

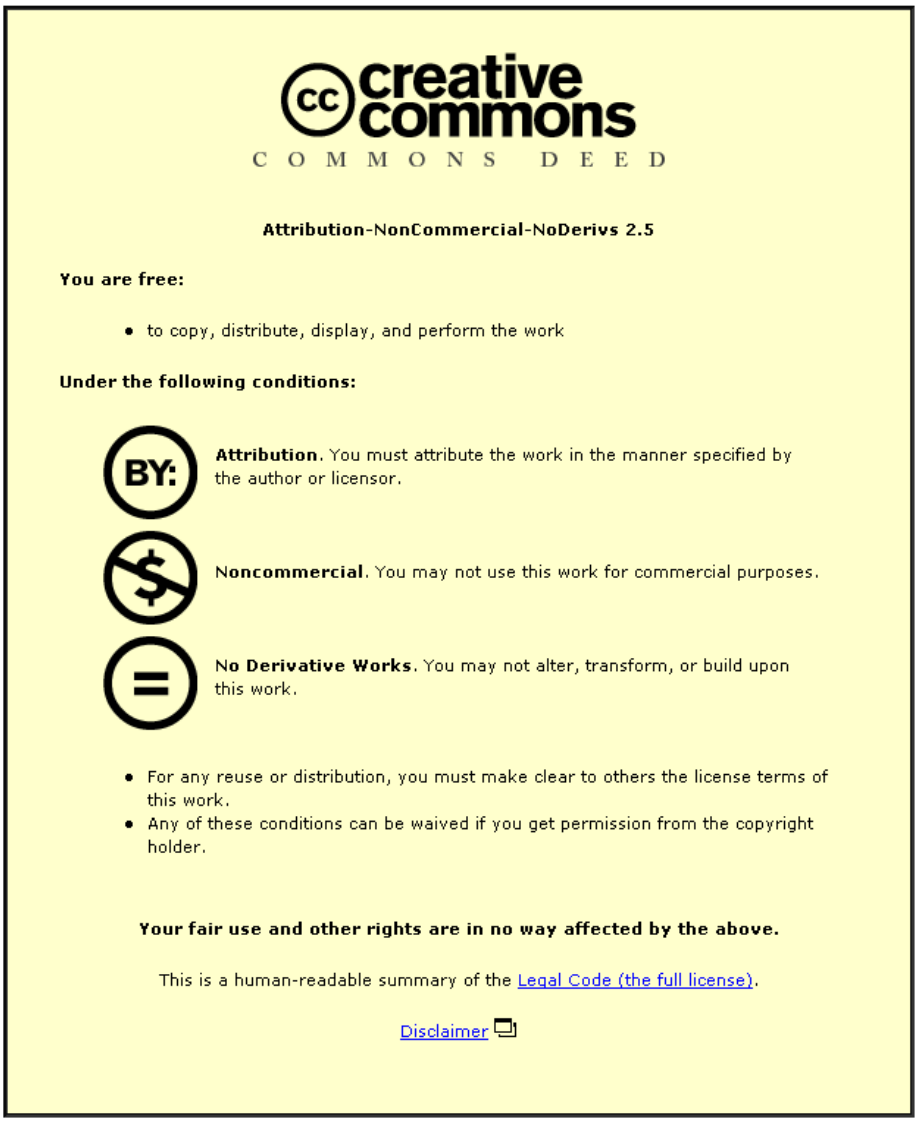

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# Physical Activity to the Current Recommended Guidelines and Sleep Quality of Adults with Insomnia

by

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A Doctoral Thesis

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## Table of Contents

**List of abbreviations**

BMI – Body mass index

CBT-I - Cognitive Behavioural Therapy for insomnia

DSM-5 -Diagnostic and Statistical Manual of Mental Disorders, 5th Edition

DSM-IV -Diagnostic and Statistical Manual of Mental Disorders, 4th Edition

ICSD-2 - International Classification of Sleep Disorders, 2nd Edition

MVPA - Moderate to vigorous physical activity

NLSAA - Nottingham Longitudinal Study of Active Ageing

PA - Physical activity

QoL – Quality of life

RCT - Randomised controlled trial

RDC - Research Diagnostic Criteria

SE - Sleep efficiency

SOL - Sleep onset latency

TIB - Time in bed

TST - Total sleep time

WASO - Wake after sleep onset

# OUTPUTS ARISING FROM THIS THESIS

## CONFERENCE PROCEEDINGS

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Hartescu, I., Morgan, K., & Stevinson, C.D. (2012). *Is long sleep duration 'sedentary behaviour' in later life?* Journal of Aging and Physical Activity; 20: S251-S251. (Abstracts of the World Congress of Active Ageing, Glasgow, 2012). Awarded Best Student Oral Presentation by the conference organisers.

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Hartescu, I., Morgan, K., & Stevinson, C.D. (2013). (in preparation) *Physical activity to the current recommended guidelines improves cognitive processes of attention in people with insomnia.*

# CHAPTER ONE

## 1.0 Insomnia and physical activity

## 1.1 Insomnia

### 1.1.1 Classification for research and clinical practice

There are established classification systems for diagnosing insomnia in clinical practice, the most widely used being the International Classification of Sleep Disorders -2 (ICSD-2; 2000) and the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; 2013). Each of these nosologies historically listed sub-types of insomnia, essentially distinguishing between insomnia occurring independently of other known pathology (i.e. stand-alone insomnia, or primary insomnia); and insomnia temporally concurrent with other pathologies (i.e. co-morbid insomnia).

DSM-IV-TR (2000) was current in clinical practice at the time of design of the present research programme[1]. It listed four sub-types of insomnia, and the one relevant to this work was primary insomnia. DSM-5 (2013) replaces the old classification, essentially reducing it to *insomnia disorder*, with concurrent comorbidities, if any. The new criteria recognises the fact that insomnia, regardless of its origin and comorbidities, should be diagnosed and treated on its own.

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[1] Insomnia is now explicitly defined in the second edition of the International Classification of Sleep Disorders (ICSD-2: American Academy of Sleep Medicine, 2005) and the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013). While these nosologies largely agree on the symptoms of insomnia, there remain important differences both in terminology and emphasis. Importantly, during the course of the research described in this thesis, a profound 'shift' took place in the categorisation of insomnia in relation to comorbid conditions. While the earlier (revised 4th edition) of the DSM (DSM-IV-TR: APA, 2000) and the ICSD-2 distinguish between insomnia occurring independently of other known pathology (i.e. 'primary insomnia'); and insomnia concurrent with other pathologies (i.e. 'co-morbid insomnia'), this distinction (and many of the causal assumptions which accompanied this distinction) have now been rejected in favour of the single classification of "insomnia disorder" as defined in DSM-5. This new classification recognises that insomnia, regardless of its origin and comorbidities, can be diagnosed, and effectively treated, as a 'stand-alone' condition. The DSM-5 diagnostic criteria for Insomnia Disorder require predominant difficulty in initiating or maintaining sleep, or non-restorative sleep, despite adequate opportunity to sleep, accompanied by clinically significant distress or impairment in important areas of daily functioning, for at least one month.

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The ICSD-2 consists of 11 sub-types, three of which are primary insomnia categories: psychophysiological insomnia, idiopathic insomnia, and paradoxical insomnia. The criteria requires complaints of difficulty in initiating or maintaining sleep, waking up earlier than the desired time, or non-restorative sleep, accompanied by specific daytime impairments related to these complaints; despite adequate opportunity and circumstances to sleep.

The inter-rater reliability between the different classifications is modest (Buysse, Reynolds, Kupfer, & Thorpy, 1994). Most recent multi-trait analyses of the different nosologies of insomnia similarly show marginal reliability and validity for insomnia sub-types from DSM-IV-TR and ICSD-2 (Edinger et al, 2011). Nonetheless, these criteria are nowadays increasingly being used in epidemiological and experimental research (Ohayon, 2002).

In an effort to standardise research definition criteria, the *Research Diagnostic Criteria* (RDC) for insomnia was developed by the American Academy of Sleep Research (AASR) (Edinger et al, 2004). Drawing on the DSM-IV-TR and the ICSD-2, the AASR developed criteria for diagnosing primary insomnia, and several other overlapping ICSD-2 insomnia sub-types.

Insomnia disorder is defined by listed nighttime and daytime symptoms; whereas primary insomnia is defined to subsume the disorder, as well as providing temporal conditions, and necessary exclusions. For primary insomnia, sleep complaints must be present for at least 1 month; in addition, the sleep complaints must show temporal independency from current or past psychiatric disorder, other medical condition, or other sleep disorder.

There is a need for further empirical evidence to refine the RDC criteria, to quantify insomnia symptoms. For example, sleep onset latency (the time it takes to fall asleep) inclusion criteria is disputed, with some researches considering 31 minutes or more is appropriate for insomnia criteria inclusion (Lichstein, Durrence, Taylor, Bush, & Riedel, 2003); whilst there is also the view that 21 minutes provides adequate sensitivity and specificity to capture insomnia symptoms (Lineberger, Carner, Edinger, & Means, 2006) .

Additional quantitative and qualitative elements, related to the non-restorative nature of sleep, or to the frequency of complaints, could aid in identifying the target population better (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006).

The methods for assessing insomnia in research populations are also varied, as the symptoms of insomnia do not easily translate into objective evidence recorded using polysomnography (Edinger et al, 2000). In addition, self-reported daytime impairment accompanying insomnia does not always match objective evidence of sleep disturbance (Orff, Drummond, Nowakowski, & Perlis, 2007). The results is that different research groups adopted their own method of assessment, often consisting of structured clinical interviews, sleep diaries, or polysomnography (Buysse et al, 2006).

The *Research Assessment Criteria* (RAC) for insomnia was developed in an effort to standardise the approach in research practice (Buysse et al, 2006). The RAC makes recommended and essential guidelines concerning the assessment of sleep and insomnia symptoms, measures and reporting standards. Although there is still great variability between criteria used for inclusion of participants in studies, there is a greater uniformity in the instruments used to report changes in sleep quality.

The literature reviewed in this thesis reflects a wide range of definitions in relation to insomnia. For the purpose of reviewing high quality experimental evidence, efforts were made to include randomised controlled studies which used definitions and assessments of insomnia as recommended by the RDC and RAC for insomnia (Edinger et al, 2004; Buysse et al, 2006). However, in reviewing historical and epidemiological studies, many of which pre-date the publication or adoption of such criteria, a wide range of insomnia definitions, and insomnia symptoms was accepted.

### 1.1.2 Measures of sleep structure, quantity and quality

There are a number of operational measures of sleep, encompassing physiological, behavioural and psychological approaches. The ‘gold standard’ physiological measure of sleep is polysomnography (PSG), usually performed in the laboratory, under the supervision of a qualified sleep expert. Sleep structure is classified based on various characteristics of scalp-recorded electroencephalogram EEG (waveform, amplitude, frequency), coupled with electrodes which detect muscle activity and eye movement related to sleep.

