study is ongoing. There were no negative comments regarding the feasibility or design of the first device and was seemingly acceptable to the participants, especially in terms of its expected effectiveness, as discussed in the above theme.

The moderator then prompted the groups to comment on the recruitment methods suggested in the proposed protocol. Before discussing the methods in detail, the groups had opinions regarding recruitment to the study in general. There were positive comments made, with one participant indicating that they felt there would be no issue recruiting to a trial such as this:

“I don’t think you’d have any problems recruiting though, to be honest... I think there’ll be lots of people who’ll give it a go” FGA7

There were, however, also some negative views shared that may pose a problem for the future recruitment. The first of these being that the group felt that they may not be able to identify all the issues with the recruitment methods as they would have greater motivation levels than those of the general patient population for depression. This is a limitation, discussed in detail in the above attitude theme, which is ultimately an unavoidable drawback of a self-selecting or convenience method of recruitment which was considered within the analysis of these data.

“The only thing is, we’ve all made the effort to come here tonight, so I’m guessing that we’re already pretty motivated. I’m not sure how people [who] wouldn’t like [to] come to this (focus group), if you see what I mean.” FGA1

Additional general negatives suggested regarding the recruitment to the study are the amount of information pertaining to the study and confusion related to the indication of LT. The participants were supplied with a sample copy of the recruitment pack that would be received by potential volunteers and, although the questionnaires were familiar to them and not seemingly the issue, the sheer amount of information needed to explain the comprehensive study may be too much for those dealing with depression.

“[I] think some people... they would find it (the study) an awful lot to [] take in.” FGA6

The latter, confusion with the indication with LT, was also an emergent issue that could obtrude recruitment. Some participants expressed some confusion towards the beginning of the focus group as they believed that LT was primarily, if not solely, for use in cases of SAD. As the proposed study is designed to run over the course of the year it may result in a much lower recruitment during the spring/summer seasons if this is not explained as a treatment for depression symptoms year-round.

“The one thing I’m not clear about, [] it’s seasonal affective disorder. [SAD is] quite separate... because obviously there’s a theory that people use it this time of year (winter) but, if it’s the middle of the summer [and] you’re feeling depressed, you go to the doctors they’ll still ... give you the lamp right? “ FGA7

The groups were then presented with two potential methods of recruitment to the future feasibility trial. The first of these methods, which will be referred to from here as Method A, involved general practitioners recruiting potential participants during the course of a consultation. It was explained that local GP surgeries who have agreed to be part of the trial would be supplied with the inclusion criteria of the feasibility study, to identify suitable volunteers, and asked to provide the recruitment pack for the full study information. The potential volunteer would then be able to contact the research team if they wished to be involved. Some of the participants were positive about this method of recruitment and felt it even gave the study a sense of credibility if it were to come from their GP, as opposed to other means:

“I’d rather [] the GP give you the option. [] If you’re going to the GP you think [], I’m feeling a bit off... and he says, okay yeah unfortunately [] it looks like you’re suffering [from] depression. There’s this new light study going on etc, would you like to participate? Fine.” FGB1

“... if the GP was to mention it (the study) there’s that feeling of I’m... honoured to do it because the GP said it. But, if you’re contacted independently, you may have a different response to that think “Oh someone’s contacted me?”” FGA6

However, there were other participants who felt that this method may have limitations. The first of these, some patients may be seeing the doctor during a time of crisis, or when they are first experiencing depression symptoms and receiving their diagnosis, and would therefore not be in the right phase of their condition to be considering volunteering in an exploratory trial.

“I suppose it depends what state you are with the GP. If you are going in there [because] I need more medication, [] okay yeah, here’s a light box? It depends on what stage...” FGA6

“If you are [] going there (the GP surgery) in crisis and [] then it’s possibly not the [best time]” FGA3

“I think it’d be too much for somebody to cope with initially.” FGB2

Furthermore, the focus group participants worried that the GP would not have enough time to be able to fully explain a comprehensive trial such as this within the confines of the rigid ten-minute consultations that most GP contend with.

“Yeah, they’re not going to have time are they?” FGA6

“... the doctor wouldn’t really have that much time to explain the [study]” FGA7

Although, it was agreed that if it were only the recruitment pack that was needed to be disseminated by the GP, this would more realistic than having to also supply all the equipment and counselling that would be required for the trial and relieved this issue somewhat.

“Would you be expecting the GP to [hand out the light watch and that? [Moderator indicates no] I was going to say because a GP sees you for about five minutes.” FGA3

Additional to these potential issues identified by the groups, they also revealed a surprising negative attitude towards general practitioners through a number of comments shared by a few participants,

both in general and their involvement in the recruitment of this future study; this is discussed in depth under the theme of attitude, seen above.

“... the thing about the screening is that [] some people feel [and] are quite negative about GPs.”

FGA6

This could result in some potential volunteers being lost due to their avoidance of their GP if this was the sole recruitment method employed. Nonetheless, it appeared that the group members who expressed issues with GPs would not base their response to the study recruitment based on the fact that the information was from the GP and, therefore, would not necessarily be a barrier in this manner.

“Positive for the GP to come out with (offering LT)” FGB4

This was further confirmed in one group where the moderator suggested that a researcher from the University could be present at the surgery. This would enable the GPs to refer potential participants and give the researcher the opportunity to explain the trial to them. This was met by an equal level of resistance.

“... that would probably be even worse!” FGA3

There was one participant that stated they would prefer direct researcher recruitment. They explained that they would be apprehensive of the GP involvement in recruitment as it may end lead to study findings being included in their medical records.

“I think people might feel a bit happier about that (recruited through the researcher) rather than GP because I think you’d think, oh my GPs given you this watch, what’s going on my medical records.”

FGA3

It was clarified with the participant that no study results, regardless of the recruitment method, would be shared to be included in their medical records with the GP by the research team and that the doctor, although informed of their inclusion within the study, would only be contacted if there was a safety issue. The group members were ensured that this would be explained to potential volunteers prior to involvement in the LT study.

The groups were then informed of a second potential method of recruitment to the trial, which will be referred to as method B, whereby participating surgeries would send a letter of invitation to the LT study. Potential participants who meet the study criteria would be identified by the surgery, filtering the patient database using the study criteria, and sent a letter from the surgery inviting them to contact the research team if they are interested in volunteering for the study.

The strongest initial reaction from the participants to his method was one of concern for confidentiality. The main issue for the participants was the filtering and/or access to patient files with personal information, especially their depression diagnosis which would be an essential to the search for the study at hand.

“On the other hand, I might feel a bit like, whose looking at my medical records without my permission?” FGA3

“... some people get a little bit annoyed [or] worried how their details are passed around...” FGB1

Despite the clarification regarding the confidentiality pertaining to personal information from the surgery, it was still seen as unfavourable to some of the focus group members.

“I mean, I can appreciate the fact that it’s coming from the GP, but... [going] down through their records... for light study...” FGB1

There were at least two participants who purported to have experience with this method of recruitment to a study, having received letters from the surgery in the past. Although others were uncomfortable with this method, these participants did not seem to have an issue with this method.

“I wouldn’t mind having a letter... I only went (to the GP) when I was absolutely desperate, so you might catch... more people that way...” FGB3

Moreover, many participants were also able to see advantages to this method when compared to the method A. Firstly, a larger proportion of the target sample could be reached as many people with depression do not require GP appointments when they have reached maintenance period of their treatment.

“... but then if you did it just like that (method A) you’d be missing out a whole load of people that don’t perhaps see their GP on a regular basis but are still depressed. And they still have [] their regular medications.” FGB2

“Would you get enough people if you just did it (method A)?” FGB3

One patient was also in favour of receiving a letter, as opposed to being directly recruited by a person, as it would be less intimidating and allow more space for potential volunteers to consider participating.

“ Whereas, if it was in [] a letter, you could sit and think about it in your own time... I think I’d rather have a letter because you got [] a bit of space to think about it and its already done for you, sort of, [] you haven’t actually got to go and [] put the arrangements in place.” FGB6

Other aspects potentially affecting the feasibility of the study protocol were also discussed. How potential participants contact and are contacted by the research team was a topic that was debated throughout the session. Many of the participants felt that certain methods could pose a barrier to recruitment including the ones suggested: letter, phone and email. Each of these could pose an issue as they could envision people with depression being nervous about some of these contact methods, while others, namely email, may not be feasible for all.

“ I know some people might (nervous to receive a letter)” FGB2

“I think if the GP gives you something, sometimes people can find it quite hard to... I’ve got to phone this person, oh I don’t know this person, is it alright for me to call?” FGA3

“... they’ve [] gone to the GP, if people are nervous of ringing up this number?” FGA6

“But then you will miss out on people that don’t use computers.” FGB3

“Yeah, because not everyone’s got internet and email.” FGB4

After discussing each of these methods, it was agreed that the best strategy to avoid such issues would be to offer as many choices as possible in hope that at least one method would be an option the patient is comfortable utilising.

“You can have you can have [] the option then couldn’t you?” FGB5

Incentives, and their role in recruitment for the future study, were proposed to the group as a discussion topic. Here we will be dealing with the feasibility of incentives for recruitment through the opinions shared by the groups.

The first and most strongly suggested incentive to be stated by the first group was monetary compensation for their participation in the study.

“Pay us money” FGA1

“I was about to say, I was waiting for someone to say that... I might be persuaded to do that.” FGA6

This is a common incentive used to aid recruitment in research and, in fact, the group attendees were themselves being offered a gift voucher of monetary value as an incentive, so in this sense it was not surprising to find that this would be a suggestion made. Having said that, monetary incentives were not suggested in the second group and was not readily received when the moderator mentioned it.

“No... I think it’s down to a [] personal choice really... If you if you want to do a trial and expect to get paid for it, then [you] should be up front... [or] just do it.” FGB1

This sentiment was echoed by other participants within that group. Furthermore, in the case of the first group, the participants in favour of a monetary incentive admitted that this would influence their behaviour in the study by adhering to the intervention assigned, more than if they were not paid to. Adherence to the treatment is one of the primary outcome measures of the trial, posing a problem in assessing the true level of compliance if this incentive were employed.

“Yeah, of course it would... If I was getting paid for something, I’d feel guilty if I didn’t do it, so, I would do it because I’d think, I’m taking the money for this, I need to do it.” FGA1

Most of the group felt that the offer of using a LT device for free, with the bonus of being monitored by the researcher, would be the strongest incentive for them to personally participate in such a trial.

“I think [] actually doing the LT with the light box, patients [are] getting something anyway aren’t they? They’re getting something for themselves anyway.” FGB6

“... you get individual feedback...” FGA5

A small number of participants believed that no incentive would be required or that being involved in research helping people in the future would be incentive enough.

“Plus you’re doing [the LT] in your own home anyway so, why should [you] be paid to sit at home in front of a light box?” FGB1

“... whatever the outcome is, [] it’s going to help other people, hopefully in the future [] their GP is going offer them LT rather than medication.” FGB4

Lastly, there were some advice recommended by the participants that could be implemented within the draft protocol, with a view to aiding recruitment of the trial. During discussions surrounding recruitment, one participant suggested that an advert or poster that could be circulated would be effective at attracting potential participants who are not a patient at one of the participating surgeries or visit the surgery often. Moreover, it was an advert that had been the method of recruitment for members of the current focus groups and, therefore, may be successful for the future study also.

“Yeah, I think a poster [would] be really good because often doctors don’t tell you about the stuff anyway.” FGA1

“... and then you could put some posters up as well perhaps?” FGA6

Another suggestion related to the recruitment pack, and counselling on recruitment, was to include a flowchart that detailed each step of the trial, with dates, to simplify the many components of the trial. The chart would allow the researcher to explain the trial comprehensively to new participants. Additionally, it could be personalised and kept by the participant to aid them during the study.

“I’d like everything all [] laid out at the beginning, so [] what dates you need to do things, so it wouldn’t interfere with my life too much.” FGA4

“Just thinking, another thing be like a flow chart. I work quite well with a flow chart... see, do this, do this, do this... something [] graphical” FGA6

The trial components, namely the Actiwatches™, salivary sampling, questionnaires, and the assessments, were then discussed in terms of their feasibility of use and ease of completion by potential participants of the future light study. The feasibility of the LT devices, the other additional component of the trial, was discussed above under the details of the intervention.

The Actiwatch™ was brought to the group to demonstrate their appearance and how they are worn. A hand out was provided to show the data collected from wearing the watch. The initial comments made by the group were in reference to the watches appearance. Unfortunately, generally the participants did not like the way watches looked:

“Back to the eighties” FGA7

“Retro” FGA6

“Do you do them in other colours?” FGA6

“I don’t think I’d want to wear it... going out or something” FGA4

However, there was at least one participant that didn’t look so unfavourably on the watch’s appearance, even to go as far to say it could be fashionable.

“They’re back in fashion actually, so you’re lucky” FGA7

On the practicalities of wearing the device, largely the group were comfortable to wear it, as it is worn as one would a normal watch; resembling an average watch in both size and function (this was important to the group that the device tells the time). The only issue with wearing the device that was shared among some of the members of the group was the instruction to wear it at all times, during the night as well as during the day. For some, it is common practice for them to remove all jewellery, including watches, when they sleep. Therefore, this aspect of wearing the device would be the most challenging for these users.

“I wouldn’t want to wear it all night long.” FGA1

“Yeah, I’d feel weird wearing a watch in bed” FGA4

There was also an apparent level of paranoia associated with the watch. Participants commented that the watch looked like a 'tag', likening it to what would be used on criminals. Its visibility was a particular problem for some participants as they felt it would draw attention to them, perceiving this negatively and intensifying their feelings of paranoia in relation to wearing the device.

"It's like a tag" FGA5

"Yeah, I was going to say, it's not a tag is it?" FGA6

"... it's the sort of feeling of being [] owned." FGA6

"... some people [are] suspicious, thinking [] 'what else is going on? [There] might be a chip inside here?' You know what I mean?" FGA7

"... people might know that this watch is to do with some study... paranoia..." FGA6

Nevertheless, none of the participants stated that they wouldn't wear the watch as part of the study if they were to participate. Conversely, there were also those who were excited to wear the Actiwatch™ in order to be able to access as much information about their condition and reaction to LT as possible.

"I personally don't have an issue because I like to know, [to be] monitor[ed] you know find out [information]..." FGA5

"If it was comfortable enough... I think I do it anyway [even though] I don't really like wearing things but I don't think it would stop me" FGB6

One participant reported experience with the device as they had participated in a sleep study in the past. With this experience, this participant did not express any negative remarks regarding the use of the watch device and completed this past study without issue.

“...like in your sleep study (speaking to FGB1)” FGB2

Ultimately, the participant seemed willing to wear the Actiwatch™ if it were required of the study, even though it was identified as the component of this trial that could receive the most resistance, in their opinion.

“ I can imagine that (the Actiwatch) being a more of a difficult sell.” FGA6

“If you have to do it you have to do it.” FGA6

The salivary sampling protocol, a non-invasive method to measure melatonin and cortisol levels, was explained to the group as involving a series of saliva gathering the night before and the morning of their final days of the introductory week and final week of LT intervention. Although the idea of saliva sampling was somewhat off-putting as a method, generally the group were accepting of this method being employed. However, the protocol for the series of saliva samples collected hourly before predicted bedtime was highlighted as a specific problem for some of the group. The crux of the issue for these participants was the difficulty in attempting to predict their ‘normal’ bedtime.

“What do you mean by normal bedtime because I go to bed all over the shop?” FGA1

“Yeah, you might go to sleep (meaning to bed) but not fall asleep for hours...” FGA5

Insomnia and disturbed sleeping patterns are common symptoms in depression (American Psychiatric Association, 2013). As the protocol is designed to reveal the melatonin concentration curve and dim-light melatonin sleep onset (DLMO), a perfect prediction of bedtime would not be required and, therefore, best estimation would be appropriate in these cases.

A second issue raised was this method fitting the saliva schedule into their lifestyle:

“I’m just imagining people coming around going, what’s that in your fridge?” FGA1

“So do we get to choose these days (to collect saliva samples)? Because we can’t just take time off work... coming in on a certain morning.” FGA4

But, as it is only at two points of the study timeline and scheduled the night before and morning of their weekly assessments, this means that saliva samples would not be stored long within their homes and participants would be able to predict and plan the sample collection in advance. Overall, this extra information helped calm the fear of those bringing these issues forward.

The questionnaires to be used for recruitment and during assessments were, for the most part, familiar to the focus group members, as discussed previously. This familiarity was received as a positive with the view that potential participants would be comfortable filling and completing these forms without issue.

“These are basically the same as you’d get from a GP now aren’t they. they’re designed on them aren’t they?” FGB4

“Bog standard” FGA1

However, not all of the questionnaires are the ones used frequently in primary care and, although the questions are of a similar nature and designed to be self-rating (denoted by the SR in the title of the questionnaires e.g. SIGH-SAD-SR), some individual questions were identified as having difficult language that would perhaps need explaining by the researcher.

“... this one’s a bit confusing, [] what’s that about?” FGA3

It was therefore agreed by the group that it would be best to have the researcher on hand for these less familiar questionnaires, at least in the first instance, to help potential participants be able to complete the form with ease.

Finally, the group discussed the feasibility of weekly assessment with the researcher as part of the

six-week protocol. The location of these assessments and their suitability for potential volunteers was addressed, with the options including the University, the GP surgery, home visit and telephone assessments discussed.

Both the University campus and GP surgery were found to be favourable to the groups. GP surgery was received slightly better as most will live near their GP's. Understandably, the University did not sound as appealing to one group (group A) as the majority of this group did not live in the Medway area, having travelled a distance to attend to meeting that evening. However, despite this barrier, most in the group were still positive about the University location, highlighting its strengths as an assessment location in the future study.

"Well we live quite close to our surgery..." FGB2

"I'd prefer the surgery if [] you could get the room." FGA7

"I wouldn't mind if [] you'd prefer me to come here (the University). [It] would be feasible but, obviously, I'd prefer it nearer to home." FGA7

Home visits and telephone assessments were also discussed, but were met with mixed review. Home visit was an option that, initially, received positive opinions from the group, owing to the ease for patient and familiar surroundings. However, a few participants then expressed their strong opposition to the idea.

"The home [visits]... a lot of people would really go for that." FGA6

"I don't like people coming into my home" FGA1

"I'd have to tidy up" FGA3

Discussions surrounding the suitability of telephone assessments transpired in a similar manner. Although some group members group see the benefit, particularly those who had busy lifestyles, one participant was avidly against the idea.

"In my life, phone would be better because there's just no time for anything." FGB6

"Definitely not the telephone." FGA1

Overall, as was the consensus reached in many the discussions pertaining to feasibility of the future exploratory trial, a choice of location was agreed to be the best solution in attempt to make all potential participants feel comfortable with the assessments.

"...think people would love the choice" FGA6

An additional suggestion made by the group in relation to assessment was the idea of having online assessments that could be completed from home. Although this potential method had merit, most of the groups could see the issues that could arise, especially if this was the only mode of assessment available, including access to computers/internet, lack of face-to-face contact and confidentiality.

"An online thing would be the other thing. A website to log onto things to tick." FGA6

"... a lot of people would still prefer... the person, some people would still prefer the face-to-face personal thing wouldn't they?" FGA6

"Everything you worry with the data going missing [] or somebody else is picking it up, things like that." FGB1

Lastly, the moderator proposed to the idea of reminders, in the form of text messages used to remind participant of assessments or treatment, and asked for opinions regarding how useful this may be to potential participants. The group was mostly in favour of moderate use of reminders (for assessments, rather than daily for treatment), with a few exceptions who were strongly against the

idea.

“I think [it] would probably be helpful... I’m bit notoriously forgetful at the moment... it’s never a bad idea to be reminded.” FGA3

“I’d hate it because I feel bombarded anyway [] and that makes me really stressed, all the emails and messages continuously and I’d be like, oh this is just stressing me out now, I don’t want it anymore.”

FGA1

Once again, it was agreed that, for most, this would be a useful tool that perhaps could be offered the participants on entering the trial, but that it would not be compulsory for those who would not find this service appropriate for their lifestyle.

3.10 Conclusion

In conclusion, in terms of awareness, there was a paucity of experience and limited awareness of other’s use of LT for depression. Awareness in relation to the scientific basis or treatment details of LT was also low in both groups, with the majority of their awareness surrounding its use in SAD, despite emerging evidence. Their knowledge, sourced from support group meetings and marketing information about commercially available products, had not lead to detailed knowledge of the treatment or persuaded participants to try it for themselves, perhaps owing to the perceived barriers of cost of the device and older age of some patients.

This lack of experience of LT by all the group members indicates that the criterium of no prior experience of LT or influence of prior knowledge or awareness are unlikely to be major factors impeding recruitment to the future trial. However, the participants strict association of LT with SAD, as opposed to general depression symptoms as an indication, may pose as a barrier due to lack of awareness.

There were no reliable reports of the effectiveness of LT from the groups, therefore, expectation of LT’s effectiveness was a more significant factor. The participants were generally positive with their expectation of its effectiveness, with some limitations. These limitations included the assertion that LT’s indication is solely or primarily for SAD, as mentioned, but furthermore, to their minds, LT did

not receive the levels of confidence to attempt it as a monotherapy for their symptoms, but as an adjunctive therapy alongside their current treatment. Regarding their expectations of the LT device itself, they expected the most effective device to be brightest. Little was known about coloured LT, but generally the groups were most accepting of white LT and, although they expressed some resistance, were willing to accept a red LT, if they were told it would work. This would indicate that red light could act as an appropriate placebo in a future controlled LT trial.

Moreover, these findings indicate that expectations of LT's effectiveness would have to be accounted for, for example with an expectation questionnaire, as it may be influenced by the season in which it is being used, as the future trial is to run the year round. Within the proposed protocol, LT is to be an additional treatment to standard care, circumventing the possibility of monotherapy deterring volunteers.

The safety of LT was generally perceived to be high owing to its 'natural' and 'external' action on the patient. Although there were some contraindications and minor side effects associated with LT that were identified and queried by the groups, this did not appear to alter their opinions of its safety. Additionally, there were side effects proposed by the groups that were untrue of LT, for example gaining a suntan, which were common and unfounded. These falsehoods are of a concern as they could result in potential participants rejecting the study unnecessarily. It was noted that particular attention should be given to the side effects listed within the participant information leaflet and counselling points of future trial.

Considering the participants' attitude towards LT, they regarded it as a credible and desirable treatment for those seeking an additional or alternative therapy for their depression symptoms. There were, however, some emergent negative attitudes, including claims that the action of LT may be that of a placebo effect and the stigma attached to LT use, and depression diagnosis in generally, which may hinder a future LT trial. This would be alleviated by increasing research into the treatment offering more conclusive evidence of its effect and, consequently, increasing uptake to counteract these attitudes ultimately.

As none of the participants of the focus groups had experience of using LT, the ease of integrating LT use into daily living could not be determined from these discussions. As for the feasibility of the proposed trial protocol for LT, the six-week length, morning use of LT for 30 minutes duration daily, both devices demonstrated and the components of the trial (Actiwatch, Saliva samples and Assessments) were all received favourably by the majority of the group with some minor issues that could be noted for participant counselling before entering the trial. As points of significance, the use of the larger LT device, for the purposes of consistency and limiting variable of use, proved the most

feasible choice for the trial. Multiple methods of recruitment, including an advert or other method of self-referral, was advocated by the group in order to avoid possible issues recruiting through GP surgeries alone. Another potential obstacle to recruitment, information overload, could be overcome with the inclusion of a personalised flow chart. Finally, through the discussion of recruitment, it became clear that monetary incentives may alter participant behaviour and that the use of LT alone was incentive enough for most of the group and should therefore be the focal point of adverts and recruitment materials.

CHAPTER FOUR

GP Interviews

4.1 Introduction

This chapter builds on the previous one, with the addition of insights obtained from local GPs through semi-structured interviewing. GPs are uniquely placed to give insight into the current Primary Care management of depression. These interviews, therefore, enabled their opinions, regarding the use of LT in the management of depression, to be gathered, as well as providing insight into LT's current and potential future use by patients within Primary Care. This was also an opportunity to seek their advice regarding the design of a pilot Primary Care research trial investigating the feasibility and effectiveness of LT for depression. This chapter details how the interviews were conducted and the subsequent findings; culminating to a discussion on how the findings then impacted the pilot trial design.

4.2 Aims and Objectives

The aim of these semi-structured qualitative interviews was to obtain the views of GPs regarding the use of LT for the management of depression in Primary Care practice. The objectives were:

- A. To explore the GPs' awareness, views of effectiveness and concerns surrounding LT use for depression.
- B. To determine the GPs' opinions regarding the potential future role of LT for depression in Primary Care.
- C. To ascertain GPs' opinions regarding the design of the proposed exploratory LT pilot trial in order to inform the research with respect to identifying/recruiting the target group and to provide general comments concerning the trial feasibility.

4.3 Ethical approval

Ethical approval was sought and granted for this study from the Medway School of Pharmacy Research Ethics Committee (Appendix 1). Research governance assurance was provided by RM&G Consortium for Kent & Medway and permission was sought from each GP surgery before interviews were conducted on their premises. An Information Leaflet (Appendix 13) was provided to explain

the study objectives and described what the potential GP volunteers should expect as a participant within the study. A consent form (Appendix 14) was provided to each participant and informed consent was confirmed prior to interview. Incentives were not provided to GPs for this study. A number of minor amendments were made shortly after study commencement, as explained in detail below; ethical approval was sought from and granted by the School Research Ethics Committee (SREC) for each.

4.4 Declaration

This research was completed by myself (primary researcher) and supervised by Dr Sarah Corlett (primary supervisor). The primary researcher and supervisor undertook the design and development of the protocol. The researcher conducted the interviews. The transcripts were produced and analysed by the researcher and confirmed with the supervisor.

4.5 Sampling strategy

All GPs practicing with the Medway Clinical Commissioning Group (CCG) area were included within the sampling strategy for this study. The study intended to recruit 6-8 GPs. The GPs were identified using the publicly accessible NHS Choices website (<http://www.nhs.uk/Service-Search/GP/LocationSearch/4>), narrowing the search results by location.

4.6 Study recruitment

As discussed above, the target population for this study were GPs practicing within the Medway CCG area. In the original protocol, the recruitment strategy described postal invite to all GPs that fall under Medway CCG as defined by the NHS Choices search. However, on the advice of a former general practice manager known to the research team, the protocol was amended such that the researcher would contact the listed practice manager on NHS Choices, for each practice identified by the sample strategy described above, to discuss with them the present study. This decision was made as it was acknowledged that GPs are difficult to recruit via 'cold' methods of contact, such as an unexpected letter. Therefore, it was agreed that a discussion with the practice manager regarding the study, prior to posting the study invitation, would allow tailoring of potential contact with GPs and practices to those with specific interest in mental health or Primary Care research. The aim was

to increase the response rate and limit wasted GP and practice time, as well as research resources. An amendment was made to the study protocol and the GP volunteer information leaflets, to reflect this change, and was subsequently approved by the SREC.

However, this method of recruitment proved troublesome as it was difficult to gain a response from the majority of the practice managers identified, both via telephone and email. Moreover, the practice managers were often interested primarily on whether an incentive would be on offer. As incentives were not included within the study protocol, this often led to an end in the conversation regarding recruitment of their practising GPs. Therefore, all GPs were sent the recruitment material within the Medway CCG area and, where successful, a snowballing technique of recruitment was employed in order to gain further volunteers. GPs returned their consent and contact information forms via a prepaid envelope, or contacted the researcher using the email address provided. GPs were then contacted by their preferred method of contact, as indicated on their contact information form (Appendix 12), to arrange a suitable date for the face-to-face interview to take place. This was at least a week after the forms had been returned, to allow the GP time to consider their inclusion within the study.

4.7 Interview schedule development and design

A semi-structured interview schedule was created for the purposes of this study; informed by published literature within this field of research. The interview schedule was developed to explore the following topics: Awareness or experience of LT use for depression, expectations of LT, safety of LT use and the feasibility of a Primary Care pilot trial investigating the potential use of LT for depression. A funnelling questioning technique was employed, influencing the order and phrasing of the questioning, whereby the researcher would begin with an open question followed by a series of closed and probing questions, in the attempt to fully explore and clarify the GPs' response. Broadly speaking these topics remained unchanged during the course of the interviews, with slight adjustments made to the wording and refining the use of prompts, on review of the transcripts with senior research team members, in order to improve interview conduct. See final interview schedule included in appendix 15.

4.8 Conduct of interviews

As previously mentioned, the face-to-face interviews were arranged with the GP volunteer for a mutually convenient time, subsequent to receiving their completed consent and contact forms. The interviews with the GPs were conducted on the practice premises within a private meeting/consultation room, where privacy could be ensured for the duration of the interview. On first contact with the GP, the necessity of a suitable location for the interview to take place was explained. However, as the rooms used for the conduct of these interviews were assigned as consultation or private meeting rooms, it was relatively easy to ensure no interruptions or unforeseen issues of noise interfering with the recording of the interview.

The interview with the GP lasted approximately thirty minutes following the interview schedule developed. The GP was asked prior to the beginning of the interview if they had any questions or queries regarding the conduct of the interview. The researcher confirmed with the GP that they still wish to continue and confirmed their consent. It was explained to the GP that the interview would be recorded but that the information they gave would be anonymised and not attributable to them if excerpts of their interview was used for the purposes of research. The GP was reminded that anything they say in the interview would be kept confidential as outlined in the GP information leaflet. Brief field notes were taken by the researcher during the course of the interview to capture relevant aspects that may be lost in the audio recording of the interview and also used as a prompt for the researcher, so as not to interrupt the flow of a GPs answer. It was explained to the GP that these were also covered by the confidentiality agreement, as previously discussed. The interview began once the GP indicated they had fully understood this information and had no further questions at that time.

In the second section of the interview topic guide, full topic guide can be seen in appendix 15, the GPs were given a five-minute overview of the proposed pilot trial, with the aid of a timeline, seen in appendix 11. The overview included an explanation of each component of the trial, namely: active and placebo treatment of LT, hormone analysis via saliva sampling, actigraphy monitoring through the use of the Actiwatch, and the assessments to be carried out by the researcher each week of the six-week trial. Although the interviewees were encouraged to comment or question any part of the proposed trial, the topic guide focussed primarily on the recruitment of GPs to the potential pilot trial. Interviewees were asked for their advice generally on how they would recommend recruiting patients from Primary Care to the pilot LT trial.

4.9 Data analysis

Audio files collected from each focus group was transcribed verbatim, using transcription software *Transcription Module*, by the primary researcher and double checked by the primary supervisor to ensure transcript accuracy. All audio files and transcripts were saved onto a password protected University computer accessible only by the research team. Transcripts and file names were anonymised of all potentially identifiable content during the transcription process.

Framework analysis was chosen as the method for the qualitative data analysis for this study. This approach involves a five-step process developed by Ritchie and Spencer (1993) in order to identify themes including those developed from the topic guide, informed by literature and the study objectives, and additional emergent themes from the transcripts. These five stages of the framework analysis approach are namely: Familiarisation, identifying a thematic framework, indexing, charting and mapping, and interpretation. Each of the steps are described fully within Chapter Three. This analysis was facilitated by QSR International's NVivo 10 qualitative data analysis Software, used to identify verbatim quotations and excerpts to develop these themes and the findings of this study.

4.10 Findings

4.10.1 Response rate

There were 220 GPs from 68 different general practices that were identified via the sample strategy, with each individual GP sent the postal invite for the research study. 6 completed sets of paperwork were returned to the School of Pharmacy and, of these, 4 GPs were recruited from 3 separate general practices in the Medway CCG area and 1 further GP from the Kent area (identified via snowballing recruitment technique). 1 GP declined following the return of their paperwork, due to health reasons. In total 5 GPs were recruited and interviewed as part of this research study between January and June 2014.

4.10.2 Emergent Themes

Following analysis of the data collected, five overarching themes were identified: awareness, expectations, feasibility, safety, and attitudes. These were further divided in subcategories as

described in Appendix 17.

Each of the themes listed will be discussed below, supported by quotations taken from the interview transcripts. Although counts of GP interviewees will be provided in some instances when discussing the findings, this is in no way an attempt to quantify or substantiate these data. Rather, these are to be used in a manner so as to portray balance and context surrounding the arguments put forward, following analysis of these data.

4.10.3 Theme 1: Awareness

Awareness of LT was reported with great inconsistency between GPs. None of the GPs interviewed had personally used a LT device of any description. Their awareness was reported via the accounts of experience by others, both patients and peers, who had used LT. Their knowledge related to the scientific basis, clinical evidence or treatment details for LT use, which was derived from a combination of personal and third-party sources.

With regards to experience with LT, the GPs reported very few encounters with LT through their own personal practice. They did not describe recommending LT to patients themselves or advising those patients who were already using LT about any aspects of this treatment. There was, however, some acknowledgment of LT being used and promoted outside of the healthcare environment. For example, the mass market availability of LT lamps commercially.

"...[I had] a look for myself, not that I have SAD... So I just had, you know, a quick look for fun really, to see what's the latest on light boxes and how much are they and where, what do they look like. But not for patient purposes." GP3

"...I think I've seen them for sale in John Lewis's?" GP5

One GP identified a former colleague and peer as the source of their initial experience with LT. However, although this colleague ran something of a LT clinic for patients from the surgery premises, this did not equate to any greater championing of the therapy by the interviewee. These practices have not been continued within the surgery and the GP had admitted that they had never seen a LT device, including the one which he thought may be still be stored within the surgery where he currently practices.

“we had a senior partner who’s left since then, but a senior partner who facilitated a light box in our surgery and it was popular with a number of patients, [] but I never really accessed it for my patients” GP2

“Good confession to obtain from me, I never saw it.” GP2

This illustrates the limited experience of LT by the GPs, even within this self-selected sample. However, it is worth noting that the majority of the GPs interviewed, despite their limited personal experience, could describe various models of LT devices, including floor standing, desk and dawn simulation designs.

All but one interviewee could recall at least one patient sharing their own personal use of a LT device with the GP during a consultation. These accounts by the patients were generally positive in their description to their experience of the treatment.