PSG standard scoring is used to then classify sleep into 4 distinct stages, as per ‘The AASM Manual for the Scoring of Sleep and Associated Events’ (2007): Stage N1 (a relative low voltage, mixed frequency EEG, also called ‘light sleep’); Stage N2 (relatively low voltage, mixed frequency EEG, with additional characteristics waveforms, such as spindles and K-complexes); Stage N3 (large amounts of high amplitude, low frequency EEG activity, also called ‘slow wave’ sleep, or ‘deep’ sleep); and Stage REM – Rapid Eye Movement (low voltage, mixed frequency EEG, accompanied by muscle atonia and characteristic rapid ocular movement; also known as ‘dream sleep’).

The EEG characteristics are also used to quantify indices of sleep, including length of sleep (total sleep time), time taken to fall asleep (sleep onset latency), time spent awake after the first episode of falling asleep (wake after sleep onset), or movement during sleep (sleep fragmentation index). In addition, sleep efficiency can be inferred from the amount of time spent asleep whilst in bed. Another method to quantify these indices of sleep is based on actigraphic measures, which describe patterns of movement/non movement. Actigraphy has the advantage of being less intrusive than EEG, and thus offer a reliable measure of sleep patterns over longer periods of time.

Self-reported measures include daily sleep diaries, questionnaires, and momentarily-assessment tools. They can be used to quantify sleep indices (as above); or to describe the experience of sleep, e.g. light, deep, restful, agitated, short.

Most adults report sleeping around 6 to 8 hours per night (Ohayon & Vecchierini, 2005). There are individual variations in what is considered a 'normal' amount of sleep. These may be attributed to a preference of sleep time (an 'owl' type, preferring to sleep late at night; or a lark type, preferring to sleep early), while some people are naturally 'short' sleepers. For most people, normal sleep is self-reported good sleep, with sleep quality being reflected in continuity of sleep over night (i.e. unbroken sleep) (Akerstedt, Hume, Minors, & Waterhouse, 1994), and feeling refreshed or alert the following day (Harvey, Stinson, Whitaker, Moskovitz, & Virk, 2008).

Subjective reports of 'normal' sleep do not always reflect in known physiological measures of sleep. There are people who report good sleep, but show a disturbed sleep pattern when physiologically monitored; and conversely there are people who report disturbed sleep, but show normal sleep patterns when objectively monitored (Edinger et al, 2000). The most reliable indicator of sleep disturbance is self-reported global sleep dissatisfaction (Ohayon, Riemann, Morin, & Reynolds, 2012).

### 1.1.3 Insomnia: prevalence and personal impact

Sleep complaints, which include problems getting to sleep, staying asleep or waking up too early, are the most commonly reported psychological symptoms in Britain (Office for National Statistics [ONS], 2001). When such complaints are chronic, and accompanied by daytime symptoms or impairments such as fatigue and sleepiness, mood dysregulation and psychomotor deficits, then the diagnosis of *insomnia* can be made (DSM-5; Diagnostic and Statistical Manual of Mental Disorders, DSM-5, 2013). Applying diagnostic criteria (specifying the frequency, severity and duration of insomnia symptoms) the prevalence of insomnia in the adult population is estimated at about 10% (Morin, LeBlanc, Daley, Gregoire, & Mérette, 2006; Léger, Scheuermaier, Philip, Paillard, & Guilleminault, 2001; Morgan, 2012). However, age-specific prevalence rates show a steady increase across the lifespan, from an estimated 3-5% among those aged 18 to 25, to 25-30% among people aged 65 and over (Ohayon, 1996; Morgan, 2012). Amongst the older population, up to 57% report at least one chronic insomnia symptom in point prevalence surveys (Foley et al, 1995). Across all age groups, insomnia is more prevalent among women, and those of low socioeconomic and educational level (Ohayon, 2002).

As to the incidence of insomnia, the proportion of people reporting symptoms of insomnia over two years duration also increases significantly with age, with older people also more likely to report taking benzodiazepine hypnotic medication (Stewart et al, 2006). Objectively, polysomnographic studies show that ageing is associated with a notable decline in 'deep' or slow-wave sleep, starting in midlife, and an increase in 'lighter' stages of sleep (stages 1 and 2 or N1: Hoch et al, 1997; Ohayon & Lemoine, 2004). Subjectively, older adults report more frequent awakening during the night, earlier awakening in the morning, and lighter overall sleep (Ancoli-Israel & Cooke, 2005). The impact of insomnia symptoms grows stronger with age, even when accounting for physical functioning status (Stewart et al, 2006).

### 1.1.4 Daytime consequences of insomnia

Night-time symptoms of insomnia, described mainly as difficulties in getting to sleep at night, are often distressing and have daytime consequences. Daytime symptoms or impairments associated with insomnia include increased fatigue (Orff et al, 2007), impairment of sustained and shifting attention (Altena, Van Der, Ysbrand, Strijers, & Van Someren, 2008) and poorer working memory (Bonnet & Arand, 1995). It is this perceived overall dysfunction that mostly leads to people with insomnia to seek medical help (Stepanski et al, 1989).

Daytime performance is consistently associated with sleep quality as perceived both by people with insomnia, and by people who are normal sleepers (Harvey et al, 2008).

***Fatigue and sleepiness***

People with insomnia commonly report experiences of fatigue. Fatigue seems to describe physical tiredness (Ream & Richardson, 1996). The concept is distinct from the experience of sleepiness, which is related to drowsiness, and a measurable propensity to fall asleep (George, 2001). Insomnia has been independently associated with both fatigue, and daytime sleepiness. The prevalence of both conditions increases with age (Theorell-Haglöw, Lindberg, Janson, 2006). People with insomnia report disrupted sleep patterns, with increased sleep onset latency and increased wake after sleep onset, resulting in less total sleep time and poorer sleep efficiency (Orff et al, 2007; Haimov et al, 1994). It might therefore be inferred that people with insomnia would report increased daytime sleepiness as a consequence. However, in experimental research depriving people with insomnia of sleep, the amount of fatigue reported went up with the percentage of sleep loss, whilst sleepiness levels remained stable (Bonnet & Arand, 1998). Only when totally deprived of sleep for a night did people with insomnia show daytime sleepiness (Stepanski, Zorick, Roehrs, & Roth, 2000). Even then the recovery process matched that of normal sleepers deprived of sleep (Edinger et al, 2000). Thus, research into the daytime consequences of insomnia indicates that fatigue is both a more likely consequence, and a more useful measurement, than is sleepiness.

***Impairment of mood***

There is strong evidence showing that insomnia is a risk factor for psychiatric disorders, independently contributing to new onset of depression and anxiety (Ford & Kamerow, 1989; Breslau, Roth, Rosenthal, & Andreski, 1996; Riemann & Voderholzer, 2003). Furthermore, insomnia and fatigue are the only 'universal' symptoms present in most people reporting major depression around the world (Weissman et al, 1996). Ford & Kamerow (1989), using data from a large prospective community sample, concluded that insomnia develops in many cases prior to depression; and those people with insomnia at baseline had much higher odds ratio of reporting depression one year later. A recent meta-analysis of epidemiological evidence in this field found that people with insomnia have a twofold risk to develop depression, compared to people with good sleep (Baglioni et al, 2011). Affect-insomnia relationships, however, are not necessarily 'one-way'. In a prospective design study Jansson & Lindblom (2008) assessed anxiety, depression, and insomnia in a representative sample of the general Swedish population over a year and concluded that relationships between mood disturbance and insomnia are bi-directional.

Such findings are important since the anxiety state is at the core of the current influential cognitive view of insomnia. Harvey (2002) proposed that people with insomnia selectively attend to and monitor the internal and external environment for sleep-related cues, and this process is precipitated by anxiety related to sleep. Research into psychophysiological mechanisms underpinning this relationship points to sleep processes being related to emotional regulation processes in people with insomnia (Baglioni, Spiegelhalder, Lombardo, & Riemann, 2010).

***Impairment of attention and working memory***

Recent meta-analyses of results of studies of people with insomnia have found evidence of mild to moderate cognitive impairment in specific functions such as episodic and working memory, and in decision making (Fortier-Brochu, Beaulieu-Bonneau, Ivers, & Morin, 2012). Nevertheless, an earlier review of neurocognitive tests used to elicit daytime cognitive deficits in people with insomnia found significant heterogeneity in the samples used, which led to difficulty in forming firm conclusions about the extent of impairment in different cognitive domains, or indeed the existence of any cognitive impairments in this clinical group (Shekleton, Rogers, & Rajaratnam, 2010).

It has been suggested that the limited published evidence of cognitive impairment in people with insomnia might indicate either the absence of such impairment (Riedel & Lichstein, 2000); or an overestimation and exaggeration of symptoms by those reporting them, due to cognitive bias in their attention processes (Orff et al, 2007). Alternatively, the evidence might also suggest that the tests used are insufficiently specific to be able to elicit insomnia-related deficits. Many of the currently used cognitive tests were originally designed to detect and measure gross cognitive deficits, and subsequently adapted for people with insomnia (Fortier-Brochu et al, 2012). While such tests are a useful starting point, the more we learn about the neurophysiological complexity of insomnia, the more it becomes apparent that neurocognitive tests required to detect deficits in people with insomnia need to be specifically refined and tuned (Riemann et al, 2010).

It has been suggested that people with insomnia may appear to perform no differently in such tests than those with healthy sleep because, comparatively, they are able to recruit additional neurocognitive resources in order to match the demands of the task (Orff et al, 2007). Thus, the subjective impairment reported may be a reflection not of difficulties of performance, but of the additional neurophysiological effort needed to perform the task. This hypothesis is supported by evidence that people with obstructive sleep apnoea, a breathing disorder which leads to impaired sleep, show a compensatory neural activation mechanism, which increases with increased severity of the disorder (Archbold, Borghesani, Mahurin, Kapur, & Landis, 2009). The hypothesis may explain why, as task complexity increases, and thus the demand on extra neurophysiological resources also increases, people with insomnia find it harder to keep the pace, and perform worse on these more complex tasks than normal controls (Altena et al, 2008). The deficiency in performance in people with insomnia may reflect a trade-off between immediate response to presenting unambiguous stimuli (simple reaction time), and recruiting extra neurocognitive functions when the task difficulty increases (complex reaction time).

The study by Altena et al (2008) makes this important distinction in attention deficits shown by people with insomnias. The authors used both a 'simple' reaction time task, and a ‘complex’ vigilance task, which required participants to make a choice, rather than the same response to incoming stimuli. The insomnia group proved faster than the control group in the simple vigilance task, but slower than the control group in the complex vigilance task.

Following targeted intervention in respect of insomnia (including physical activity, light exposure, sleep hygiene), the ratio (or trade off) in performance between the simple and the complex task improved in the insomnia group, and their performance time 'normalised' near to the level of the control group.

These results suggest that insomnia may affect simple cognitive functions required to monitor incoming stimuli, as well as higher cognitive functions required to monitor and decide on more ambiguous stimuli. Altena's findings are consistent with those of other neurocognitive studies of people with insomnia, revealing the 'complexity cost' reflected in performance of tasks involving other more complex functions, such as working memory and decision-making processes (Edinger, Carney, & Wohlgemuth, 2008; Fortier-Brochu et al, 2012).

***Occupational impairment***

Linton & Bryngelsson (2000) assessed sleep problems and daytime work performance in a representative sample from the Swedish population, aged 20 to 60 years. The prevalence of sleep disturbance in the sample ranged from 35% (poor perceived sleep) to 8% (fulfilling DSM-IV diagnostic criteria). Just under 50% of the group with insomnia reported daytime impairments related to their sleep difficulties: poorer concentration and memory, headaches, problems making decisions; and feeling listless and 'blue'. Poor sleep was reported to reduce work productivity and increase absenteeism and healthcare utilization, pointing to associated substantial indirect costs, added to those direct costs noted elsewhere in the literature (Leger, Levy & Paillard, 1999). In a study of the occupational impact of sleep quality among 1054 adults in England, Kucharczyk, Morgan and Hall (2012) found that 23% of workers reported that poorer quality of sleep affected their vitality throughout the day, and their ability to perform effectively in the workplace.

***Quality of life***

People with insomnia experience significantly poorer quality of life, both in physical and mental domains, compared to the general population. Comparing those with insomnia and without insomnia Bolge, Doan, Kannan, and Baran (2009), for example, found that the insomnia group had on average 10% lower scores on the physical and mental components of a quality of life measure. These significantly lower scores, which were adjusted for demographics and comorbid conditions, translated into significant lost work productivity, more than three times greater than the non-insomnia group.

Those people experiencing insomnia reported significantly more absenteeism, presenteeism (productivity impairment at work), and daytime activity impairment. The health related quality of life of those people experiencing insomnia symptoms decreases with the increased severity of their sleep disorder (Schubert et al, 2002). This study found that insomnia symptoms had a negative impact on health related quality of life, with a significant decrease in every domain of quality of life with increasing number of insomnia traits. This effect remained significant even when adjusting for chronic disease, incontinence, smoking, alcohol use and impaired vision. In this large representative adult British sample, all categories of reported insomnia were significantly associated with lower health-related quality of life, after adjustment for physical health and common mental health disorders.

### 1.1.5 Discussion of present treatment options for insomnia

The NIH consensus statement on insomnia (Leshner, Baghdoyan, & Bennett, 2005) concluded that the main evidence-based current treatment options for insomnia are pharmacological and psychological. Pharmacological treatment aims to target the most obvious night-time symptoms, the inability to fall, or stay, asleep. Commonly used pharmalogical agents are benzodiazepines (such as temazepam). These have a long half-life, contributing to their efficacy in maintaining sleep throughout the night (Scharf, Roth, Dominguez, & Ware, 1990), but can also result in next day sedation and impaired next day cognitive functioning (Holbrook, Crowther, Lotter, Cheng, & King, 2000). Nonbenzodiazepine hypnotics, such as zolpidem, have proved less problematic in terms of next day consequences (Verster et al, 2002). These seem to be effective to aid sleep onset, though they are less efficacious as sleep maintaining agents (Scharf, Mendels, Thorpy, & Weiss, 1994).

Although a high proportion of people with insomnias use pharmacological agents long-term, (Mellinger, Balter, & Uhlenhuth, 1985), no currently approved insomnia agents have been evaluated in trials exceeding 12 weeks (Benca, 2005). Prolonged use of benzodiazepines, and of nonbenzodiazepine hypnotic agents, has been associated with both acute, and next day residual effects (Verster et al, 2002). People using pharmacological treatment for insomnia on a long term basis have higher mortality risk (Kripke et al, 1998).

Recent large longitudinal analyses of hypnotic medication use in relation to health and mortality outcomes show that people prescribed hypnotics (even in relatively small dosage of less than 18 pills a year) have significantly elevated hazards not only of mortality but of other adverse health outcomes (such as incident cancer), compared to people who were not prescribed hypnotics (Kripke, Langer, & Kline, 2012). In addition, pharmacological trials for insomnia treatment find that the placebo effect is a major contributor to the reported effect size of medication; it accounts for up to half of the effect size of the drugs response (Huedo-Medina, Kirsch, Middlemass, Klonizakis, & Siriwardena, 2012.).

Thus, overall, pharmacological treatment with hypnotic medication can be an effective short term solution for managing the symptoms of insomnia. Such treatment can give rapid relief in the short term from the most immediate night-time symptoms, of inability to get to, or to maintain sleep (Buscemi et al, 2005). There are serious adverse consequences of long term use, coupled with the large placebo effects accompanying such insomnia treatment; the remaining beneficial effect should be balanced against harmful effects set out above.

The findings on the significant effect of placebo on the effectiveness of pharmaceutical treatment for insomnia point to the importance of psychological variables (Huedo-Medina et al, 2012). Nondrug alternatives for treating insomnia include cognitive and behavioural forms of therapy, such as CBT-I (Cognitive Behavioural Treatment for Insomnia), sleep hygiene, forms of meditation, and relaxation and mindfulness (Ong & Sholtes, 2010).

CBT-I often consists of a combination of several techniques: cognitive restructuring, stimulus control, sleep restriction, sleep hygiene and relaxation (Morin & Espie, 2003). The efficacy and effectiveness of cognitive behaviour therapy for improving night-time symptoms of insomnia (CBT-I) is well established. The most recent American Academy of Sleep Medicine review of 85 clinical trials found 70% of people with insomnia who underwent CBT-I experienced enduring symptom reduction (Morin et al, 2006b).

Predictably, CBT-I shows longer term benefit in reducing the severity of insomnia symptoms and in improving sleep quality than pharmacological therapy for insomnia (Jacobs, Pace-Schott, Stickgold, & Otto, 2004), and it is also effective in reducing the long-term use of sleep medication in people with insomnia (Morgan, Dixon, Mathers, Thompson, & Tomeny, 2004). CBT-I is also cost effective when compared to "treatment as usual" (i.e. prescription of hypnotics) in primary care settings (Morgan et al, 2004). Also, cognitive behavioural interventions contain the method of treatment preferred by patients with insomnia, when compared to medication (Vincent & Lionberg, 2001).

As to reductions in daytime consequences of insomnia, such as fatigue, irritability and concentration difficulties, the evidence available of CBT-I's efficacy is more sparse. One of the larger clinical trials comparing the effectiveness of CBT-I and pharmacological interventions in treatment of insomnia found no improvement in daytime insomnia-related variables (mood and fatigue) (Jacobs et al, 2004). More recent CBT-I trials found no significant treatment effect of CBT-I on daytime insomnia symptoms (sleepiness, fatigue, depression or anxiety) (Morin et al, 2006b; Bothelius, Kyle, Espie, & Broman, 2013).

If CBT-I may have a direct effect only upon night-time symptoms of insomnia, this leaves open the possibility that a multi-therapeutic modality is necessary to improve daytime symptoms (Bothelius et al, 2013). Given the multi-factorial nature of insomnia, daytime related impairments may need targeting separately via specific behavioural and cognitive techniques. These techniques might address such difficulties sometimes related to chronic insomnia such as circadian rhythm desynchrony, excessively negatively toned cognitive functioning, or high anxiety levels.

### 1.1.6 Summary

Insomnia is a prevalent condition affecting not only night-time sleep, but also negatively impacting mood, cognitive performance, occupational efficiency and quality of life. Current pharmacological treatment for insomnia efficaciously addresses short-term nighttime insomnia symptoms. Cognitive and behavioural therapies for insomnia offer longer term relief of insomnia symptoms for a large proportion of sufferers, but do not always adequately address daytime insomnia-related symptoms. Current treatment options point to the multi-factorial origins of insomnia, to include psychological variables.

## 1.2 Physical activity

### 1.2.1 Definition of terms

Physical activity, fitness, and exercise are terms which are often used interchangeably in the research literature, though they describe different concepts. Physical activity is any bodily movement produced by skeletal muscle that results in energy expenditure beyond the energy expended at rest. Exercise is a sub-set of physical activity, its defining features being structure, repetitiveness, planning, and having physical fitness as a motivational goal. Physical fitness comprises of a set of abilities which enable the ability to carry out physical activity, such as muscle strength, body composition, flexibility, and cardiovascular fitness.

There is an important interrelationship between the amount of physical activity, and its intensity. Here, *amount* refers to the total energy expended in a given physical activity, and is usually described in minutes, while *intensity* refers to the rate of energy expenditure when engaged in physical activity (Pate et al, 1995). Intensity can be defined in absolute or relative terms. Absolute intensity is expressed in Metabolic Equivalents (METs), where 1 MET equals the resting metabolic rate ($\approx$3.5 mL $O_2$ x $kg^{-1}$ x $min^{-1}$). Relative intensity refers to the proportion of aerobic power used during exercise and is expressed as percent of the maximal heart rate (or $VO_2$ max).

Moderate intensity physical activity is considered the easiest achievable level for most strata of the general population, and is the intensity recommended by the current guidelines on physical activity and health (Chief Medical Officer [CMO], 2011). Moderate intensity activity, for example brisk walking, refers to an absolute energy rate of expenditure of 4 – 6 METs, or a relative energy expenditure of 40-70% $VO_2$ max. However, the relative intensity takes account of the maximal heart rate, which could vary depending on age, or health status.

Since physical activity is a complex behavioural construct, it poses specific measurement challenges in research and clinical practice. There are various measurement techniques available, from which activity-related energy expenditure can be calculated: self-report (through questionnaires and diaries), direct behavioural observation, physiological markers (such as heart rate, temperature), motion sensors (pedometers or accelerometers), and indirect calorimetry (Schutz, Weinsier, & Hunter, 2012). They each have advantages over others. For example, self-report questionnaires and diaries can offer type of activity performed and context, whilst motion sensors are more accurate and less burdensome for participants.

Current physical activity guidelines for the UK, published by the Chief Medical Office (CMO, 2011), specify that adults should aim to be active daily and that, over a 1-week period, individuals should accrue at least 150 minutes (2½ hours) of moderate intensity activity in bouts of 10 minutes or more. This could be achieved by doing 30 minutes of moderate intensity activity on at least 5 days a week.

### 1.2.2 Physical activity and health

Increased physical activity levels are related to a host of physical and mental health indicators. Moderate physical activity using large muscle groups, such as brisk walking, produce cardiovascular adaptations that aid in increasing exercise capacity, endurance and skeletal muscle strength. Regular exercise is associated with a range of physical and mental health benefits. These include reduced risk of coronary heart disease (Sattelmair et al, 2011), non-insulin dependent diabetes (Jeon, Lokken, Hu, & Van Dam, 2007), some cancers, particularly colon (Wolin, Yan, Colditz, & Lee, 2009) and breast cancer (Friedenreich, 2011), and neurodegenerative disorders (Hamer & Chida, 2009). An overall dose-response relationship between physical activity and all-cause mortality also exists (Samitz, Egger, & Zwahlen, 2011), and a recent analysis suggested that physical inactivity accounts for 9% of premature deaths worldwide (Lee et al, 2012).

In addition, exercise has been shown to have a role in the management of chronic conditions such as coronary heart disease (Leon et al, 2005), stroke (Gordon et al, 2004), diabetes (Colberg et al, 2010), obesity (Donnelly et al, 2009), and mental health problems, such as anxiety (Wipfli, Rethorst, & Landers, 2008) and depression (Rethorst, Wipfli, & Landers, 2009).