“...some patients do self-diagnose and then they get their own lamps and they feel the benefit so they carry on and because it’s something they can do themselves well I guess, they don’t necessarily come to the doctor.” GP3

“...a lot of patients seem to find it of reasonable benefit.” GP5

Although, between the GPs there was some disagreement regarding the most appropriate indication for use of LT: depression versus SAD and whether these diagnoses could be confirmed.

“Patients use it for what they think is seasonal affective disorder so they come in and say they’ve tried it out, but I’ve not had anyone’s use it in depression.” GP1

“I just wonder whether some of them were actually just depress[ed]” GP2

Where the GPs described cases of their patients using LT, the revelations from patients appeared to be quite vague and were generally unexplored further by the GP. These patients were using LT without the GPs perceived responsibility or role; LT is not currently a recommended evidence-based treatment for depression. Furthermore, work pressures within Primary Care, including the 10 minute

consultation, do not facilitate open ended discussions with patients.

When asked how LT worked, in the majority of cases the GPs were able to correctly describe the very basic model and mode of action or scientific basis of LT. These explanations generally connected the use of LT with responses seen by 'biological' pathways or 'sleep' patterns. Sleep disturbance is identified as one of the core symptoms present in depression by the ICD-10.

"...different wavelengths that might hinder your sleep pattern and [] your rods and cones [are] more sensitive to certain ones and it make[s] it harder for you to fall asleep if you have too much blue light..." GP3

"...from my limited understanding, I know that the light rays really do have an effect on the biological pathway within the brain itself" GP4

Despite this, no GPs linked other salient symptoms of depression, including low mood or anadonia, to LT's mode of action. Nonetheless, all the GPs believed LT to have some actual effects, with the implication of credibility of this treatment beyond that of a placebo effect.

Interviewees were questioned regarding their awareness of the application of different colours of light, or wavelengths, within LT. The GPs gave conflicting responses, conveying both mistaken and accurate theories, often within the same account. GPs who had seen a LT device before gave more accurate answers when speaking about LT options, presumably benefitting from their experience.

"[What] I've seen tends to be white light." GP5

Interviewees reported little if any knowledge on uses of different colours in LT, particularly for placebo devices.

"Red light is part of something to do... with the sun. When the sun setting there's a red light emitted.... That has an effect on the brain, the red light it makes us feel sleepy. Is that right?" GP4

Overall there was much hesitancy and lack of clarity in responses when questioned about their knowledge of different colours of light, and their use. One GP also indicated that patients have poor knowledge when it comes to the scientific action of LT and that GPs are unlikely to provide this

information.

"...[patients think] that it's the action of the light on their whole body" GP1

"...to be honest,[I] don't really talk about light colours to patients" GP1

When asked about the clinical evidence for using LT for depression, all of the GPs interviewed talked about their lack of awareness of evidence to support its use in general practice. They viewed this lack of evidence as a major barrier to them recommending LT to patients.

"I think it's difficult because I'm not sure of what evidence there is around the use of LT in depression" GP1

"we can only do that if we know what to expect of it." GP1

Furthermore, when asked about the place of LT within the current national guidance for the treatment of depression, GPs found it difficult to envision where it may fit in due to the lack of evidence.

"...if there's not that much evidence to say it works, I can't see it fitting in." GP1

"...that's why the evidence has to be there but NICE are there to assess that ... it would be a technology appraisal. Erm, I think if it was approved and if there was more evidence then, obviously, yes you'd feel happier recommending it" GP1

Therefore, this lack of evidence is perceived as a major barrier to the adoption of LT for use in Primary Care.

"I wasn't either particularly mad on it [LT] or against it I just didn't have enough understanding of whether it was successful, whether we should be using it. There was nothing coming through on an evidence basis to say that it was something I should be looking at." GP2

"Show me the evidence" GP2

Finally, interviewees were questioned regarding their knowledge of how widely LT is used within the general population and, for those who are using it, details of how it should be used. GPs had only minimal awareness of individuals who were using LT, as discussed. When asked about whether there was a mechanism to refer patients for LT, the interviewees replied that there wasn't one in place. Furthermore, they acknowledged that there is nothing in the way of guidance to support GPs wishing to provide it themselves.

"No, quite honestly, no there isn't" GP1

"There's not much in the way of guidance" GP1

The GPs had much to say about the treatment details of LT, including reference to indication, duration of treatment, onset of action and types of devices for LT use. All the GPs had heard of the use of LT for SAD as an indication:

"I think my belief is that it was focussed on seasonal affects." GP2

The GPs were able to discuss general patient cases where LT was used for SAD, strengthening the association of LT treatment with this particular subtype of depression.

However, as discussed previously, the GPs were divided in their opinion regarding the evidence to support the use of LT in non-seasonal depression or low mood.

"LT ... I don't []I associate it mainly with SAD ... I haven't really seen much in the way of it being used in normal depression" GP1

"If you had a light box[] that maybe comes on before you actually wake up, before your alarm comes on, [] you would wake up more cheerfully so to speak." GP3

"My understanding is that it work for some people to alleviate mood" GP5

Similarly, when discussing how long a patient would have to use LT for their treatment, their guesses varied from half an hour per week to a few hours per day.

"I think they sat in the room for about half an hour [to] an hour once a week" GP2

"...presumably you must have to put that on for a few hours a day." GP3

This trend followed for suggested duration of onset of action for the treatment by the GPs, often using antidepressant medication as a comparator:

"...but I don't know how long it takes to start working" GP3

"Yeah probably will be a bit of a lag there [] maybe not very dissimilar to say SSRIs" GP3

Most GPs were aware of light boxes available commercially as alarm clocks, floor and desk standing devices. Two GPs had not seen a light box before and this was either admitted or evidenced by their fairly vague descriptions.

"...like a spherical shape but... not only does it look like the sun but, you know, it's a softer effect. Anything with sharp edges would just seem a bit harsher I guess, so something like, spherical, something that would be nice to look at." GP4

"Good confession to obtain from me, I'd never saw it [a light box]." GP2

In summary, knowledge of treatment details for LT was lacking, and this was openly acknowledged by the majority of interviewees.

4.10.4 Theme: Effectiveness

Two GPs described patients that had claimed to derive benefit from their self-reported use of LT.

"They sort of self-diagnose and then they try out these light lamps that they can buy over the internet and feel they help. So they'll come in for their depression review and say I've tried it out I think this is what I have and it helps." GP1

“They get their own lamps and they feel the benefit so they carry on” GP3

None of the interviewees offered any examples of a patient who had reported using LT that had not alleviated their symptoms to some degree. One GP did, however comment upon the lack of effectiveness of the current therapies at their disposal for the treatment of depression in Primary Care.

“...anything for me that might be a breakthrough in depression would be fantastic, because what we’re using at the moment [is] often not working.” GP2

When interviewees were asked to share their views regarding their expectations of the effectiveness of LT for depression symptoms, the GPs expressed their cautious optimism.

“I think there may turn out to be some effectiveness” GP3

“My understanding is that it can work for some people to alleviate mood” GP5

“I’m expecting that it’ll work to a degree.” GP5

These positive expectations of effectiveness were especially true in relation to seasonal depression. Furthermore, when GPs reported the expectations of effectiveness held by their patients – it was solely in relation to SAD as an indication.

“So they’re probably patients who have a history of depression who find that in the winter months their depression symptoms are worse” GP1

“...they have a current, recurrent history of depression and sometimes tend to[] be a bit of a link to seasonal pattern, but maybe it’s not formally investigated” GP3

However, regardless of experience through their practice of patients using LT, most of the GPs did expect effectiveness for the treatment of SAD, with some reference to general depression symptoms also:

“...you know just anecdotally you know people in better countries, with better weather, seem to have less problems” GP3

“I think there’s a lot more evidence to say it works [for] seasonal affective disorder...” GP1

“I think it’s probably a number of people out there who’re labelled as [having] depression who’ve probably got seasonal affective disorder and there’s certainly a bit of overlap between the two, and it’s probably more likely effective for those people.” GP5

Following this, the GPs were asked about their expectations of effectiveness of different colours of LT. As discussed above, when asked about their awareness of different colours of LT, the responses given were not very accurate. In turn, they were asked to comment on the expectations, if any, they held for the colours of LT they were aware of. For those who shared any expectations, blue, white, yellow and red all received positive expectations – two of which (yellow and red) are normally chosen as placebo devices.

“...for some reason the blue light seems soothing as well” GP4

“...in a similar form to getting some sunlight (in reference to yellow light)” GP2

“Yes based on that and also, when you see the sun setting it’s literally red so there’s some logical connection” GP4

There were, however, a number of caveats to these positive expectations towards the effectiveness of LT. The interviewees expressed that LT may not be suitably effective for all severities of depression. All the GPs stated their preference for LT to be recommended only in mild to mild/moderate depression diagnoses.

“... I can’t see it fitting in first-line with moderate depression because they’re the ones you’d be treating, sort of, with medication, so possibly mild depression, and you might want to think about using it first-line” GP1

“I can’t imagine that if you’re severely depressed that it’s going to make a huge amount of difference.” GP5

It was also a concern of a few GPs that other therapies would be more appropriate to recommend above considering LT due to their extra benefits or their existing knowledge of the treatment:

“There’ll be negative effects where you know they might spend an hour sitting in front of a lamp... versus going out to do some exercise and have some serotonin release. Which is more beneficial?”

GP1

“I think it’s the thought process of will it... if they’re eating healthily and exercising they’ll hopefully make their depression better, but equally it’s better for their cardiovascular health as well, whereas sitting in front of a lamp I’m not convinced, I’m not sure.” GP1

“...maybe the fact we’re constantly getting guidelines about depression related to CBT and to drugs and nothing about LT at all.” GP2

These concerns, when explored, were predominately linked with the lack of clinical evidence or professional experience the GPs have had available to them. It was this lack of evidence that prohibited them from considering LT in all severities of depression, rather than a reason linked to the biological action of the treatment. Despite this, some of the GPs would be still willing to consider LT based on their expectations of its effectiveness, to some degree:

“I’d still put CBT at the top but, I think LT would probably come next.” GP2

“I think, LT, it’d be something I’d be very interested in exploring for a referral pathway.” GP4

“I think in the ideal world you could try to use it for all categories, because I think based on the efficacy there’s going to be some benefit for all patients regardless of the depression” GP4

“I think my expectation is that [] I would imagine it works for mild depression” GP5

4.10.5 Theme: Safety

The majority of the GPs interviewed expressed that they felt that LT would be safe, when asked about any concerns they may have about the treatment. Two GPs used their experience of patients’

personal use of LT, or the experience reported by their peers in the case of GP2, to base their assessment of LT's safety.

"Yeah it's well tolerated" GP1

"... no one's really said [] they have eye pain, vision problems or whatever, no." GP1

"... from what I know of it, it's not harmful." GP1

"I can't remember anybody, ever coming back from this partner" GP2

"there's nothing on my records about getting you know severe headaches, or dizziness" GP2

Furthermore, even those GPs who had not reported patient experience with LT seemed to have formed a positive opinion of the safety of its use through their own estimations.

"What are the side effects? Well, we'd have to see but I can't see there being that many side effects of sitting [in] front of a light box." GP2

"I'm not aware of any problems with it, I think it's seen as a pretty safe thing" GP3

"probably really safe" GP3

"...in terms of side effects we [], as doctors, always worry about side effects and interactions with other medication and I think, I'm hopeful that there'll be no side effects and no drug interactions at all [with LT]." GP4

When those GPs holding positive views of the treatment were probed further and asked if they had any other concerns including side effects or its use, no additional concerns were shared.

"not really, no, I can't think of anything" GP4

One of these GPs suggested that their view regarding the safety of LT was connected to its 'natural' mode of action, as opposed to the experience purported by the GPs first discussed.

"I think at the end of the day the concept of LT - it sounds so natural" GP4

One GP supported this advantage of LT, suggesting it would be a safe treatment in vulnerable patient groups.

"...a mum with young children who says I'm not having medication... [you] may then do this" GP1

Two GPs, however, did express some concerns with its safety. Despite having many positive views in this area for LT, GP1 did have one caveat with regards to the severity of depression it would be recommended for use. There was a concern of the reliability of the treatment. The GP worried that, even with evidence to suggest it would be appropriate in severe depression, it would not be appropriate to prescribe for fear that the treatment would let the patient down.

"... not really I may [] not want to use it for my severely depressed patients, [even] if there was evidence to say it worked... the fact that they're expecting to get better and they're not...their expectation's making them worse..." GP1

In addition, GP5 expressed concerns regarding specific side effects and did not share fellow interviewees' positive opinions of the therapy's safety. GP5 listed concerning side effects associated with the use of LT, of which they believe personally and, also, including those they have gathered from patients. This GP listed many serious side effects, including cancer, as being the possible adverse effects of LT use. This could be a major barrier to the use of LT if not corrected by their doctor or other healthcare professional.

"increased rates of cataracts, photosensitive rashes, that sort of thing" GP5

"I've had patients who're concerned about sort of skin cancer and that kind of thing... that's quite a common concern" GP5

Although the majority of the GPs interviewed believed that LT would be safe and reported no issues or concerns with its use, these views were based on their assumptions of the treatment rather than evidence or experience with the therapy. With this view, unsurprisingly, there were also statements of their uncertainty and misinformation when addressing the topic of safety of LT, within their

overall assertion that LT is a safe treatment for depression.

“Don’t they have to wear like, do they have to wear sun glasses? Well I think that’s the whole point isn’t it? You wouldn’t wear a UV blocker?” GP1

“In a similar form to getting some sunlight, but without the adverse effects I would hope” GP2

“Not going to be harmful to your eyes is it?” GP3

Therefore, although it is promising that there isn’t any major concerns regarding LT, there is a clear need for further education and dissemination of accurate information for those providing mental health advice in Primary Care.

4.10.6 Theme: Attitude

It was clear that there was consensus by GPs that they were open to a new treatment for depression available in Primary Care. This was particularly highlighted through their critique of the NICE recommended treatments currently at their disposal for the management of depression in their practices:

“Yes it sounds very exciting because at the end of the day with medication there’s always side effects and even if a patient does start to feel better on these antidepressants you have the issue of tapering it off as well, later on sometimes, if they stop suddenly, they get something called discontinuation syndrome vertigo dizziness, nausea...” GP4

“I think anything which can try and avoid unnecessary medication has to be good thing.” GP4

“We do use counselling... we try to refer for counsellors as well, but in the current climate with the NHS there’s only so much one can do with counselling, limited number of sessions available for each patient on the NHS.” GP4

“Anything for me that might be a breakthrough in depression would be fantastic, because what we’re using at the moment [is] often not working.” GP2

Moreover, one GP shared that they would enthusiastically take on board LT as an answer to this gap in treatment available to use in depression.

“[The] potential benefit from LT can only be a good thing in terms of helping them improve quality of life, because depression has substantial effect on the physical health as well as mental health, co-morbidities do co-exist, and anything which can help [] with the depression will have a benefit on the patient’s physical health [and] their overall well-being.” GP4

“...I’d be very, very happy to try and refer patients to use it.” GP4

Further support of this positive attitude towards LT was shared by another GP who considered the practical elements of the treatment, if it were to be introduced in Primary Care - specifically the lower cost per treatment to the NHS, and revealed their plans to use LT for their own private use:

“...probably quite cost effective if you compare it with say prescribing antidepressants for nine months to twelve months. You’ve the lamp for, I don’t know, fifty quid or whatever, it’ll last you for the year” GP3

“I just had, you know, quick look for fun really, to see what’s the latest on light boxes and how much are they and where, what do they look like. But not for patient purposes... having a look for myself” GP3

However, although still portraying an optimism towards LT, some GPs were more reserved in their attitude, seemingly due to their lack of confidence in the treatment:

“I think there may turn out to be some effectiveness” GP3

“I’m expecting that it’ll work to a degree.” GP5

“I hope that it works. I’m not sceptical about it I’m feeling relatively positive about it.” GP2

Further still, others were stronger in their reservations regarding their confidence in LT in the same role:

“I wasn’t either particularly mad on it or against it” GP2

“...just as something else to offer, really, when he was stuck.” GP2

“If you’ve got someone who is severely depressed, I’m not sure [no matter] how much light you shine at them [that] they’re going to be any better.” GP3

“I can’t imagine that [] if you’re severely depressed that it’s going to make a huge amount of difference.” GP5

One GP vigorously advocated for lifestyle advice, such as exercise, as the alternative to pharmacological and psychological treatments currently recommended by NICE. This was due to its additional positive effects and practicalities of recommendation, as opposed to LT and its unknown mode of action and possible placebo effect within the depression population seen by Primary Care surgeries.

“but equally you’d be also doing the lifestyle advice and everything else so, it may be difficult to separate out what’s worked and what’s not ... they might spend an hour sitting in front of a lamp versus going out to do some exercise and have some serotonin release, which is more beneficial?”

GP1

“... with exercise therapy and sort of patients doing things for themselves, you’re passing it back to them. Whereas giving them LT is like giving them a tablet... it’s this expectation of it will make me better and I don’t need to do anything about this” GP1

“... you know if they’re eating healthily and exercising they’ll hopefully make their depression better, but equally it’s better for their cardiovascular health as well... whereas sitting in front of a lamp I’m not convinced, I’m not sure.” GP1

“... who supplies them? You know why should patients go out and buy these things? Should they go out and buy these things? ... it’s that sort of moral argument I suppose as well isn’t it.” GP1

Despite concerns of access expressed earlier in the interview, one GP shared that they would still support referral to CBT before LT:

“Therapy, counselling I’d still put, probably, at this stage, ahead of that. I still favour [] all the

evidence they've got on CBT." GP2

Concerns regarding the practicalities of using LT seemed also to affect their initial open attitude towards LT as an alternative treatment for depression, including predicted issues with compliance, supply of devices and length of treatment.

"I mean yes, with a tablet people get fed up with it and they gradually take it less. But the LT they might not be able to do it at all, because it might just be not practical." GP3

"... who supplies them? You know why should patients go out and buy these things? Should they go out and buy these things?" GP1

"Thirty minutes is probably more reasonable, I think if [] I saw sixty minutes, I think when am I going to do that?" GP1

"I didn't really see myself as facilitating extended periods of them sitting in the surgery with a light box." GP2

More telling, perhaps, is their perception of the use of LT as something that is stigmatised, which in turn would indicate presumed issues with its use and compliance by the patients. The GPs suggest below that, in their opinion, patients would want to find a way to hide the device from others, as they would be self-conscious:

"Whereas if you're at a desk at work you could put that on and your colleagues probably wouldn't even notice. You could fit that into your lifestyle..." GP1

"...feel self-conscience when using it (speaking from the point of view of the patient)." GP5

The following account given of a patient's attitude of LT, however, may be more of a reflection of the GP's perception of LT as ineffective; LT would not be sufficient for a patient as a monotherapy.

"They eventually want you to prescribe something so, it's that side of things..." GP1

This uncertain attitude towards LT was not necessarily linked to its credibility as a therapy. Many of the same GPs had exhibited some knowledge and understanding regarding the logic of how LT works, as discussed above, for example

“using ipads and I get told off about this quite regularly, using an ipad at bedtime is more likely to evoke or stop you from sleeping.” GP2

“we know there is a link between sunlight and feeling better generally,” GP5

However, as we have seen, these same GPs showed hesitancy when asked about using LT in their future practice.

While credibility and knowledge of the treatment did not improve their attitude towards LT, there were many suggestions from the interviews that further evidence would be beneficial.

“I think if it was approved and if there was more evidence then obviously, yes you’d feel happier recommending it” GP1

“if it shows effectiveness it would come ahead of antidepressants.” GP2

“I think there may turn out to be some effectiveness” GP3

“If you’ve got somebody who’s more depressed, you’re not so keen to try something that you don’t know is going to work” GP3

However, ultimately it seems that an endorsement of LT for depression by NICE is essentially what would be preferred by the GPs, as indicated directly by this GP:

“... that’s why the evidence has to be there but NICE are there to assess. It would be a technology appraisal.” GP1

Moreover, it does not seem to be what they experience, either personally or through their practice, or even their knowledge of treatment as discussed above, but its appearance in guidance such as NICE or QoF that will result in the uptake of this therapy by the GPs - as shared by GP2 who would

recommend a treatment in the guidance such as MRI without necessarily having these other factors present.

“...it’s like many things in general practice actually you’re surprised when you suddenly think gosh I’ve never seen an open MRI scanner, I don’t know what I’m talking about when I’m trying to explain to the patient” GP2

For a shift in attitude from an openness for any alternative treatment in this field, to one which is specifically in favour of LT to fill this identified gap in current recommended management of depression in Primary Care, this ‘seal of approval’ should be sought. The first steps towards achieving approval such as this would be to provide more research into the use of LT for depression symptoms in Primary Care of a quality that would be considered by NICE, adding to that which exists for other settings such as that in Secondary Care.

4.10.7 Theme: Feasibility

4.10.7.1 Feasibility of Light Therapy

The GP interviewees were asked about their views and opinions of the feasibility of using LT as a treatment for the symptoms of depression.

The two major concerns discussed by the interviewees regarding feasibility were access and compliance/adherence to LT. Firstly, the GPs dealt with present-day access to LT as an alternative to pharmacological and psychological treatments recommended by the NICE pathway for depression. The GPs stated that, where they have encountered cases of patient use of LT for depression symptoms, the patients had acquired the device on their own rather than through any healthcare or Primary Care route.

“... you know they’re buying them for themselves.” GP1

“... some patients do self-diagnose and then they get their own lamps and they feel the benefit so they carry on and because it’s something they can do themselves. Well, I guess, they don’t necessarily come to the doctor.” GP3

For the most part, it is identified by the GPs that the patients are buying the LT devices for

themselves as they have become easily accessible on the general market and online.

“[the patients] try out these light lamps that they can buy over the internet” GP1

“I think if they are readily available and reasonably priced it’s probably something the patients will buy themselves” GP5

The reason for the lack of accessibility of LT from the surgery, however, may be because none of the GPs were aware of any mechanism in place that would allow them to recommend LT for a patient, even under a diagnosis of SAD, where LT has been a widely accepted and recognised treatment in literature. There is simply no direct way to access LT through the GP surgery currently, according to the interviewees.

“No, quite honestly, no there isn’t.” GP1

One GP spoke about an ex-colleague within the practice that facilitated LT use within the surgery for the patients. As this was the only type of use of LT this GP had encountered, rather than home use LT as we have intended for the pilot trial, he was unsure about the feasibility of accessing LT through the surgery in this manner, if we were to consider this as an alternative means of access.

“I didn’t really see myself as facilitating extended periods of them sitting in the surgery with a light box.” GP2

Another attribute which could affect access to LT is the expense of the device to the patient. As mentioned above, currently the majority of patients who access LT for their symptoms will purchase a device of their own. This is clearly in contrast with how traditional treatments are acquired by the patient with antidepressants and counselling available on the NHS, with negligible to no cost to the patient in need. Although this is not necessarily how this would continue if the therapy were to be adopted by the NHS, it is certainly the present case as reported anecdotally by the GPs. The GPs were not unanimous as to whether this would be a true barrier to access, however.

“But at least you don’t have to go to a gym to do it and you don’t have to have pay for it, you’ve got it.” GP2

“I think if they are readily available and reasonably priced, it’s probably something the patients will

buy themselves” GP5

One GP spoke about their concerns on this issue, to reveal that, with evidence and a limited amount of research, these issues could be easily resolved in their mind.

“Should they go out and buy these things?” GP1

“If the evidence is there and the lamps aren’t available, you might suggest to a patient the evidence is there, this is the evidence, it’s up to you [if] you want to pay for this?” GP1

“...be bit worried about how expensive it [would be] to recharge (the LT device), batteries and things like that.” GP1

Therefore, although it could potentially be identified as a barrier to access, these arguments could be rebuffed with more research into LT treatment in Primary Care.

The GPs also spoke about their perceptions of the compliance/adherence to the LT treatment by the patients and identified several barriers and facilitators which could influence its feasibility as a treatment of choice for the general public.

The GPs discussed compliance issues that they see generally within the public when it comes to medications.

“We’ve problems with tablets as well and that is simply a tablet a day... We have huge problems with getting people to counselling sessions, even people who want it and have shown a genuine desire, we still have trouble getting them to the sessions.” GP2

Nevertheless, it was clear that the GPs foresaw compliance or adherence issues with LT as a treatment – perhaps further than that which we see in the current medicine taking:

“...remembering to use it (LT)? I think taking a tablet, they’ll remember.” GP1

“You’ll have problems with adherence, obviously.” GP2

“I mean yes, with a tablet, people get fed up with it and they gradually take it less. But, the LT they might not be able to do it at all because it might just be not practical.” GP3

This hesitancy regarding the adherence to LT specifically, when explored, seemed to pertain to LT treatment details and lifestyle/patient groups that may have limitations when it comes to the use of this treatment. Treatment details, for example the frequency and duration of LT periods, were raised as potentially influential on the acceptance and adherence to the treatment. One thing that had become clear after speaking to the GPs is that they had little knowledge about the treatment details for LT. When asked how feasible they felt the duration and frequency of LT is, they offered what they felt to be a reasonable amount of time rather than what they knew to be the common duration of LT prescribed (this is further explored under the theme awareness seen above). Although this was the case, two of the GPs suggested that thirty minutes, which is a common duration of LT used as per the literature (Terman and Terman, 2005), would be acceptable in their opinion.

“Thirty minutes is probably more reasonable...” GP1

“Thirty minutes I think you might be able to[] thirty minutes is probably doable.” GP1

“I can see some of my patients sitting for half an hour an hour a day” GP2

Although one of these GPs did seem conflicted with their initial acceptance of thirty minutes, recalling difficulty they have with patients adhering to exercise recommendations.

“They find it hard to fit exercise in for half an hour an hour a day, so they’d probably find it hard to fit the light box in for an hour/half an hour a day.” GP2

Nevertheless, it was felt that duration of the treatment would be a factor in the successful adherence to the treatment, along with a quick onset of action and, to a lesser extent, GP support and involvement.

“I think it’s how much time of day they have to spend in front of the lamp.” GP1

“... it’s got to be fairly quick acting, they need [] a benefit because if they see a benefit it will reinforce use of the lamp.” GP1

“we just need to know. Maybe they should keep a diary of what they’re doing?” GP2

It could be suggested that the GPs were merely identifying factors they felt were important to the adherence to any treatment for depression, rather than anything specific to LT itself. This is supported by their lack of awareness of the treatment discussed in the theme ‘awareness’ above. For this reason, it may be that these recommendations cannot be applied to LT with any specificity. Instead, through piloting and accumulation of further evidence, disseminated usefully for GP or clinical use, the opinions of these practitioners will become more specific to LT. Evidently, this would be more helpful with a view to optimising the treatment in the future. Nonetheless these data have been viewed with this critique in mind and still go towards building a better picture of the current landscape of LT in Primary Care.

Certain lifestyle factors were identified by the GPs as ones they would note in their consideration of the treatment as it could affect their potential adherence to the treatment in the GPs’ eyes. Employment status, whether or not the patient is in work, was discussed as a possible barrier to adherence to LT as a treatment:

“... busy lifestyle, working, catching the kings ferry to London - they’d probably have big issues with that, so compliance might be the problem.” GP1

“... quite a number of them are unemployed or they’re off sick with their depression. So, actually, they have got the time [for] some of them. It’s probably harder for your working people who are trying to maintain work to keep the mood good, because work is good for some of my depressives. They would perhaps find it harder to [] fit that time in” GP2

“just getting yourself ready for work, and then you might be in and out the door in twenty minutes and you [won’t] have time to do the LT” GP3

Conversely, one GP suggesting that, if LT could be completed at work, that this could in fact aid compliance.

“Whereas, if you’re at a desk at work you could put that on, [] your colleagues probably wouldn’t

even notice. You could fit that into your lifestyle...” GP1

Patients with children, particularly young children, were also a group identified as a patient group that may have issues with compliance to treatment due to specific lifestyle considerations for these patients.

“I think it depends, if you’ve got someone again [with] children... compliance might be the problem.”

GP1

“I don’t know whether that could be difficult if you’re, you know, [you have a] whirlwind day, getting kids ready for school...” GP3

“...sitting or trying to do something with your children which can probably be quite difficult.” GP1

However, it could also be a safer option of treatment for a woman who is pregnant or nursing, a significant disadvantage to the use of pharmacological treatments such as SSRIs which can have serious adverse effects for both mother and baby. LT has been identified as a potential treatment in perinatal and postnatal depression due its limited systemic effect profile and natural mode of action of the symptoms of depression (ref). This ‘pharmacological-free’ element of LT was acknowledged by one of the GPs as a possible value to this patient group.

“you may have a mum with young children who says that I’m not having medication” GP1

Other patient groups that GPs felt would specifically be unsuitable for LT included those with certain disabilities, those of a lower education or intelligence level and those with substance misuse issues.

“How would my disabled patients cart that around and move it?” GP1

“I suppose, in terms of the individual patients one has to take into account the patient’s individual educational level; their understanding of LT. They have to be able to understand the information, weigh it up, come to a decision.” GP4

“... clearly it may not be suitable for somebody who, for example, has severe alcohol problems and drug addiction problems.” GP4

The GP interviewees were then asked about how they would see LT fitting into a Primary Care setting as a treatment for depression. They were asked to express their opinions regarding its potential place within the NICE pathway for treatment in depression (NICE, 2009) and how feasible it would be to recommend, as well as how they would advise on or prescribe LT to their patients in a surgery consultation.

All the GPs communicated that they felt LT would be most useful either in the mild or mild-moderate severity classification of depression.

“... I can't see it fitting in first-line with moderate depression because they're the ones you'd be treating [] with medication - so possibly mild depression and you might want to think about using it first-line.” GP1

“I would have thought the mild to moderate.” GP3

“I think my expectation is [] I would imagine it works for mild depression.” GP5

One GP felt that LT could be recommended at all severities of depression, suggesting it as a potentially useful co-therapy:

“I think in the ideal world you could try use it for all categories because I think, based on the efficacy, there's going to be some benefit for all patients regardless of the depression.” GP4

However, there was much more hesitancy to recommend LT to those who have been classified as having severe depression, as discussed previously regarding the expectation of effectiveness.

“ [I] guess my feeling is that they're probably more useful down at the mild to moderate end rather than the more severe end.” GP5

Although a consensus was mostly reached as to where LT would appear, ideally within the treatment strategy of a patient with depression in terms of severity, they had, however, identified some issue

with the practicalities of 'prescribing' LT in their practice.

Counselling a patient on LT was an issue that was much discussed by the GPs:

"With medication or with counselling, you'd talk about side-effects, you review [] their medication and [] you'd review their depression, but, I don't know how much time it would take for me to counsel about using [LT], side effects, what to do when things go [wrong], what if it's not working? It's having some backup I think as well. Even things like technical problems. What if a bulb blows?"

GP1

"I need some guidance" GP2

It was evident that the GPs would not feel comfortable recommending on the use of LT to their patients at this stage. However, this would improve with increased evidence which show favourable results for the use of LT in Primary Care, as well as investment into resources for GPs on how to advise and 'prescribe' LT, as is available for current medication. Alternatively, if it was deemed to be too cumbersome to carry this out through a routine consultation at a surgery, a referral system could be designed, similar to how counselling referrals are in place in Primary Care, to help support LT utilisation in the community.

Following this, the supply of the LT devices was also a salient issue considered by the GPs when discussing the feasibility of LT as a future treatment. Firstly, the constraints surrounding the physical supply of LT devices was deliberated, with the majority of GPs regarding this as a possible obstacle.

"Should they go out and buy these things?" GP1

"Do we loan them out? [] I think that's not for us to decide that's more for [the] commissioners to decide..." GP1

"Yeah, I think we'd have to know that it was adequately resourced." GP2

"... making sure you get stuff back. We have trouble getting stuff back from patients and I suppose you have to sign them up [], like you would in the business world. You would [] get some deposit from them [] which they get back in full at the end, [] if they can afford it, which some of our patients can't,

but if you can get some kind of guarantee that they will bring the machine back...” GP2

One GP, as discussed above, had only encountered LT used within the surgery and had reservations regarding this method of supply and use also:

“I didn’t really see myself as facilitating extended periods of them sitting in the surgery with a light box.” GP2

Despite this, there was some acknowledgement that LT devices are not the most expensive treatment as a one-off cost of equipment. Furthermore, one GP envisioned the supply to be similar to that of blood pressure machine services that are already practiced within their surgery, with either a loan service or with patients buying the equipment themselves.

“If you’re going to roll it out then you’re going to have to have the equipment... which shouldn’t be too much I don’t think. They’re not really very expensive, the equipment.” GP3

“I would imagine some practices could supply the [devices] to patients, on a sort of loan basis, like we do with blood pressure machine with some patients. But, the majority of patients buy their own blood pressure machines, and they’re [the] same sort of price as that and readily available from places like Boots. I would imagine that would work.” GP5

Moreover, the way in which this supply would be financed was also a topic that was discussed by the GPs, as this would be important to their practices as a business. Overall, it was determined by two GPs to be a cost-effective option in this area, with no other GPs sharing conflicting opinions.

“...there’s going to be financial support for this to take place so, before we even thought about where it fitted in the process, we’d have to feel it was adequately supported and remunerated. Number of machines available and purchase cost, and all that kind of thing, has to be taken into account” GP2

“[if] there [were] evidence to prove that it worked, [it would be] pretty high on the on the on the scale because the cost is just a box at the end of it all, that can’t be hugely costly either. So, if it’s effective, then it’s looking like it’s going to be cost effective” GP2

“[LT is] probably quite cost effective if you compare it with say prescribing antidepressants for nine

months to twelve months. You've the lamp for, I don't know fifty quid or whatever, it's lasts you for the year." GP3

As revealed during the course of these interviews, there is no current direct involvement of the GPs themselves, their practices or, to their knowledge, any other Primary Care service providing LT. The feasibility of a patient treating their symptoms with LT, therefore, would be hindered by lack of access to the treatment within a Primary Care setting at present. As for LT as a potential treatment for depression in future Primary Care services, there were concerns regarding issues with difficulty for certain patients to adhere to the therapy relating to non-modifiable lifestyle factors. Furthermore, there were also apprehension regarding aspects of LT treatment that differentiates it from conventional pharmacological treatment - namely, the time it takes each day to comply with the recommended treatment duration. However, more evidence would help to alleviate some concerns that are routed in lack of knowledge of the treatment when applied to a relevant sample of patients in the community and their own homes. Encouragingly, it was agreed among the interviewees that, in their opinions, LT would be useful and has a potential place within the NICE treatment pathway, as well as posing as a very cost effective solution compared to the on-going expense of prescription items. For these reasons, novel research is required to build upon existing clinical evidence in order to strengthen the case for LT for depression and to investigate its feasibility within the target population.