More specifically, physical activity also contributes to the attenuation and reversal of symptoms in coronary heart disease (Taylor et al, 2004), benefits the glycaemic control in type 2 diabetes (Boule, Haddad, Kenny, Wells, & Sigal, 2001), and reduces the impact of existing mental health problems (Singh, Clements, & Fiatarone, 1997; Barton, Griffin, & Pretty, 2011). Evidence shows that the most benefit in mortality reduction is seen in those physically inactive people who take up regular physical activity (Myers et al, 2004), implying a role for physical activity in both the incidence and prevalence of chronic disease. Thus, adults who are physically active have lower rates of all-cause mortality and chronic disease, and exhibit higher levels of functional health than their less active peers (Morgan, 2003).

### 1.2.3 Sleep and daytime activity levels

Sleep is defined as an altered state of consciousness, characterized by immobility, reduced responsiveness and quick reversibility to the awake state, unlike anaesthesia or coma (Siegel, 2004). Sleep behaviour, alternating periods of reduced activity and alertness, can be observed in virtually all animal species (Drucker-Colín, 1995); and in plants too (Covington et al, 2008). Many theories have been put forward on the function of sleep, contending that sleep relieves a deficit in body or brain tissue, fulfilling a physiological or psychological need accumulated during awaking periods. Of these, Horne (2006) holds that sleep varies in function with increasing complexity of the brain: in humans it serves the purpose of cerebral recovery; and in animals with less cerebral complexity, it serves the purpose of energy conservation. Others hold that sleep's essential function is to reduce the energy expenditure below the level attainable by rest alone (Walker, Garber, Berger & Heller, 1979). Still others contend that sleep is serving to enforce rest and limit metabolic requirements (Zepelin & Rechtscaffen, 1974).

The 2-process model of sleep regulation proposes that sleep results from the combined action of two independent processes: the sleep/wake homeostasis, which is dependent upon sleep/wake behaviour (process S); and the circadian biological clock, which runs independently of sleeping and waking (process C) (Borbely, 1982). By process S, sleep tendency (or sleepiness) increases with the duration of time one is awake. Thus, sleep is regulated in its intensity as a function of the duration of previous wakefulness. Process C, on the other hand, regulates the timing of alternating periods of sleep and wakefulness over 24 hours.

The natural oscillation of the internal clock can be measures through temperature and hormonal changes over 24 hours. The 'dips' in the circadian rhythm result in the strongest sleep drive occurring in most adults between 2-4am and in the afternoon between 1-3pm. The sleepiness experienced during those times will be more intense if more awake time has been accumulated; and less intense if sufficient sleep occurred beforehand. Thus, the homeostatic drive for sleep is accumulated through the day, is then dissipated through adequate sleep, and the cycle begins again.

Physical activity during the daytime can influence both the homeostatic drive, and the internal biological clock. Increased physical activity levels through the day will increase the energy expenditure, and metabolic requirements of the body, and potentially act upon process S by increasing the drive to sleep and restore energy. Under natural environments, the internal body clock is synchronized to the geophysical day/night cycle by environmental time cues (Zeitgebers). The most powerful zeitgeber for our bodies is the pattern of light exposure over 24 hours. Other social zeitgebers are meal times, activity patterns, work schedule etc. Physical activity is one such zeitgeber, shown to have influence upon the entrainment of the circadian rhythm to the environmental time pattern, by contributing to effective temperature regulation maintenance (Youngstedt, 2002). From this perspective, daytime activity behaviour serves to maintain the robustness of the sleep/wake circadian rhythm (van Someren & van der Lek, 2007).

## 1.3 Physical activity and sleep quality: epidemiological research

### 1.3.1 Introduction

The evidence suggests that, in general, people perceive physical activity as behaviour promoting better sleep quality. In a survey reported by Shapiro and Bachmayer (1988), for example, 83% of those participants who exercised at least twice a week reported the belief that exercise helped them fall asleep. Just over a third of people randomly selected for a survey in Finland listed exercise as the best sleep-promoting practice (Urponen, Vuori, Hasan, & Partinen, 1988) while, in a large representative sample of the Japanese population, Ohida et al (2001) found that lack of regular exercise was associated with *perceived* insufficient sleep duration.

Similarly, in a study reported by Gerber, Brand, Holsboer-Trachsler, and Puehse (2010) it was found that those participants with a perceived lack of physical activity also reported prolonged sleep onset latencies.

### 1.3.2 Summary of literature

Large population datasets have consistently shown significant associations between increased physical activity levels and better sleep quality, as evidenced by comprehensive data reviews (Youngstedt & Kline, 2006; Buman & King, 2010). Epidemiological studies in which activity and insomnia outcomes have been assessed (and in which physical activity was clearly quantified) are presented in Table 1.

Sherrill, Kotchou, and Quan (1998) analysed data from a cross section of 722 American adults randomly sampled, aged 40 years or over, obtained using structured questionnaires. The level of physical activity was categorised according to its frequency, intensity and duration, distinguishing between those subjects who engaged in physical activity vigorously, for more than one hour per day; those who walked at least 6 blocks per day for less than one hour per day, at a brisk pace (moderate intensity); and those who walked at least 6 blocks a day for less than one hour a day, at a low pace (low intensity).

Insomnia was identified where subjects reported current difficulties in initiating and maintaining sleep. Sherrill et al's study identified an optimal threshold level of physical activity required for identifiable sleep quality benefits as being "regular activity at least once a week, participating regularly in an exercise program, and walking at a normal pace for more than 6 blocks per day" (95% CI, ORs=0.47 to 0.71). This level of physical activity may be below the level of the current public health guidelines (6 blocks is the equivalent of 0.5 miles, which one could walk in 10 minutes, at a brisk pace). The authors also noted that there may be an inverted 'U' shaped relationship between physical activity and sleep, with women who exercised more vigorously, and women with insufficient exercise, having worse sleep than those men and women who had the 'optimal' amount of physical activity. This is supported by recent observational data in athletes' sleep, which suggest athletes have poorer sleep quality markers compared to non-athlete controls, presumably due to high levels of exercise/training (Leeder, Glaister, Pizzoferro, Dawson, & Pedlar, 2012).

Janson, Lindberg, Gislason, Elmasry, & Boman (2001) analysed longitudinal data obtained from 2,602 men, randomly sampled, aged between 30 and 69 years of age, using the authors' own questionnaire on the severity of sleep disturbance. Two groups of subjects were identified: being those who were physically active (defined as carrying out physical activity of at least moderate intensity, such as walking, cycling, gardening) for at least 240 minutes per week; and those who were sedentary (defined as almost completely inactive, engaging mostly in sitting, watching TV). Insomnia was classified according to the authors' own questionnaire on severity of sleep disturbance. Janson et al's study found that being physically inactive significantly increased the risk of reporting insomnia 10 years later (CI 95%, OR=1.4). However, the threshold definition used for being physically active (of at least 240 minutes per week), was higher than the current recommended public health guidelines (of at least 150 minutes per week).

Morgan's longitudinal study (2003) analysed data from a random sample of 1042 people aged 65 years or more. Physical activity was assessed using a structured detailed interview, where activities likely to promote health benefits were categorised according to their type, frequency and duration. These were then divided into quintile ranges, from a very low level, through to a high level of customary physical activity (CPA). Insomnia was classified if self-reported symptoms were present often, or always, during the preceding week. Insomnia prevalence in the sample was 21%. Morgan's study (2003) found that walking for less than 11 minutes per day was significantly associated with prevalence of insomnia. In unadjusted bivariate analyses, there was also a marked activity gradient present, with lower levels of CPA associated with higher prevalence of insomnia. In final adjusted models, low or intermediate CPA levels were significantly associated with prevalent and incident insomnia. Thus, lower physical activity levels were associated with a significant higher risk for insomnia persistence, and insomnia incidence (CI 95%, ORs=2.0-2.2).

The National Sleep Foundation Poll (2003) analysed data from a cross-sectional random sample of 1506 American adults aged between 55 and 84 years. Levels of physical activity were assessed according to frequency, based on how many times each week participants engaged in exercise of sufficient intensity to elicit health benefits. Using DSM-IV criteria, the poll assessed detailed sleep profiles, including sleep duration, quality, and insomnia symptoms.

The National Sleep Foundation Poll 2003 found that those adults who exercised less than once a week were significantly more likely to report experiencing symptoms of insomnia, than those adults who exercised three or more times per week. A dose response pattern was observed, with increased exercise accompanying decreased reported insomnia symptoms. In this sample, exercising to at least moderate intensity, for at least three times a week, delivered significant sleep benefits. The more recent National Sleep Foundation Poll 2013 delivered similar results: those who reported carrying out no physical exercise experienced more sleep problems, and lower sleep quality, than those who reported that they were physically active. There was an apparent dose-response relationship present, with those exercising at higher intensity reporting fewer sleeping problems, and better sleep quality (National Sleep Foundation, 2013).

Kim et al's longitudinal study (2009) analysed data from 1204 adults aged at least 65 years. Participants were divided into those who were active or inactive based on a structured assessment of both work and leisure activity, and validated measure of insomnia were used (i.e. DSM-IV criteria). Kim et al found that a lack of habitual physical exercise was significantly associated with prevalent and incident insomnia (95% CI, OR=1.8, and OR=1.6, respectively).

Another recent epidemiological study, by Paparrigopoulos et al (2010a), analysed data from a cross section of 1005 adults aged between 18 and 99 years. Participants were divided according to the International Physical Activity Questionnaire (IPAQ) into two groups: those carrying out light, moderate or vigorous physical activity, and those who were sedentary. Insomnia was assessed on the Athens Insomnia Scale, a standardised validated questionnaire. In adjusted analyses, sedentary participants were found to have a significantly increased risk of reporting insomnia, as compared to those participants engaging in light, moderate or vigorous physical activity (95% CI, OR=1.4). In a separate analysis of data from the same sample, based only of those participants who reported cardiac problems, physical activity was found to be a significant protective factor against reporting insomnia (95% CI, OR=0.69) (Paparrigopoulos, Tzavara, Theleritis, Soldatos, & Tountas, 2010b).

Table 1

*Selection of epidemiological studies of insomnia symptoms and physical activity*

| Author and year | Design | Sample characteristics | Insomnia assessment | Physical activity assessment |
|---|---|---|---|---|
| Sherrill et al, 1998 | Cross-sectional<br>Random sample | N=722<br>>40 years | Self-reported current difficulties in initiating and maintaining sleep | Three groups, according to intensity and duration:<br>1: walked > 6 blocks/day at a brisk pace, < 1 h/day<br>2: walked > 6 blocks/day at a low pace, < 1 h/day;<br>3: vigorous physical activity, > 1 h/day. |
| Janson et al, 2001 | Longitudinal<br>Random sample | N=2,602 men,<br>30-69 years | Authors' own questionnaire on severity of sleep disturbance | Two groups (validated questionnaire):<br>1: sedentary-almost completely inactive: sitting, watching TV<br>2: physically active-at least medium intensity physical activity (walking, gardening, riding a bicycle), at least 4 h/week. |
| Morgan, K. 2003 | Longitudinal<br>Random sample | N=1042<br>>65 years | Self-reported current sleep difficulties | Two groups, by duration:<br>1: walking > 11 min/day<br>2: walking < 11 min/day<br>Also, quintile ranges, from very low customary physical activity level (CAP), through to high CAP level. |
| National Sleep Foundation, 2003 | Cross-sectional<br>Random sample | N=1506<br>55-84 years | DSM-IV criteria | Four groups, by frequency:<br>< 1 time/week<br>1-2 times/week<br>3-5 times/week<br>> 5 times/week |
| Kim et al, 2009 | Longitudinal | N=1204<br>>65 | DSM-IV criteria | Dichotomous variable:<br>Active<br>Inactive |
| Paparrigopoulos et al, 2010a | Cross-sectional<br>Random sample | N=1005<br>18-99 years | Athens Insomnia Scale | International Physical Activity Questionnaire (IPAQ) 2 groups:<br>1. Sedentary<br>2. Light, moderate, vigorous |

### 1.3.3 Summary

The epidemiological studies reviewed above support the view that lower levels of physical activity are a significant risk factor both for present insomnia, and for the development of insomnia in the future (Janson et al, 2001; Morgan, 2003). Furthermore, the evidence shows a consistent trend of improved sleep quality with increased duration and intensity of physical activity (Morgan, 2003; National Sleep Foundation, 2003). All the above studies assessed physical activity in different ways, mostly clustered in intensity and duration, and frequency (Table 1). Though earlier studies use unvalidated questionnaires for assessing both insomnia and physical activity, later studies used validated instruments with known reliability (e.g. Paparrigopoulos et al, 2010a). Even with this variety of assessment instruments, the effects shown in these studies, while modest, are broadly similar.

### 1.3.4 Limitations identified in the reviewed literature

Nevertheless, there are limitations to the inferences which can be drawn from this research. The causal ordering of sleep-activity relationships reported in cross sectional epidemiological studies, for example, remains unclear. People with poor sleep quality feel more fatigued, sleepy and cognitively impaired during the daytime, which in turn reduces the energy and motivation necessary to exercise (Suskin, Ryan, Fardy, Clarke, & McKelvie, 1998). The pathways which mediate possible sleep-activity inter-relationships are also unclear from the epidemiological research. Light exposure, for example, is known to influence circadian rhythm indicators (Gordijn, Korte, & Van den Hoofdakker, 1998) and sleep quality (Guilleminault et al, 1995). Both light and physical activity have chronobiotic properties (Atkinson, Drust, Reilly, & Waterhouse, 2003; Knight, Thompson, Raboud, & Hoffman, 2005; Buxton, Lee, L'Hermite-Balériaux, Turek, & Van Cauter, 2003). The effects on sleep quality could vary significantly depending on the timing of light exposure, and exercise intensity and duration (Youngstedt, Kripke, & Elliott, 2002).

Youngstedt et al (2003), in an observational study of sleep quality and exercise, found that the mean reported time spent outdoors was almost three times higher (142 minutes) on days when participants were active, than on days when they were not active. Disentangling the effects, of light exposure and exercise cannot be reliably achieved in the present epidemiological research. In the absence of recorded data in time spent outdoors, or the amount of daily light exposure, it is difficult to estimate the confounding effect of light on sleep quality.

A further important issue which is not addressed in the sleep-activity epidemiological literature concerns the practical identification of a level of activity (expressed in terms of intensity, frequency and duration) necessary to positively impact sleep quality. This is in marked contrast to the emphasis now placed in public health on the identification of precise *minimum* levels of physical activity likely to deliver a range of health benefits. Thus, the amount, frequency, intensity and type of physical activity required to achieve mental and physical health benefits have all been examined in systematic reviews, and translated into international public health messages. These reviews have consistently found that moderate intensity physical activity levels at or above a threshold value of 150 minutes per week reliably deliver cardiovascular, metabolic and musculo-skeletal health benefits (Warburton, Charlesworth, Ivey, Nettlefold, & Bredin, 2010). This overall weekly volume of engagement appears beneficial irrespective of the type of activity performed (Warburton et al, 2010), though walking has been identified as the most convenient and achievable form of exercise for a high proportion of the adult population (Department for Transport, 2012). While promoting this level of activity is now a public health priority for reducing levels of stroke, heart-disease, cancers, diabetes and obesity, the evidence base does not yet allow such precision in predicting activity-related sleep benefits. Rather, the sleep-activity literature presents a range of possibly effective activity levels which might reduce insomnia symptoms and improve sleep quality, ranging from high intensity exercise regimes (see Driver & Taylor, 2000) to above-average levels of customary physical activity (Morgan, 2003).

## 1.4 Activity and Insomnia: a research agenda

Establishing a minimum level of activity likely to impact sleep quality could have implications for both public health generally, and behavioural sleep medicine specifically. Behavioural approaches to the management of insomnia include cognitive and behavioural forms of therapy, such as Cognitive Behavioural Treatment for Insomnia (CBT-I), sleep hygiene, and relaxation and mindfulness approaches (Ong & Sholtes, 2010). CBT-I often consists of a ‘package’ of techniques, typically cognitive restructuring, stimulus control, sleep restriction, sleep hygiene and relaxation (Morin & Espie, 2003).

While the American Academy of Sleep Medicine's recommendation for behavioural and psychological treatment approaches to insomnia is based on the evidence of their high degree of clinical effectiveness (see Morgenthaler et al, 2006), it is also the case that CBT-I does not benefit all patients. In reviews prepared by the Task Force of the American Academy of Sleep Medicine, Morin and colleagues (1999; 2006b) concluded that CBT-I delivers lasting benefits to 80% of treated patients. Similarly, Montserrat Sanchez-Ortuno and Edinger (2010) note that not all people with insomnia benefit equally from standardised forms of CBT-I, and that responses vary along psychological and behavioural dimensions, including daytime sleepiness, anxiety and depression. Some of these variables may be modifiable by other behavioural or psychological interventions, augmenting the CBT-I treatments. Physical activity presents as a strong candidate for behavioural intervention for insomnia; few other daytime behaviours are more linked to subsequent night-time sleep. However, before physical activity can be offered as a practical and effective adjunct to CBT-I, two important scientific objectives need to be met. First, an appropriate minimal level of activity intervention should be empirically established. This would introduce clarity for practitioners, and avoid the unnecessary exclusion and attrition from treatment programmes which would result if the level was set too high, and beyond that achievable by many patients. And second, any such minimal level should be subjected to a randomised and appropriately controlled clinical trial, in order to establish effectiveness independent of confounders like light exposure, and the methodological issue of causal ordering.

The programme of research presented in this thesis was designed to address both of these needs. Since a level of $\geq$150 minutes of moderate intensity physical activity per week has already: a) proved sufficient to deliver a range of health benefits; and b) been adopted by agencies around the world as an 'aspirational' public health goal, it would seem reasonable to initially adopt this threshold value in preliminary explorations of a minimal level of activity likely to impact sleep quality and insomnia symptoms. In order to test proof of concept, secondary analyses of existing longitudinal data were conducted to assess whether walking to current WHO guideline levels of physical activity ($\geq$150 minutes/week) was associated with sleep quality benefits in a representative sample of UK older people. The rationale, method, analysis, results and conclusion from these assessments are presented in Chapter 2.

# CHAPTER TWO

## 2.0 Proof of concept: physical activity and insomnia in the Nottingham Longitudinal Study of Active Ageing

## 2.1 Background

Systematic reviews have consistently found that moderate intensity physical activity levels at or above a threshold value of 150 minutes per week reliably deliver health benefits (See Chapter 1). This overall weekly volume of engagement appears beneficial irrespective of the type of activity performed (Warburton et al, 2010), though walking has been identified as the most convenient and achievable form of exercise for a high proportion of the adult population (Department for Transport, 2012). Whether a minimum of 150 minutes per week of walking can also impact sleep quality has not previously been investigated. None of the major UK surveys which include measures of physical activity (e.g. the Health Survey for England; the Time Use Survey; the General Household Survey; the Active People Survey) also include suitable measures of sleep quality. However, the opportunity to explore relationships between sleep quality and precise levels of walking is presented by the Nottingham Longitudinal Study of Activity and Ageing (NLSAA), an ongoing study of physical activity and health outcomes which has already delivered epidemiological profiles of insomnia and activity levels in England (Morgan, 2003). While it could be argued that results from a sample of older adults may not necessarily generalise to the whole adult population, the utility and validity of the present approach is supported by four counter-arguments: first, the NLSAA provides the only accessible nationally representative sample on which such analyses are possible; second, since the aim of the proposed analyses is to test proof of concept, the demographic composition of the sample is less relevant; third, the dose-response relationship between sleep quality and activity level reported from the National Sleep Foundation Poll (2003) was found to be age independent; and fourth, levels of physical activity show a significant degree of 'tracking' across the lifespan, with individuals showing a strong tendency to maintain their activity rank positions within the population (see Armstrong and Morgan, 1998; Malina, 2001).

## 2.2 Aim of present analyses

Using models controlling for appropriate confounders, the analyses reported in this chapter assess whether older adults who report habitual walking levels at or above a threshold value of 150 minutes per week: i) show a significantly lower risk of all-cause mortality over a 27 year period (these analyses were conducted in order to assess the validity of the walking measure); and ii) demonstrate a reduced risk of insomnia symptoms.

## 2.3 The Nottingham Longitudinal Study of Activity and Ageing (NLSAA) description

The NLSAA commenced in 1985 with the aim of meeting three core objectives: i) to quantify customary physical activity (CPA) and physical capabilities within a representative sample of elderly people living at home; ii) to quantify physical and psychological wellbeing within a representative sample of elderly people living at home; and iii) to examine, cross-sectionally and longitudinally, inter-relationships between CPA, health, and psychological wellbeing. Within the structure of a panel study with repeated survey measurements (but without sample replacement) data were collected in three waves: baseline measurement (T1: 1985); the first follow-up (T2: 1989); and the second follow-up (T3: 1993). In order to preserve numbers for longitudinal analyses, yet allow for change in the variables of interest, 4-year follow-up periods were considered optimal. To control for possible seasonal variations in CPA, all three interview waves were conducted in the summer period May-September. Data were collected by lay interviewers recruited at each survey phase (n = 10, 8 and 8 for T1, T2 and T3 respectively). All interviewers were women, with ages ranging from 27-68. Information on mortality within the baseline sample continues to be provided by the UK Medical Research Information Service, allowing for ongoing survival analyses.

## 2.4 The sample

Using electoral ward-level statistics from the 1981 census, three areas of greater Nottingham were combined to provide a study population whose demographic composition (as regards age, sex, social class, ethnicity and proportion of elderly people living alone) reflected the average national pattern for England and Wales (Table 2). The resulting area included a total of 48 733 individuals served by 25 general practitioners. With the consent and cooperation of these general practitioners, NHS age-sex lists were used to identify all patients aged 65 years and over within the survey areas. Since the aim was to identify a representative community sample, those living in institutions (i.e. those whose permanent address was a residential or nursing homes) were excluded. A total of 8409 elderly people were identified, from which 1299 eligible individuals (those alive and still living at the address provided) were randomly selected for interview. At sampling those aged 75 years or older were intentionally over-represented in order to admit sufficient numbers for subsequent longitudinal analyses.

Accordingly, while the ratio of "old" (65-74 years) to "very old" (75+ years) people in the 1985 British population was approximately 1.62:1 [4] a baseline ratio of 1:1 was the target for this study.

The baseline (T1) survey was conducted between May and September 1985. All potential respondents were first sent a letter inviting them to participate in the survey. After a minimum of three clear days, each respondent was then visited by an interviewer. Of the 1299 individuals approached, 1042 were interviewed, a response rate of 80% (Table 2).