4.10.7.2 Feasibility of Protocol

The GPs offered advice regarding the recruitment of depression patients to the study and shared possible opportunities to recruit within this setting. One GP spoke about research-ready surgeries that may be equipped and eager to be involved within a study such as the one proposed:

"I think what you're going to have to do is target practices that are interested in research so you may want to target practices that are RCGP research ready. [] The RCGP, Royal College of GPs, should have a list so it may not be necessarily be Kent and Medway, it may be where ever. But, if they're 'research ready', it means they're happy to be involved in Primary Care research so they're more likely to be geared up to do things like that." GP1

They were also able to confirm that patients, depending on the practice, would be seen for a review

every three to six months.

"... we try to see them six-monthly, definitely." GP1

As the trial is projected to run for at least one year, this would suggest that the majority of potential GPs would access their surgery during the time of the trial and could be recruited to the pilot trial, if their surgery was involved in the recruitment method.

One GP recounted that any previous studies their patients had been identified by, or recruited to, had been through secondary care and suggested that this seemed the norm:

"... with depression, they'd have gone to the psychiatrist, instead of us - the psychiatrists love research, [] they're involved in it. They pick up the people who are already in secondary care." GP2

However, they did understand that this could be inappropriate for this study as it is focussed specifically within Primary Care.

"[... but for this kind of study, [] you want a spread don't you really. You're looking for Primary Care guys." GP2

GPs believed that the sample size proposed for the study, twenty GPs per arm of the study, would be achievable and believed a surgery would be able to identify enough patients to be able to meet this estimation.

"That shouldn't be a problem... you know that number people is not a problem." GP3

"yes I think that's achievable" GP5

As for sample inclusion and exclusion criteria, the GPs had some hesitancy concerning the severity range the research team had chosen for the study, moderate to moderately severe. This range had been chosen so as to be able to detect response to the interventions and, as revealed by an audit carried out in a local surgery, there were a majority of patients that had a PHQ-9 score within this range (Unpublished Data). Nevertheless, the GPs felt, as discussed previously, that LT would be more beneficial in the lower score ranges and that the research may be lacking if mild depression patients

were omitted.

“... actually, they’re probably [] easier for us to counsel, for example if it was our practice, [] we see them for depression reviews...” GP1

“I think maybe even mild depression could be included (in the study) as well because it can fluctuate, the score, on a day to day basis and it’d be a shame. You don’t want to miss [an] opportunity because if it is a mild depression then it could [], well theoretically, if it’s mild the efficacy could be even better...” GP4

One GP had a concern with the PHQ-9 score used as the inclusion criteria as it may allow those with suicidal tendencies into the study:

“What about people with suicide risk? ... or people who have had previous suicide attempts?” GP3

However, it was agreed since normal treatment would continue within both active and placebo intervention groups, this should not pose a problem to the safety of the trial.

“If you have a [] study where this (the intervention) is on top of your normal treatment, then it may not be such an issue. But, obviously, if you can’t give your normal treatment, then you could be a big issue.” GP3

Although the GPs offered many points of advice regarding the potential recruitment process for this trial, it became clear that the majority of those being interviewed had not taken part directly or had little interaction with Primary Care research previously. Therefore, these GPs were commenting on possible recruitment strategies from the perspective of general practice, as opposed to what would be feasible for research purposes.

“I’ve never helped patients onto a trial” GP2

“Well we have had [trials] fortunately, but not in recent years. I wouldn’t [] have thought most surgeries would not have had experience of recruiting for research.” GP3

The interviewees also warned of prospective barriers or concerns they had regarding recruitment to

the study that had been proposed. The questionnaires that had been shown to the GPs as examples of ones that would be used throughout the trial were identified as a possible barrier to patients, but also to GPs – if they were expected to complete them for the recruitment of a patient:

“...most GPs now are filling in referrals for depressions for counsellors. Referrals forms for somebody’s secondary care, psychiatry... the PHQ-9s and the GAD-7s for most of our depression, depression/anxiety, and so we are kind of used to filling in forms. It’s the duplication... how much of what you need could be got from a similar form to the ones that KCA ask of us?... Is your form going to be that kind of form?” GP2

Furthermore, the PHQ-9 that had been chosen as one of the key questionnaires to be completed before, as a screening tool, and weekly during the trial, to record response to intervention, was also a point of issue for two of the GPs. It was advised that with the frequency with which the PHQ-9 was being scored and with the sensitivity of the tool itself, the study could encounter problems with large fluctuations of PHQ-9 score from patients, week to week.

“... [with] PHQ-9s, when we’re seeing our patients, we don’t see them [for] at least two three weeks [], and that’s the guidelines. Is doing them too quickly [] actually helpful?” GP1

“... the thing about PHQ-9 scores, they’re very, very subjective, in a way because patient can see you with a PHQ score which is very high and then the next day they wouldn’t feel that way.” GP4

However, the questionnaire was acknowledged as a well-recognised and widely used instrument within Primary Care practice – this can be linked to its inclusion of questionnaires required for QoF, making it very representative of what would be seen in Primary Care.

“It was in the last QoF year, the PHQ-9. I think that’s still part of the quality outcome framework, it’s one of the tools available.” GP4

Further still, it would be well known to patients for the same reason. The PHQ-9 is one of two questionnaires that are completed at each stage at the trial. With two questionnaires measuring symptom response, covering different domains of response, the study should not encounter these issues with sensitivity and possible fluctuation in depression scores.

Overall, there was certainly some general advice given about the opportunities and barriers to recruitment from Primary Care, however, it was evident that most of the GPs interviewed had little to no experience of research in their practice and revealed that practice research recruitment to a trial is not something commonly seen.

"I've never helped patients onto a trial" GP2

"Well we have had [trials] fortunately, but not in recent years. I wouldn't [] have thought most surgeries would not have had experience of recruiting for research." GP3

This could pose a barrier to recruitment through the surgeries as GPs and practice staff may not be open to the unfamiliar.

Following these discussions, the GPs were presented with two potential methods that had been identified by the research team as possibilities for the recruitment of patient GPs to this trial. The first of these two methods would involve the GP directly recruiting patients from their surgery or during consultations on behalf of the researcher. The second method would involve the identification of potential GPs using their PHQ-9 score as coded by the practice in order to filter appropriate patients. In each of these cases, the patient GP identified would subsequently be contacted by the research team to invite them to join the study.

In response to the first of these two proposed recruitment methods, recruitment of patients by the GP, three of the five GPs seemed strongly in favour of this option.

"I think you need to do it through the GP." GP1

"... gives them the impression their GP's involved" GP1

"I think that's the thing, that's the way to do isn't it?" GP3

"I think it's good from your perspective, [and] the GP wants to encourage the patient as well at the same time." GP4

They felt that the GPs involvement in the study would help to legitimise it and would help toward a greater number of patients coming forward, rather than just receiving a letter.

However, there were a few points raised that would limit this method. It was felt that time would be the greatest limiting factor of both the GP and the researcher, particularly if the inclusion criteria for depressed patients to be included is too broad.

“... it's time isn't it? It is a bit of time initially to have them recruited...” GP1

“I think they (referring to researchers of other studies) recognise that GPs are so busy...” GP2

“... you might be deluged with far too much information, you might almost feel overcome by GPs referring into this. The people who aren't necessarily suitable for this but [are] basically depressed people...” GP2

Saying this, one GP felt assured that, if the surgery was on board, that 'lack of time' on the part of the GP would not be an issue:

“So that's not an issue (doctors being unwilling to recruit) but I think you've got to identify practices that buy into doing research.” GP1

Outside of the issue of time, there were other matters of concern with this method. One GP thought that this method would be introducing bias, with the GP recommending patients to the pilot trial. A subsequent GP was worried that a patient would become upset with them if they were ineligible/non-responsive to LT and would return to them with their complaints.

“[You] can't give too much away and can't be seen to be biased” GP3

“... so if we refer to you and you say 'oh I'm really sorry you're not suitable', the problems are that the patient's going to be cross, because they thought they were getting a shot at LT.” GP2

For those who were either firmly or tentatively in favour of this option, the interviewees offered their advice if this method of recruitment was included in the pilot trial. These recommendations could be summarised as: the researcher should be heavily involved to avoid over-burdening of GPs, a supplementary recruitment guide of bullet points for potential patient GPs should be supplied to recruiting GPs, and include a blank letter that would give supporting information to the patient

during and after the consultation. This letter would also, ideally, further advise the patient how to show their interest to the research team.

“So, signpost [to] them that [] this is something that’s going on, here’s the information, read it and whatever. Is it okay? Are you interested? Then, I can get the researcher to contact you, that’s probably the way.” GP3

“... [include] a few bullet-points [that] he can say to the patient [] that could facilitate that process (the recruitment) quite easily in terms of the [] actual machine itself. Obviously, it’s important that you liaise with them before handing it (the LT device) over and I think the GP has to [] be careful [which] patients they select as well [as to who to] [] offer the LT to. You have your criteria there and I think the patients the GPs will be aware of [are the] kind of patients [that] would [be suitable].” GP4

“... if you give us a blank letter, or whatever, then I can send that on to the patient or give that to a patient.” GP5

The interviewees were then asked for any comments they had regarding the second proposed recruitment method, whereby potential trial patients would be identified via surgery records, using entered PHQ-9 scores, and invite them to join the study through postal invitation.

Most of the GPs could see an advantage to this method of recruitment. Firstly, it was acknowledged that this was often the recruitment strategy employed by other research studies within surgeries that they were aware of:

“... they’ve always been kind of sucked out of general practice [from] our practice by researchers [who] pick them up through whatever indicators, through secondary care or they ask us if they can do a kind of a search through our patients and then seek the patient’s permission.” GP2

“...we haven’t been asked often and the vast majority of time we’ve been asked [] when they’ve already recruited and they’re sending us a letter [that] says “is it okay with you?”” GP2

This would also allow a quick and targeted method to identify potential patients, even those who no longer visit the doctor for review regularly, thus increasing the number of potential patients that

could be recruited to the pilot trial.

"We can do that way as well, that will be quicker because, obviously the first way (recruitment through consultation), we're talking about opportunistic recruiting. This way would be more systematic, you can identify [eligible patients]." GP3

"... if there's the letter, depending on the wording of the letter, if you could provide us [] within the letter [] the rationale and the evidence already, then it could be [] something really straight forward we could send that letter to the patient..." GP4

"...you then [would] identify a GP practice, send [the letter to] all their patients who are stable depressives on medication..." GP1

However, one GP was particularly concerned with the possible confidentiality issues attached to this method. They highlighted that the research team would not be allowed to view patient data in order to fulfil the protocol for this method and would need appropriate ethical approval along with the cooperation and involvement of GP staff to identify and send the recruitment materials.

"... but actually, as a GP, should I be giving you that information?... how would patients feel about that data being shared about them with a researcher and them not knowing?" GP1

"I couldn't just give you [] a list of patients, that wouldn't be suitable." GP5

"... if I got a phone call from research person saying "oh you've scored this on your [questionnaire] or we know you're being treated", I'd be quite alarmed and think, well hang on, I haven't consented to this data sharing." GP1

This consideration could pose an issue for the study as it would introduce a gatekeeper to recruitment and may require further resources, perhaps incentives, depending on what the surgery would require in exchange for their increased involvement with recruitment.

One further critique of this method was in response to the PHQ-9 score being used as the filter for

identifying potential GPs in the surgery records. It became clear that, although required by QoF, PHQ-9 questionnaires are not always carried out with the patient and/or recorded within the records. Furthermore, this PHQ-9 score information may be out of date for that patient by the time the records are searched for the pilot trial.

“It depends we don’t really PHQ them.” GP1

“... obviously, we don’t know how old the PHQs [are]. You have to have a time frame because otherwise the PHQ is going to be too old isn’t it?” GP3

It was therefore agreed with this GP that it would be appropriate to include within the recruitment pack a PHQ-9 questionnaire to be filled in and returned by the patient, along with the rest of the recruitment paperwork, to ensure the patient is still within the criteria of the study. This, the interviewee agreed, would remedy this concern for this recruitment method.

4.11 Limitations

A small sample size was achieved within this phase of the study due to difficulties recruiting local GPs. The study was unable to offer any incentives at the time, monetary or otherwise, and it proved difficult to obtain an appointment to interview the subjects, even when interest was expressed. As with any self-selected sample, there could be bias present leading to, among many other issues, an inflated positivity or knowledge of the topic being investigated. However, the findings of this sample show a relative balance of positive and negative opinions towards LT as a treatment, with no GP expressing a significant stance. Furthermore, although there was clearly some knowledge of how LT worked, it was not beyond that which could be expected from a person from a medical/scientific professional background.

4.12 Conclusion

This chapter goes further to portray the current role of LT in Primary Care, both through the experiences of the GPs, but also in their reported encounters with patients suffering with depression. As mentioned previously, GPs are well placed within primary healthcare with the majority of those with a mental health issue accessing their local surgery for advice and/or treatment.

LT as a treatment for depression symptoms, although generally known to the interviewees, was not recognised with a great level of depth. Most had heard of the therapy in connection to SAD, but had admittedly little to no working experience of the therapy and limited or flawed knowledge of the therapy's scientific basis, details of the treatment or the clinical evidence to support its use. Interviewees were cautiously optimistic in their expectations of LT's effectiveness in the treatment of depression symptoms, but again, appeared more certain when thought of in the context of use in seasonally driven depression. The GPs concern for the safety of this treatment was low, with the few concerning side effects that were raised being unfounded. There was a clear desire for something new or additional to offer patients with persistent depression symptoms, with LT being accepted as a potential treatment to fulfil this need. However, contrary to the focus group members, the GPs were more reserved in their optimism due to the underwhelming amount of evidence finding its way to the GPs. Moreover, the means of administering LT, through the LT device, led the GPs to be concerned of the resulting compliance. It is perhaps these issues that have resulted in a lack of access to LT in Primary Care, however, GPs felt that there would be a place for LT within the treatment guidelines for depression, pending further evidence. This chapter's findings confirms the aforementioned deficit of relevant Primary Care clinical evidence to support the use of LT in the management of depression.

Within this chapter the feedback from GPs regarding a proposed pilot trial design, presented within the latter section of the interview, is also discussed with a view to examine and, ultimately, optimise its feasibility. Although research experience was not high among the interviewees recruited, the GPs were certainly well placed to be able to advise on the recruitment strategies that were centred around the GP surgery. The interviewees surmised that recruitment through the surgery would be appropriate for the sample size and inclusion criteria anticipated. It was advised that mild and mild to moderate scoring patients should be included in the trial, as this is where GPs felt LT would be most helpful within their own practice and experience of treating depression. Furthermore, the perception that there may be confidentiality issues pertaining to specific recruitment practices were voiced, both by the focus group members and GPs. The GPs strongly advised that the direct involvement of a GP in recruitment would prove advantageous, in particular in allaying concerns surrounding the perceived confidentiality issues. Overall, the GPs expressed their confidence and approval of the proposed plans following this advice.

CHAPTER FIVE

Light Therapy Exploratory Trial Protocol

5.1 Protocol

Title of Project:

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Name of Researcher (s): Jacqueline Walsh, Dr Sarah Corlett, Dr Gurprit Lall

Background to the study:

Depression is a debilitating and recurrent disease that affects up to a fifth of the UK population between the ages of 16-64 (The Health and Social Care Information Centre, 2007). Currently the most common interventions are pharmacological agents and psychological treatments as recommended by national guidance (NICE 2004, amended 2009). Antidepressant medication has become the prevailing method of treatment; however Cognitive Behavioural Therapy (CBT) has also been shown to be effective. CBT is a form of short-term psychological support, which includes problem solving therapy, counselling and behavioural therapy. CBT is recommended for all severities of depression. However, its benefits are limited by waiting times for appointments, typically around 9 months, if available at all (Mukuria et al., 2013; London School of Economics and Political Science, 2006). First line pharmacological treatments in depression, as recommended by NICE, typically involve the prescription of selective serotonin re-uptake inhibitors (SSRI). These drugs are considered appropriate for moderate to severe depression; however commonly cause serious adverse effects. SSRIs have a slow onset of action consisting of two to eight weeks, or greater, in achieving detectable therapeutic response.

Recent advances in the field of circadian neurobiology have shown that the environmental day night cycle plays a key role in stabilising mood via regulating our internal physiology. This is achieved through the entrainment of a circadian pacemaker located within the brain. This 'clock' relies heavily on the ability of the eye in interpreting sunlight and consequently synchronising our physiological processes to the day and night. Alterations in such rhythmic profiles can contribute to symptoms associated with depression such as difficulty sleeping. The links between circadian disruption due to deficits in light synchronisation and characteristic symptoms of depression, sleep disturbance/fatigue, are extremely strong (Germain and Kupfer, 2008). Taken together, it is highly

likely that impairment of light input to the clock drives some of the symptoms of depression in many sufferers.

LT has gained recognition over the last 25 years as a potent non-pharmacological treatment for SAD and is now established as the treatment of choice for this condition (Terman and Terman, 2005). Recently the use of LT has progressed beyond SAD, and has been shown to be effective in a range of disorders. It is evident that, at optimal intensity and duration, LT has a profound antidepressant effect associated with resynchronisation of the biological clock (Tuunainen et al., 2004). There has been a wealth of emerging evidence endorsing the promising outputs resulting from LT use in non-seasonal trials demonstrating that LT is both effective and safe. Trials utilising LT have yielded effect sizes equivalent to those in antidepressant pharmacotherapy trials (Golden et al., 2005). Response to treatment was rapid with depression questionnaire scores, generic tools to measure response to depression therapies, falling in as little as one week (Tuunainen et al., 2004; Kripke, 1998). The Cochrane review of LT in non-seasonal depression (2004), noted that the majority of studies are based in the highly controlled settings of hospitals and long-term care facilities. LT is therefore not currently identified as a routine non-pharmacological therapy under the current NICE guidance for non-seasonal depression (NICE 2004, amended 2009). There is a need to determine the effectiveness of LT in a primary care setting.

The design of this exploratory trial was developed in line with guidance by the Medical Research Council, *Developing and evaluating complex interventions: new guidance* (MRC, 2008) and the guidance pertaining to feasibility and pilot studies as outlined by National Institute of Health Research (NIHR, n.d.). We aim to establish the effectiveness and feasibility of a LT intervention for mild to moderate depression in a primary care setting. We wish to explore whether this intervention is effective in everyday practice and whether variability between the characteristics of the participants, such as their biochemistry, degree of seasonality, awareness, attitudes towards and motivation to use LT, influence the likelihood of achieving benefit.

The efficacy of LT when used by mild to moderate, non-seasonally depressed patients in their own homes has not previously been determined. The trial therefore aims to measure the effectiveness, presented as a reduction in depression score, in the target population and environment.

Due to the relationship between circadian synchronisation and mood we will measure the participants' biochemistry and explore the relationship between their melatonin and cortisol saliva

concentrations and the observed response. The behaviours of the participants, a typically unmotivated group, may be greatly influenced by LT use. The true impact of LT on these behaviours (activity level and sleep patterns) have not been observed in the controlled studies previously reported for this population, and will therefore also be measured within this study.

We will explore participants' expectations and awareness of LT, and their self-efficacy and social support, to determine the impact these variables have on participant adherence to the intervention. A previous study conducted in America, in members of the public who had experience of depression and had or had not used LT, concluded that self-efficacy and social support were significant determinants of LT use (Roeklein et al., 2012). Adherence to the study protocol will be determined directly using actigraphy and diaries, furthering the examination of the feasibility of LT. The feasibility of using LT in a patient's home will therefore be determined.

The economic burden of common mental illnesses in the UK is a growing concern. The importance of determining the cost associated with an intervention with its potential extent of health gain, is prudent. Quality-adjusted life-year (QALY) combines these components to provide a "common currency" that can be used to assess an intervention's value from an economic perspective (Phillips, 2009). This study aims to calculate this health economic unit, for four weeks use of LT, through the use of a validated quality of life questionnaire.

The suitability of study design, including participant recruitment to the study will also be explored using two different recruitment strategies; via the general practitioner or self-help/depression support groups. Participant retention within the study and study power will be determined following completion of the exploratory trial.

The MRC guidance also proposes the value of primary qualitative research. A preliminary qualitative project to explore the awareness of, attitudes towards and expectations of LT as a prospective treatment of depression through focus group and interview techniques has been carried out with service users (n=13) and General Practitioners (n=5). The data collected was analysed using framework analysis. This previous project has provided valuable insight in relation to the underlying assumptions and beliefs regarding LT and has helped strengthen the design aspects of this proposed study. Specifically the findings of the focus groups with service users informed the recruitment methods chosen, confirmed the validity of the placebo in terms of appropriate blinding and highlighted the possible influence of offered incentives to adherence to treatment. Participating GPs

advised on the feasibility of both the recruitment methods and the target population proposed considering their experience of primary care GP surgeries. We plan to interview participants who have completed the exploratory trial, in a similar manner, to explore their views and experiences of using LT.

This study will allow appraisal of the effectiveness and feasibility of LT in a primary care setting for mild to moderate depression. It will provide evidence that will be used to shape the design of a future large scale randomised controlled trial, subject to securing the necessary funding.

Aim and objectives:

Aim:

To investigate the feasibility and effectiveness of LT in the treatment of individuals suffering from mild to moderate depression in primary care.

Objectives:

- To conduct an exploratory two-arm, double-blind, randomised controlled trial comparing active LT intervention with an appropriate control LT treatment for people suffering with mild to moderate depression in a primary care setting.
- To measure the participants' depression score in response to active or control LT intervention, and with one week standard care post-intervention, by means of validated depression scoring questionnaires used weekly throughout the trial.
- To examine how the degree of seasonality of participant depression symptoms, as determined by the Seasonal Pattern Assessment Questionnaire (SPAQ), impact the measured response to active or control LT intervention.
- To determine if melatonin and cortisol concentrations, as measured by salivary sampling, can be used as an indicator to predict a positive response to LT.
- To monitor participants' behavioural rhythms at baseline, during intervention and post-treatment to determine the impact LT has on the activity and sleep patterns/quality of the participants, as measured via actigraphy technique.
- To investigate the feasibility of LT as a prospective treatment for depression in primary care by examining recruitment to the trial, adherence to therapy by means of diary and actigraphy data, and adverse effects as collected by a validated questionnaire at weekly assessments.

- To explore participants' experience of the trial and reveal their perception of the acceptability and effectiveness of LT following the study utilising semi-structured interviews.
- To compare health related quality of life, via validated questionnaire, at baseline and at completion of the LT intervention in order to ultimately calculate the economic benefit of LT as a potential treatment.
- To evaluate the suitability of the methodologies employed within the exploratory trial for use in a future larger/full-scale randomised controlled trial.

Methodology:

Ethical Approval

National Research Ethics Service approval is being sought for this project. NRES approval is required due to the recruitment and inclusion of NHS patients as participants in this study. The study also involves the collection, storage and analysis of saliva samples, for the purpose of examining the concentrations of melatonin and cortisol, from participants within the trial. The University of Kent does not hold a Human Tissue Licence, and therefore the study must be reviewed by a recognised body. NRES is considered to be the appropriate recognised body.

Setting

Recruitment of participants for this project will take place from GP practices in Kent or via direct advertisement of the study to mental health self-help groups.

Face-to-face assessments will be conducted within a consultation room of the general practice where the participant was recruited from, or within a private meeting room within Universities at Medway campus.

General method

This study is a six week exploratory double-blind two-arm randomised-controlled trial. The trial consists of a baseline week of monitored standard care, four weeks of monitored active or control intervention additional to their standard care, followed by a final week of monitored standard care. One follow-up telephone interview and a short 6 month follow-up questionnaire will be used to gather participant experience of LT following the study. The trial will take place over the course of a year.

Participant inclusion and exclusion criteria

Inclusion and exclusion criteria have been chosen to attempt to represent a true depiction of primary care population, whilst ensuring that safety of the patient is taken into account.

Inclusion Criteria:

1. Aged 18 - 64 years (Age range cut off in order to limit variation of response to treatment. There is a documented decline in photoreception in the elderly as seen in Turner and Mainster, 2008).
2. Current diagnosis of mild-moderate depression defined via a PHQ-9 score of 5 to 14.
3. Ability to provide informed consent for randomisation, treatment and follow up, including a good command of the English language.
4. Ability to access their general practice surgery / University campus at Medway for assessment.

Exclusion Criteria:

1. Pregnant/planning pregnancy or breastfeeding.
2. Alterations to participant antidepressant treatment, including medication and counselling/talk therapy, in the previous four weeks of trial commencement or during the trial.
3. Current treatment with antipsychotic drugs.
4. Previous use of LT, including use of light boxes, light visors and dawn simulation lamps. This does not include the use of SAD alarm clocks.
5. History of or current substance/drug abuse.
6. History or current diagnosis of; psychosis, severe depression, bipolar disorder, Parkinson's, dementia or Alzheimer's disease.
7. A history of light-induced migraine or epilepsy.
8. A history of traumatic brain injury (TBI).
9. Presence of ocular disorders including retinal blindness, cataract, retinal diseases of the eye and glaucoma.
10. Current oral diseases, such as candidiasis, or inflammation or lesions within the mouth.
11. Is currently or has recently been involved in any research prior to this study.

Participant recruitment procedures

The study will utilise two methods of recruitment in an attempt to optimise participation in this exploratory trial, and furthermore to reveal which method will be appropriate for a future full-scale randomised controlled trial. No incentives will be provided for participation.

Recruitment Method One:

A convenience sample of general practices was chosen due to the participation of one of the doctors from each practice in an earlier qualitative study. This explored the general practitioners (GP's) awareness, expectations of and views on LT as a potential treatment for depression in primary care. Through this preliminary qualitative study, the GPs also had the opportunity to comment on the feasibility and appropriateness of the design of this study.

GPs will be given an information leaflet (Section 5.2) explaining the purpose of the trial and their role in the recruitment of participants. Those who agree to take part in this study will be supplied with recruitment packs. The packs contain the following documents:

- a letter of invitation to the study (Section 5.3)
- a participant information leaflet informing the participant of the purpose of the study, what their participation will involve and any risks and benefits associated with taking part (Section 5.4)
- a screening form (Section 5.5)
- a personal information form (Section 5.6)
- a consent form (Section 5.7)
- a Patient Health Questionnaire 9 (PHQ-9) (Appendix 23) to assess participant depression score.

The GPs will identify those individuals who may be eligible to participate during routine consultations and provide them with a recruitment pack. Contact details of the research team will be supplied within the pack. Potential participants will be advised to contact the research team if they have any further questions or queries. Included in the participant information leaflet are the contact details of a researcher independent to the study. This researcher is happy to discuss research study participation if required. Interested participants will complete the relevant paperwork and return these directly to the research team using a prepaid envelope provided. The GPs recruiting through this method will be informed, via a letter (Section 5.9), if any of their patients participate in this study.

Recruitment Method Two:

An announcement of the project and invitations to participate will be distributed via e-mail to local mental health charities and depression self-help/peer support groups (Section 5.8). These charities and groups will be initially identified using national and local mental health support websites, using the contact details advertised for each group/charity, including Depression Alliance, Mind, Depression UK, Students against depression, and Live it well. A snowballing technique will be utilised in the case where further groups or charities are identified through these organisations. Social media including facebook and twitter may be used where an organisation has an active account, and they agree to share the study advert with their members.

Individuals or groups who express interest will be sent the recruitment pack as described above, with some forms altered to reflect this method of recruitment (method 2) (Appendices 19-22) by post. For participants recruited via this method, the participants' General Practitioner will be informed via a letter of their inclusion in the trial (Appendix 22) and will receive a copy of the participant information leaflet (Appendix 20). Details regarding how to contact the research team will also be provided as described in recruitment method one.

For both methods, the individual will be asked to read the invitation letter and participant information leaflet. They will then be asked to complete and return the screening form, personal information form, the PHQ-9 questionnaire and consent form. Participants that have completed all of the recruitment pack forms, and have met the inclusion criteria, will be contacted via telephone or email to arrange the introductory assessment. Their preferred method of contact with the research team will be specified on the submitted personal information form.

The screening form has been designed to enable the participant to self-assess their eligibility for participation in this study (Sections 5.5). However in the case that a participant returns a screening form who has not met the study criteria, the research team will contact them to explain why they are not eligible for the study, recommend they to speak to their GP if they require further advice regarding their symptoms and to reassure them that that any material or data collected from them will be shredded or deleted.

Sample Number

This is an exploratory trial, therefore, as explained within NIHR guidance for feasibility studies (NIHR n.d.), the results of this study will be used to inform the design and power calculation of a future full-scale RCT. Although we are not aware of any existing studies that incorporate placebo-controlled light intervention, actigraphy and hormone analysis as proposed in this protocol in a primary care setting, a sample size calculation has been performed on a placebo-controlled LT study. With 80% power and 5% two-sided alpha, 80 recruited participants would be required for each treatment group. Considering the resources available to the project, this number is unachievable and inappropriate for a feasibility study. It has been estimated that approximately 20 participants in each treatment group would be sufficient to measure the outcomes defined the study objectives. Considering the characteristic lack of motivation within the target population, we anticipate a difficult recruitment process and a number of participants withdrawing during the trial. A systematic review of pharmacotherapy trials in depressed adults report 20-40% drop-out rates (Williams et al., 2000). Assuming an approximate 30% loss to follow-up, we therefore aim to recruit 30 participants to each arm of the study, totalling 60 participants to recruit for this study.

Informed consent

In both recruitment methods, each participant will be provided with a participant information leaflet, and a consent form. The participation information leaflet includes a summary of the study, and explains the potential risks and benefits to the volunteer of participating. Contact details of the research team are provided on the participant information leaflet. The signed consent form must be received by the research team before the participant can be entered into the study. There will be a period of at least 7 days between receiving written consent and the introductory assessment meeting. Verbal consent will be re-affirmed at the introductory assessment and each weekly assessment of the trial to confirm the participant is satisfied to continue in the trial.

Instruments to be used

a) Instruments to be used: Questionnaires

The questionnaires used within this study are, where possible, standard tools which are used routinely in clinical practice/ research. Each questionnaire is listed and explained below. Copies of the questionnaires to be used can be found in Appendix 23.

i. *Structured Interview Guide for the Hamilton Depression Rating Scale – Seasonal Affective Disorder version Self-rating scale (SIGH-SAD-SR)*

This 29 item questionnaire is used when assessment of both typical and atypical depression symptoms is needed and is often used in both seasonal and non-seasonal studies to measure clinical response outcomes of LT (Williams, 2001).

ii. *Patient Health Questionnaire (PHQ-9)*

The Patient Health Questionnaire is a 9 item self-administered questionnaire that has been validated for use in primary care to monitor the severity of a patient's depression, and their response to treatment (Kroenke et al., 2010). The PHQ-9 will also be used at recruitment as a screening tool to identify the participants' depression severity. We have chosen this questionnaire as our screening tool due to the fact that GPs have access to this tool, and both GPs and participants are familiar with this questionnaire as it is currently used in primary care.

iii. *Seasonal Pattern Assessment Questionnaire (SPAQ)*

The Seasonal Pattern Assessment Questionnaire is a simple and brief 5–10 minute self-administered questionnaire that retrospectively assesses the magnitude of seasonal changes an individual experiences in their sleep, social activity, mood, weight, appetite and energy. The SPAQ is used to cover degree of seasonality and to calculate the global seasonality score (GSS). The questionnaire used will be a modified version of the SPAQ first devised by Rosenthal et al. in 1984.

iv. *Expectancy questionnaires (Pre and Post study)*

These self-administered questionnaires developed from the literature and validated by the research team, will be used to assess the participants' awareness of, attitude towards and expectations regarding LT as a treatment for their symptoms. The pre-study questionnaire will be administered at baseline and the post-study questionnaire at the end of week 4 after completion of the four week light intervention. This will allow researchers to assess the appropriateness of the control used in the trial. The expectation questionnaire contains sections regarding self-efficacy and social support; two factors which have shown to be potential key determinants of adherence to LT in a previous study (Roeklein et al., 2012) permitting further understanding of adherence to the light treatment in this trial.

v. *Short Form 36 (SF-36)*

This is a self-administered 36 item questionnaire that assesses 8 domains relating to the patients' health relating to quality of life. This will be administered at baseline and on completion of the four weeks of LT intervention. The data collated from this questionnaire can be used in order to calculate quality-adjusted life-year (QALY) combined with the cost of providing an intervention. This result indicates additional costs required to generate a year of perfect health (one QALY). These measurements will give an indication of the economic benefits of recommending LT in primary care practice (Mukuria et al., 2013)

The SIGH-SAD and PHQ-9 questionnaires will be repeated weekly following baseline week to monitor the participants' response to the intervention.

The SPAQ, SF-36 and expectation questionnaire will be completed at the introductory assessment. Both the SF-36 and expectation questionnaire will be repeated at the end of week 4 following four weeks of receiving the intervention.

A further questionnaire, the SAFTEE-SR (Systematic Assessment for Treatment Emergent Effects) questionnaire will be used each week of the four week intervention, for the self-report of adverse and side-effects resulting from active or control therapy use. This form has been altered to include common ocular effects reported as a result of LT use in the literature including eye irritation and impaired vision (Wirz-Justice et al., 2012).

b) Instruments to be used - Actigraphy

Participants will be asked to wear Actiwatches for the duration of the study. The Actiwatch records behavioural activity profiles by continually monitoring the participants' movement. The activity is plotted against the time of day in order to produce an actogram. It is worn for the duration of the six week trial, both day and night, in order to produce a robust behavioural activity profile of the subject. The participants will be given the watches with instructions on its use before the baseline week commences at the introductory assessment. The Actiwatches are designed to look like normal sports watches and can be worn throughout normal day to day activities.

The Actiwatch is equipped with light sensors that provide irradiance and lux recordings in three colour bands of the visible spectrum: red, green, and blue.

Participants will be asked to complete a diary relating to their activity on a day to day basis in order to verify the actograms produced using the Actiwatches. For details regarding the diaries, please see below.

c) Instruments to be used – Diaries

Participants will be asked to complete a diary relating to their sleep pattern (bedtime, get-up times after final awakening, and times and durations of napping) and time of LT equipment onset and offset of use. The diary has been developed from similar tools available which were identified from literature (National Sleep Foundation, 2014) will be completed by the participant every day of the six week trial. These data will be used to support the data collected by the Actiwatches. The diaries will also prompt the participant to record their alcohol consumption (in units) and their weekly level of physical activity adapted from the International Physical Activity Questionnaire short form (IPAQ, 2005). These factors are recorded as they may compromise the validity of the measured mood score. The template of the diary is shown in Section 5.11.

Biochemical Measurements

Salivary Sample Measurements

Melatonin and cortisol concentrations will be measured by means of saliva samples. All participants will be asked to produce saliva samples at two time points during the trial: at the end of the baseline week and at the end of week 4, following four weeks of the intervention. On the evening of the final day of baseline week and week 4, participants will be asked to produce one sample per hour until anticipated bedtime, starting 4 hours before bedtime under dim light condition (<50 lux).

Participants will be advised to remain in the dim light condition for the 4 hour prior to bedtime and only partake in minimal activity. Reading, listening to music, conversations (both face-to-face and on telephones) and watching a television at a distance will be permitted. The following morning, on the final day of baseline/intervention week, the participant will be asked to produce one sample every half an hour, for two hours starting upon awakening, totalling 4 samples (Lieverse et al., 2011). The light sensor integrated into the Actiwatch™ will allow researcher to assess the compliance of the participant to the dim light conditions and validate the samples collected.

The saliva samples will be collected at the face-to-face assessment and returned to the University and be frozen at -80°C until analysed. The participants will be advised not to eat, drink, chew gum or

brush teeth for 30 minutes before sampling. If they do any of these activities within this timeframe, they must rinse their mouth thoroughly with cold water 5 minutes prior to sampling.

Participants will be given labelled bottles for collection of saliva samples. These will be labelled with the study name, participant number, date and anticipated time of collection. Participants will be asked to record the actual time of the sample collection on the vials. Participants will be asked to store the samples in the fridge prior to collection. The postgraduate researcher will offer participants a reminder text message service; a text message on the day that the participant must start collecting their saliva samples. This will be offered and noted at the introductory assessment.

Interventions

Intervention – Baseline Week Assessments

Introductory assessment

All participants will undergo an introductory assessment. Assessments, unless otherwise stated below, will be carried out by the postgraduate researcher face-to-face in a consulting room at the General Practice they were recruited from, or, for those participants recruited via self-help groups, at a meeting room at the Universities at Medway Campus.

- Introductory assessment: Will commence on the first day of the trial. The meeting will take approximately one hour and will consist of:
 - Reiteration of the information provided to them regarding the specifics of the trial provided in the recruitment pack.
 - Confirmation that the information provided on their screening form is still valid as the participant enters the trial. Participants will be asked to alert the postgraduate researcher if their response to any of these screening questions changes for the duration of the trial.
 - Completion of the following questionnaires: PHQ-9, SPAQ, SF-36 and an pre-study expectation questionnaire.
 - An introduction to and guidance on the use of the Actiwatch™, diary and salivary sampling equipment. Participants will be offered a text message reminder on the days that they must start collection of saliva samples, and/or the day before an assessment appointment.

- An opportunity to ask any questions they may have regarding the trial to the postgraduate researcher.

Baseline assessment

This assessment will take place at the end of baseline week. The meeting will take approximately thirty minutes and will consist of:

- Collection of the saliva samples from the participant.
- Completion of the following questionnaires: PHQ-9 and SIGH-SAD questionnaires.
- The participant will be provided with and advised on the use of the light box equipment. The participant will be reminded that they must not discuss the colour of the light with the postgraduate researcher.
- Participants will receive further saliva sample bottles to be used at the end of week 4.
- Participants will receive 3 envelopes marked weeks 1-3. These contain the questionnaires which will need to be completed at the end of each week. Pre-paid envelopes addressed to the University will also be provided to return the completed questionnaires to the research team.

Intervention - Randomisation

Participants will be randomised to one of two arms of the trial; active or placebo treatment of LT. Allocation of participants will be carried out using Graphpad online computer programme (Suresh, 2011), generated by the senior members of the research team. However this allocation will be concealed from the postgraduate researcher who alone will carry out assessment, data collection and data analysis throughout the duration of the trial. This will maintain blinding of the study.

Intervention - Follow-up

Follow-up data collection will be scheduled at the end of each week of the trial, totalling five follow-up assessments. Assessments will be carried out by the postgraduate researcher face-to-face at the General Practice they were recruited from, or at Universities at Medway campus (week 4 and post-intervention week). Weeks 1-3 will be carried out over the telephone.

- Week 1-3 Assessment (telephone): These assessments will take approximately 10 minutes to complete.
 - Participants will be prompted to complete the PHQ-9, SIGH-SAD and SAFTEE questionnaires, and return them to the research team using the pre-paid envelope provided.
- Week 4 Assessment (face-to-face): This assessment will mark the end of the four intervention weeks. This assessment will take approximately 30 minutes.
 - Participants will be asked to return the light box equipment and saliva samples that have been collected.
 - Participants will be asked to complete the PHQ-9, SIGH-SAD, SF-36, SAFTEE and the post-study expectation questionnaire.
- Post-Intervention Week Assessment (Face-to-face): this is the final assessment of the trial. This assessment will take approximately 30 minutes.
 - Participants will be asked to return their Actiwatch and diaries.
 - Participants will be asked to complete the PHQ-9 and SIGH-SAD questionnaire.
 - Participants will be invited to make an appointment for their follow up interview regarding their experience of participating in the trial and using LT.

Intervention – Participant Post-trial Interview

Following participation in the trial, the participants will be invited to be interviewed by the postgraduate researcher via telephone. The interview will be approximately 20-30 minutes long. The proposed semi-structured interview schedule is shown in Section 5.10. Themes to explore have been defined by the literature and data collected from the qualitative study which was carried out previous to the trial commencement. The interviewer will examine the participants' experience of the trial and explore their perception of the feasibility, acceptability and effectiveness of LT following the study.

Intervention – 6 month follow-up questionnaire

Participants will be sent a short 6 month follow-up questionnaire regarding their use of LT following the study (Section 5.12). This will be sent to them via post with a pre-paid envelope addressed to the University. In the case that a response is not received, the postgraduate researcher will send a reminder by their preferred means of contact as specified on their personal information form.

Intervention – LT

Participants will receive a LT box, (active or placebo), at the end of the baseline week. The four week's use of LT will be additional to the participant's standard care. The participants' current treatment will not be compromised or altered in any way during the intervention weeks. Both the postgraduate researcher and participant will be blinded to the allocation. The participant will be verbally instructed to use the LT equipment for 30 minutes each day for the next four weeks; this must be within ten minutes of waking and before midday. These instructions will be the same for both active and placebo group participants. The participants will be asked not to discuss the nature of their treatment with the postgraduate researcher or anyone else, in order to maintain the blinding of the trial.

LT – Active Group

Patients randomised into the active treatment arm of the trial at the end of baseline week will receive, from the postgraduate researcher, a standard active light box. The LT box will generate white light at an intensity of 10,000 lux.

LT – Placebo Group

Patients randomised into the control treatment arm of the trial at the end of baseline week will receive, from the postgraduate researcher, a light box which has been altered by the research team. Neutral density (ND) of 2ND and a colour filter (far red) will be fitted to the light box in order to create a placebo intervention. The altered LT box will generate dim red LT of <100 lux.

Adherence to LT will be monitored using the Actiwatches, which detect and record the intensity and wavelengths of light the participants are exposed to during the trial. Adherence will also be monitored by analysis of the diaries which will be completed daily by each participant. Details of these can be found under the 'Instruments to be used' section of this protocol.

Outcome measures

Proposed Outcome Measures:

The primary outcome measurement is defined as response to treatment at four weeks of the intervention as compared to baseline, measured by the Structured Interview Guide for the Hamilton Depression Rating Scale – Seasonal Affective Disorder version Self-rated (SIGH-SAD-SR).

The resulting SIGH-SAD score will be treated in two ways. A total SIGH-SAD-SR score of less than or equal to 50% of the baseline total score will be used to define “response”. A total SIGH-SAD-SR score less than or equal to 50% of the baseline total score, and a total score of less than or equal to 8 will be used to define “remission”. These parameters provide a quantitative measurement of improvement and estimate participant recovery.

Secondary Outcome Measures:

- I. Response to intervention defined by a change in depression score as measured by the Patient Health Questionnaire 9 (PHQ-9), an established primary care depression assessment tool. This measurement will be used to investigate the suitability of this questionnaire to measure response of a patient using LT in primary care, by comparing with SIGH-SAD-SR scores which are collected concurrently.
- II. Measurement and comparison of total weekly SIGH-SAD-SR scores of the active and control intervention arms, collected from weeks 1 to 4 of the trial, as compared to baseline SIGH-SAD-SR score.
- III. To investigate the relationship between the global seasonality score (GSS), collected for each participant at baseline by the SPAQ, and the difference between the total SIGH-SAD-SR score measured at baseline and after 4 weeks of the intervention.
- IV. Comparison of the phase angle between time to peak of cortisol concentration and dim-light melatonin onset (DLMO), between participants who responded and did not respond to active LT intervention. DLMO will be determined through analysis of the evening saliva samples. It is defined as the interpolated clock time at which melatonin concentration reaches 20pg/ml.
- V. Comparison of active and control intervention groups’ behavioural activity profiles (actigraphy) by analysing duration of sleep, sleep efficiency (percentage of actual sleep between sleep onset and final awakening) and sleep onset latency in response to intervention, and one week post-intervention.
- VI. The feasibility of using LT in patients’ own homes will be evaluated using the adherence data gathered by Actiwatch data, participant diary entries, and post-trial semi-structured interviews. The relationship between self-efficacy and social support, two factors which

have shown to be potential key determinants of adherence to LT in a previous study (Roecklein et al., 2012) will be explored through the expectation questionnaires.

- VII. Health related quality of life using the SF-36 pre and post intervention. The data collated from this questionnaire can be used in order to calculate quality-adjusted life-year (QALY) combined with the cost of providing an intervention. This results in the additional costs required to generate a year of perfect health (one QALY). These measurements will give an indication of the economic benefits of recommending LT in primary care practice
- VIII. Suitability of the methodologies employed within the exploratory trial, for use in a future larger/full-scale randomised controlled trial, will be evaluated by comparing recruitment methods, observing retention rates, testing procedures, calculation of appropriate sample sizes, and through qualitative interviews with the participants on completion of the trial.

Methods for data analysis

Differences between the two groups for continuous data will be assessed using Student's *t*-test for normally distributed data, or Mann-Whitney U test for non-parametric data. Categorical data will be compared using Pearson's X^2 test. Treatment effect analysis will be conducted on an intention-to-treat basis. The primary outcome, SIGH-SAD-SR score after four weeks of intervention (week 4), will be presented as the difference in mean score between the intervention and control groups. Response and remission outcomes will be presented as a ratio of the intervention as compared to control group. Analysis of covariance ANCOVA will be used in order to combine seasonality data collected with response to intervention. A secondary repeated-measures ANCOVA will be used to investigate differences between groups in total score over time (weeks 1-4 of intervention). These will be carried out using SPSS (V21) statistical package (SPSS Inc, Chicago, USA).

Dim light melatonin onset (DLMO) will be determined through analysis of the evening saliva samples. DLMO is defined as the interpolated clock time at which melatonin concentration reaches 20pg/ml. Morning saliva samples will be used to identify cortisol peak. The phase angle is the time period between DLMO-20 and cortisol peak (Buckley and Schatzberg, 2011). A Mann-Whitney test will be used to compare the phase angle, the time period between each of these markers, between the intervention and the control groups.

Quantitative data collected from the Actiwatches™ using the Actiwatch™ software (ActiWare™), supported by participant diary, will be entered into SPSS to compare baseline, intervention and post-treatment weeks for both the active and placebo groups. Parameters that will be analysed include duration of sleep, sleep efficiency (percentage of actual sleep between sleep onset and final awakening) and sleep onset latency.

Semi-structured interviews:

Qualitative data from the post-trial semi-structured interviews will be digitally recorded, transcribed verbatim and analysed using content analysis (deductive approach). These will be conducted either face-to-face or via telephone. The processes will comprise of four main phases: preparation/familiarisation of the transcripts, identification of codes, organisation of categories and reporting. Qualitative software, NVivo (QSR International, London, UK), will be used to facilitate the analysis of this data.

Risk analysis

i. Failure to recruit sufficient participants

Failure to sufficiently power studies within mental health is a recognised problem due to the highly unmotivated nature of the population targeted. However, depression is a common morbidity within the general population. The estimated prevalence of depression is reported as 10% of the adult population of the UK (Office for National Statistics, 2001). The average GP practice in England has an average of over 6000 patients (King's Fund, 2009). We anticipate that this study will be carried out in collaboration with three GP practices which should ensure that it is viable to recruit at least 60 participants. Recruitment will also be carried out online via self-help groups.

ii. Adherence to therapy

Adherence to therapy is a common problem within most disease states. It is accepted that using 30 minutes of LT daily could be a challenge for an unmotivated patient. Adherence will be monitored using the sleep log diaries and the spectrum recording of the Actiwatches that the participants will be required to wear. The patients will be guided on what activities can be carried out during LT in order to encourage compliance with this treatment.

iii. Failure to achieve follow-up

The follow-up period consists of the six months following the end of the 4 week intervention treatment.. The six month follow-up questionnaire has been designed to be short and easy to complete. The researcher will also send a reminder, in the case that a response is not received, in order to attempt to secure this follow-up intervention.

iv. Deterioration of participant mental health

In the case that a participant's PHQ-9 depression score deteriorates beyond the range defined by the inclusion criteria during the trial, action will be taken by the research team. In the case that a participant displays symptoms of more severe depression, the research team will encourage the participant to make an appointment to see their GP. The research team will contact the participant's GP, as stated on their personal information form, to inform them of the patient's status (Section 5.13).

v. Participant general mental wellness

In the case where a participant's PHQ-9 score has not deteriorated beyond the range of the inclusion criteria but they have shown signs to the research team that their general mental wellness has deteriorated during the course of the study, the participant will be encouraged to attend their GP to be reviewed urgently.

vi. Accidental revelation of participants group status

Participants will be advised at the baseline assessment the importance of blinding for the duration of the trial. The participant will be advised not to discuss the colour of their LT with anyone. If a participant accidentally reveals their group status to the postgraduate researcher, they will be reassigned to another researcher in the team who has been blinded to the randomisation of the participants.

vii. Malfunction of equipment

In the case of malfunction of equipment supplied by research team (Actiwatch, light box equipment) the participant will be advised that they should contact the research team, using the contact details provided, as soon as possible. The research team will then attempt to repair or swap the faulty equipment as soon as possible.

Confidentiality and anonymity:

All researchers will maintain confidentiality of all data, including potential and actual participant identities, their questionnaire responses, diary, actigraphy and laboratory results. Personal and trial data (hard copy) will be stored in a secure filing cabinet in Universities at Medway Campus to which only the research team will have access. The randomisation list will be stored in a sealed envelope to ensure that all members of the research team can access this information in an emergency if required to do so. All contact details and completed screening forms for those individuals who expressed interest but who were not eligible for the trial, if applicable, will be destroyed immediately after they have been informed of this by letter/email. Contact details of participants who have participated in the trial will have their contact details destroyed one year after the trial is completed, unless they have expressed that they wish to be contacted with a report on the findings of the trial. In this case their contact details will be held in a secure manner, as described above, until the report has been shared with them.

All interview transcripts will be anonymised using a study code. Each General Practice will be assigned a corresponding study code in order to remain anonymous. Audio-recordings, transcripts and computer-aided analysis files will be stored electronically on a password-protected university computer system or in a secure filing cabinet.

All research data is kept for five years post final publications.

Dissemination strategy:

The results of this study will be reported as part of a Master's of Philosophy thesis. The findings from the data collected and analysis completed by the researchers will be presented at relevant conferences and/or submitted as paper for publication in peer-reviewed journals.

Participants and GP practices included within the trial will be offered a copy of the project report on the findings, which will be produced on completion of the trial.

GENERAL PRACTITIONER INFORMATION LEAFLET

Title of Project: Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Name of Researcher (s): Jacqueline Walsh, Dr Sarah Corlett, Dr Gurprit Lall

You are being invited to take part in the recruitment process of this study. The purpose of this document is to explain why the study is being done and what your role in recruitment for this study would involve. Please take time to read the following information. Ask if anything is not clear or if you would like more information.

Why is the study being done?

The purpose of this study is to investigate the effectiveness and feasibility of light therapy use in the management of mild to moderate depression in a primary care setting. Through this six week exploratory trial, we aim to measure the antidepressant effect of light therapy by using validated depression questionnaires. In addition, we will study the effect of light therapy on sleep through activity monitoring. We will also determine whether hormone levels measured in saliva samples can be used to predict response to light therapy. We would also like to evaluate how usable light therapy is by asking participants to keep a diary, and by discussing their experience of the trial in an interview with the researchers.

The findings of this study will be used to inform the design of a future, larger randomised controlled trial.

As a General Practitioner, what would I have to do?

We ask that you give recruitment packs to patients you have reviewed who you think would be eligible for the study and may be interested in participating. We ask you to do this during a 'normal' consultation. We are not asking you to specifically meet the patients for the purposes of recruitment to the study.

The inclusion criteria for this study are:

1. Aged 18 - 64 years
2. Current diagnosis of mild-moderate depression defined by a PHQ-9 score of 5 to 14. (We are interested in anyone who you assess clinically as having mild to moderate depression. If the patient reads the study information and decides that they would like to participate then we will ask them at that time to complete a PHQ-9 questionnaire, to confirm that they meet the inclusion criteria of the study).
3. Ability to provide informed consent for randomisation, treatment and follow up, including a good command of the English language.
4. Ability to access the general practice for weekly assessments with the researchers.

The information packs include an invitation letter, a participant information leaflet, a screening form, a consent form, a demographics form and a PHQ-9 questionnaire. The patient should be asked to read the information carefully and consider whether they would like to participate. Completion of the screening form will help the patient to self-assess whether they would be eligible for the study. If they have further questions or queries, the contact details for the research team are provided within the recruitment pack. If the patient decides they would like to participate, and are eligible, they can complete the forms and return them to the University using the pre-paid envelopes provided, or using the contact details in the pack.

Are there any risks if I take part in the recruitment of this study?

Passing the recruitment packs to patients may take time out of their consultation with you. However, this potential time-loss has been limited with the inclusion of the participant information leaflet (PIL). The PIL should answer any questions the patient may have regarding the study, and gives details on how to contact the research team if they have further questions or queries.

Also included within the recruitment pack are the screening form and PHQ-9 questionnaire. These forms allow the patient to self-assess for exclusion criteria and their PHQ-9 score will be calculated by the research team. You will not be required to re-assess the patient. If patients ask you for more information regarding the inclusion requirements for this study, you should refer them to the research pack or advise them to contact the research team.

Are there any benefits if I take part in the recruitment of this study?

There are no personal benefits from participating in this study. We are unable to provide financial incentives for you to participate. However, through your participation in this study you may increase your awareness of clinical research. This study will also provide valuable information to inform the design of a larger randomised controlled trial (RCT). If we are successful in acquiring funding to support a RCT, we would hope that you/ your practice would continue to work with us in this venture.

Will anyone know that I've taken part in the recruitment of this study?

We will not tell anyone that you have taken part in the study. However, the patients you have provided with a recruitment pack will obviously know your involvement with the recruitment of this study.

During the study you will be assigned a study code "GP Code"; this will allow any data associated to your recruitment to be anonymised.

What will happen to the results?

Any public presentations or publications will not contain information that may lead to the identification of practitioners or practices.

The data from this trial will be used to inform the protocol of a large scale randomised controlled trial investigating light therapy for the management of depression.

Who should I contact if I want to know more about the study?

Who should I contact if I have any questions?	Who should I contact if I have any problems?
Jacqueline Walsh Phone: 01634 202920 Mobile: 07840630633 Email: jw586@kent.ac.uk	Dr Sarah Corlett Phone: 01634 888909 Email: S.A.Corlett@kent.ac.uk Dr Gurprit Lall Phone 01634 202946 Email: G.Lall@kent.ac.uk

5.3

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

I am currently recruiting participants for a study to investigate the effectiveness of light therapy in improving mood and treating depression when it is used by people in their own homes. Your General Practitioner has given you this information pack because they thought that you may be interested in participating in this study. However, it is important for you to understand that your doctor is not advising you to join this study. Whether you participate or not is your decision. Either way it will have no effect on your relationship with your doctor or the care you receive. If you are not interested in this study you do not have to respond and no one from the School of Pharmacy will contact you further.

In this information pack there are a number of documents. The participant information leaflet tells you about the study, and what your participation would involve. Reading this document should help you decide if you wish to take part. However, if you need more details or have further questions please do get in touch with me by e-mail (jw586@kent.ac.uk), or telephone on 01634 202920 or 07840630633.

Once you have read the information leaflet, and if you would like to take part, the next thing you need to do is to complete the screening form. This will confirm whether you are eligible for the study. If you are eligible and wish to continue, please complete the personal information form, the mood questionnaire (PHQ-9), and the consent form. Return all of these with the screening form by post in the pre-paid envelope provided.

When I receive your forms I will contact you to arrange our first meeting. Returning the consent form and other documents does not mean that you are committed to take part in this study.

Thank you for your time and consideration. I look forward to hearing from you.

Yours sincerely,

Jacqueline Walsh MRPharmS
PhD Research Student, Medway School of Pharmacy
Universities of Kent and Greenwich
Anson Building
Central Avenue
Chatham Maritime
Kent ME4 4TB

Academic supervisors

Dr Sarah Corlett, Clinical Lecturer, Medway School of Pharmacy
Dr Gurprit Lall, Lecturer in Circadian Biology/ Pharmacology, Medway School of Pharmacy

PARTICIPANT INFORMATION LEAFLET

Title of Project: Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Name of Researcher (s): Jacqueline Walsh (MPharm), Dr Sarah Corlett (BPharm, PhD, ADCPT), Dr Gurprit Lall (BSc, MSc, PhD, PGCHE, FHEA)

Institution: The Medway School of Pharmacy is a unique collaboration between the University of Greenwich and the University of Kent based on a shared campus in Chatham Maritime. Alongside the training of pharmacist, the School is actively involved in research, such as the study below.

You are being invited to take part in a feasibility study. Before you decide if you want to take part, you must understand why the study is being done and what it involves. Please take time to read the following information. Ask if anything is not clear or if you would like to know more.

Why is the feasibility study being done?

Studies in hospitals and clinics have shown that light therapy is effective in treating depression. However, we do not know if the same effect could be obtained when a person uses light therapy in their own home. Therefore we need to test how effective light therapy is in two different groups of participants; one using white light and the other red. For both groups we will measure the effect of light therapy on mood, sleep duration and the levels of two hormones within your body that are known to be associated with mood and sleep, called melatonin and cortisol. The results of this feasibility study will be used to inform and design future research.

Randomisation

We will be putting people that agree to take part into two groups. The groups will be selected by chance, as if by flipping a coin. One will receive white light, and the other red light. It is important that the researcher, and the other study participants, do not know which colour group you have been assigned. This information is in our files, but we will not look at the files until after the study has finished. This is the best way to test the effect without being influenced by what we think.

Who is eligible to take part?

To be eligible for the study you must have mild to moderate depression and be between the ages of 18-64. You must also be able to visit your GP's surgery for four assessments: the introductory meeting, baseline week, week 4, and the post-intervention week assessments.

To check whether you are eligible for this study, you will need to complete the screening form. If you are eligible, and agree to take part, you will also need to complete the personal information form, the mood questionnaire (PHQ-9) and sign a consent form. The PHQ-9 (Patient Health Questionnaire) is a simple one page questionnaire to measure whether your symptoms are categorised within the target range for this study. All of these documents are included in this pack. Please return the completed forms in the pre-paid envelope. I will then contact you to arrange our first meeting.

There are a number of treatment options available, including psychological and medication, for those who suffer with depression. If you wish to consider these options before entering this study, please consult your general practitioner.

Who is not eligible to take part?

If you have any of the following conditions or any of the following circumstances apply to you then unfortunately you are not eligible to participate in this study:

- Current treatment with antipsychotic drugs. (If you are taking medicines prescribed by your doctor and are not sure if they are antipsychotics please contact me).
- Alterations to your antidepressant treatment, including medication and counselling/talk therapy, in the previous four weeks of trial commencement or during the trial. You will be asked during the study assessments to inform the researcher if your treatment changes as you will need to be withdrawn.
- Previous use of light therapy, including use of light boxes, light visors and dawn simulation lamps. This does not include the use of SAD (seasonal affective disorder) alarm clocks.
- History of or current substance/drug abuse.
- History or current diagnosis of psychosis, severe depression, bipolar disorder, Parkinson's, dementia or Alzheimer's disease.
- A history of light-induced migraine or epilepsy.
- A history of traumatic brain injury (TBI).
- Presence of eye conditions including retinal blindness, cataracts, retinal diseases of the eye and glaucoma.
- Current oral diseases, such as candidiasis (thrush), or sores, swelling or cuts within the mouth.
- Current or recent participation in research prior to this study.

The conditions and treatments listed above may interfere/interact with the light therapy treatment, interfere with the accuracy of measuring hormones in saliva samples, or are outside the remit of this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Even if you agree to take part, you can change your mind at any time without giving any reason. If you decide not to take part in the study, the care that you receive from the National Health Service will not be affected in any way.

If I do take part, what would I have to do and what would be done to me?

The study will last six weeks. We will need to meet with you four times for assessments (introductory meeting, baseline week, week 4 and post-intervention assessments). The first meeting will take up to an hour. The other appointments should take no more than 30 minutes. The meetings will take place at your GP's surgery and will be arranged at a time that is convenient for you. For week 1, 2 and 3 assessments, we will telephone you at home to check how you are getting on.

Your participation in this study will involve using the light therapy for 30 minutes within ten minutes of waking up, and before midday, every morning for four weeks (weeks 1-4). We will also ask you to complete various questionnaires and a diary. For the diary you will be asked to record your bed time, the time you wake and when you get up, the duration and number of any naps that you have during the day, and times that you use light therapy. We will also ask you about how much alcohol you drink and your level of activity, as this can have an effect on your mood questionnaire results.

To give us information about your sleep patterns we need you to wear an Actiwatch for the duration of the study, both day and night. The Actiwatch measures your activity levels during the day and your sleeping patterns. It looks like a typical sports watch. You can continue with your normal day to day activities including showering and bathing without having to remove the watch.

We will also ask you to provide us with eight saliva (spit) samples at the end of baseline week and week 4. This will allow us to measure the effect of light therapy on the levels of two hormones within your body, cortisol and melatonin, which are known to be associated with mood and sleep.

The night before the final day of these weeks, you will be asked to produce four saliva samples, one each hour starting four hours before your usual bedtime. The next morning, you will be asked to produce four saliva samples, one each half hour for two hours after you wake up. We will give you the containers to keep your samples in your fridge until we collect them at the assessment.

It is important when you are giving saliva samples that you do not eat, drink, chew gum or smoke for 30 minutes before producing your samples. The containers for your samples will be labelled with your participant code, the date and predicted times of collection, not your name. Melatonin in the body is influenced by light. Therefore, we ask that you stay in a semi-dim light condition during the 4 hours of saliva sampling in the evening. Reading, listening to music, conversations (both face-to-face and on the phone) are allowed. Watching TV at a distance is allowed, but not sitting directly in front of a TV, or a computer display, nor keeping all lights on. We ask that you keep your activity levels to a minimum during this time.

At the end of this leaflet, there is a table which summarises what will happen on a week by week basis

What happens first?

Introductory Assessment

On the first day of the study, you will be invited for an introductory assessment in a private room at your GP surgery. This meeting will take approximately one hour. The researcher will talk to you about the study and you will have the opportunity to ask any questions. You will be assigned a "Participant Code" which will be used to anonymise all of the paperwork associated with the study.

You will be asked to complete four questionnaires at this meeting. These will assess the severity of your depression, measure how much your symptoms vary from season to season, assess your current quality of life, and your expectations of how effective the treatment with light therapy will be.

You will be given an Actiwatch, a diary and 8 saliva containers. The researcher will talk to you about each of these individually and answer any questions you may have.

You will be offered by the researcher a text message reminder service. With this service you will be sent a text message reminder on the days that you must start collection of saliva samples, and/or the day before an assessment appointment.

Baseline Assessment

This will take place at your GP surgery and will take approximately 30 minutes. The researcher will collect the saliva samples that you produced that morning and the night before. You will complete two questionnaires which assess your mood. The researcher will then give you a light box to take home with you. They will verbally instruct you on how to use the equipment, when to use it and for how long. You will use the light box every day for the next 4 weeks. You will receive another 8 containers to collect your saliva samples at the end of week 4.

You will also be given three envelopes, containing questionnaires, marked weeks 1, 2 and 3. Each envelope will contain two mood questionnaires, a questionnaire to assess whether you have noticed any side-effects of treatment, and a pre-paid addressed envelope to return your completed forms to the University.

Weeks 1-3 Assessment

Each week at an agreed time the researcher will telephone you to check how you are getting on. They will remind you to complete and return the questionnaires for that week.

Week 4 Assessment

At the week 4 assessment, we will arrange a meeting at the GP surgery. This meeting will last approximately 30 minutes. You will return the light box and the saliva samples that you have collected that morning and the evening before. You will be asked to complete two mood questionnaires, a quality of life questionnaire, a questionnaire on whether you have experienced any side-effects of treatment and a light therapy expectation questionnaire.

Unfortunately we will not be able to give you a light box to use once you have completed the study. However, light therapy boxes are widely available on the market and can be easily purchased if you wish to continue independent treatment.

Post-intervention Assessment

Following the completion of the light therapy weeks 1-4, you will continue to wear the Actiwatch and completing the diary entries in this post-intervention week. At the end of this week, we will arrange a meeting with you at the GP surgery. You will be asked to complete the two mood questionnaires, and return your Actiwatch and diary.

At this meeting the researcher will then ask you to make a final appointment to talk about your experience of the study and using light therapy in a telephone interview. If you agree to this it will be arranged at a time that is convenient for you. The interview over the telephone will be audio recorded, and will take approximately 20-30 minutes. We may publish comments that you have made within the interview but all comments will be anonymised. Nobody will know that you have taken part in this study or be able to identify you from the comments made.

Six months after the study has ended we will send you a short questionnaire in the post. It will ask you if you have used light therapy since the study. We will provide a pre-paid envelope to return your questionnaire to the University.

Are there any risks if I take part?

The studies on light therapy that have taken place in hospitals and clinics have shown that light therapy is very well tolerated and has few side-effects. The most common of these side effects include elevated mood, eye irritation and headaches.

Before and during the trial, we will be closely monitoring your depression score (mood) using the Patient Health Questionnaire 9 (PHQ-9), as mentioned above. We use this to measure your response to the light therapy. In an event where your mood worsens above the maximum PHQ-9 score defined by the trial's inclusion criteria, or we are concerned that your general mental health has deteriorated, you will be advised to make an appointment to see your GP. We will contact your GP to inform them that your depression symptoms have become more severe. This is for your safety.

Some people find it uncomfortable or embarrassing to spit into a container. You will be able to do this in private so nobody is watching you.

Are there any benefits if I take part?

You will not be paid to complete this study. There are no personal benefits from participating in this research. However, your participation may provide us with a better understanding of using light therapy in terms of effectiveness, its usability, how it affects sleep and it may lead us to a method of identifying individuals who would benefit most from light therapy.

Will anyone know that I've taken part?

Only the research team and your GP, as listed on your screening form, will know that you have participated in this trial. Your GP will be informed for your own safety.

All researchers will maintain confidentiality of all data, including potential and actual participant identity, their questionnaire responses, activity data, diary entries, and biochemical results.

What should I do if I change my mind?

You are free to withdraw from the study at any time and if you wish, have any data collected removed from the study, without reason. We do ask that you inform us of your decision and return equipment to the research team.

What will happen to the results?







All of the data collected will be identified using your participant code and not your name. The data we collect does not contain any personal information about you. No one will link the data you provided prior to the trial to the identifying information you supplied (e.g., name, address, email). Any results published or presented at scientific meetings will not have any identifying information about you.

Contact details that we have for you will be stored securely separately to study data. Contact details will be destroyed immediately following your completion of the study unless you choose to receive a report summarising our findings. In that case we will hold your contact details until this information has been sent to you. Your personal details will not be used for any other reason.

The data from this trial will be included in a PhD thesis as part Jacqueline Walsh’s doctorate qualification. The results will be used to inform the protocol of a future large scale study investigating light therapy for the management of depression.

Who should I contact if I want to know more about the study?