## 2.5 Survey assessments

The structured questionnaire contained a total of 318 items, and was designed to take 45-90 minutes to administer. Assessments directly related to the present analyses are described below.

**Walking** Levels of customary physical activity likely to promote muscle strength, joint flexibility, or stamina were assessed using detailed activity inventories administered in the single face-to-face interview. These activities were divided into five mutually exclusive functional categories: outdoor productive activities (e.g. gardening, house and car maintenance); indoor productive activities (e.g. housework, decorating, indoor maintenance); walking (purposeful walking outside the house or garden); shopping (i.e. continuous ambulatory behaviour associated with shopping); and leisure activities (e.g. cycling, swimming - walking was included as a leisure activity only if it was described as such).

'Customary' defined those activities with a probable minimum energy cost of 2kcal/min, performed continuously for a minimum of three minutes, at least weekly, for at least the previous six weeks. In administering the questionnaire on outdoor, indoor, and leisure activities the interviewer first determined whether the respondent's participation in the activity met the criteria for 'customary', and then asked in detail about the frequency and duration of participation. Each reported activity was scored as minutes per week. Non-participation was scored as zero.

In the assessment of walking, the interviewer asked in detail about walking done on a typical day, selecting preferentially the day prior to interview. If, however, this day had been atypical, then another was selected (up to a maximum of six days previously). For the purposes of the interview, the selected day was divided into hours, and the amount of walking (purposeful walking, shopping, and recreational walking) in each hour was coded in minutes, and finally expressed as minutes per typical day. These were then aggregated in minutes per week.

**Sleep** Subjectively estimated sleep quantity was assessed using the items: 1) “At what time do you usually go to bed?”; 2) “At what time do you usually settle down in bed to go to sleep?”; 3) How long does it normally take you to fall asleep?”; 4) “At what time do you finally wake up?”; and 5) “At what time do you usually get up?”. Responses were then used to estimate time in bed (TIB = time elapsed between going to bed and getting up); sleep latency (SOL = time taken to fall asleep); and total sleep time (TST = TIB minus all non-sleep time in bed).

Quality of sleep was assessed using the item "Do you ever have problems sleeping (i.e. problems getting to sleep and/or staying asleep and/or waking too early?)", with five response categories (never, seldom, sometimes, often, all the time). Positive responses were followed with the question “Have you had this problem (or these problems) in the past week?”. Insomnia symptoms were considered present if the respondent reported a sleep problem "often" or "all the time", and if that problem had been experienced within the previous week.

Two sleep outcome variables were calculated for the present analyses: sleep efficiency (the percentage of time spent asleep in bed: SE = (TST/TIB) x 100)) and the presence of insomnia symptoms. While separately reflecting quantitative and qualitative estimates, these measures are not unrelated, since sleep efficiencies below 85% typically indicate poor quality sleep (Perlis, McCall, Jungquist, Pigeon, & Matteson, 2005).

**General health** was assessed using a health index scored from zero (no health problems) to 13 (multiple health problems) covering the presence or absence of: heart, stomach, eyesight, or foot problems; giddiness, headaches, urinary incontinence, arthritis, falls, and chronic disease; drug and walking aid use, and recent (1 month) contact with (primary and secondary care) medical services. The scale showed full activity across its score range (0-13) and acceptable reliability (Cronbach’s alpha = 0.7).

**Weight and skeletal size** At interview weight measurements (fully clothed with shoes removed) were made using calibrated analogue scales. To reduce error arising from kyphotic changes in measuring the height of older people, skeletal size was assessed using demispan (Bassey, 1986), the distance between the finger roots and the sternal notch (with the arm laterally outstretched). Body mass was then estimated using the Quetelet Index (BMI) based on weight and predicted height (Lehmann, Bassey, Morgan, & Dallosso, 1991). Those with a BMI >25 were classified as overweight.

**Mental health status** Affective status was assessed using the separate anxiety and depression subscales from the Symptoms of Anxiety and Depression (SAD) Scale (Bedford, Foulds, & Sheffield, 1976) which focuses exclusively on recent symptoms. Clinically significant levels of either anxiety or depression are indicated by subscale scores of ≥4. In validation trials conducted at baseline, scores at or above these cutpoints showed high levels of concordance with clinical diagnostic ratings (Morgan, 1998).

**Cognitive functioning** At the beginning of the interview all respondents were initially screened for cognitive impairment using the 12-item Information/Orientation (I/O) scale from the Clifton Assessment Procedures for the Elderly (Pattie & Gilleard, 1979). If, after appropriate prompting, the respondent failed to achieve a maximum I/O score of 8 and, in the opinion of the interviewer, was unlikely to respond reliably to the remaining questionnaire items, the interview was discontinued. In validation trials conducted at baseline, scores at or above this cutpoint showed high levels of concordance with clinical diagnostic ratings of dementia (kappa coefficient = 0.83, $p<0.001$; Morgan, 1998).

## 2.6 Statistical analyses

Data were appropriately weighted to compensate for oversampling of the age group 75+ at baseline. Initial examination of the log-minus-log plot of the survival function showed no departure from the assumption of proportional hazards.

To investigate relationships between physical activity (as walking) and mortality, baseline walking durations were categorized as below guidelines (<150 minutes/week) or equal to, or above guidelines (≥150 minutes/week).

Two Cox regression models were employed: a partially adjusted model (Model 1) and a fully adjusted model (Model 2). In Model 1 survival (period from baseline assessment in 1985 to death or censorship in March 2012) was the dependent variable, and walking category (<150 minutes/week or ≥150 minutes/week), chronological age at baseline, and sex were covariates. To improve the interpretability of results, chronological age was entered as a 4-category variable (65-69; 70-74; 75-79; 80+). Model 2 was similar to Model 1, but also included baseline measures of physical health (above and below median value), BMI, the presence/absence of clinically significant levels of anxiety and depression, and social class as covariates. A forced entry approach to model selection was used.

To assess the consistency of physical activity-survival relationships over the duration of study, the fully adjusted Cox regression model (Model 2) was repeated for the data collected at the 1989 and 1993 study measuring points.

To assess cross sectional relationships between walking category and sleep quality at baseline, logistic regression models were fitted separately for insomnia symptoms (present/absent) and sleep efficiency (<85%/≥85%). In both cases models were adjusted for age (65-70; 70-74; 75-7; 80+), sex, physical health status (above and below median Health Index value), BMI, the presence/absence of clinically significant levels of anxiety and depression, and social class. Where appropriate, means were compared using independent samples t-tests, and the chi-square test was used to analyse contingency tables. All data were analysed using SPSS for Windows v 19.0.

## 2.7 Results

### 2.7.1 Descriptives

From the original baseline survey 1042 respondents provided information at interview. Information on both physical activity and sleep quantity and quality was available from 926 respondents (with omissions due primarily to cognitive impairment or physical disability at baseline).

Sample characteristics and attrition are shown in Table 2. Overall, 21.6% of the sample reported insomnia symptoms, with 49% reporting sleep efficiencies below 85%. The prevalence of insomnia symptoms was also relatively stable over time, with rates of 25% and 22% respectively reported in the 1985 and 1993 follow-ups. The prevalence was higher in women than men (Figure 1).

Table 2

*Sample characteristics and attrition in the study sample between 1985 to 2012*

| Variable | Total analysed<br>N (%) | Women<br>N (%) | Men<br>N (%) |
|---|---|---|---|
| Baseline respondents (1985) | 926 | 557 (60) | 369 (40) |
| Walking to guidelines:<br>≥150 walking minutes/week | 345 (37) | 197 (21) | 148 (16) |
| Walking below guidelines:<br><150 walking minutes/week | 581 (63) | 360 (39) | 221 (24) |
| BMI > 25 (Overweight & Obese): | 366 (39) | 233 (25) | 133 (14) |
| Follow-up respondents(1989): | 609 | 363 (60) | 246 (40) |
| Walking to guidelines:<br>≥150 walking minutes/week | 272 (44) | 147 (24) | 125 (21) |
| Follow-up respondents(1993): | 383 | 250 (65) | 133 (35) |
| Walking to guidelines:<br>≥150 walking minutes/week | 142 (37) | 84 (22) | 58 (15) |

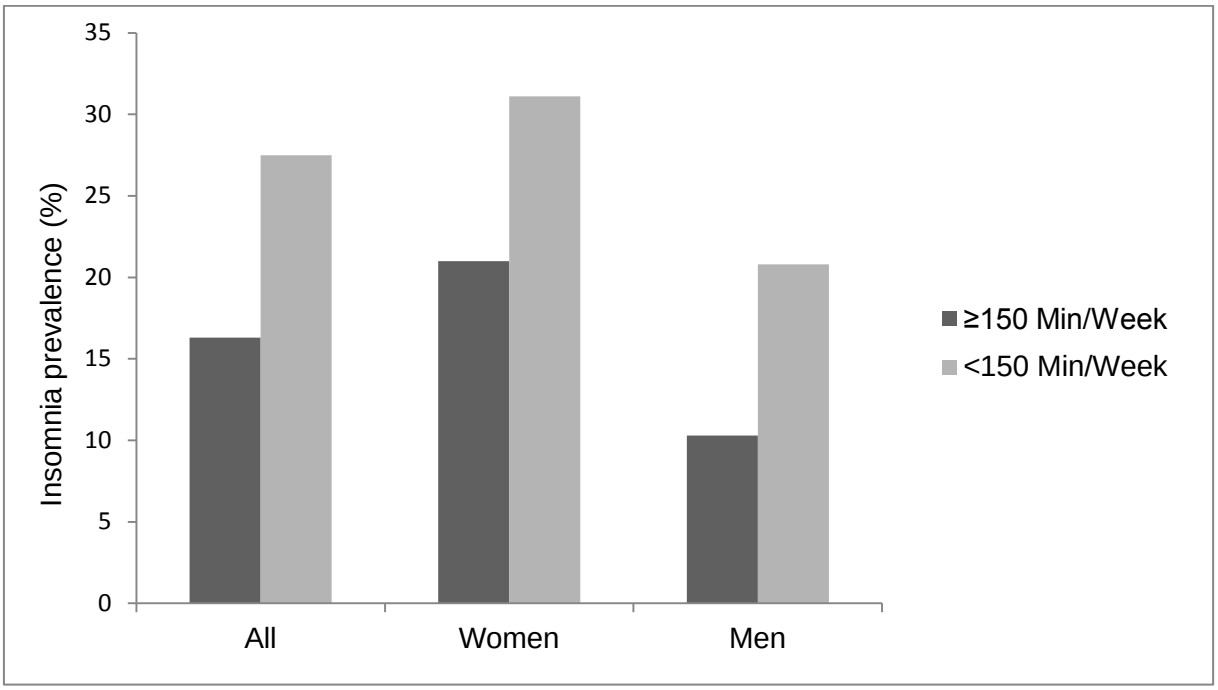


*Figure 1.* Prevalence of insomnia symptoms in each walking category.

The activity threshold of ≥150 walking minutes/week divided the sample at baseline into 37% above, and 63% below the recommended guidelines. Overall, 42% of women and 36% of men were classified as overweight/obese at baseline (Table 2).