Who should I contact if I have any questions?	Who should I contact if I have any problems?
<p>Jacqueline Walsh Phone: 01634 202920 Mobile: 07840630633 Email: jw586@kent.ac.uk</p> <p>Dr Sarah Corlett, PhD Phone: 01634 888909 Email: S.A.Corlett@kent.ac.uk</p> <p>Address: Medway School of Pharmacy Universities of Kent and Greenwich Anson Building Central Avenue Chatham Maritime Kent ME4 4TB</p>	<p>Dr Gurprit Lall, PhD Phone: 01634 202946 Email: G.Lall@kent.ac.uk</p> <p>Independent Researcher: (For individuals seeking further guidance regarding taking part in research, or to speak to someone outside of the research team)</p> <p>Dr Shivaun Gammie, PhD Phone: 01634 202963 Email: s.m.gammie@kent.ac.uk</p>

Week	Date									
Baseline	To: __/__/__ From: __/__/__	Assessments Intro: __/__/__ BL: __/__/__ Where: _____	Actiwatch To be worn throughout the study	Diary Entries To be kept each day the study		4 Evening Saliva Samples Date: __/__/__	4 Morning Saliva Samples Date: __/__/__			
1	To: __/__/__ From: __/__/__	Assessment Date: __/__/__ Via telephone								Light Therapy 30 minutes Within 10 minutes of waking
2	To: __/__/__ From: __/__/__	Assessment Date: __/__/__ Via telephone								Light Therapy 30 minutes Within 10 minutes of waking
3	To: __/__/__ From: __/__/__	Assessment Date: __/__/__ Via telephone								Light Therapy 30 minutes Within 10 minutes of waking
4	To: __/__/__ From: __/__/__	Assessment Date: __/__/__ Where: _____						4 Evening Saliva Samples Date: __/__/__	4 Morning Saliva Sample Date: __/__/__	Light Therapy 30 minutes Within 10 minutes of waking
Post-Intervention	To: __/__/__ From: __/__/__	Assessment Date: __/__/__ Where: _____								

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Participant Screening Form

Complete and return this form to Jacqueline Walsh, PhD student, Medway School of Pharmacy, Anson Building, Universities of Kent and Greenwich at Medway, Central Avenue, Chatham Maritime ME4 4TB, using the pre-paid envelope provided, if you are interested in participating in this study. Please answer all questions on this form.

1. What is your age? (years)

(If you have entered an age under 18 or over 64 years of age, unfortunately you will not be eligible for this research study at this time. Thank you for your interest.)

2. Have you been diagnosed with depression by your GP?

Yes

No

(If you have answered No, unfortunately you will not be eligible for this research study at this time. Thank you for your interest.)

3. Are you currently receiving treatment for depression from your GP?

I am currently receiving antidepressant medication

I am currently receiving CBT, or another form of talking therapy

I am not receiving any treatment at this time

4. If you are receiving medicines or talking therapy, have there been any changes to your treatment in the past 4 weeks, or any planned changes in the near future?

Yes

No

(If you have answered Yes, unfortunately you will not be eligible for this research study at this time. Thank you for your interest.)

5. Please tick if any of the conditions or categories below applies to you:

- Pregnant/breast feeding or planning pregnancy.

- Current treatment with antipsychotic drugs. Commonly used examples include: amisulpride, aripiprazole, clozapine, olanzapine, quetiapine, risperidone, sertindole chlorpromazine, flupentixol, haloperidol, levomepromazine, pericyazine, perphenazine, pimozide, sulpiride, trifluoperazine, and zuclopenthixol.
(If you are taking medicines and you are not sure if they fall into this category please contact the researcher).

- History of or current substance or drug abuse.

- History of or current diagnosis of psychosis; severe depression; bipolar disorder; Parkinson's; dementia; Alzheimer's disease.

- A history of light-induced migraine or epilepsy.

- A history of traumatic brain injury (TBI).

- Presence of eye disorders such as retinal blindness, cataracts, retinal diseases of the eye and glaucoma.

- Current diseases of the mouth, such as thrush, or sores, cuts or inflammation within the mouth.

- I have used light therapy before. This includes use of light boxes, light visors and dawn simulation lamps. This does not include the use of SAD (seasonal effective disorder) alarm clocks.

- Current or recent participation in research prior to this study.

(If you have ticked yes for any of the conditions or treatments listed above, unfortunately you will not be eligible for this research study at this time. Thank you for your interest.)

6. Have you been diagnosed by a doctor with any other conditions? If so, please write them in the space provided below:

7. Are you able to access your GP surgery for assessments throughout the study?

Yes

No

(If you have answered No, unfortunately you will not be eligible for this research study at this time.

Thank you for your interest.)

8. Please complete the PHQ-9 questionnaire and return it for scoring.

Thank you for taking the time to fill in this screening form and completing the PHQ-9 mood questionnaire. Please return both with your personal information form and consent form in the pre-paid envelope provided within this information pack. If you have any queries regarding the study, please refer to the Participant Information Leaflet enclosed or contact the research team using the details provided on the Participant Information Leaflet.

A member of the research team will soon be in contact to arrange your first appointment.

medway school of pharmacy

5.6

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Complete and return this form to Jacqueline Walsh, PhD student, Medway School of Pharmacy, Anson Building, Universities of Kent and Greenwich at Medway, Central Avenue, Chatham Maritime ME4 4TB, using the pre-paid envelope provided, if you are interested in participating in this study. Please complete all questions on both pages of this form.

Personal Information

Name

Telephone Number

E-mail address

How would you like to research team to contact you?

Telephone

Email

Postal Address

Postcode

Name of GP

GP Address

Are you?

Male

Female

Which ethnic group best describes you? (Please tick *one* box only)

White

Mixed

Asian or Asian British

Black or Black British

Chinese

Other

What is your current working status?

Full-time

Part-time

Retired

Not working

Student

Thank you for taking the time to fill in this form.

For further questions or queries, please contact the research team using the details provided on the Participant Information Leaflet.

PARTICIPANT CONSENT FORM

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Name of researcher(s): Jacqueline Walsh, Dr Sarah Corlett, Dr Gurprit Lall

I have read and understand the information provided for the above trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily

Initial Here

I confirm that the information I provided on my screening form is accurate

Initial Here

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason

Initial Here

I understand that I may be given a light box which has either red or white light. This allocation will be completely due to chance and I should not share with the researcher any information about the colour of light during the assessment meetings

Initial Here

I understand that any personal information collected during the trial will be anonymised, remain confidential and will be destroyed immediately after the trial finishes, unless I have requested a study report. In this case my details will only be held until it has been produced and shared with me.

Initial Here

I understand that any responses to questionnaires, diary entries and data collected and analysed during the trial will be anonymised

Initial Here

I understand that if during the study I display symptoms of more severe depression I will be encouraged to make an appointment to see my GP, and my GP will be contacted by the research team

Initial Here

I agree to give saliva samples

Initial Here

I agree to allow saliva samples to be stored anonymously at Medway School of Pharmacy. I understand that they will be used for this trial, and that they will be destroyed at the end of the trial

Initial Here

I agree to wear the Actiwatch device for the duration of the trial. I understand that the data collected will be anonymised, and destroyed at the end of the trial

Initial
Here

I understand if I agree to be interviewed at the end of the study that the interview will be digitally audio recorded and that this recording will be transcribed verbatim (word-for-word). I understand that direct quotes taken from the recording of our conversation may be used in publications and reports, but that these will be anonymised and not traceable to me

Initial
Here

I agree to take part in this study

Initial
Here

Name of Participant (Print)

Signature

Date

Name of Researcher (Print)

Signature

Date

5.8 Are you interested in trying Light Therapy for Depression?

Volunteers needed for a research study

You may be eligible if:

- You are aged between 18 and 64 years old
- You have been diagnosed with mild to moderate depression
- You have not used light therapy before
- You are able to attend Medway School of Pharmacy, Chatham Maritime, where the trial is being held

As a participant in this study you will:

- Be part of a 6 week research study
- Receive light therapy treatment using light box equipment within your own home
- Have your activity, sleep pattern and hormone levels monitored and analysed by a team of researchers



**For more information
please contact
Jackie or Sarah on:**

jw586@kent.ac.uk
S.A.Corlett@kent.ac.uk

01634 202920/
01634 888909



University of
Kent

5.9

Date: [enter date]

Dear [GP Name]

RE: Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

[Patient Name and Address]

I am writing to inform you that this patient, having received and read the recruitment pack, that was kindly passed on to them, by you, on our behalf, has agreed to participate in the above trial at Medway School of Pharmacy.

As you will recall, this light therapy study is a six week exploratory two-arm trial. The purpose of this study is to investigate the effectiveness and feasibility of light therapy for the management of mild to moderate depression in a primary care setting. The study has been reviewed and received ethical approval from the NRES Committee.

The trial consists of a baseline week of monitored standard care, four weeks of monitored light therapy intervention, followed by a final week of monitored standard care. Participants will be randomised to receive either white or red light therapy in their home using light therapy equipment provided by the research team, to be used for 30 minutes each morning. Activity data will be monitored using an Actiwatch device which will be worn for the duration of the trial. Saliva samples will be collected before and after intervention to monitor levels of the hormones melatonin and cortisol, which are known to change in response to light therapy.

There will be no alterations made to the patient's medications or treatments; standard treatment will not be compromised as a result of participation in this study. Alterations to participant antidepressant treatment, including medication and counselling/talk therapy, in the four weeks prior or during the trial, will result in delayed entry or withdrawal from the study. In the event that your patient's mental health deteriorates during the course of the trial, the research team will inform you via letter and we will encourage the patient to make an appointment to see you.

The main side effects, contraindications, medication/procedure interactions and trial exclusion criteria are included in the Participant Information Leaflet which I have enclosed with this letter for your reference. However, if you have any queries or require further information please contact me using the contact details I have included below.

In the event of an emergency please call: 07840630633.

Yours sincerely

Jacqueline Walsh MRPharmS
PhD Research Student, Medway School of Pharmacy
Universities of Kent and Greenwich
Anson Building
Central Avenue
Chatham Maritime
Kent ME4 4TB
Office Tel: 01634 202920
Mobile Tel: 07840630633

Academic supervisors

Dr Sarah Corlett, Clinical Lecturer, Medway School of Pharmacy
Dr Gurprit Lall, Lecturer in Circadian Biology/ Pharmacology, Medway School of Pharmacy

5.10

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Interview Schedule for Semi-structured participant interviews

The following themes will be explored:

Explore Participant Experience of the Exploratory Trial
Can you tell me, in your own words, your experience as a participant in this trial?
How did you find the recruitment process? ↳ Is there any way this could have been improved, in your opinion?
How did you find the assessments during the trial? Scheduling/frequency/durations/content
I would like to ask you about some specific elements of the trial. Can you tell me about how you got on with: The Actiwatch The Diary The salivary samples “We will speak in detail about the light therapy component of the trial a little later in the interview.”
How did you find fitting the tasks of the trial into your everyday life?
Did you find anything particularly difficult with this trial? ↳ What changes could be made to make this easier for you?
Were there elements of the trial you found particularly useful or good for you as a participant?
Do you have any other comments about the trial that you would like to share?
Explore Participant Experience of Using Light Therapy
Can you tell me, from your experience during the trial, how you found using light therapy?
Did you find it effective at managing your depression or mood?
How easy or hard did you find it to use light therapy during the trial? Physically/timing/duration/frequency/location(home)
Do you have any concerns regarding using light therapy?
Would you now consider using light therapy for your symptoms (low mood, sleep disturbances, other)? Would you recommend others to use light therapy to manage their symptoms (low mood, sleep disturbances, other)?
Do you have any other comments about light therapy that you would like to share?

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

5.11

Participant Diary: Template Baseline & Post-intervention weeks

Week ____							
Date	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
Wake up time							
	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
Get-up time after final awakening							
	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
Last night I fell asleep:							
Easily	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
After some time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
With difficulty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This morning I feel:							
Refreshed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Somewhat refreshed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Took a nap?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
If yes, for how long and what time?	__h __m AM/PM	__h __m AM/PM	__h __m AM/PM	__h __m AM/PM	__h __m AM/PM	__h __m AM/PM	__h __m AM/PM
Bedtime							
	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
How many units of alcohol did you drink today? (See back of page for guidance)							
Notes (Record any factors that may have affected your sleep)							
Activity							Please fill in activity question on back of page at the end of the week

To help answer the question regarding alcohol intake, we have given some information about units of alcohol below:

Version 1 19/01/2015

These measures all contain **one** unit of alcohol:



Activity Question: Please answer the following question at the end of the week.

Days	Time (Hours and minutes)
<p>a. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling,?</p> <p><i>Think about only those physical activities that you did for at least 10 minutes at a time.</i></p>	<p>How much time in total did you usually spend on one of those days doing <u>vigorous physical</u> activities?</p>
<p>Answer: Days _____</p>	<p>Answer: Hours _____ Minutes _____</p>
<p>b. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis?</p> <p><i>Do not include walking. Think only about those physical activities that you did for at least 10 minutes at a time.</i></p>	<p>How much time in total did you usually spend on one of those days doing <u>moderate physical</u> activities?</p>
<p>Answer: Days _____</p>	<p>Answer: Hours _____ Minutes _____</p>
<p>c. During the last 7 days, on how many days did you walk for at least 10 minutes at a time? This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.</p>	<p>How much time in total did you usually spend <u>walking</u> on one of those days?</p>
<p>Answer: Days _____</p>	<p>Answer: Hours _____ Minutes _____</p>

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Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Participant Code: _____

Participant Diary: Template Weeks 1-4



Week ____							
Date	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__	__/__/__
Wake up time	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
Get-up time after final awakening	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
Last night I fell asleep:							
Easily	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
After some time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
With difficulty	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
This morning I feel:							
Refreshed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Somewhat refreshed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Light Therapy Use:							
Start time	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
End time	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
Today, I found using light therapy...							
Easy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Somewhat difficult	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficult	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Took a nap?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
If yes, for how long and what time?	__h__m AM/PM	__h__m AM/PM	__h__m AM/PM	__h__m AM/PM	__h__m AM/PM	__h__m AM/PM	__h__m AM/PM
Bedtime	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM	AM/PM
How many units of alcohol did you drink today? (See back of page for guidance)							
Notes: (Record any factors that may have affected your sleep)							
Activity (Please fill in activity question on back of page at the end of the week)							Please fill in back of page ->

Version 1_19/01/2015

To help answer the question regarding alcohol intake, we have given some information about units of alcohol below:

These measures all contain **one** unit of alcohol:



Act

Days	Time (Hours and minutes)
<p>a. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling,?</p> <p><i>Think about only those physical activities that you did for at least 10 minutes at a time.</i></p>	<p>How much time in total did you usually spend on one of those days doing <u>vigorous physical</u> activities?</p>
<p>Answer: Days _____</p>	<p>Answer: Hours____ Minutes ____</p>
<p>b. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis?</p> <p><i>Do not include walking. Think only about those physical activities that you did for at least 10 minutes at a time.</i></p>	<p>How much time in total did you usually spend on one of those days doing <u>moderate physical</u> activities?</p>
<p>Answer: Days _____</p>	<p>Answer: Hours____ Minutes ____</p>
<p>c. During the last 7 days, on how many days did you walk for at least 10 minutes at a time? This includes walking at work and at home, walking to travel from place to place, and any other walking that you did solely for recreation, sport, exercise or leisure.</p>	<p>How much time in total did you usually spend <u>walking</u> on one of those days?</p>
<p>Answer: Days _____</p>	<p>Answer: Hours____ Minutes ____</p>

5.12

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Complete and return this form to Jacqueline Walsh, PhD student, Medway School of Pharmacy, Anson Building, Universities of Kent and Greenwich at Medway, Central Avenue, Chatham Maritime ME4 4TB, using the pre-paid envelope provided, if you are interested in participating in this study.

6 month follow-up questionnaire

1. Have you used light therapy (LT) to treat your symptoms since finishing the study?

- Yes (Please answer questions 2-5)
 No (Please answer question 6)

2. Please answer the following questions regarding your use of light therapy:

- I have used LT at approximately (time) _____ AM or PM, and I have used LT for approximately _____ minutes each time.
- Typically I use LT as described in the previous question...
 - Everyday
 - Other. Please fill in the box below with details of when you use LT (e.g. only working days, only at weekends etc.) and include any reasons why this is.

a. Please indicate when you plan to use LT during the year:

- All year round

Or only during specific months:

- January
- February
- March
- April
- May
- June
- July
- August
- September
- October
- November

December

3. What type of equipment do you use for light therapy (LT)? Please tick all that apply.

- I use a tabletop light therapy box.
- I use a light visor.
- I use a light box that stands on the floor.
- I use a dawn simulator.
- I use equipment for LT not listed above. (Please describe below)

4. What do you do when using light therapy (LT)? Please tick all that apply.

- My eyes are more than 18 inches (45 cm) from the light source when I use LT.
- My eyes are more than 24 inches (61 cm) from the light source when I use LT.
- I am not directly facing the light box when I use LT.
- I do not stay seated in front of the light box the entire time I am using LT.
- I eat while I use LT.
- I watch TV while I use LT.
- I use the computer while I use LT.
- I talk on the phone while I use LT.
- I read while I use LT.
- I sleep or nap while I use LT.
- I shut my eyes while I use LT.
- I listen to music or the radio while I use LT.
- Other:

5. Please tick all options below that describe your experience of side effects resulting from your use of LT since finishing the study:

- I experienced side effects that were bad enough that I stopped using LT.
- I experienced side effects that were so bad I thought about not using LT.

I experienced side effects but they were not bad enough that I thought about stopping LT.

I experienced no side effects from LT.

6. If you have not used light therapy (LT) since finishing the study, please tick all of the following reasons that explain why:

- My doctor (or mental health professional) advised against LT.
- I do not think LT was effective for managing my symptoms.
- LT was partially effective at managing my symptoms, but not effective enough.
- LT takes too much time.
- Light therapy boxes are too expensive.
- Having to use LT reminds me that I am not well.
- I am embarrassed to use LT around the people I live with.
- I am embarrassed to use LT around the people I work with.
- My symptoms are not severe enough to warrant treatment
- I can manage my symptoms well enough with prescription medication.
- I can manage my symptoms well enough with therapy (talk therapy, psychotherapy or cognitive behavioural therapy).
- I can manage my symptoms without any treatment.
- I can manage my symptoms with alternative methods.

Please list these other methods:

Other reasons which are not listed above (please fill in below):

Thank you for taking the time to fill in this form.

For further questions or queries, please contact the research team using the details provided on the Participant Information Leaflet.

medway school of pharmacy

5.13

Date: [enter date]

Dear [GP Name]

RE: Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

[Patient Name and Address]

As you will be aware from my previous letter, your patient, as stated above, is participating in the above trial at Medway School of Pharmacy. I am writing to inform you that your patient is displaying symptoms of more severe depression. As per the study protocol, we have asked your patient to make an appointment to see you regarding these symptoms.

If you have any queries or require further information, please contact me using the contact details below. In the event of an emergency please call: 07840630633.

Yours sincerely

Jacqueline Walsh MRPharmS
PhD Research Student, Medway School of Pharmacy
Universities of Kent and Greenwich
Anson Building
Central Avenue
Chatham Maritime
Kent ME4 4TB
Office Tel: 01634 202920
Mobile Tel: 07840630633

Academic supervisors

Dr Sarah Corlett, Clinical Lecturer, Medway School of Pharmacy

Dr Gurprit Lall, Lecturer in Circadian Biology/ Pharmacology, Medway School of Pharmacy

5.14

SUPPLEMENTARY INFORMATION ON INSTRUCTIONS FOR LIGHT THERAPY DEVICE USE

Set up

1. Remove the unit from the packaging
2. Place the unit on a solid surface, such as a table, and adjust the folding tripod.
3. Connect the unit only to the mains voltage listed on the type plate – push the plug completely into the mains socket. Lay the mains cable in such a way that no one can trip over it.

Operation

1. Switching on/off the lamp

Press the ON/OFF button on the upper edge to switch on/off the device.

2. Using the device

Sit in front of the light device, with the device positioned towards your face approximately 20cm away. Maintain the recommended distance between your face and the device for the full treatment period.

You are to use the device for **30 minutes** in the **morning (before midday) within 10 minutes** after you wake up.

You can go about normal activities while using the device for example reading, writing, eating, making telephone calls etc. Please do not walk away from the device once in use.

Safety

- Do not look directly into the light continuously.
- Do not leave the device unattended whilst it is switched 'on'.
- Do not touch the device when it is on. Let it cool down for at least 10 minutes before moving it.
- Do not block the vent holes on the back of the device.
- Do not let children use the device. Children should be supervised so that they do not play with the device.
- When you have finished your treatment, make sure that you turn the device off and unplug it from the mains.
- If something happens to the device, for example the light does switch on, do not attempt to fix it. Immediately call the researcher on the mobile number XXX to make alternative arrangements for your treatment.

Note

For further information, or if you have any questions, please contact the research team.

5.15

SUPPLEMENTARY INFORMATION ON INSTRUCTIONS FOR ACTIWATCH

What is Actiwatch?

Actiwatch is a device used in this study to record motion and light.

Where and how do I wear it?

You will be asked to wear the Actiwatch during all six weeks of the study.

You wear the Actiwatch just like a normal watch. Wear the Actiwatch on either wrist and adjust the strap to secure it in place.

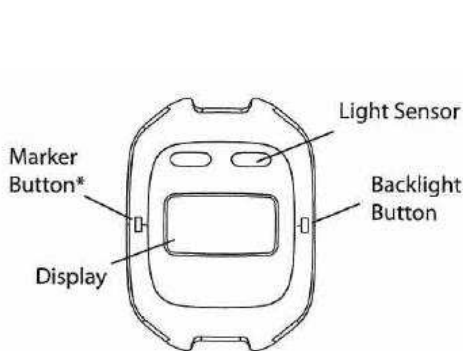
Is the Actiwatch water resistant?

Yes. Wear it while you shower or bathe for up to 30 minutes.

Warnings:

- Discontinue use if skin reddening or inflammation appears, and contact the research team as soon as possible.
- If the device becomes damaged, or stops working for any reason, contact the research team as soon as possible to arrange replacement. Do not attempt to repair the device in any way.

Actiwatch features and screen symbols:



Visual Indicators	Description	Visual Indicators	Description
	Shows the time of day in either 12- or 24-hour format, depending on your medical professional's settings. If either AM or PM appears on the display (as shown here) the device is showing the time in 12-hour format.		Indicates that the device is not fastened properly on your wrist. It might be too loose or too tight. Refasten the device to your wrist until the flashing stops.
	When you press the backlight button and hold it for 3 seconds, the date is shown in either MM-DD or DD-MM format depending on your medical professional's settings. This sample shows March 17th, in MM-DD format.	(Backlight turns on.)	Indicates that the backlight button has been pressed. The backlight automatically turns off after 5 seconds.
	The circling black border indicates that data collection has begun. Although not shown here, the time or date appears in the center.	(A pattern appears on the display and the backlight turns on briefly.)	Indicates that you have successfully marked an event by pressing the Marker Button for 3+ seconds.
	When the time or date is displayed but the black border is not visible, this indicates that the device is waiting to begin data collection. Your medical professional will tell you when data collection will begin.		When these symbols appear, the Actiwatch Spectrum's battery is running low. Return the device to your medical professional for battery replacement.
			Indicates that data collection is complete or that the device is in sleep mode. Remove the Actiwatch and return it to your medical professional so your data can be analyzed.

Note

For further information, or if you have any questions, please contact the research team.

CHAPTER SIX

Summary

The aim of this thesis was to develop a protocol to explore the feasibility of using LT in primary care for patients with NSAD. A review of how circadian rhythms can contribute to depression and the theoretical basis for how LT can modify these rhythms to improve mood was discussed in chapter 2. A further literature search was then undertaken to identify the key aspects that should be included within a LT study. The results of this literature search have not been presented within this thesis. However, they guided the qualitative studies undertaken with the general public and GPs. The aim of exploring the views of these stake-holders was to ascertain their awareness of the use of LT for the treatment of depression, their expectations for its effectiveness and any concerns regarding its use and their opinions on the proposed LT therapy; specifically, their views on recruitment methods, the type of LT device, the duration of use and feasibility of salivary sampling and Actiwatch™ use. The findings from these studies which are presented in chapters 3 and 4 were then used to design a protocol for an exploratory study. This protocol, which has received NHS Ethics and research governance approval, was presented in chapter 5. The main findings from two qualitative chapters of this thesis are summarised below, together with the strengths and limitations of the research, and the recommendations for how the work should be taken forward.

Despite emerging evidence, participants of the focus groups, who themselves had experience of depression, were unaware of the use of LT as a therapeutic option outwith its use in SAD. Although none of the participants had used LT themselves, the participants were generally positive regarding LT's potential benefit to them and regarded it as safe. However, they viewed LT more appropriate as an adjunct rather than a substitute to their current therapy. Additionally, participants were uninformed of the treatment details in relation to LT use, including duration, timing etc., and particularly the use of colour in LT and its impact on effectiveness.

The General Practitioners interviewed were open to using LT for depression, but similarly to the general public, associated its use primarily with the treatment of SAD. They agreed that there is a need for more evidence to support its use routinely as an option for patients. However, they believed that, provided this evidence was available, it would prove a useful option for them, particularly for those who were in the early phase of management.

Participants' views from both the focus group and interviews guided the development of essential aspects of the exploratory trial protocol, including the inclusion/exclusion criteria (for example, no alterations to participant treatment during the trial, or prior four-week period), recruitment strategy, choice of active and placebo devices and measurement tools.

The strength of the research presented in this thesis lies in the rigorous and systematic approach to the design of an exploratory trial. It successfully employs qualitative methodology to integrate the views of those who would be directly involved in the future trial, participants with experience of depression and GPs as Primary Care providers, in early phases of development of a protocol.

Although the study held two focus groups, the dependence on convenience sampling to recruit participants from a notoriously unmotivated population resulted in a lower sample size than desired. Equally, the recruitment of GPs proved similarly challenging, even with many measures put in place by the research team to facilitate the interviews, the time pressure experienced by GPs was difficult to minimise. Ideally a greater number of participants would have been included in order to achieve as broad a view on the topics as possible, achieving saturation of information for the methods. Notably, these recruitment issues could be experienced in the future implementation of the exploratory trial also.

The MRC framework for complex interventions has been used to design a feasibility study to evaluate the therapeutic potential for the use of LT in the management of depression in Primary Care. The results from this exploratory study will test whether the design is feasible, for example the effectiveness of the recruitment strategy, and will enable the effect size of LT to be estimated. This will be used to define the number of participants that need to be recruited to a definitive randomised controlled trial with appropriate statistical power.

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Appendix 1

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13th February 2014

Your application for minor amendment to the project entitled ***Light therapy; therapeutic potential for the management of depression in primary care*** has now been considered on behalf of the Medway School of Pharmacy School Research Ethics Committee (SREC).

I am pleased to inform you that the amendment has been approved, with suggested changes as attached, with immediate effect.

I must remind you of the following:

1. that if you are intending to work unaccompanied with children or with vulnerable adults, you will need to apply for a CRB check; the project must be conducted under the supervision of someone who has an up-to-date CRB check; you must not be in the presence of children alone except if you have completed a CRB check;
2. that you must comply with the Data Protection Act (1998);
3. that you must comply throughout the conduct of the study with good research practice standards;
4. If you are completing this project off site, you must obtain prior approval from relevant authorities and adhere to the MSOP off site protocol.
5. to refer any amendment to the protocol to the School Research Ethics Committee (SREC) for approval.
6. You are required to complete an annual monitoring report or end of project report and submit to j.mowbray@kent.ac.uk

Yours sincerely



Dr Sarah Corlett

medway school of pharmacy

PROJECT PROTOCOL

Title of Project: Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Name of Researcher (s): Dr Sarah Corlett, Dr Gurprit Lall, Jacqueline Walsh (Postgraduate Researcher) & Zena Yasen, Ruhina Kassam (Undergraduate Researcher)

Background to the study:

Depression is a debilitating and recurrent disease that affects up to a fifth of the UK population between the ages of 16-64 (The Health and Social Care Information Centre, 2007). Unipolar depressive disorders are the leading cause of 'years lost due to disability' (YLD) across gender, economic status and societies worldwide (WHO, 2004). Depression is a devastating disorder, defined by the Diagnostic and Statistical Manual (DSM) criteria, with key symptoms of persistent low mood, anhedonia and fatigue. The presence of depression for an individual does not merely indicate a poor prognosis, in terms of quality of life, but indeed shortens life expectancy due to susceptibility to other medical diseases and suicide (Cassano and Fava, 2002).

Depression severity is typically classified into the following groups: mild, moderate, moderately severe or severe in accordance with the Diagnostic and Statistical Manual (DSM) or the International Classifications of Diseases (ICD) criteria. Such categorisation plays a vital role in evaluating the appropriate treatment for a patient suffering from depression. Currently the most common interventions are pharmacological agents and psychological treatments as recommended by national guidance (NICE 2004, amended 2009). Antidepressant medication has become the prevailing method of treatment; however Cognitive Behavioural Therapy (CBT) has also been shown to be effective. CBT is a form of short-term psychological support, which includes treatments of problem solving therapy, counselling and behavioural therapy. CBT is recommended at all severities of depression. However, its benefits are limited by waiting times for appointments, typically around 9 months, if available at all (Mukuria et al., 2013; London School of Economics and Political Science, 2006).

First line pharmacological treatments in depression, as recommended by NICE, typically involve the prescription of selective serotonin re-uptake inhibitors (SSRI). SSRIs exhibit their anti-depressant action by increasing the global concentration of the neurotransmitter serotonin, within the brain, by preventing its re-uptake by neurons. These drugs are considered appropriate for moderate to severe depression, however commonly present with serious adverse effects. Indeed, recent media attention has highlighted the previously

unrecognized adverse effects of SSRI use during pregnancy causing birth defects during development in utero (BBC, 2013). Moreover, SSRIs have a slow onset of action consisting of two to eight weeks, or greater, in achieving detectable therapeutic response. Combining the adverse effects and slow response rates, it is not surprising that the adherence of patients to SSRIs is poor with a recent study reporting 40-50% during the maintenance period of treatment (López-Torres et al., 2013). Thus, there is a distinct need for an accessible and effective non-drug treatment for depression, which is acceptable to both patients and clinicians (Kadam et al., 2001).

Recent advances in the field of circadian neurobiology have shown that the environmental day night cycle plays a key role in stabilising mood via regulating our internal physiology. This is achieved through the entrainment of a circadian pacemaker located within the brain. This 'clock' relies heavily on the ability of the eye in interpreting sunlight and consequently synchronising our physiological processes to the day/ night oscillation. The most obvious of these processes is the regulation of our daily sleep/ wake cycle. Alterations in such rhythmic profiles can contribute to symptoms associated with depression such as difficulty sleeping. The link between circadian disruption and the most characteristic symptoms of depression, sleep disturbance/fatigue, are extremely strong (Germain and Kupfer, 2008). Deficits in the ability of the internal body clock in synchronising these rhythms to the environment are likely to cause symptoms of depression. It is in these cases that light can be of great benefit in re-establishing synchronisation between the environment and internal circadian rhythms. Consequently research into the use of light as a therapeutic tool has become increasingly eminent.

Non-pharmacological/psychological therapies, such as light therapy, are currently being explored and have gained much attention. Light therapy has gained recognition over the last 25 years as a potent non-pharmacological treatment for seasonal affective disorder (SAD) and is now established as the treatment of choice (Terman and Terman, 2005; Lam et al., 1999). Recently light therapy has progressed beyond SAD, and has been shown to be effective in a range of disorders. It is evident that, at optimal intensity and duration, light therapy has a profound antidepressant effect associated with resynchronisation of the biological clock (Tuunainen et al., 2004).

There has been a wealth of emerging evidence endorsing the promising outputs resulting from light therapy use in non-seasonal trials. Light therapy use in non-seasonal depression has been practiced using a range of intensities, durations, wavelengths, timing of administration and combined antidepressant agents, and has been shown to be both effective and safe. Remission rates of 50% have been achieved using light therapy at 10,000 lux for one hour daily (Tuunainen et al., 2004). Response to treatment was rapid with depression scores, generic tools to measure response to depression therapies, falling in as little as one week (Tuunainen et al., 2004; Kripke, 1998). This resolves the long onset of action times of traditional antidepressant therapy. The side effect profile of light therapy is minimal with the most severe side effect 'risk of mania' in bipolar populations which can be controlled with mood stabilisers (Kripke 1998). However, light therapy is not currently identified as a routine non-pharmacological therapy under the current NICE guidance for non-seasonal depression (NICE 2004, amended 2009).

As reported in the Cochrane review of Light therapy in nonseasonal depression (2009), majority of studies are based in the highly controlled settings of hospitals and long-term care facilities. Although there was an inclusion of a couple of outpatient studies, the reviewers were unable to compare the data in terms of setting. A project set in primary care will highlight an unexplored aspect of light treatment as it will allow more realistic outcomes surrounding compliance, acceptability and tolerance. It is an important aspect to judging the feasibility of the prospective treatment for largely unmotivated population.

Aim:

There are two aims to this study:

- A. To obtain the views of members of the general public, whom have a history of or are receiving treatment for depression, regarding the use of light therapy for this indication.
- B. To obtain the views of general practitioners regarding the potential use of light therapy in the treatment of depression

These data will be used to inform an exploratory study investigating the effectiveness and feasibility of light therapy use in the management of depression in primary care (PhD study). The views of practitioners and the general public as to the use of light as a therapeutic strategy will also be compared (undergraduate projects).

Objectives: Unless specified for objectives relate to both Parts A and B

1. To assess the participants' awareness, views of effectiveness and concerns surrounding light therapy To evaluate the feasibility of the study design with respect to identifying the target group (Part B only) and recruiting the target group. To determine facilitating factors and barriers which may influence participation in the trial
2. To determine participants preferences regarding specifics of the study design including: equipment to be used, duration of therapy, duration of study, difficulty of adherence, salivary sample timing, number and frequency of questionnaires, actiwatch use, setting of study and electroencephalogram component.

Methodology:

Qualitative methods will be used to explore both the general public's (focus groups) and the general practitioners' (semi- structured interviews) views of light therapy and on the proposed randomised controlled trial (RCT) study design.

Part A: The general public

Two focus group discussions will be held in the Medway School of Pharmacy. Each focus group will consist of 6-10 participants.

The focus groups will be led by a facilitator (SC) whose main function will be to keep the discussions on track, to encourage an open and relaxed discussion and to probe into areas that need clarification. The facilitator will ensure that all questions in the focus guide are covered. With respect to the undergraduate project the facilitator will explore:-

- Participants previous awareness or experience of light therapy
- Their views and concerns regarding light therapy as a treatment option

- Their opinion on the colour of the light used (red or white). Is one perceived to be more effective than the other?
- What would be the main facilitators and barriers to using light therapy
- Focus group participants will also be asked open-ended questions related specifically to shaping the design of the future RCT: What do they think of the proposed recruitment material
- Which of the two example light boxes do they think would be most effective and why?
- What do they think of the proposed duration of the study, and the duration and timing of light therapy each day?
- How would they accommodate the schedule into their daily routine (adherence)How would they feel about wearing the Actiwatches
- How do they feel about the schedule of saliva sampling
- About the number of questionnaires and the preferred method of assessment (telephone/face-to-face)
- How would they feel about returning to the Health Centre/ surgery for assessment and review
- Their views on including electroencephalogram recordings within the trial

These themes are summarised in the topic guide (Appendix 5)

Setting

The focus group discussions will take place in the meeting rooms of Medway School of Pharmacy. This setting has parking and is regularly used by the school to conduct research of this kind.

Participant inclusion and exclusion criteria

Inclusion criteria:

- Aged over 18 years old
- History of unipolar depression or receiving treatment for depression.
- Ability to provide informed consent and a good command of the English language.

Exclusion criteria:

- Under 18 years old
- Suffers with bipolar affective disorder
- Suffers with neurodegenerative diseases: such as dementia or Alzheimer's
- Suffers with Parkinson's disease

Participant recruitment procedures

An announcement of the project and invitations to participate will be distributed via local mental health charities and self-help groups to attract 12-20 participants over the age of 18 years (Appendix 1). Participants who have expressed interest will be sent by e-mail or post a participant information leaflet (Appendix 3) and consent form (Appendix 4). If they are interested in the focus group they will also be asked to complete and return a survey which requests their demographic details and availability (Appendix 2). If too many volunteers

come forward then participants will be purposively selected, using the information contained in the demographic form, to cover as broad a range of experience (number and severity of depressive episodes, pharmacological and psychological treatment strategies), ethnicities, ages and both genders as possible. Participants will be informed by letter or e-mail at least one week prior to the date of the focus group that they have been selected (Appendix 6). A letter or e-mail will also be sent to those that have not been selected to thank them for volunteering (Appendix 7). All focus group participants will receive a £20 gift voucher as a thank you for giving their time to attend and prepare for the focus group.

Informed consent

Participants will have opportunity to ask questions prior to the focus group. Written informed consent will be obtained before the focus group discussion begins.

Instruments to be used

A topic guide has been developed for the focus group (Appendix 5). Themes to explore have been defined by the literature and the draft protocol for the exploratory randomised controlled trial. A summary of techniques and equipment used, including light box equipment and electroencephalogram (EEG) recording, will be used to prompt discussions for these aspects of the future study (Appendix 8 and 9 respectively).

Part B – GP interviews

Semi-structured interviews will be conducted in person with 6-8 General Practitioners

Recruitment

Contact information for all GP practices within Medway CCG will be obtained from the NHS Choices website. Practice managers will be contacted by telephone by the PhD student who will briefly describe the purpose of the study and request the name of the senior partner and any GP(s) within the practice who have a particular interest in mental health. A standard letter (Appendix 11) asking whether they would be interested in being interviewed about their views on light therapy in general (part 1 of the interview schedule, (Appendix 15)) and/or participating in the future exploratory RCT will then be sent to these GPs.

Setting

The interviews will be held at the general practitioners surgery. All interviews will be conducted by the PhD student, Jacqueline Walsh

Inclusion criteria:

General Practitioner within Medway Clinical Commissioning Group

Informed consent

A consent form (Appendix 14), participant information leaflet (Appendix 13) and contact form (Appendix 12) will be sent with the recruitment letter. Participants will have

opportunity to ask questions prior to being interviewed. Written informed consent will be obtained.

Instruments to be used

A semi structured interview schedule has been developed (Appendix 15). Themes to explore have been defined by the literature and the draft protocol for the exploratory randomised controlled trial. Those that express interest in the RCT will be asked about the feasibility of the design of the study in addition to the general questions about light therapy (part 2 of the interview schedule).

Methods for data analysis

Data will be analysed at Medway School of Pharmacy. Qualitative data from the focus groups and the semi structured interviews will be digitally recorded, transcribed verbatim and analysed using content analysis (deductive approach).

Confidentiality and anonymity: Confidentiality and anonymity

Personal data (hard copy) of the demographic information for focus group participants will be stored in a secure filing cabinet in Medway School of Pharmacy to which only the research team will have access. All contact details and demographic survey results for those volunteers who expressed interest but who were not selected for the focus group discussion, if applicable, will be destroyed immediately after the focus group has taken place. Contact details of volunteers who have participated in the focus groups will have their contact details destroyed one month after the focus group.

All contact details for GPs will be stored in a secure filing cabinet in Medway School of Pharmacy. All focus group and interview transcripts will be anonymised.

Audio-recordings, transcripts and computer-aided analysis files will be stored electronically on a password-protected university computer system or in a secure filing cabinet.

All research data is kept for five years post final publications.

Safety

The PhD researcher will be aware of the School's safety procedures regarding interviews off-site.

Dissemination of the findings:

Each final year pharmacy undergraduate student will produce a report based on the data collected. Each report will be assessed individually; the resulting mark will contribute to the student's final pharmacy degree classification. In addition, the students will present the findings of their reports in a poster session.

The results will also be reported as part of a doctoral thesis, and may be presented at relevant conferences or submitted as paper for publication in peer-reviewed journals.

Roles:

The academic supervisor for all students (SC) will facilitate the focus groups. The undergraduate and postgraduate students will be present to observe and take notes. Each focus group will be transcribed by one of the 4th year pharmacy undergraduates. They will then quality check each other's work. GP interviews will be conducted and transcribed by the postgraduate researcher (JW). These will be quality assured by the undergraduates.

Both the focus group & the interviews will be analysed separately by each of the two 4th year pharmacy students and the postgraduate researcher (JW). JW will use the findings to shape the final design of the exploratory randomised controlled trial. The undergraduate will write up their findings discretely to JW as their sustained research project (Light therapy as a treatment for depression – The patient and the practitioners view). The data arising from the evaluation will remain the intellectual property of Medway School of Pharmacy.

Timescale:

Activity	August	September	October	November	
Design Protocol and obtain ethics approval	X				
Advertisement and recruitment to focus group		X			
Conduct focus groups		X	X		
Transcribe focus groups			X		
Recruitment to GP interviews			X		
GP interviews			X		
Analysis of interview transcripts			X (JW)	X (Undergrads)	
Analysis of transcripts			X (JW)	X (Undergrads)	
Amend study protocol			X (JW)	X (JW)	
Project report					X (Undergrads)

Costs:

Category	Item	Cost
Focus Groups	Vouchers, refreshments, travel expenses, postage	£500
Interviews	Postage, travel	£50

- **Have you been, or are you currently receiving treatment from your General Practitioner for Depression?**
- **Have you ever heard of Light Therapy?**
- **Do you have an hour to spare?**

Interested?

- ☀ Focus Groups will take place in October
- ☀ Participants will be given a **£20 voucher** and reasonable travel expenses.
- ☀ Interested? Please contact Jacqueline Walsh, PhD Researcher by Monday, September 30th 2013 – see details below.

We are planning to run a clinical study to test whether **light therapy** benefits patients with depression in the community.

We would therefore like to talk to you about your views on, and expectations of, the effectiveness of light therapy for depression, so we can explore whether people with depression would be interested in joining such a study.

We would like to tell you about our plans so that you can tell us whether they are relevant and realistic to you.



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Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Complete and return this form to Jacqueline Walsh, PhD student, Medway School of Pharmacy, Anson Building, Universities of Kent and Greenwich at Medway, Central Avenue, Chatham Maritime ME4 4TB or e-mail to jw586@kent.ac.uk if you are interested in attending a focus group.

I would like to attend the Focus Group on:

Wednesday 9th October at 3pm

Thursday 10th October at 6:30pm

Personal Information

Name

Telephone Number

E-mail address

Are you?

Male

Female

What is your age
(years)

Which ethnic group best describe you? (Please tick **one** box only)

White

Mixed

Asian or Asian British

Black or Black British

Chinese

Other

Have you or are you currently receiving treatment for depression from your GP?

I am currently receiving treatment

I have received treatment in the past

Which therapies have you used? (tick all that apply)

Cognitive Behavioural Therapy

Medicines

Other (please specify)

How long have / did you receive treatment for? years

What is your current working status?

Full-time

Part-time

Retired

Not working

Please tell us your full postcode (*we will **not** contact you or pass your details on to anyone else*)

PARTICIPANT INFORMATION SHEET

Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care.

Name of Researcher (s): Jacqueline Walsh, Zena Yasen, Ruhina Kassam, Dr Sarah Corlett, Dr Gurprit Lall,

You are being invited to take part in a study because of your previous or current experience of suffering with depression. Before you decide if you want to take part, you must understand why the study is being done and what it involves. Please take time to read the following information. Ask if anything is not clear or if you would like more information. Take time to decide whether you want to take part or not.

Why is the study being done?

To obtain your views regarding light therapy and its use. These data will be used to inform an exploratory investigation of the effectiveness and feasibility of light therapy use in the management of depression in primary care.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Even if you agree to take part, you can change your mind at any time without giving any reason. If you decide not to take part in the study, your rights will not be affected in any way.

If I do take part, what would I have to do and what would be done to me?

If you agree to be a part of this study, you will be invited to participate in a group discussion with up to 9 others which will be audio recorded and last about an hour. During the discussion we would like you to tell us about your views regarding light therapy and its use. You will be asked to sign the consent form before starting discussion. We might publish your comments but nobody will be able to identify you from these.

What should I do if I change my mind?

If you initially agree and then decide not to participate in the interview, either before or during the interview, please tell the researcher that you have changed your mind. Any discussions that you have had will then be excluded from the analysis.

Are there any risks/benefits if I take part?

There are no risks in taking part. You will be given a £20 voucher of high street shop or supermarket plus reasonable travelling costs.

Will anyone know that I've taken part?

We will not tell anyone that you have taken part in the study. Only researchers will know what you have said. Because the quotes from the focus group will be anonymised no one else will know who has made these comments.

What will happen to the results?

The data we collect does not contain any personal information about you. No one will link the data you provided prior to the focus group to the identifying information you supplied (e.g., name, address, email). Contact details that we have for you will be destroyed immediately following the focus group.

The data from the focus group will be used to compare the views of practitioners and patients regarding light therapy and to inform the protocol of a future exploratory trial.

Who should I contact if I want to know more about the study?

Who should I contact if I have any questions?	Who should I contact if I have any problems?
Dr Sarah Corlett Phone 01634 888909 Email: s.a.corlett@kent.ac.uk	Professor Janet Krska Phone 01634 202950 Email: j.kraska@kent.ac.uk

This project has been approved by the Medway School of Pharmacy Ethics Committee

CONSENT FORM

Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Name of researchers: Dr Sarah Corlett, Dr Gurprit Lall, Jacqueline Walsh, Zena Yasen, Ruhina Kassam

I have read and understand the information provided for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily

Initial Here

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and that this will not affect my legal rights

Initial Here

I understand that any personal information collected during the study will be anonymised and remain confidential

Initial Here

I agree to maintain the confidentiality of other participants

Initial Here

I understand that the focus group will be digitally audio recorded and that this recording will be transcribed verbatim

Initial Here

I understand that verbatim quotes taken from the recording of our conversation may be used in publications and reports, but that these will be anonymised and not traceable to me

Initial Here

I agree to take part in this focus group.

Initial Here

Name of Participant (Print)

Signature

Date

Name of Researcher (Print)

This study has been approved by MSoP Ethics Committee

Signature

Date

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Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Topic Guide for Focus groups

The following themes will be explored:

Awareness or experience of light therapy?
Expectations and concerns (for example side effects) regarding light therapy as a treatment option? How, if at all, does this change with colour of light (red and white)? <ul style="list-style-type: none">• Which of the two example light boxes do they think would be most effective and why?
What would help you to use light therapy? What would make adherence to this treatment strategy more challenging? <ul style="list-style-type: none">• Duration and timing of light therapy each day?• How would they accommodate the schedule into their daily routine (adherence)
An overview of the study design (5 minutes) would be presented and feedback sought on: <ul style="list-style-type: none">• The proposed recruitment material & options for method of recruitment (i.e. following consultation with GP, via letter of invitation from surgery)• The proposed duration of the study• Wearing the Actiwatches for the duration of the study• The schedule of saliva sampling• Frequency and setting: Returning to the Health Centre/ surgery for assessment and review
An overview of electroencephalogram testing (10 minutes) presented and feedback sought on: <ul style="list-style-type: none">• Effect of including electroencephalogram recordings within the trial design on recruitment• Preferred method• Preferred setting for EEG measurement

Appendix 8

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Dear [Name of participant]

Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Thank you for volunteering to take part in the light therapy discussion groups.

I am writing to confirm that you have been allocated a place to the session on Wednesday 9th/ Thursday 10th October. The focus group will start at 3pm/6:30pm and will be held at Medway School of Pharmacy. With introductions it will take about 1.5 hours. I have attached directions as to how to reach us. On arrival please report to Anson Building reception (ground floor). Unfortunately we are unable to pay participants, but we will be able to provide all participants with a voucher for £20 and reasonable travel expenses. Light refreshments will also be provided.

An information leaflet that explains more about the purpose of the focus group is attached together with a consent form.

I would be grateful if you would confirm your attendance by contacting Jacqueline Walsh by email jw586@kent.ac.uk or by telephone on 01634 202920 by the 7th October 2013.

Yours sincerely,

Jacqueline Walsh

PhD Research Student, Medway School of Pharmacy
Universities of Kent and Greenwich
Anson Building
Central Avenue
Chatham Maritime
Kent ME4 4TB

Appendix 9

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Dear [Name of participant]

Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Thank you for volunteering to take part in the light therapy discussion groups.

I am writing to inform you that the focus groups were oversubscribed and unfortunately on this occasion I have not been able to allocate you a place.

I would like to reassure you that the contact information and other details that you returned to me when you expressed interest in taking part will be destroyed.

Yours sincerely,

Jacqueline Walsh

PhD research student, Medway School of Pharmacy
Universities of Kent and Greenwich
Anson Building
Central Avenue
Chatham Maritime
Kent ME4 4TB

Appendix 10

Dear [Name of GP]

Light Therapy: Therapeutic Potential for the management of Depression in Primary Care.

Medway School of Pharmacy, in collaboration with the Medway Clinical Commissioning Group (CCG), is conducting research within the area of mental health. The School of Pharmacy's neuroscience and clinical practice divisions are interested in novel approaches in the treatment of depression. One of our fundamental research areas investigates the impact of our environment on the circadian regulation of both human behaviour and physiology, and consequently its implications to health and wellbeing.

We are developing a protocol for an exploratory study investigating the feasibility and effectiveness of light therapy as a treatment for depression in primary care and are looking for General Practitioners within the Medway CCG who would be interested in collaborating in this project.

As you may be aware there has been a wealth of emerging evidence endorsing the promising outputs resulting from light therapy use in non-seasonal trials. However, there is a paucity of data from primary care with most of the studies that have been carried out being conducted in specialised centres. We have developed a draft protocol, which is summarised on the flow diagram overleaf, and now wishing to fine-tune this by talking to practitioners to ensure that the processes developed for recruitment and review of patients are optimal. I realise that your time is very valuable but if you have an interest in mental health, whether or not you have had experience of using light therapy, we would very much welcome the opportunity to come and talk to you.

We would like to interview you to firstly explore your perceptions and expectations of light therapy, and then to get your thoughts on the feasibility of my study design. Agreeing to be interviewed in no way commits you to collaborating in the clinical study. The interview, which can take place at your surgery a time that is convenient to you, should take no more than 30 minutes. An information leaflet and consent form to participate in the interview are attached. If you are interested in taking part please contact Jacqueline Walsh by e-mail jw586@kent.ac.uk or by telephone on 01634 202920 by Monday, 27th January 2014, or complete and return the contact information sheet and consent form in the pre-paid envelope provided.

If you would like to know more about the clinical study but do not wish to be interviewed please contact us and we can arrange to see you at a later date.

Yours sincerely,

Jacqueline Walsh

PhD Research Student, Medway School of Pharmacy
Universities of Kent and Greenwich
Anson Building
Central Avenue
Chatham Maritime
Kent ME4 4TB

Academic supervisors

Dr Sarah Corlett, Clinical Lecturer, Medway School of Pharmacy

Dr Gurprit Lall, Lecturer in Circadian Biology/ Pharmacology, Medway School of Pharmacy

Appendix 11

Dear [Name of GP]

Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care.

As you may be aware, following our conversation with your Practice Manager, we at Medway School of Pharmacy Neuroscience and Clinical Practice Divisions are developing a protocol for an exploratory study investigating the feasibility and effectiveness of light therapy as a treatment for depression in primary care. We are looking for General Practitioners within the Medway CCG who would be interested in collaborating in this novel project.

We have recently run a series of focus group discussions with members of the general public, who have experience with depression, to explore views of light therapy and on the proposed exploratory randomised controlled trial (RCT) study design from the patient's perspective. These discussions have revealed invaluable information on the perceptions held regarding light therapy collected directly from the target population of this proposed exploratory trial.

To further this research, we wish to gain the perspective of General Practitioners within Medway CCG. We would like to interview you to firstly explore your perceptions and expectations of light therapy, and then to get your thoughts on the feasibility of our study design. Agreeing to be interviewed in no way commits you to collaborating in the clinical study. The interview, which can take place at your surgery a time that is convenient to you, should take no more than 30 minutes. A Research Passport and Letter of Access, for myself and the appropriate ethics and research governance approvals, for this project, have been obtained.

There has been a wealth of emerging evidence endorsing the promising outputs resulting from light therapy use in non-seasonal trials. However, there is a paucity of data from primary care with most of the studies that have been carried out being conducted in specialised centres. We have developed a draft protocol, which is summarised on the flow diagram overleaf, and now wish to fine-tune this by talking to practitioners to ensure that the processes developed for recruitment and review of patients are optimal

We would be delighted if you would agree to collaborate with us on this unique research opportunity. An information leaflet and consent form to participate in the interview are attached. If you are interested in taking part please contact Jacqueline Walsh by e-mail jw586@kent.ac.uk or by telephone on 01634 202920 by Monday, 10th March 2014, or complete and return the contact information sheet and consent form in the pre-paid envelope provided.

If you would like to know more about the clinical study but do not wish to be interviewed, please contact us and we can arrange to see at a convenient time and location.

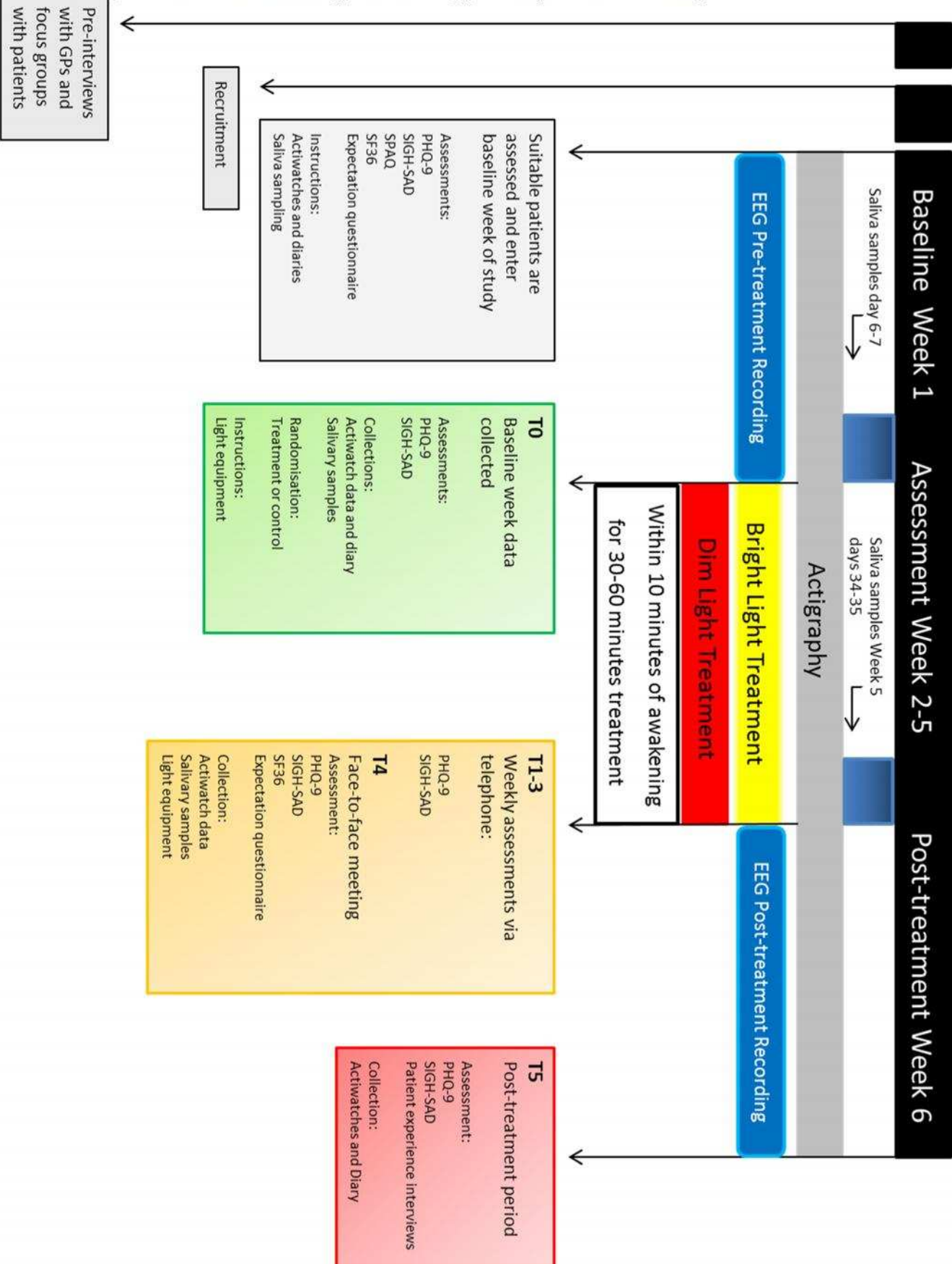
Yours sincerely,

Jacqueline Walsh MRPharmS
PhD Research Student, Medway School of Pharmacy
Universities of Kent and Greenwich
Anson Building
Central Avenue
Chatham Maritime
Kent ME4 4TB

Academic supervisors

Dr Sarah Corlett, Clinical Lecturer, Medway School of Pharmacy

Dr Gurpreet Lall, Lecturer in Circadian Biology/ Pharmacology, Medway School of Pharmacy



Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care**Contact Details Sheet - GPs**

If you are interested in either being interviewed about light therapy and/ or finding out more about the exploratory study please complete the sections below and then return this in the freepost envelope provided. **If you are volunteering to be interviewed please also complete and return the consent form.**

1. I am happy to be interviewed about light therapy: Yes/ No

Name : _____

Practice Name: _____

Contact Details:

Telephone: _____

Preferred time and day to be contacted: _____

2. I am interested in finding out more about the exploratory study: Yes/ No

I would prefer to receive further information by: post/ email/ in person

Name: _____

Practice Name: _____

Contact Details:

E-mail: _____

Telephone: _____

The details on this sheet will used only to contact you regarding this study. It will be stored securely at the Medway School of Pharmacy and accessed only by the research team

Returning this form does not commit you to anything. It is OK to change your mind and decide not to take part in the interview, or the study, even if you have returned this sheet. The information sheet which was sent with this form tells you how you can contact the research team.

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Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Contact Details Sheet - GPs

If you are interested in either being interviewed about light therapy and/ or finding out more about the exploratory study please complete the sections below and then return this in the freepost envelope provided. **If you are volunteering to be interviewed please also complete and return the consent form.**

3. I am happy to be interviewed about light therapy: Yes/ No

Name : _____

Practice Name: _____

Contact Details:

Telephone: _____

Preferred time and day to be contacted: _____

4. I am interested in finding out more about the exploratory study: Yes/ No

I would prefer to receive further information by: post/ email/ in person

Name: _____

Practice Name: _____

Contact Details:

E-mail: _____

Telephone: _____

The details on this sheet will used only to contact you regarding this study. It will be stored securely at the Medway School of Pharmacy and accessed only by the research team

Returning this form does not commit you to anything. It is OK to change your mind and decide not to take part in the interview, or the study, even if you have returned this sheet. The information sheet which was sent with this form tells you how you can contact the research team.

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Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Contact Details Sheet - GPs

If you are interested in either being interviewed about light therapy and/ or finding out more about the exploratory study please complete the sections below and then return this in the freepost envelope provided. **If you are volunteering to be interviewed please also complete and return the consent form.**

5. I am happy to be interviewed about light therapy: Yes/ No

Name : _____

Practice Name: _____

Contact Details:

Telephone: _____

Preferred time and day to be contacted: _____

6. I am interested in finding out more about the exploratory study: Yes/ No

I would prefer to receive further information by: post/ email/ in person

Name: _____

Practice Name: _____

Contact Details:

E-mail: _____

Telephone: _____

The details on this sheet will used only to contact you regarding this study. It will be stored securely at the Medway School of Pharmacy and accessed only by the research team

Returning this form does not commit you to anything. It is OK to change your mind and decide not to take part in the interview, or the study, even if you have returned this sheet. The information sheet which was sent with this form tells you how you can contact the research team.

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Light Therapy: Therapeutic Potential for the Management of Depression in Primary Care

Indicative Interview schedule - GPs

Awareness or experience of light therapy?

Please would you tell me what you know about using light therapy for depression?

Have you ever referred or cared for a patient with depression who has used light therapy? Could you tell me more about this (prompts: diagnosis, self-management or specialist referral, how did they get on? Was it effective? Was it well tolerated?)

What are your expectations regarding light therapy as a treatment option?

What are your concerns regarding light therapy as a treatment option?

How, if at all, do these change with colour of light (red and white)?

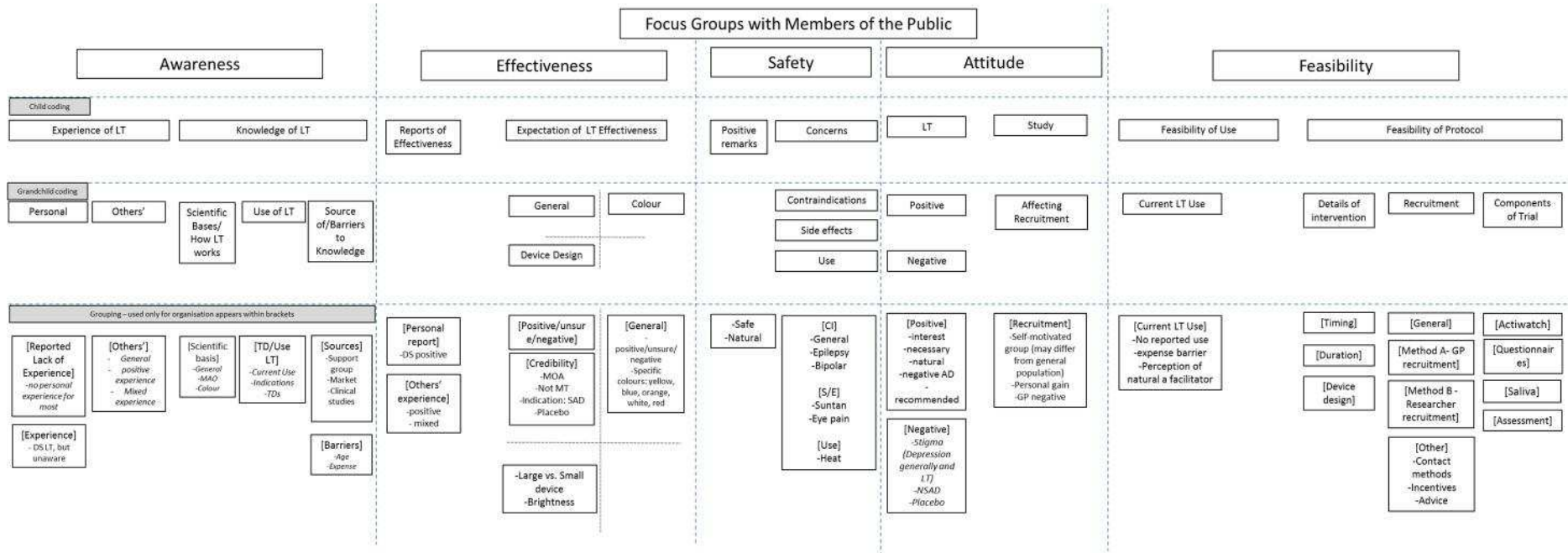
Which of the two example light boxes do they think would be most effective and why?

When, if at all would you think about using light therapy in a patient with depression? What do you think would be the principal challenges for the patient? (adherence)

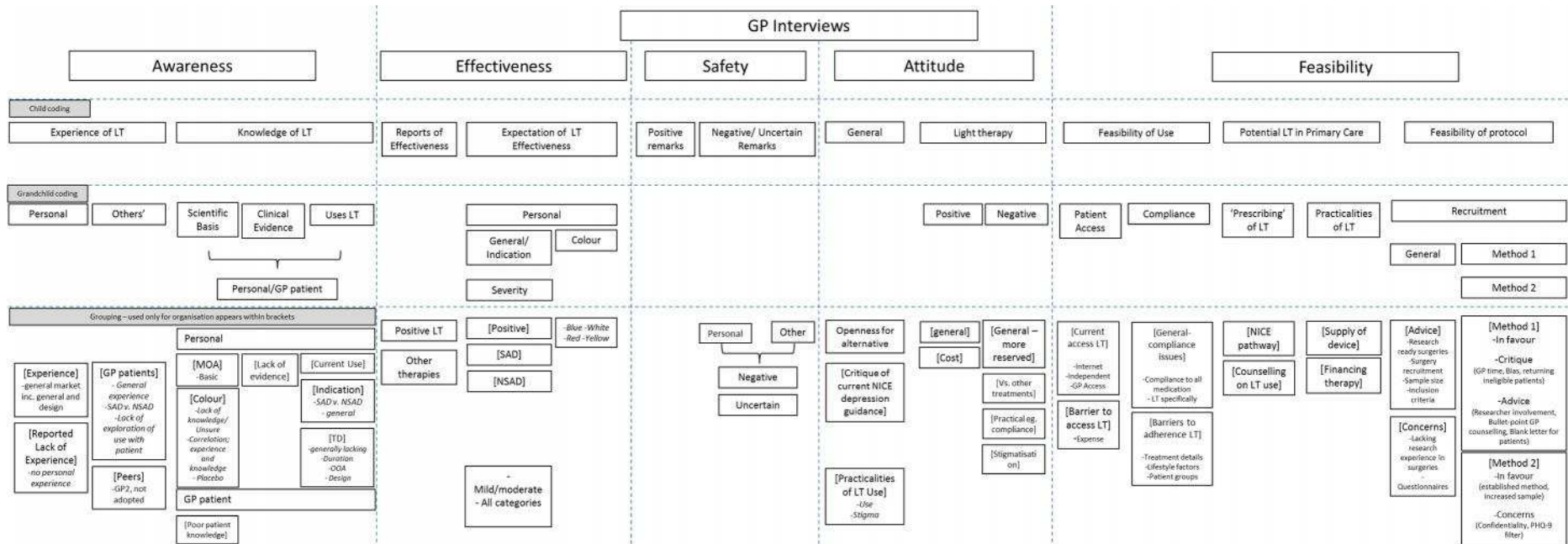
An overview of the study design (5 minutes) would be presented and feedback sought on:

- The proposed recruitment material & options for method of recruitment (i.e. following consultation with GP, or via letter of invitation from surgery, following identification through patients notes)
- The proposed duration of the study
- Duration and timing of light therapy
- Wearing the Actiwatchers for the duration of the study
- The schedule of saliva sampling
- Frequency and setting: Returning to the Health Centre/ surgery for assessment and review

Appendix 16



Appendix 17



Appendix 18

NRES Committee South East Coast - Brighton & Sussex

Health Research Authority
Ground Floor, Skipton House

80 London Road

London

SE1 6LH

Telephone:

Fax:

27 April 2015

Miss Jacqueline Walsh Medway
School of Pharmacy Universities of
Kent and Greenwich

Anson Building, Central Avenue, Chatham Maritime
ME4 4TB

Dear Miss Walsh

Study title: **Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care**

REC reference: **15/LO/0418**

IRAS project ID: **131652**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute

contact point, wish to make a request to defer, or require further information, please contact the Acting REC Manager, Mrs. Alison O'Kane at the email address listed at the end of this

letter. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study. Management permission or approval must be obtained from each host organisation prior to the

start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of advertisement materials for research participants [Appendix 9: Study Advert]	Version 1	19 January 2015
Covering letter on headed paper [Cover letter in response to NRES Committee provisional opinion]	Version 1	01 April 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters	Version 2	30 January 2015
GP/consultant information sheets or letters [Appendix 1: GP Information Leaflet]	Version 2	24 March 2015
GP/consultant information sheets or letters [Appendix 1: GP Information Leaflet (Tracked)]	Version 2	24 March 2015
GP/consultant information sheets or letters [Appendix 10a: Template GP letter - Participants recruited via GP (method 1)]	2	24 March 2015
GP/consultant information sheets or letters [Appendix 10a: Template GP letter - Participants recruited via GP (method 1) (tracked)]	2	24 March 2015
GP/consultant information sheets or letters [Appendix 10b: Template GP letter - Participants recruited via GP (Method 2)]	2	24 March 2015
GP/consultant information sheets or letters [Appendix 10b: Template GP letter - Participants recruited via GP (Method 2) (tracked)]	2	24 March 2015
Instructions for use of medical device [Appendix 15: Light Therapy Device instructions for use]	Version 1	05 February 2015
Instructions for use of medical device [Appendix 16: Actiwach Device instructions for use]	Version 1	18 February 2015
Interview schedules or topic guides for participants [Appendix 11: Participant Interview Schedule]	Version 1	19 January 2015
IRAS Checklist XML [Checklist_18022015]		18 February 2015
IRAS Checklist XML [Checklist_08042015]		08 April 2015
Letter from sponsor		
Letters of invitation to participant	Version 1	19 January 2015
Non-validated questionnaire [Appendix 8F1: Pre-study expectation questionnaire]	Version 1	19 January 2015
Non-validated questionnaire [Appendix 8F2: Post-study expectation questionnaire]	Version 1	19 January 2015
Non-validated questionnaire [Appendix 13: 6 month follow-up participant questionnaire]	Version 1	19 January 2015
Other [Academic Supervisor CV - Dr Gurprit Lal]		12 February 2015
Other [Sponsor Insurance/Indemnity - Professional Negligence]		
Other [Sponsor Insurance/Indemnity - Public Liability]		
Other [Appendix 5a: Screening form - Participants recruited via GP (Method 1)]	Version 2	30 January 2015
Other [Appendix 5b: Screening form – Participants recruited via advertising (Method 2)]	Version 2	30 January 2015
Other [Appendix 6: Personal Information Form]	Version 1	19 January 2015
Other [Appendix 14: Template GP Letter]	Version 1	19 January 2015

Other [Appendix 12: Participant Diary Template]	Version 1	19 January 2015
Participant consent form	Version 1	19 January 2015
Participant information sheet (PIS)	Version 2	30 January 2015
Participant information sheet (PIS) [Appendix 4A: Participants recruited via GP (Method 1)]	Version 3	24 March 2015
Participant information sheet (PIS) [Appendix 4A: Participants recruited via GP (Method 1) (Tracked)]	Version 3	24 March 2015
Participant information sheet (PIS) [Appendix 4B: Participants recruited via advertising (Method 2)]	Version 3	24 March 2015
REC Application Form [REC_Form_12022015]		12 February 2015
Referee's report or other scientific critique report [Referee Report - Dr Maria Gardani]		11 February 2015
Research protocol or project proposal [Project Protocol]	Version 2	24 March 2015
Research protocol or project proposal [Project Protocol (tracked)]	2	24 March 2015
Summary CV for Chief Investigator (CI)		30 January 2015
Summary CV for student [CI/Student CV - Jacqueline Walsh]		30 January 2015
Summary CV for supervisor (student research) [Academic Supervisor CV - Dr Sarah Corlett]		11 February 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow chart of protocol]	Version 1	19 January 2015
Validated questionnaire [Appendix 8A1: SIGH-SAD-SR]	Version 1	19 January 2015
Validated questionnaire [8A2: SIGH-SAD-SR instructions]	Version 1	19 January 2015
Validated questionnaire [Appendix 8B1: PHQ-9]	Version 1	19 January 2015
Validated questionnaire [Appendix 8B2: PHQ-9 instructions]	Version 1	19 January 2015
Validated questionnaire [Appendix 8D: SF-36 with instructions]	Version 1	19 January 2015
Validated questionnaire [Appendix 8E: SAFTEE-SR]	Version 1	19 January 2015
Validated questionnaire [Appendix 8C1: SPAQ]	Version 1	19 January 2015
Validated questionnaire [Appendix 8C2: SPAQ instructions]	Version 1	19 January 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

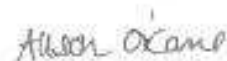
We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/LO/0418

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



Dr Simon Walton
Chair

Email: NRESCCommittee.SECOast-BrightonandSussex@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Nicole Palmer
Mr Richard Collins, Kent & Medway Consortium

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

I am currently recruiting participants for a study to investigate the effectiveness of light therapy in improving mood and treating depression when it is used by people in their own homes.