**2.7.2 Physical activity and sleep outcomes**

In bivariate analyses lower levels of walking were significantly associated with higher levels of reported insomnia symptoms for the sample overall ($X^2$= 17.1; df = 1; p<0.001), and for women ($X^2$= 7.3; df = 1; p<0.01) and men ($X^2$= 7.9; df = 1; p<0.01) separately.

Results from the fully adjusted logistic regression models examining relationships between walking levels and the sleep outcomes of insomnia symptom prevalence, and sleep efficiency are shown in Tables 3 and 4, respectively. The analyses show that higher levels of walking were significantly and independently associated with a lower likelihood of either reporting insomnia symptoms (OR = 0.67 (95% CI = 0.45 – 0.91), p=0.04), or experiencing poor sleep efficiency (OR = 0.70 (95% CI = 0.52 – 0.94, p=0.02).

Table 3

*Odds ratios and 95% confidence intervals for insomnia outcomes in walking categories*

| Model & Variables | B(SE) | Odds Ratio | 95% CI | P* |
|---|---|---|---|---|
| Included in the model: | | | | |
| Constant | -1.86(0.54) | | | |
| Walking category (lower) | -0.40(0.20) | 0.67 | 0.45 – 0.91 | =0.04 |
| Physical Health Status (higher category) | 0.97(0.19) | 2.64 | 1.79 – 3.88 | <0.001 |
| Anxiety | 1.28(0.23) | 3.61 | 2.26 – 5.77 | <0.001 |
| Age † | | 1.26 | N/S | =0.39 |
| Sex (male) | | 1.42 | N/S | =0.07 |
| Depression | | 1.33 | N/S | =0.30 |
| Social Class (Class I & II) | | 0.96 | N/S | =0.88 |
| BMI | | 1.02 | N/S | =0.22 |

*2 tailed significance of regression coefficients.

†As 4 categories: 65-69;70-74;75-79;80+

Table 4

*Odds ratios and 95% confidence intervals for sleep efficiency outcomes in walking categories*

| Model & Variables | B(SE) | Odds Ratio | 95% CI | p* |
|---|---|---|---|---|
| Included in the model: | | | | |
| Constant | -0.05(0.04) | | | |
| Walking category (lower) | -0.35 (0.15) | 0.70 | 0.52 – 0.94 | =0.02 |
| Physical Health Status (higher category) | -0.52 (0.15) | 0.58 | 0.43 – 0.78 | <0.01 |
| Anxiety | -0.06 (0.25) | 0.54 | 0.33 – 0.86 | <0.01 |
| Age † | | 0.81 | N/S | =0.31 |
| Sex (male) | | 0.75 | N/S | =0.06 |
| Depression | | 0.75 | N/S | =0.30 |
| Social Class (Class I & II) | | 1.05 | N/S | =0.79 |
| BMI | | 0.99 | N/S | =0.78 |

*2 tailed significance of regression coefficients.

†As 4 categories: 65-69;70-74;75-79;80+

### 2.7.3 Physical activity and mortality outcomes

In the 27-year period 1985-2012 the project received notification of 878 deaths within this subgroup (Table 2). Results from Cox regression analyses are shown in Table 5.

In Model 1, the higher level of walking at baseline was significantly associated with a decreased mortality hazard (HR = 0.75 (95% CI = 0.65 - 0.86) $p<0.01$), after controlling for age and sex.

Hazard outcomes were similar in Model 2 after controlling for age, sex, and baseline measures of physical health, anxiety, depression, and social class (HR =0.78 (95% CI = 0.68-0.84) $p<0.01$).

To assess data consistency, we repeated the fully adjusted survival model for the 1989 (T2) and 1993 (T3) follow-ups. The results again showed a significant association between higher levels of walking and decreased mortality (1989: HR = 0.80 (95% CI = 0.67 - 0.95) p=0.01; 1993: HR = 0.78 (95% CI = 0.62 - 0.98) p=0.04).

Table 5

*Hazard ratios and 95% confidence intervals for 27-year mortality*

| Model & Variables | Hazard Ratio | 95% CI | p* |
|---|---|---|---|
| Model 1 (Partially adjusted) | | | |
| Walking category (lower) | 0.75 | 0.65 – 0.86 | <0.001 |
| Age [b] | 1.48 | 1.18 – 1.75 | <0.001 |
| Sex (male) | 0.72 | 0.63 – 0.83 | <0.001 |
| Model 2 ( Fully adjusted) | | | |
| Walking category (lower | 0.78 | 0.68 – 0.90 | <0.01 |
| Age [†] | 1.41 | 1.15 – 1.73 | <0.001 |
| Sex (male) | 0.70 | 0.62 – 0.81 | <0.001 |
| Physical Health Status (higher category) | 1.30 | 1.11 – 1.51 | <0.001 |
| BMI | 0.86 | 0.74 – 0.99 | =0.04 |
| Anxiety | 1.12 | N/S | =0.29 |
| Depression | 0.92 | N/S | =0.58 |
| Social Class (Class I & II) | 1.04 | N/S | =0.63 |

*2 tailed significance of regression coefficients.

[†] As 4 categories: 65-69;70-74;75-79;80+

## 2.8 Discussion

Given the representativeness of the original NLSAA survey sample, the relatively high response rates obtained at baseline, and the known reliability and validity of the survey measures used, the present analyses offer a robust test of the hypothesis that levels of physical activity consistent with being at or above the recommended threshold, positively impact sleep outcomes independent of concomitant health status.

Insomnia was assessed using questions which evaluated the frequency of the sleeping problems (whether often or all the time), and the period over which those sleeping problems were reported (if symptoms had been present over the last week). Even though these criteria do not map onto the present DSM-5 diagnostic insomnia criteria, a balance between brevity of assessment and accuracy of diagnosis must be reached within large epidemiological surveys. The prevalence of insomnia symptoms reported in the baseline survey (21.6%) is within the range seen in more recent samples, and is also consistent with epidemiological trends over the past 30 years (Morgan, 2012). In addition, the characteristics of the identified sub-section of people with insomnia within the whole sample follow those noted in other major population surveys: most people with insomnia are women, the odds of reporting insomnia increase with age, and prevalence of chronic disease is higher in this sub-group, compared to the rest of the sample.

In contrast, for all age and gender groups, levels of walking at or above the recommended threshold were greater among NLSAA respondents than in contemporary samples. For example, using data from the 2008 Health Survey for England, Craig, Mindell & Hirani (2009) found that only 13% of adults over the age of 65 reported walking levels at or above 150 minutes/week. While some of this difference may be explained by methodological factors, the results are also consistent with evidence of an overall reduction in certain physical activity types throughout the 1990s (e.g. Brownson, Boehmer, & Luke, 2005). Brownson et al (2005) reviewed long-term trends in physical activity over the past 50 years, and noted declines in work-related activity, transportation activity, and activity in the home, coupled with an increase in sedentary behaviour (e.g. television watching).

Further support for the validity of the activity measure used in the NLSAA survey is provided by the survival outcomes. The results indicate that walking over 150 minutes (2.5 hours) a week at was associated with increased survival at 27-year follow up, amounting to a 22% (0.78) decrease in hazard rate. This is consistent with findings of other studies examining survival risks associated with physical activity generally (e.g., Hamer & Chida, 2009) or walking specifically (Samitz et al, 2011: 0.93 (0.87–0.97); Woodcock, Franco, Orsini, & Roberts, 2011: 0.89 (0.82-0.96)). Woodcock et al (2011) reported a very similar decrease in mortality risk ratio (0.76) was associated with physical activity of light or moderate intensity, of at least 7 hours per week. This level of physical activity – 7 hours per week – is close to the median duration of walking time shown in those walking ≥150 minutes/week in the present analyses.

## 2.9 Conclusions

Using activity measures validated by longitudinal follow-up, the present analyses show that walking at or above the threshold of 150 minutes/week was associated with a significantly lower likelihood of reporting insomnia symptoms. It would appear, then, that in general, those who walked more, slept better. Since the models took into account age, gender, mood, body mass and health status, it is unlikely that walking was simply a proxy for superior health status, leading to less sleep disruption. Rather, the evidence presented here strongly suggests that walking mediated the sleep benefit.

Indicative of a dose-response relationship, the present results also show a more modest odds reduction than that shown when higher levels of habitual physical activity are examined in relation to sleep outcomes (e.g. Hublin, Kaprio, Partinen, & Koskenvuo, 2001; Kim et al, 2009). The limitations of secondary analyses performed on data collected from an earlier generation of older people are self-evident. Changes in physical activity and in general health trends during the past 27 years, coupled with an increase in overweight/obesity trends over the same period, could have introduced generational or cohort effects which impacted the key variables reported here. Yet while these trends may be reflected in overall levels of physical activity - such as walking - in the contemporary older population aged 65+, it is less clear how secular change would impact on relationships between walking and health and wellbeing outcomes.

That the relationships identified in these analyses accord with contemporary findings supports the validity of the conclusions drawn and, at the very least, offers ‘proof of concept’ that physical activity-sleep relationships operate on a continuum, even at relatively low levels of activity. A major implication of the present findings, therefore, is that significant improvements in both the structure and quality of sleep may be added to those health benefits already demonstrated for those meeting recommended guidelines for physical activity. The next step is the identification and assessment of experimental evidence attesting to the causality of this relationship.

# CHAPTER 3

## 3.0 The effects of physical activity on sleep outcomes: reviews of experimental and controlled trials

## 3.1 Introduction

In Chapter 1, sleep quality and physical activity relationships were introduced, and reviewed at the epidemiological (population) level. The conclusion, that the literature suggests a dose-response relationship between levels of physical activity and reported sleep quality, led to the proposition that a 'minimal threshold' of activity, similar to that associated with a range of non-sleep health benefits, may operate for insomnia symptoms. This proposition was formally tested in the secondary analyses reported in Chapter 2, which showed that, among older people, levels of activity (as walking) at or above the currently recommended threshold of 150 minutes/week were associated with a significantly lower odds of reporting insomnia symptoms.

Epidemiological data are useful in identifying patterns, associations and interactions among variables within the general population. While such cross-sectional data can establish risk, it cannot definitively establish causal links between factors. Levels of physical activity and sleep quality show consistent associations, but one cannot be certain of the directionality of (i.e. the causal ordering within) this relationship. Randomised controlled trials, on the other hand, are considered the 'gold standard' methodology of research designed to evaluate whether, and to what extent, a given intervention impacts a nominated outcome (Jadad, 1998). This type of methodology is considered robust enough to establish causality between factors, and it is suited to situations where the effect sizes might be small to medium. In order to contextualise the further study of 'minimal' activity thresholds in the management of insomnia (in Chapter 4), the present chapter will review experimental evidence examining the impact of activity/exercise on sleep outcomes. This relatively small literature broadly divides into 3: studies of the acute effects of exercise on sleep; studies of the impact of activity/exercise on the experience of chronic conditions related to insomnia; and clinical trials (RCTs) which have assessed the impact of physical activity interventions on sleep outcomes.