In this information pack there are a number of documents. The participant information leaflet tells you about the study, and what your participation would involve. Reading this document should help you decide if you wish to take part. However, if you need more details or have further questions please do get in touch with me by e-mail (jw586@kent.ac.uk), or telephone on 01634 202920 or 07840630633. It is important to know that this letter is not to tell you to join this study. Whether you participate or not is your decision. If you are not interested in this study you do not have to respond and no one from the School of Pharmacy will contact you further.

Once you have read the information leaflet, and if you would like to take part, the next thing you need to do is to complete the screening form. This will confirm whether you are eligible for the study. If you are eligible and wish to continue, please complete the personal information form, the mood questionnaire (PHQ-9), consent form. Return all of these with the screening form by post in the pre-paid envelope provided. I have also asked you to provide the details of your current GP. These details are taken so that we can inform your GP that you have decided to take part in this study. Your participation in this study will have no effect on your relationship with your doctor or the care you receive from them.

When I receive your forms I will contact you to arrange our first meeting. Returning the consent form and other documents does not mean that you are committed to take part in the study.

Thank you for your time and consideration. I look forward to hearing from you.

Yours sincerely,

Jacqueline Walsh MRPharmS
PhD Research Student, Medway School of Pharmacy
Universities of Kent and Greenwich
Anson Building
Central Avenue
Chatham Maritime
Kent ME4 4TB

Academic supervisors
Dr Sarah Corlett, Clinical Lecturer, Medway School of Pharmacy
Dr Gurprit Lall, Lecturer in Circadian Biology/ Pharmacology, Medway School of Pharmacy

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PARTICIPANT INFORMATION LEAFLET

Title of Project: Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Name of Researcher (s): Jacqueline Walsh (MPharm), Dr Sarah Corlett (BPharm, PhD, ADCPT), Dr Gurprit Lall (BSc, MSc, PhD, PGCHE, FHEA), Wuraola Obadahun

Institution: The Medway School of Pharmacy is a unique collaboration between the University of Greenwich and the University of Kent based on a shared campus in Chatham Maritime. Alongside the training of pharmacist, the School is actively involved in research, such as the study below.

You are being invited to take part in a feasibility study. Before you decide if you want to take part, you must understand why the study is being done and what it involves. Please take time to read the following information. Ask if anything is not clear or if you would like to know more.

Why is the feasibility study being done?

Studies in hospitals and clinics have shown that light therapy is effective in treating depression. However, we do not know if the same effect could be obtained when a person uses light therapy in their own home. Therefore we need to test how effective light therapy is in two different groups of participants; one using white light and the other red. For both groups we will measure the effect of light therapy on mood, sleep duration and the levels of two hormones within your body that are known to be associated with mood and sleep, called melatonin and cortisol. The results of this feasibility study will be used to inform and design future research.

Randomisation

We will be putting people that agree to take part into two groups. The groups will be selected by chance, as if by flipping a coin. One will receive white light, and the other red light. It is important that the researcher, and the other study participants, do not know which colour group you have been assigned. This information is in our files, but we will not look at the files until after the study has finished. This is the best way to test the effect without being influenced by what we think.

Who is eligible to take part?

To be eligible for the study you must have mild to moderate depression and be between the ages of 18-64. You must also be able to visit the Universities of Medway campus for four

assessments: the introductory meeting, baseline week, week 4, and the post-intervention week assessments.

To check whether you are eligible for this study, you will need to complete the screening form. If you are eligible, and agree to take part, you will also need to complete the personal information form, the mood questionnaire (PHQ-9) and sign a consent form. The PHQ-9 (Patient Health Questionnaire) is a simple one page questionnaire to measure whether your symptoms are categorised within the target range for this study. All of these documents are included in this pack. Please return the completed forms in the pre-paid envelope. I will then contact you to arrange our first meeting.

There are a number of treatment options available, including psychological and medication, for those who suffer with depression. If you wish to consider these options before entering this study, please consult your general practitioner.

Who is not eligible to take part?

If you have any of the following conditions or any of the following circumstances apply to you then unfortunately you are not eligible to participate in this study:

- Current treatment with antipsychotic drugs. (If you are taking medicines prescribed by your doctor and are not sure if they are antipsychotics please contact me).
- Alterations to your antidepressant treatment, including medication and counselling/talk therapy, in the previous four weeks of trial commencement or during the trial. You will be asked during the study assessments to inform the researcher if your treatment changes as you will need to be withdrawn.
- Previous use of light therapy, including use of light boxes, light visors and dawn simulation lamps. This does not include the use of SAD (seasonal affective disorder) alarm clocks.
- History of or current substance/drug abuse.
- History or current diagnosis of psychosis, severe depression, bipolar disorder, Parkinson's, dementia or Alzheimer's disease.
- A history of light-induced migraine or epilepsy.
- A history of traumatic brain injury (TBI).
- Presence of eye conditions including retinal blindness, cataracts, retinal diseases of the eye and glaucoma.
- Current oral diseases, such as candidiasis (thrush), or sores, swelling or cuts within the mouth.
- Current or recent participation in research prior to this study.

The conditions and treatments listed above may interfere/interact with the light therapy treatment, interfere with the accuracy of measuring hormones in saliva samples, or are outside the remit of this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Even if you agree to take part, you can change your mind at any time without giving any reason. If you decide not to take part in

the study, the care that you receive from the National Health Service will not be affected in any way.

If I do take part, what would I have to do and what would be done to me?

The study will last six weeks. We will need to meet with you four times for assessments (introductory meeting, baseline week, week 4 and post-intervention assessments). The first meeting will take up to an hour. The other appointments should take no more than 30 minutes. The meetings will take place at the Universities of Medway campus and will be arranged at a time that is convenient for you. For week 1, 2 and 3 assessments, we will telephone you at home to check how you are getting on.

Your participation in this study will involve using the light therapy for 30 minutes within ten minutes of waking up, and before midday, every morning for four week (weeks 1-4). We will also ask you to complete various questionnaires and a diary. For the diary you will be asked to record your bed time, the time you wake and when you get up, the duration and number of any naps that you have during the day, and times that you use light therapy. We will also ask you about how much alcohol you drink and your level of activity, as this can have an effect on your mood questionnaire results.

To give us information about your sleep patterns we need you to wear an Actiwatch for the duration of the study, both day and night. The Actiwatch measures your activity levels during the day and your sleeping patterns. It looks like a typical sports watch. You can continue with your normal day to day activities including showering and bathing without having to remove the watch.

We will also ask you to provide us with eight saliva (spit) samples at the end of baseline week and week 4. This will allow us to measure the effect of light therapy on the levels of two hormones within your body, cortisol and melatonin, which are known to be associated with mood and sleep.

The night before the final day of these weeks, you will be asked to produce four saliva samples, one each hour starting four hours before your usual bedtime. The next morning, you will be asked to produce four saliva samples, one each half hour for two hours after you wake up. We will give you the containers to keep your samples in your fridge until we collect them at the assessment.

It is important when you are giving saliva samples that you do not eat, drink, chew gum or smoke for 30 minutes before producing your samples. The containers for your samples will be labelled with your participant code, the date and predicted times of collection, not your name. Melatonin in the body is influenced by light. Therefore, we ask that you stay in a semi-dim light condition during the 4 hours of saliva sampling in the evening. Reading, listening to music, conversations (both face-to-face and on the phone) are allowed. Watching TV at a distance is allowed, but not sitting directly in front of a TV, or a computer display, nor keeping all lights on. We ask that you keep your activity levels to a minimum during this time.

At the end of this leaflet, there is a table which summarises what will happen on a week by week basis

What happens first?

Introductory Assessment

On the first day of the study, you will be invited for an introductory assessment in a private room at the Universities of Medway campus. This meeting will take approximately one hour. The researcher will talk to you about the study and you will have the opportunity to ask any questions. You will be assigned a "Participant Code" which will be used to anonymise all of the paperwork associated with the study.

You will be asked to complete four questionnaires at this meeting. These will assess the severity of your depression, measure how much your symptoms vary from season to season, assess your current quality of life, and your expectations of how effective the treatment with light therapy will be.

You will be given an Actiwatch, a diary and 8 saliva containers. The researcher will talk to you about each of these individually and answer any questions you may have.

You will be offered by the researcher a text message reminder service. With this service you will be sent a text message reminder on the days that you must start collection of saliva samples, and/or the day before an assessment appointment.

Baseline Assessment

This will take place at the Universities of Medway campus and will take approximately 30 minutes. The researcher will collect the saliva samples that you produced that morning and the night before. You will complete two questionnaires which assess your mood. The researcher will then give you a light box to take home with you. They will verbally instruct you on how to use the equipment, when to use it and for how long. You will use the light box every day for the next 4 weeks. You will receive another 8 containers to collect your saliva samples at the end of week 4.

You will also be given three envelopes, containing questionnaires, marked weeks 1, 2 and 3. Each envelope will contain two mood questionnaires, a questionnaire to assess whether you have noticed any side-effects of treatment, and a pre-paid addressed envelope to return your completed forms to the University.

Weeks 1-3 Assessment

Each week at an agreed time the researcher will telephone you to check how you are getting on. They will remind you to complete and return the questionnaires for that week.

Week 4 Assessment

At the week 4 assessment, we will arrange a meeting at the Universities of Medway campus. This meeting will last approximately 30 minutes. You will return the light box and the saliva samples that you have collected that morning and the evening before. You will be asked to complete two mood questionnaires, a quality of life questionnaire, a questionnaire on

whether you have experienced any side-effects of treatment and a light therapy expectation questionnaire.

Unfortunately we will not be able to give you a light box to use once you have completed the study. However, light therapy boxes are widely available on the market and can be easily purchased if you wish to continue independent treatment.

Post-intervention Assessment

Following the completion of the light therapy weeks 1-4, you will continue to wear the Actiwatch and completing the diary entries in this post-intervention week. At the end of this week, we will arrange a meeting with you at the Universities of Medway campus. You will be asked to complete the two mood questionnaires, and return your Actiwatch and diary.

At this meeting the researcher will then ask you to make a final appointment to talk about your experience of the study and using light therapy in a telephone interview. If you agree to this it will be arranged at a time that is convenient for you. The interview over the telephone will be audio recorded, and will take approximately 20-30 minutes. We may publish comments that you have made within the interview but all comments will be anonymised. Nobody will know that you have taken part in this study or be able to identify you from the comments made.

Six months after the study has ended we will send you a short questionnaire in the post. It will ask you if you have used light therapy since the study. We will provide a pre-paid envelope to return your questionnaire to the University.

Are there any risks if I take part?

The studies on light therapy that have taken place in hospitals and clinics have shown that light therapy is very well tolerated and has few side-effects. The most common of these side effects include elevated mood, eye irritation and headaches.

Before and during the trial, we will be closely monitoring your depression score (mood) using the Patient Health Questionnaire 9 (PHQ-9), as mentioned above. We use this to measure your response to the light therapy. In an event where your mood worsens above the maximum PHQ-9 score defined by the trial's inclusion criteria, or we are concerned that your general mental health has deteriorated, you will be advised to make an appointment to see your GP. We will contact your GP to inform them that your depression symptoms have become more severe. This is for your safety.

Some people find it uncomfortable or embarrassing to spit into a container. You will be able to do this in private so nobody is watching you.

Are there any benefits if I take part?

You will not be paid to complete this study. There are no personal benefits from participating in this research. However, your participation may provide us with a better understanding of using light therapy in terms of effectiveness, its usability, how it affects sleep and it may lead us to a method of identifying individuals who would benefit most from light therapy.

Will anyone know that I've taken part?

Only the research team and your GP, as listed on your screening form, will know that you have participated in this trial. Your GP will be informed for your own safety.

All researchers will maintain confidentiality of all data, including potential and actual participant identity, their questionnaire responses, activity data, diary entries, and biochemical results.

What should I do if I change my mind?

You are free to withdraw from the study at any time and if you wish, have any data collected removed from the study, without reason. We do ask that you inform us of your decision and return equipment to the research team.

What will happen to the results?







All of the data collected will be identified using your participant code and not your name. The data we collect does not contain any personal information about you. No one will link the data you provided prior to the trial to the identifying information you supplied (e.g., name, address, email). Any results published or presented at scientific meetings will not have any identifying information about you.

Contact details that we have for you will be stored securely separately to study data. Contact details will be destroyed immediately following your completion of the study unless you choose to receive a report summarising our findings. In that case we will hold your contact details until this information has been sent to you. Your personal details will not be used for any other reason.

The data from this trial will be included in a PhD thesis as part Jacqueline Walsh's doctorate qualification. The results will be used to inform the protocol of a future large scale study investigating light therapy for the management of depression.

Who should I contact if I want to know more about the study?

Who should I contact if I have any questions?	Who should I contact if I have any problems?
<p>Jacqueline Walsh Phone: 01634 202920 Mobile: 07840630633 Email: jw586@kent.ac.uk</p> <p>Dr Sarah Corlett, PhD Phone: 01634 888909 Email: S.A.Corlett@kent.ac.uk</p> <p>Address: Medway School of Pharmacy Universities of Kent and Greenwich Anson Building Central Avenue Chatham Maritime Kent ME4 4TB</p>	<p>Dr Gurprit Lall, PhD Phone: 01634 202946 Email: G.Lall@kent.ac.uk</p> <p>Independent Researcher: (For individuals seeking further guidance regarding taking part in research, or to speak to someone outside of the research team) Dr Shivaun Gammie, PhD Phone: 01634 202963 Email: s.m.gammie@kent.ac.uk</p>

Week	Date	 Assessments							
Baseline	To: __/__/____ From: __/__/____	Intro: __/__/____ BL: __/__/____ Where: _____	Actiwatch To be worn throughout the study	Diary Entries To be kept each day the study	4 Evening Saliva Samples Date: __/__/____	4 Morning Saliva Samples Date: __/__/____			
1	To: __/__/____ From: __/__/____	Assessment Date: __/__/____ Via telephone					Light Therapy 30 minutes Within 10 minutes of waking		
2	To: __/__/____ From: __/__/____	Assessment Date: __/__/____ Via telephone					Light Therapy 30 minutes Within 10 minutes of waking		
3	To: __/__/____ From: __/__/____	Assessment Date: __/__/____ Via telephone					Light Therapy 30 minutes Within 10 minutes of waking		
4	To: __/__/____ From: __/__/____	Assessment Date: __/__/____ Where: _____					4 Evening Saliva Samples Date: __/__/____	4 Morning Saliva Sample Date: __/__/____	Light Therapy 30 minutes Within 10 minutes of waking
Post-Intervention	To: __/__/____ From: __/__/____	Assessment Date: __/__/____ Where: _____							

medway school of pharmacy

Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

Participant Screening Form

Complete and return this form to Jacqueline Walsh, PhD student, Medway School of Pharmacy, Anson Building, Universities of Kent and Greenwich at Medway, Central Avenue, Chatham Maritime ME4 4TB, using the pre-paid envelope provided, if you are interested in participating in this study. Please answer all questions on this form.

9. What is your age? (years)

(If you have entered an age under 18 or over 64 years of age, unfortunately you will not be eligible for this research study at this time. Thank you for your interest.)

10. Have you been diagnosed with depression by your GP?

Yes

No

(If you have answered No, unfortunately you will not be eligible for this research study at this time. Thank you for your interest.)

11. Are you currently receiving treatment for depression from your GP?

I am currently receiving antidepressant medication

I am currently receiving CBT, or another form of talking therapy

I am not receiving any treatment at this time

12. If you are receiving medicines or talking therapy, have there been any changes to your treatment in the past 4 weeks, or any planned changes in the near future?

Yes

No

(If you have answered Yes, unfortunately you will not be eligible for this research study at this time. Thank you for your interest.)

13. Please tick if any of the conditions or categories below applies to you:

- Pregnant/breast feeding or planning pregnancy.

- Current treatment with antipsychotic drugs. Commonly used examples include: amisulpride, aripiprazole, clozapine, olanzapine, quetiapine, risperidone, sertindole chlorpromazine, flupentixol, haloperidol, levomepromazine, pericyazine, perphenazine, pimozide, sulpiride, trifluoperazine, and zuclopenthixol.
(If you are taking medicines and you are not sure if they fall into this category please contact the researcher).

- History of or current substance or drug abuse.

- History of or current diagnosis of psychosis; severe depression; bipolar disorder; Parkinson's; dementia; Alzheimer's disease.

- A history of light-induced migraine or epilepsy.

- A history of traumatic brain injury (TBI).

- Presence of eye disorders such as retinal blindness, cataracts, retinal diseases of the eye and glaucoma.

- Current diseases of the mouth, such as thrush, or sores, cuts or inflammation within the mouth.

- I have used light therapy before. This includes use of light boxes, light visors and dawn simulation lamps. This does not include the use of SAD (seasonal effective disorder) alarm clocks.

- Current or recent participation in research prior to this study.

(If you have ticked yes for any of the conditions or treatments listed above, unfortunately you will not be eligible for this research study at this time. Thank you for your interest.)

14. Have you been diagnosed by a doctor with any other conditions? If so, please write them in the space provided below:

15. Are you able to access the Universities of Medway Campus for assessments throughout the study?

Yes

No

*(If you have answered No, unfortunately you will not be eligible for this research study at this time.
Thank you for your interest.)*

16. Please complete the PHQ-9 questionnaire and return it for scoring.

Thank you for taking the time to fill in this screening form and completing the PHQ-9 mood questionnaire. Please return both with your personal information form and consent form in the pre-paid envelope provided within this information pack. If you have any queries regarding the study, please refer to the Participant Information Leaflet enclosed or contact the research team using the details provided on the Participant Information Leaflet.

A member of the research team will soon be in contact to arrange your first appointment.

Date: [enter date]

Dear [GP Name]

RE: Light Therapy: An Exploratory Trial Investigating the Effectiveness and Feasibility of Light Therapy for the Management of Depression in Primary Care

[Patient Name and Address]

I am writing to inform you that your patient has agreed to participate in the above trial at Medway School of Pharmacy. This light therapy study is a six week exploratory two-arm trial. The purpose of this study is to investigate the effectiveness and feasibility of light therapy for the management of mild to moderate depression in a primary care setting. The study has been reviewed and received Ethical Approval from the NRES Committee.

Light therapy has gained recognition as a potent non-pharmacological treatment for seasonal affective disorder (SAD) and is now established as the treatment of choice for this condition. However recently the use of light therapy has progressed beyond SAD, and has been shown to be effective in a range of disorders, including non-seasonal depression. We are interested in studying this indication for light therapy further in a primary care setting.

The trial consists of a baseline week of monitored standard care, four weeks of monitored light therapy intervention, followed by a final week of monitored standard care. Participants will be randomised to receive either white or red light therapy in their home using light therapy equipment provided by the research team, to be used for 30 minutes each morning. Activity data will be monitored using an Actiwatch device which will be worn for the duration of the trial. Saliva samples will be collected before and after intervention to monitor levels of the hormones melatonin and cortisol, which are known to change in response to light therapy.

There will be no alterations made to the patient's medications or treatments; standard treatment will not be compromised as a result of participation in this study. Alterations to participant antidepressant treatment, including medication and counselling/talk therapy, in the four weeks prior or during the trial, will result in delayed entry or withdrawal from the study. In the event that your patient's mental health deteriorates during the course of the trial, the research team will inform you via letter and we will encourage the patient to make an appointment to see you.

The main side effects, contraindications, medication/procedure interactions and trial exclusion criteria are included in the Participant Information Leaflet which I have enclosed with this letter for your reference. However, if you have any queries or require further information please contact me using the contact details I have included below.

In the event of an emergency please call: 07840630633.

Yours sincerely

Jacqueline Walsh MRPharmS

PhD Research Student, Medway School of Pharmacy

Universities of Kent and Greenwich

Anson Building

Central Avenue

Chatham Maritime

Kent ME4 4TB

Office Tel: 01634 202920

Mobile Tel: 07840630633

Academic supervisors

Dr Sarah Corlett, Clinical Lecturer, Medway School of Pharmacy

Dr Gurprit Lall, Lecturer in Circadian Biology/ Pharmacology, Medway School of Pharmacy

Appendix 23

SIGH-SAD SELF REPORT

In the questions that follow, please circle the number of one alternative in each set that best describes how you have been during the past week. If you have changed during the last few days, circle the alternative that best describes how you are today. Before you select an alternative in each set, read all of the choices to make sure you pick the most accurate one. Each new set of alternatives that you should consider begins with a pointer sign

DURING THE PAST WEEK . . .

- 0 - I have *not* been feeling down or depressed at all.
- 1 - I have been feeling somewhat down or depressed.
- 2 - I have been feeling quite down or depressed.
- 3 - I have been feeling and looking very depressed (or others have said so).
- 4 - I haven't been able to think about anything except how bad or depressed I feel.

- 0 - I have been keeping busy and have been interested in the things I've been doing.
- 1 - I haven't been quite as interested in doing things as I used to be.
- 2 - I have definitely not been as interested in things as I used to be, and I have had to push myself to do them.
- 3 - I have not been doing much because I feel so bad.
- 4 - I have stopped doing nearly everything — I just sit or sleep most of the day.

Note: When an item refers to how you "normally" are, it means when you are feeling OK, or as close to OK as you get.

- 0 - I have been interested in socializing with others as much as normal.
- 1 - I have still been interacting with others but am less interested in doing so.
- 2 - I have been interacting less with other people in social situations.
- 3 - I have been interacting less with others at home or at work.
- 4 - I have become quite withdrawn at home or at work.

(This question is about your interest in sex, not your actual sexual activity.)

- 0 - My interest in sex has been about the same as it was before I became depressed, or greater than normal.
- 1 - I have not been quite as interested in sex as I was before I became depressed.
- 2 - I have been much less interested in sex than I was before I became depressed.

Assessor use only

(H1/___4_x)
(max H↑ A↑)

(H2/___4_x)

(A1/x___4)

(H3/___2_x)

This inventory (SIGH-SAD-SR) was developed by J.B.W. Williams, D.S.W., M.J. Link, B.S., and M. Terman, Ph.D. It is based on the Structured Interview Guide for the Hamilton Depression Rating Scale - Seasonal Affective Disorder Version (SIGH-SAD), by J.B.W. Williams, M.J. Link, N.E. Rosenthal, and M. Terman (1998). The work was supported in part by BRSG Grant 903-E759S from the Research Foundation for Mental Hygiene, Inc., and NIMH Grant MH-42931. © 1998. All rights reserved. Permission is granted for reproduction for use by researchers and clinicians. For correspondence: Dr. Williams or Dr. Terman, New York State Psychiatric Institute, 1051 Riverside Drive, New York, NY 10032. For masters: *Clinical Assessment Tools Packet*, Center for Environmental Therapeutics, 767 Broadway, Norwood, NJ 07648; www.cet.org or info@cet.org. 7/98 version

DURING THE PAST WEEK . . . Page 2

Remember, "normal" means how you're feeling when you're OK.

Assessor use only

- 0 - My appetite has been normal or greater than normal.
- 1 - I have had less appetite than normal, but I eat without anyone having to urge me.
- 2 - I have had so little appetite that I have not been eating regularly unless someone urges me to.

(H4/ __ 2 x)

- (Circle "0" for this question if you have lost weight due to dieting, or have lost weight that you had previously gained when you were depressed.)**
- 0 - I don't think I have lost any weight since I became depressed, or if I have lost weight, I have started to gain it back.
 - 1 - I have probably lost some weight (that I haven't gained back at all) because I haven't felt like eating.
 - 2 - I have definitely lost weight (that I haven't gained back at all) because I haven't felt like eating.

(H5/ __ 3 x)

- 0 - I have **not** gained weight above my normal level in the past week.
- 1 - I have probably gained weight (two or more pounds) in the past week, and my current weight is above normal for me.
- 2 - I have definitely gained weight (two or more pounds) in the past week, and my current weight is above normal for me.

(A2/ x __ 2)

(A3/ x __ 3)

- (This question is about your appetite, not what you have actually been eating.)**
- 0 - My appetite has been normal or less than normal.
 - 1 - I have wanted to eat just a little more than normal.
 - 2 - I have wanted to eat somewhat more than normal.
 - 3 - I have wanted to eat much more than normal.

(A4/ x __ 3)

- (This question is about what you have actually been eating.)**
- 0 - I have **not** been eating more than normal.
 - 1 - I have been eating a little more than normal.
 - 2 - I have been eating somewhat more than normal.
 - 3 - I have been eating much more than normal.

(A5/ x __ 3)

- 0 - I have **not** been craving or eating sweets or starches any more than when I feel normal.
- 1 - I have been craving or eating sweets or starches somewhat more than when I feel normal.
- 2 - I have been craving or eating sweets or starches much more than when I feel normal.
- 3 - I have had an irresistible craving for sweets or starches.

**If you circled "1", "2" or "3" for the question above, please also answer the following:
The craving or eating has focused mainly on:**

- 1 - sweets
- 2 - starches
- 3 - both sweets and starches

List any specific foods you have been craving: _____

Which of the following describes you best?

- 1 - I have been craving sweets or starches, but have been able to control

eating them.

2 - I have actually been eating sweets or starches excessively.

DURING THE PAST WEEK . . . Page 3

At what time of day has the craving or eating usually occurred?

0 - It can occur at any time — it comes and goes.

1 - It usually occurs in the morning.

2 - It usually occurs in the afternoon or evening.

3 - It has been nearly all the time.

0 - I have **not** had any difficulty falling asleep at night.

1 - Some nights it has taken me longer than half an hour to fall asleep.

2 - I have had trouble falling asleep every night.

0 - I have **not** been waking up in the middle of the night, or if I have gotten up to go to the bathroom, I have fallen right back asleep.

1 - My sleep has been restless and disturbed during the night.

2 - I have been waking during the night without being able to get right back to sleep, or I've been getting out of bed in the middle of the night (not just to go to the bathroom).

0 - I have been oversleeping **or** waking up at a reasonable hour in the morning.

1 - I have been waking up very early in the morning, but I have been able to go back to sleep.

2 - I have been waking up very early in the morning without being able to go back to sleep, especially if I've gotten out of bed.

Remember, "normal" means how you're feeling when you're OK.

When I am feeling normal, I usually sleep about ___ hours each day, including naps.

0 - I have been sleeping no more than I usually do when I feel normal.

1 - I have been sleeping at least one hour more than I usually do when I feel normal.

2 - I have been sleeping at least two hours more than I usually do when I feel normal.

3 - I have been sleeping at least three hours more than I usually do when I feel normal.

4 - I have been sleeping at least four hours more than I usually do when I feel normal.

The following question asks about how difficult it has been waking up in the morning:

0 - Usually I have been waking up on time and quickly feeling wide awake.

1 - Although I've had to depend on an alarm clock to wake up on time, I've usually felt wide awake within 30 minutes.

2 - I've been feeling sleepy for 30 minutes or longer after I wake up.

3 - It's been a major effort to get out of bed, and I've continued to feel sleepy for at least three hours after I wake up.

4 - I've been falling back asleep after the alarm, or feeling sleepy for at least five hours after I first wake up.

If you have been using an alarm, what time is it set for? ___:___ AM / PM (circle)

0 - I have **not** had a heavy feeling in my limbs, back or head.

1 - I have had a heavy feeling in my limbs, back, or head, some of the time.

2 - I have had a heavy feeling in my limbs, back, or head, a lot of the time.

0 - I have **not** been bothered by backaches, headache, or muscle aches.

Assessor use only

(H6/ ___ 2 x)

(H7/ ___ 2 x)

(H8/ ___ 2 x)

(A6/ x ___ 4)

(H9a)

(H9b)

- 1 - I have been bothered some of the time by backaches, headache, or muscle aches.
- 2 - I have been bothered a lot of the time by backaches, headache, or muscle aches.

DURING THE PAST WEEK . . . Page 4

Remember, "normal" means how you're feeling when you're OK.

- 0 - I have **not** been feeling more tired than normal.
- 1 - I have felt slightly more tired than normal.
- 2 - I have been more tired than normal for at least a few hours per day.
- 3 - I have felt tired much of the time most days.
- 4 - I have felt an overwhelming fatigue all of the time.

- 0 - I have **not** been putting myself down, or feeling like a failure or that I have let other people down, or feeling guilty about things I have done.
- 1 - I have been feeling like a failure or that I have let other people down.
- 2 - I have been feeling very guilty or thinking a lot about bad things I have done, or bad mistakes I have made.
- 3 - I believe that my being depressed is a punishment for something bad that I've done.
- 4 - I have been hearing voices accusing me of bad things, or seeing things that are scary, that others said were not really there.

- 0 - I have **not** had any thoughts about dying or about hurting or killing myself, or that life is not worth living.
- 1 - I have had thoughts that life is not worth living, or that I'd be better off dead.
- 2 - I have thought about dying, or wish I were dead.
- 3 - I have thought about killing myself, or I have done something to hurt myself.
- 4 - I have tried to kill myself.

- 0 - I have **not** been feeling especially tense or irritable, or worrying a lot.
- 1 - I have been feeling somewhat tense or irritable.
- 2 - I have been worrying about little unimportant things — that I wouldn't ordinarily worry about — or I have been excessively tense or irritable.
- 3 - Other people notice that I look or sound tense, anxious, or fearful.
- 4 - I feel tense, anxious, or fearful all of the time.

Check off all the following physical symptoms that have bothered you in the past week:

- | | |
|--|---|
| <input type="checkbox"/> <i>dry mouth</i> | <input type="checkbox"/> <i>gas</i> |
| <input type="checkbox"/> <i>indigestion</i> | <input type="checkbox"/> <i>diarrhoea</i> |
| <input type="checkbox"/> <i>cramps</i> | <input type="checkbox"/> <i>belching</i> |
| <input type="checkbox"/> <i>heart palpitations</i> | <input type="checkbox"/> <i>headaches</i> |
| <input type="checkbox"/> <i>hyperventilating</i> | <input type="checkbox"/> <i>sighing</i> |
| <input type="checkbox"/> <i>having to urinate frequently</i> | <input type="checkbox"/> <i>sweating</i> |

If you checked off any of the symptoms listed above, please also answer the following:

- 1 - Altogether, the symptom(s) have only been bothering me a little bit.
- 2 - Altogether, the symptom(s) have been bothering me somewhat.
- 3 - Altogether, the symptom(s) have been bothering me a lot.
- 4 - Altogether, the symptom(s) have been making it difficult for me to function.

Circle one of the following:

- 0a - These symptoms bother me only when I am depressed.
- 0b - These symptoms bother me from time to time, but they get worse when I'm depressed.
- 2 - In my experience, these symptoms occur whether or not I am depressed.
- 3 - I think these symptoms are due to physical illness or a medication that I am taking.

Assessor use only

(H9c, A7/ __2 + __4)

(largest H9a-c after recoding 2 to 1, and 3 and 4 to 2, on item H9c)

(H10/ __4 x)

(H11/ __4 x)

(H12/ __4 x)

(H13/ __4 x)

(0 if none)

If you circled "3" above, what illness or medication? _____

DURING THE PAST WEEK . . . Page 5

Assessor use only

- 0 - I have **not** been thinking much about my physical health.
- 1 - I have been worrying about being or becoming physically ill.
- 2 - I have been spending most of my time worrying about my physical health.
- 3 - I have been complaining frequently about how I feel physically, or asking for help a lot.
- 4 - I am sure that I have a physical disease, even though the doctors tell me that I don't.

Have you had a specific medical problem this week? If yes, please describe:

- 0a - Although previously I was depressed, this past week I have felt distinctly better.
- 0b - I have become depressed, or have continued feeling depressed, in the past week.

If neither 0a nor 0b is true, circle 1 or 2 below:

- 1 - I haven't been feeling very good, but it's not because of depression — rather, I ate something bad, or overworked, or had a virus, or just have been needing a rest.
- 2 - Depression has not been a problem of mine, now or before.

Remember, "normal" means how you're feeling when you're OK.

- 0 - My rate of speech and thought are normal.
- 1 - My speech and physical movements are slightly slowed down, or my thoughts are slightly slower, which has made it difficult for me to concentrate.
- 2 - My physical movements, speech or thoughts are somewhat slow compared to normal, and other people have noticed this.
- 3 - My physical movements are markedly slower, or my speech or thoughts are so slow that it has been hard to have a conversation with me.
- 4 - My physical movements are greatly slowed down, or my speech and thoughts are so slow that it has been difficult for me to think or talk at all.

- 0 - I have **not** been restless or fidgety.
- 1 - I have been somewhat restless, or sometimes have been playing with my hands, hair, or other things.
- 2 - I have been very restless, or often have been playing with my hands, hair, or other things.
- 3 - I have trouble sitting still, and need to keep moving about a lot of the time.
- 4 - I am unable to sit still, or have been wringing my hands, biting my nails, pulling my hair, or biting my lips, nearly all the time.

- 0 - Overall, the problems I have been asked about in this questionnaire have bothered me equally in the morning and in the late evening.
- 1 - Overall, these problems have bothered me more in the morning.
- 2 - Overall, these problems have bothered me more in the late evening.

If you circled "1" or "2" for the question above, please also circle one of the following:

- 1 - I have been feeling only a little worse in the mornings (**or** evenings).
- 2 - I have been feeling much worse in the mornings (**or** evenings).

(H14/ __4 x)

(H15/ __2 x)

(recode 2 to 0?)

(H16/ __4 x)

(H17/ __4 x)

(Total H1-H17= _____)

(HAM-D 17-item subscore)

(H18a)

(H18b/ __2 x)

(0 if none)

Assessor use only

In the following question, a "slump" means a temporary reduction in mood or energy from which you recover, at least partially, later in the day.

- 0 - I have **not** regularly had a slump in my mood or energy in the afternoon or evening.
- 1 - I have regularly had a slump in my mood or energy in the afternoon or evening.

If you circled "1" for the question above, please also answer the following:

The slumps usually begin about ___ p.m. and end about ___ p.m.

Please specify:

- 0 - Once these slumps occur, they usually last till bedtime.
- 1 - I usually come out of these slumps at least an hour before bedtime.

(A8/ 3)

(0 if none)

If you usually come out of these slumps at least an hour before bedtime, please also circle one of the following:

- 1 - Usually, the slumps have been only mild in intensity.
- 2 - Usually, the slumps have been moderate in intensity.
- 3 - Usually, the slumps have been severe in intensity.

How would you characterize the slumps?

- 0 - They are mostly in my mood.
- 1 - They are mostly in my energy.
- 2 - They are in both mood and energy.

(H19/ 4 x)

- 0 - I have **not** been having any sensation that things around me are unreal, or that I'm in a dream.
- 1 - I have been having only very mild sensations of unreality.
- 2 - I have been having some definite sensations of unreality or of being in a dream.
- 3 - I have been having sensations of unreality a lot of the time.
- 4 - I have been so bothered by sensations of unreality that it has been hard for me to function.

(H20/ 3 x)

- 0 - I have **not** thought that anyone was trying to give me a hard time or hurt me.
- 1 - I have been suspicious of people.
- 2 - I have noticed certain things that probably mean that someone is trying to harm me.
- 3 - I am sure someone is trying to get me or hurt me.

(H21a)

- 0 - I have **not** had things that I've had to do over and over again, like checking the locks on the doors several times, or repeatedly washing my hands.
- 1 - I have been compelled to check certain things repeatedly — more than should be necessary.
- 2 - I have been spending excessive amounts of time checking certain things repeatedly.

(H21b)

(H21/ 2 x)
(largest 21a-b)

- 0 - I have **not** been bothered by thoughts that run over and over in my mind but don't make any sense to me.
- 1 - I have been a little bothered by thoughts that keep running through my mind but don't make any sense to me.
- 2 - I have been very bothered by thoughts that keep running through my mind but don't make any sense to me.

(T₂₉= H₂₁ +
 A₈)
(SIGH-SAD 29-item total)

[(A₈/T₂₉)x100= %]
(Atypical balance score)

INSTRUCTIONS FOR THE SIGH-SAD-SR
Structured Interview Guide for the
Hamilton Depression Rating Scale — Seasonal Affective Disorder Version
Self-Rating Version, revised 11/94
J.B.W. Williams, D.S.W., M.J. Link, B.S., and M. Terman, Ph.D.

A SCORING KEY APPEARS IN THE RIGHT-HAND COLUMN, AS FOLLOWS:

Examples: (H1/ _4 _x_) (A1/ _x_ _4)

The first entry, which is followed by a slash mark, codes the item number on the Hamilton (H) or supplementary Atypical (A) scale. The blank spaces to the right of the slash mark are for recording the respondent's score on that item: the left-hand blank is for an item from the Hamilton scale; the right-hand blank is for an Atypical scale item. The small number to the right of either of these blanks indicates the highest score possible on that item ("2", "3" or "4"). No score should be recorded in blanks in which a small "x" appears.

ITEM H5 — The Loss of Weight item provides scale values 0-2, omitting the possibility of a score of "3" ("not assessed") as found on the original Hamilton scale and SIGH-SAD interview version. Use of the ambiguous "3" category is also discouraged in the SIGH-SAD interview version, as it confounds scaling on a continuum of symptom severity.

ITEM H9c,A7 — Because the Somatic Symptoms General item (H9, Hamilton scale) and Fatigability item (A7, Atypical scale) are so similar, they have been combined in order to avoid repetitive questioning. However, the total point allocation for two questions is retained.

Key format: (H9c,A7/ _2+_4)

To score item H9c, it must first be recoded to a 0, 1, 2 scale. This is done by recoding scores of "2" to become "1", and recoding scores of "3" and "4" to become "2". The final score on item H9c, then, is the highest number scored on either item H9a, H9b, or H9c ("0", "1" or "2"), which is entered in the left-hand blank. To score item A7, simply enter the point value circled.

ITEM H13 — The Anxiety Somatic item on the original Hamilton scale (and in the SIGH-SAD interview) is scored on a 0-4 scale, with "0" representing the absence of symptoms. In the self-report, the respondent indicates the presence of symptoms only if they have been "bothersome" (scale values 1-4). Thus, if no alternative has been circled, the item is scored as "0".

ITEM H15 — A score of "2" on the Insight item (denial of illness), which is rare, should be recoded to "0" when the questionnaire is administered to asymptomatic respondents or those without history of depression.

ITEM A8 — The afternoon/evening slump is defined as a transitory event from which the respondent recovers at least an hour before bedtime. A distinct drop in mood or energy beginning in the afternoon or evening, which extends to bedtime, is not considered to be a "slump." (Such a symptom would be likely to be scored in item H18, diurnal variation/evenings worse.)

ITEM H21 — Questioning concerning Obsessional and Compulsive Symptoms has been divided into categories (H21a, repetitive behaviors; H21b, senseless thoughts). The final score on the combined item (H21) is the highest number scored on either item H21a or H21b.

TOTAL SCORE — The total SIGH-SAD-SR score (T) is calculated by adding the total scores from the left-hand set of blanks in the scoring key (Hamilton scale items, H) with the total scores from the right-hand set of blanks (Atypical scale items, A).

ATYPICAL BALANCE SCORE — The relative contribution of atypical symptoms is computed by dividing the 8-item Atypical scale score by the total 29-item SIGH-SAD score, and multiplying by 100. (In a large sample of SAD patients in New York City, those with atypical balance scores <30% at baseline (while depressed) showed relatively poor response to light therapy.)

UNSCORED ITEMS — The SIGH-SAD-SR elicits ancillary information that supplements the clinical picture but does not contribute to the score. In item A5, for example, the respondent indicates whether carbohydrates are only craved, or are actually eaten excessively, and the time of day is noted. (In a large sample of SAD patients in Switzerland, those reporting excessive eating of sweets in the afternoon or evening hours showed relatively strong response to light therapy.) In item A6, the respondent rates difficulty awakening. (Reduced difficulty awakening — in contrast to reduced hypersomnia per se — has been shown by the Seattle group to correlate with SIGH-SAD improvement under light treatment.)

SRINST94.LTU REV 11/94

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(Use to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

For office coding: 0 + + +
=Total Score:

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

PHQ-9* Questionnaire for Depression Scoring and Interpretation Guide

For physician use only

Scoring:

Count the number (#) of boxes checked in a column. Multiply that number by the value indicated below, then add the subtotal to produce a total score. The possible range is 0-27. Use the table below to interpret the PHQ-9 score.

Not at all (#) _____ x 0 = _____
Several days (#) _____ x 1 = _____
More than half the days (#) _____ x 2 = _____
Nearly every day (#) _____ x 3 = _____

Total score: _____

Interpreting PHQ-9 Scores

Diagnosis	Total Score	For Score	Action
Minimal depression	0-4	≤ 4	The score suggests the patient may not need depression treatment
Mild depression	5-9	5 - 14	Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment
Moderate depression	10-14		
Moderately severe depression	15-19	> 14	Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment.
Severe depression	20-27		

* The PHQ-9 is described in more detail at the Pfizer website: <http://www.phqscreeners.com/>

SEASONAL PATTERN ASSESSMENT QUESTIONNAIRE

1. To what degree do the following change with the seasons?

	No Change	Slight Change	Moderate Change	Marked Change	Extremely Marked Change
A. Sleep length	0	1	2	3	4
B. Social activity	0	1	2	3	4
C. Mood (overall feeling of well-being)	0	1	2	3	4
D. Weight	0	1	2	3	4
E. Appetite	0	1	2	3	4
F. Energy level	0	1	2	3	4

2. In the following questions, fill in circles for all applicable months. This may be a single month **O**, a cluster of months, e.g. **O O O** , or any other grouping. At what time of year do you....

	J	F	M	A	M	J	J	A	S	O	N	D		
	a	e	a	p	a	u	u	u	e	c	o	e	OR	
	n	b	r	r	y	n	l	g	p	t	v	c		No particular month(s) stand out as extreme on a regular basis
A. Feel best	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
B. Gain most weight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
C. Socialize most	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
D. Sleep least	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
E. Eat most	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	OR <input type="radio"/>
F. Lose most weight	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
G. Socialize least	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
H. Feel worst	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I. Eat least	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
J. Sleep most	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. How much does your weight fluctuate during the course of the year?

0-3 lbs	1	12-15 lbs	4
4-7 lbs	2	16-20 lbs	5
8-11 lbs	3	Over 20 lbs	6

SEASONAL PATTERN ASSESSMENT QUESTIONNAIRE

This questionnaire has been adapted from the original seasonal pattern assessment questionnaire. Questions in relation to demographics, questions 1-10 inclusive, were removed from the questionnaire. These details have been collected and anonymised previous to entering the study.

Question 1:

The Global Seasonality Score (GSS) is the total sum of the 6 items on Question 1 (Question 11 on the original SPAQ). This gives a score from 0 (no seasonality) to 24 (extreme seasonality). The average GSS in community samples is about 5. The average GSS in patients with SAD is about 16.

Question 2:

People with fall or winter depression tend to score 4 or more per month in a series of 3-5 months beginning anytime between September and January for options B, E, G, H and J. For months outside that range the score tends to be zero, or nearly zero. For the remaining options, the same people will usually score 4 or more points per month over a series of 3-5 months beginning anytime between March and June. Some people show a different pattern, with scores divided between the options during both winter and summer months. For example, they may feel worst and socialize least during the summer, especially July and August; during that same period, they may eat least, lose most weight, and sleep least. In winter, they may feel best and socialize most, yet still tend to eat most, gain most weight, and sleep most. Such people may experience seasonal depression of the summer type, and treatment recommendations will differ from those for winter depression. Some people show relatively high scores in the fall and winter months (winter depression), but there is also a scatter of good and bad months throughout the year. Such a pattern may indicate a winter worsening of symptoms, rather than clear-cut SAD. Recommendations for winter treatment might be similar to those for winter SAD, although there may be a need for additional treatments. Some people experience depression in the winter as well as in the summer, but they feel fine in the spring and the fall. In contrast with the winter, their summer depression is usually not accompanied by oversleeping and overeating. This is a special case of SAD, for which different treatments might be appropriate in winter and summer. Even people who experience only winter depression sometimes feel summertime slumps in mood and energy when the weather is rainy or dark for several days. They often find relief by brief use of their winter treatment during these periods.

Questions 3-5:

The higher the score in these questions, the more indicative it is of winter SAD. It is possible, however, to be depressed in winter without these symptoms — or even with opposite symptoms such as reduced sleep and appetite.

Question 6:

The screening criteria for a “diagnosis” of SAD are based on the GSS and the score on Question 6 (Question 17 in the original questionnaire), the degree of problems associated with seasonal changes. A GSS of 11 or higher on question 1 and a score on question 6 of moderate or greater is indicative of SAD.

Source: Lam and Levitt (2002) Evidence-Based Management of Seasonal Affective Disorder (SAD). Clinician Resource Package.

CET Tools

The RAND 36-Item Health Survey

Introduction

The RAND 36-Item Health Survey (Version 1.0) taps eight concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health. These 36 items, presented here, are identical to the MOS SF-36 described in Ware and Sherbourne (1992). They were adapted from longer instruments completed by patients participating in the Medical Outcomes Study (MOS), an observational study of variation in physician practice styles and patient outcomes in different systems of health care delivery (Hays & Shapiro, 1992; Stewart, Sherbourne, Hays, et al., 1992).

A revised version of the RAND 36-Item Health Survey (Version 1.1) that differs slightly from version 1.0 in terms of item wording is currently in development.

SCORING RULES FOR THE RAND 36-ITEM HEALTH SURVEY (Version 1.0)

We recommend that responses be scored as described below. A somewhat different scoring procedure for the MOS SF-36 has been distributed by the International Resource Centre for Health Care Assessment (located in Boston, MA). Because the scoring method described here (a simpler and more straightforward procedure) differs from that of the MOS SF-36, persons using this scoring method should refer to the instrument as the RAND 36-Item Health Survey 1.0.

Scoring the RAND 36-Item Health Survey is a two-step process. First, precoded numeric values are recoded per the scoring key given in Table 1. Note that all items are scored so that a high score defines a more favourable health state. In addition, each item is scored on a 0 to 100 range so that the lowest and highest possible scores are set at 0 and 100, respectively. Scores represent the percentage of total possible score achieved. In step 2, items in the same scale are averaged together to create the 8 scale scores. Table 2 lists the items averaged together to create each scale. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Hence, scale scores represent the average for all items in the scale that the respondent answered.

Example: Items 20 and 32 are used to score the measure of social functioning. Each of the two items has 5 response choices. However, a high score (response choice 5) on item 20 indicates extreme limitations in social functioning, while a high score (response choice 5) on item 32 indicates the absence of limitations in social functioning. To score both items in the same direction, Table 1 shows that responses 1 through 5 for item 20 should be recoded to values of 100, 75, 50, 25, and 0, respectively. Responses 1 through 5 for item 32 should be recoded to values of 0, 25, 50, 75, and 100, respectively. Table 2 shows that these two recoded items should be averaged together to form the social functioning scale. If the respondent is missing one of the two items, the person's score will be equal to that of the non missing item.

Table 3 presents information on the reliability, central tendency and variability of the scales scored using this method.

References

1. Ware, J.E., Jr., and Sherbourne, C. D. "The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual Framework and Item Selection," *Medical Care*, 30:473-483, 1992.
2. Hays, R.D., & Shapiro, M.F. "An Overview of Generic Health-Related Quality of Life Measures For HIV Research," *Quality of Life Research*, 1:91-97, 1992.
3. Stewart, A. L., Sherbourne, C., Hays, R. D., et al. "Summary and Discussion of MOS Measures," in A. L. Stewart & J. E. Ware (eds.), *Measuring Functioning and Well-Being: The Medical Outcome Study Approach* (pp. 345-371). Durham, NC: Duke University Press, 1992.

Please refer to www.sf-36.org for further information

Note: The Workplace Safety & Insurance Board (WSIB) acknowledges that the RAND-36-Short Form Health Survey (SF-36) was developed at RAND as part of the Medical Outcomes Study.

The RAND 36-Item Health Survey

Table 1

STEP 1: RECORDING ITEMS

ITEM NUMBERS	Change original response category (a)	To recoded value of:
1,2,20,22,34,36	1----->	100
	2----->	75
	3----->	50
	4----->	25
	5----->	0
3,4,5,6,7,8,9,10,11,12	1----->	0
	2----->	50
	3----->	100
13,14,15,16,17,18,19	1----->	0
	2----->	100
21,23,26,27,30	1----->	100
	2----->	80
	3----->	60
	4----->	40
	5----->	20
	6----->	0
24,25,28,29,31	1----->	0
	2----->	20
	3----->	40
	4----->	60
	5----->	80
	6----->	100
32,33,35	1----->	0
	2----->	25
	3----->	50
	4----->	75
	5----->	100

(a) Precoded response choices as printed in the questionnaire.

The RAND 36-Item Health Survey

Table 2

STEP 2: AVERAGING ITEMS TO FORM SCALES

Scale	Number Of Items	After Recoding Per Table 1, Average The Following Items:
Physical functioning	10	3 4 5 6 7 8 9 10 11 12
Role limitations due to physical health	4	13 14 15 16
Role limitations due to emotional problems	3	17 18 19
Energy/fatigue	4	23 27 29 31
Emotional well-being	5	24 25 26 28 30
Social functioning	2	20 32
Pain	2	21 22
General health	5	1 33 34 35 36

The RAND 36-Item Health Survey

Table 3

RELIABILITY, CENTRAL TENDENCY AND VARIABILITY OF SCALES IN THE MEDICAL OUTCOMES STUDY

Scale	Items	Alpha	Mean	SD
Physical functioning	10	0.93	70.61	27.42
Role functioning/physical	4	0.84	52.97	40.78
Role functioning/emotional	3	0.83	65.78	40.71
Energy/fatigue	4	0.86	52.15	22.39
Emotional well-being	5	0.90	70.38	21.97
Social functioning	2	0.85	78.77	25.43
Pain	2	0.78	70.77	25.48
General health	5	0.78	56.99	21.11
Health change	1	—	59.14	23.12

Note: Data is from baseline of the Medical Outcomes Study (N = 2471), except for Health change, which was obtained one year later.

RAND 36-Item Health Survey 1.0 Questionnaire Items

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. Compared to one year ago , how would you rate your health in general now ?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

Note: The WSIS acknowledges that the RAND 36-Item Short Form Health Survey was developed at RAND as part of the Medical Outcomes Study.

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All
3. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing several flights of stairs	[1]	[2]	[3]
7. Climbing one flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking more than a mile	[1]	[2]	[3]
10. Walking several blocks	[1]	[2]	[3]
11. Walking one block	[1]	[2]	[3]
12. Bathing or dressing myself	[1]	[2]	[3]

Note: The WSIB acknowledges that the RAND 36-Item Short Form Health Survey was developed at RAND as part of the Medical Outcomes Study.

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. Accomplished less than you would like	1	2
15. Were limited in the kind of work or other activities	1	2
16. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

(Circle One Number on Each Line)

	Yes	No
17. Cut down the amount of time you spent on work or other activities	1	2
18. Accomplished less than you would like	1	2
19. Didn't do work or other activities as carefully as usual	1	2

Note: The WSIB acknowledges that the RAND 36-Item Short Form Health Survey was developed at RAND as part of the Medical Outcomes Study.

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

(Circle One Number)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

21. How much **bodily** pain have you had during the **past 4 weeks**?

(Circle One Number)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

(Circle One Number)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

Note: The WSIB acknowledges that the RAND 36-Item Short Form Health Survey was developed at RAND as part of the Medical Outcomes Study.

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks . . .

(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

Note: The WSIB acknowledges that the RAND 36-Item Short-Form Health Survey was developed at RAND as part of the Medical Outcomes Study.

32. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

(Circle One Number)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

How **TRUE** or **FALSE** is each of the following statements for you:

(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Note: The WSIB acknowledges that the RAND 36-Item Short Form Health Survey was developed at RAND as part of the Medical Outcomes Study.

SAFTEE-SR

Below is a list of complaints people sometimes have. Please read each and tick the box corresponding to how much you have been bothered by that problem in the past week.

		Not at all	A little bit	Moderately	Quite a bit	Extremely
1	Headaches					
2	Dizziness or faintness					
3	Loss of consciousness					
4	Seizures					
Any other problems with your head (please specify):						
5	_____					
6	_____					
7	Eye irritation					
8	Swelling					
9	Blurred vision					
10	Double vision					
11	Poor vision					
12	Light bothering your eyes					
Any other problems with your eyes (please specify):						
13	_____					
14	_____					
15	earache					
16	discharge					
17	Trouble hearing					
18	Ringling or whistling or other noises in ears					
Any other problems with your ears (please specify):						
19	_____					
20	_____					
21	Sores in your mouth					
22	Dry mouth					
23	Too much saliva					
24	Swollen or sore tongue					
25	Bleeding gums					
26	Dental problems					
Any other problems with your mouth or teeth (please specify):						
27	_____					
28	_____					
29	Nasal congestion					
30	Nose bleed					
31	Sore throat					
32	Laryngitis					
33	Difficulty swallowing					

During the past week, how much have you been bothered by...

		Not at all	A little bit	Moderately	Quite a bit	Extremely
Any other problems with your nose or throat (please specify):						
34	_____					
35	_____					
36	Chest pain					
37	Shortness of breath					
38	Wheezing					
39	Coughing					
40	Breast or nipple pain or discharge					
41	Breast tenderness					
Any other trouble with your chest (please specify):						
42	_____					
43	_____					
44	Rapid heart rate					
45	Irregular heart beat					
Any other trouble with your heart (please specify):						
46	_____					
47	_____					
48	Stomach/ abdominal discomfort					
49	Nausea					
50	Vomiting					
51	Heartburn					
Any other trouble with your stomach or abdomen (please specify):						
52	_____					
53	_____					
54	Diarrhoea					
55	Constipation					
56	Gas					
57	Change in colour of stools					
58	Haemorrhoids					
59	Painful bowel movements					
Any other changes in your bowel movements (please specify):						
60	_____					
61	_____					
62	Appetite increased					
63	Appetite decreased					
64	Weight gain					

During the past week, how much have you been bothered by...

		Not at all	A little bit	Moderately	Quite a bit	Extremely
65	Weight loss					
66	Bad taste or change in taste					
67	Increased thirst					
Any other change in appetite (please specify):						
68	_____					
69	_____					
70	Painful urination					
71	Burning sensation with urination					
72	Difficulty in starting to urinate					
73	Decreased force of urinary stream					
74	More frequent urination					
75	Change in colour of urine					
Any other problems with urination (please specify):						
76	_____					
77	_____					
Please on complete the following section if you are female. If male, please continue from no. 88						
78	Menstrual irregularity					
79	Cramps					
80	Heavy bleeding					
81	Spotting					
82	Tension					
83	Hot flashes					
84	Lengthening of menstrual period					
85	Shortening of menstrual period					
Any other problems with your menstrual period (please specify):						
86	_____					
87	_____					
88	Discomfort in genitals					
89	Swelling of or discharge from genitals					
90	Decreased interest in sex					
91	Increased interest in sex					
92	Delayed orgasm or inability to reach orgasm					

During the past week, how much have you been bothered by...

		Not at all	A little bit	Moderately	Quite a bit	Extremely
	Males					
93	Difficulty achieving or maintaining an erection					
Any other problems with genitals or sexual function (please specify):						
94	_____					
95	_____					
96	Aches, pains in muscles, bones or joints					
97	Swelling in legs or arms					
98	Tingling or numbness in hands or feet					
Any other trouble with your muscles, bones or joints (please specify):						
99	_____					
100	_____					
101	Feeling unsteady on your feet					
102	Trouble with starting to move					
103	Controlling unwanted bodily movements					
104	Feeling restless or like you cannot stay still					
105	Shaking					
106	Feeling still or rigid					
Any other difficulty with walking or moving (please specify):						
107	_____					
108	_____					
109	Rashes, itching or irritation					
110	Bruising					
111	Increased irritation in sunlight					
112	Sweating a lot					
Any other trouble you're your scalp or skin (please specify):						
113	_____					
114	_____					
115	Fever or chills					
116	Feeling tired or fatigued					
117	Too much energy					
118	Jumpiness or feeling jittery					

During the past week, how much have you been bothered by...

		Not at all	A little bit	Moderately	Quite a bit	Extremely
119	Feeling excited, overactive or elated					
120	Problems falling asleep					
121	Problems staying asleep					
122	Waking up too early					
123	Sleeping too much					
124	Feeling drowsy during the day					
125	Trouble thinking, concentrating or remembering					
126	Feeling down, depressed or blue					
127	Feeling anxious					
128	Irritability					
	Any problems with your thinking, mood or energy, or with aspects of your health not mentioned above (please specify)					
129	_____					
130	_____					
131	_____					
132	_____					

Thank you for completing this questionnaire

Light Therapy (LT) Questionnaire – Pre study

Many thanks for participating in this study. To help us to evaluate the feasibility of using light therapy (LT) as a regular treatment in your own home we would be most grateful if you could provide information prior to starting the study on your awareness of and expectations for using light therapy by completing the questions below.

Light therapy consists of exposure to bright light, or to specific colours of light, from a lamp or light box on a regular basis.

It is normally recommended that LT is used in the morning for 30-60 minutes depending on how bright the light is.

Section A: Your awareness of light therapy (LT)

1. Before you agreed to take part in this study, please indicate which of the following applies to you (please tick **all** that apply)?

- I had never heard of LT
- I had heard of LT from someone I know
- I had heard of LT from the internet
- I had heard of LT from the media (for example TV, radio, newspaper or magazines)
- I knew someone who has used LT
- My doctor had suggested LT to me in the past
- A health professional (other than my doctor) had suggested LT to me in the past
- A friend had suggested LT to me in the past
- Other (Please list below):

2. From your current awareness of LT, which of the following condition(s) is LT used for (tick all that apply)?

- I don't know which conditions LT is used to treat
- LT is a treatment for Seasonal Affective Disorder (SAD)
- LT is a treatment for "winter blues"
- LT is a treatment for depression
- LT is a treatment for none of the disorders listed above
- LT is used for other conditions (Please list these below)

Section B: Your attitudes and expectations of light therapy as a treatment for depression

3. Answer the following questions by circling the number from 1 to 4 that best describes your view.

	Not at all logical	Somewhat logical	Logical	Very logical
How logical does LT seem to you?	①	②	③	④

	Not at all confident	Somewhat confident	Confident	Very confident
How confident are you that LT will				
.... improve your symptoms generally?	①	②	③	④
.... improve your mood	①	②	③	④
.... reduce your fatigue	①	②	③	④
.... improve your sleep	①	②	③	④

How confident are you that LT will eliminate your symptoms?	①	②	③	④
---	---	---	---	---

At this moment, how confident would you be in recommending LT to a friend who has depression?	①	②	③	④
---	---	---	---	---

	No, not at all	Possibly	Yes, Probably	Yes, definitely
Do you think that you may wish to continue using LT after the study?	①	②	③	④

4. From what you know about LT:

	Very problematic	Problematic	Somewhat problematic	Not at all problematic
How problematic do you expect side effects to be?	①	②	③	④

Please list below any side effects you feel to be particularly worrying:

Section C: How easy will the light therapy be to use?

5. For each item below, please circle a number between 1 (Disagree) and 4 (Agree) that best describes how easy you anticipate LT will be to use:

I am confident I could use LT regularly...

	Disagree	Disagree somewhat	Agree somewhat	Agree
Irrespective of whatever else was going on in my life	①	②	③	④
First thing in the morning	①	②	③	④
For 30 minutes a day	①	②	③	④
Even when I don't want to get up early	①	②	③	④
Even when I'm tired	①	②	③	④
Even when I don't feel like	①	②	③	④
Even when I'm in a bad mood	①	②	③	④
Even when I feel that I don't have the time	①	②	③	④

6. What support do you think you will need/ would you like, to help you to use LT?

For each item below, please circle a number between 1 (Disagree) and 4 (Agree) that best describes your view:

I have people in life who would...

	Disagree	Somewhat disagree	Somewhat Agree	Agree
Support me in using LT regularly.	①	②	③	④
Encourage me to use LT even when I don't want to.	①	②	③	④
Encourage me to use LT even when it is time consuming.	①	②	③	④
Give ideas for making LT more convenient.	①	②	③	④
Help me adjust to using LT.	①	②	③	④
Be upset if I stopped using LT.	①	②	③	④

7. For each item below, please circle a number between 1 (Disagree) and 4 (Agree) that best describes your view:

Disagree	Somewhat disagree	Somewhat Agree	Agree
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I would get the help I need to use LT regularly.

① ② ③ ④

There are health professionals involved in my care who I feel would support me in using LT

① ② ③ ④

8. *When using LT, I think I **should** be supported by my:*

No, not at all	Possibly	Yes, probably	Yes, definitely	Not Applicable. (This person is not currently involved in my care).
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Psychiatrist or mental health nurse

① ② ③ ④

Clinical Psychologist or Counsellor (Cognitive Behavioural Therapist)

① ② ③ ④

General Practitioner

① ② ③ ④

Community Nurse

① ② ③ ④

Community Pharmacist

① ② ③ ④

9. If you have some additional comments about LT, this study, or concerns about using LT, please write them here:

Thank you very much for your participation.

Please return your completed questionnaire to the researcher.

Light Therapy (LT) Questionnaire – Post study

Many thanks for completing the study. To help us to evaluate the feasibility of using light therapy as a regular treatment in primary care, we would be most grateful if you could provide feedback on your experiences of using light therapy by completing the questions below.

Please answer all the questions below keeping in mind your experience of using light therapy in this study.

Section A: Your attitudes and expectations of light therapy as a treatment for depression

1. Answer the following questions by circling the number from 1 to 4 that best describes your view.

	Not at all logical	Somewhat logical	Logical	Very logical
How logical does LT seem to you?	①	②	③	④

	Not at all confident	Somewhat confident	Confident	Very confident
How confident are you that LT will				
.... improve your symptoms generally?	①	②	③	④
.... improve your mood	①	②	③	④
.... reduce your fatigue	①	②	③	④
.... improve your sleep	①	②	③	④

	Not at all confident	Somewhat confident	Confident	Very confident
How confident are you that LT will eliminate your symptoms?	①	②	③	④

	Not at all confident	Somewhat confident	Confident	Very confident
At this moment, how confident would you be in recommending LT to a friend who has depression?	①	②	③	④

	No, not at all	Possibly	Yes, Probably	Yes, definitely
Do you think that you may wish to continue using LT after the study?	①	②	③	④

2. From what your experience of LT:

	Very problematic	Problematic	Somewhat problematic	Not at all problematic
How problematic do you expect side effects to be?	①	②	③	④

Please list below any side effects you feel to be particularly worrying:

Section B: How easy would the light therapy be to use?

3. For each item below, please circle a number between 1 (Disagree) and 4 (Agree) that best describes how easy you anticipate LT will be to use:

I am confident I could use LT regularly...

	Disagree	Disagree somewhat	Agree somewhat	Agree
Irrespective of whatever else was going on in my life	①	②	③	④
First thing in the morning	①	②	③	④
For 30 minutes a day	①	②	③	④
Even when I don't want to get up early	①	②	③	④
Even when I'm tired	①	②	③	④
Even when I don't feel like	①	②	③	④
Even when I'm in a bad mood	①	②	③	④
Even when I feel that I don't have the time	①	②	③	④

4. What support do you think you will need/ would you like, to help you to use LT?

For each item below, please circle a number between 1 (Disagree) and 4 (Agree) that best describes your view:

I have people in life who would...

	Disagree	Somewhat disagree	Somewhat Agree	Agree
Support me in using LT regularly.	①	②	③	④
Encourage me to use LT even when I don't want to.	①	②	③	④
Encourage me to use LT even when it is time consuming.	①	②	③	④
Give ideas for making LT more convenient.	①	②	③	④
Help me adjust to using LT.	①	②	③	④
Be upset if I stopped using LT.	①	②	③	④

5. For each item below, please circle a number between 1 (Disagree) and 4 (Agree) that best describes your view:

Disagree	Somewhat disagree	Somewhat Agree	Agree
----------	-------------------	----------------	-------

I would get the help I need to use LT regularly.

① ② ③ ④

There are health professionals involved in my care who I feel would support me in using LT

① ② ③ ④

6. *When using LT, I think I **should** be supported by my:*

No, not at all	Possibly	Yes, probably	Yes, definitely	Not Applicable. (This person is not currently involved in my care).
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Psychiatrist or mental health nurse

① ② ③ ④

Clinical Psychologist or Counsellor (Cognitive Behavioural Therapist)

① ② ③ ④

General Practitioner

① ② ③ ④

Community Nurse

① ② ③ ④

Community Pharmacist

① ② ③ ④

7. If you have some additional comments about LT, this study, or concerns about using LT, please write them here:

Thank you very much for your participation.

Please return your completed questionnaire to the researcher.