## 3.2 Method

Experimental studies and trials of the acute effects of exercise/activity on sleep outcomes, or the effects of exercise interventions on sleep outcomes in the context of chronic conditions, were identified using a range of appropriate search terms including: insomnia; sleep; activity; physical activity; exercise; comorbid insomnia; chronic conditions; and aerobic activity. Identified studies were then screened for relevance. In order to identify clinical trials evidence in relation to at least insomnia symptoms, a literature search was first conducted using the search terms: insomnia; sleep; poor sleep; RCT/Randomised Controlled Trial; pragmatic trial; activity; physical activity; exercise; and aerobic activity. Additional papers were identified using citation maps. Only papers which: i) qualified as randomised controlled trials; ii) characterised insomnia in line with RDC and RAC recommendations (Edinger et al, 2004; Buysse et al, 2006) or explicitly defined insomnia complaints/symptoms independent of comorbidity; iii) utilised outcome measures in line with RDC and RAC recommendations (Edinger et al, 2004; Buysse et al, 2006); and iv) quantified levels of the physical activity intervention were included.

## 3.3 Findings of studies of the acute effects of exercise on sleep outcomes

Several studies have documented positive results of acute physical activity (i.e. one session only) over sleep during the subsequent night. These are summarised in a review by Youngstedt (2005). The effects of acute exercise on sleep are generally modest, with a linear trend of increased total sleep time with exercise duration (Youngstedt, O'Connor, & Dishman, 1997). However, the findings show very modest effect size, and they present clinically insignificant results (for example, increase of total sleep time of 10 minutes) (Youngstedt, 2005). In addition, these studies have been performed mostly in young healthy adults, leading to ceiling effects (Youngstedt et al, 2003).

In the only study identified in the published literature of the impact of physical activity on participants with insomnia, by Passos et al (2011), the findings are clinically more significant. The randomised controlled trial examined the effect of different intensity and type of physical activity on sleep parameters and anxiety in middle aged people with chronic insomnia. The effect sizes were large, with significant reduction in sleep onset latency (36%), increase in total sleep time (26%) and decrease in pre-sleep state anxiety in the moderate intensity exercise group (treadmill for 50 minutes).

### 3.3.1 Summary and limitations

There is very limited evidence looking at the more immediate effects of exercise on sleep quality of people with disturbed sleep. The evidence suggests the same trend of increased sleep quality with increased exercise duration, as well as a significant role of psychological factors, which may moderate this relationship.

## 3.4 Findings of studies of the effect of physical activity on the sleep quality of people with chronic illnesses other than insomnia

Sleep disturbances and, more specifically, insomnia symptoms, accompany a host of chronic conditions including multiple sclerosis (Stanton, Barnes, & Silber, 2006), Alzheimer's disease (Stepanski & Rybarczyk, 2006), Parkinson's disease (Gjerstad, Wentzel-Larsen, Aarsland, & Larsen, 2006), heart disease, stroke, diabetes (Taylor et al, 2007) and cancer. Amongst some of these clinical groups, behavioural interventions for improving sleep quality, including physical activity repeated over a substantial period of time, have been successful. McCurry, Gibbons, Logsdon, Vitiello, and Teri (2005), for example, randomised Alzheimer's disease patients and their caregivers to a sleep hygiene behavioural intervention group, which included physical activity (walking) and light exposure, for two months; or to a general Alzeheimer's disease education control group. The intervention group significantly improved their sleep quality, with less awakenings during the night, improved depression scores, and less daytime sleepiness.

Some randomised controlled trials have been conducted on sleep disturbance, or insomnia, associated with cancer, and physical activity. Payne, Held, Thorpe, and Shaw (2008) randomised older women receiving hormonal treatment for breast cancer to a home exercise intervention (walking) or control usual care group for 12 weeks.

The intervention group significantly improved global sleep quality, had shorter wake time, and less movement during sleep. Tang, Liou, and Lin (2010) tested the effects of a home-based walking intervention, for eight weeks, on patients diagnosed with cancer, with sleeping difficulties. The walking intervention group reported significantly improved sleep quality, and improved quality of life, compared to the inactive control group. Both these studies are small, and the uptake and adherence to physical activity intervention was very poor, due to the nature of the illness.

However, these examples show the potential of physical activity interventions as effective treatment for improving sleep quality in people whose sleep disturbance is closely associated with another chronic disease.

### 3.4.1 Summary and limitations

There are limitations in inferring wider benefits of physical activity for other chronic illnesses. Specific physiological consequences of these other chronic diseases, or the treatment accompanying them, may have direct consequences on the biological mechanisms influencing sleep processes. Therefore, the above studies inform generally on how usual sleep pattern, structure and behaviour may deviate, and how symptoms of sleep disorder may be improved with physical activity interventions within other chronic specific disease stages; they cannot be generalized to other clinical groups. Separate studies are needed testing the intervention on those with insomnia.

Table 6

*Randomised controlled studies on physical activity and sleep quality, using populations with mild to severe (insomnia) sleep complaints*

| No | Authors, year | Duration | Participants | Intervention characteristics | Control group | Sleep outcomes | Other reported outcomes | Results reported | Jadad Scale Score |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Reid et al, 2010 | 16 weeks | N = 17 chronic people with insomnias | 100 min/week walking or jogging | Recreational activities | Self-reported PSQI[a], sleep diary | ESS[b], SF-36[c], CES-D[d] | Improved sleep quality, TST, SE, SOL, QoL | 2 |
| 2 | King et al, 1997 | 16 weeks | N = 43 moderate sleep complaints | 200 min/week mainly walking | Waiting list | Self-reported PSQI, sleep diary | | Improved sleep quality, TST, SOL | 3 |
| 3 | Li et al, 2004 | 24 weeks | N = 118 moderate sleep complaints | 180 min/week tai chi | Low impact exercise (stretching) | Self-reported PSQI | ESS, SF-12, physical functioning | Improved sleep quality, TST, SOL, sleepiness, OoL, physical functioning | 5 |
| 4 | Irwin et al, 2008 | 25 weeks | N = 112 moderate sleep complaints | 120 min/week tai chi | Health education | Self-reported PSQI | BDI[e] | Improved sleep quality, SE, TST | 5 |
| 5 | King et al, 2008 | 54 weeks | N = 66 mild to moderate sleep complaints | 210 min/week mainly endurance exercise | Health education | PSG, PSQI, sleep diary | | PSG: Decreased Stage 1, increased Stage 2, fewer awakenings PSQI: decrease sleep disturbance Sleep diary: less SOL, more rested | 4 |

[a] PSQI – Pittsburgh Sleep Quality Index: 19-item self-reported questionnaire assessing sleep quality and disturbances over the last month.
[b] ESS – Epworth Sleepiness Scale: self-administered sleepiness questionnaire
[c] SF-12/36 – Medical Outcome Study Short Form – 12/36: Health-related Quality of Life self-administered questionnaire
[d] CES-D – Self-reported questionnaire measuring depression symptoms
[e] BDI – Beck Depression Inventory- Self-reported questionnaire measuring depression symptoms † §

## 3.5 Findings of randomised controlled trials (RCTs) on effect of physical activity interventions on sleep outcomes in populations with insomnia

### 3.5.1 Methodology

A wide range of databases were searched to identify peer-reviewed articles, published in English from 1990 to May 2012, describing randomised controlled trials of the effects of regular physical activity or exercise on sleep. The inclusion criteria are described below:

- Intervention: randomised OR non-randomised and controlled design;
- Sample size > 15;
- Treatment: chronic physical activity, exercise (to include yoga and tai chi, when intensity of physical activity specified);
- Duration of treatment: > 4 weeks;
- Main outcome: sleep quality (SE, TST, SOL); and
- Study population: >18 years, mild to severe sleep disturbance.

No pre-defined frequency or intensity was selected in order to be more inclusive of studies. Physical activity/exercise included all types of such activities e.g. walking, yoga. The databases searched were PsycINFO, PubMed, Embase, Science Direct, Medline (the full search criteria are attached in Appendix 1). The search resulted in 1246 citations from which relevant studies were selected for the review. Their potential relevance was examined by title and abstract first, and 1099 citations were excluded as irrelevant. The full papers of the remaining 147 citations were assessed to select those studies employing the required methodology. This criterion excluded 142 studies and left 5 in the review.

The methodological quality of the selected randomised controlled trials was assessed using the Jadad Scale for reporting randomised controlled trials (Jadad et al, 1996), which offers excellent reliability and validity psychometric properties in assessing evidence of treatment effects in healthcare (Olivo et al, 2008). The scale includes three items assessing the control of bias: randomisation (maximum 2 points awarded), blinding (maximum 2 points), and accounting of all participants in the trial (maximum 1 point) (Appendix 1). Thus, scores range from 0 to 5, with higher scores indicating higher methodological quality.

### 3.5.2 Summary of findings

Thus, the search identified a total of 5 studies, published in the United States between 1997 and 2010 (see Table 6). The full methodology quality assessment itemised score is presented in Appendix 1. Reid et al (2010) randomised 17 people with chronic insomnia either to an intervention group treated with an aerobic activity condition and sleep hygiene; or to a control group treated only with sleep hygiene. The period of the intervention was 16 weeks. The intervention group exercised on average for 100 minutes per week, mainly through walking or jogging, whilst the control group engaged in recreational and educational activities (e.g. museum lectures). The main outcome measure was self-reported Pittsburgh Sleep Quality Index (PSQI) questionnaire. The findings included significantly better sleep quality, sleep efficiency, sleep onset latency and longer sleep duration for the intervention group (1.25 hours per night more sleep than at baseline, for the PA group). Post intervention, the PA group reported improved mood and quality of life. Although the authors used objective measures of sleep indexes at baseline (actigraphy and polysomnography), no follow up data from those measures was reported.

King, Oman, Brassington, Bliwise, and Haskell (1997) randomised 43 men and women over 50, with moderate sleep complaints, to a physical activity intervention group, or to a control list. The period of intervention was 16 weeks. The intervention consisted of 200 minutes per week of moderate intensity physical activity, mainly walking. Effects were seen at 8 weeks after the intervention started. Post-intervention, the intervention group reported significantly better sleep quality, longer sleep duration (approximately 42 minutes increase), and reduced sleep onset latency.

Li et al (2004) and Irwin, Olmstead and Motivala (2008) used large samples (118 and 112 participants respectively). Both employed Tai chi as the physical intervention type, using thresholds of 180 minutes, and 120 minutes per week respectively. Li's control group carried out low impact exercise (stretching) and Irwin's control group received health education. The period of intervention was 24 weeks, and 25 weeks, respectively. Both showed significant results for self-reported sleep quality. Irwin et al (2008) reported that the intervention group increased their sleep duration by 48 minutes, whilst the sleep onset latency decreased by 18 minutes.

King et al (2008) randomised 66 participants aged 55 and over, with mild to moderate sleep complaints, to a physical intervention group, or to a health education control group. The intervention consisted of 210 minutes a week of mainly endurance exercise. The period of intervention was 12 months. The study employed objective measures of sleep indexes both at baseline and follow up. Standard polysomnography, and self-reported sleep measures were used as outcomes, though the authors reported only 'selected variables'. The authors found those in the intervention group showed significant changes in sleep stages duration, and significantly less awakenings. In self-reported sleep measures, exercisers reported significantly lower sleep disturbance, reduced sleep onset latency, and feeling more rested in the morning.

### 3.5.3 Discussion

***Period of intervention***

The period of the physical activity intervention differed amongst these studies, ranging from 16 to 54 weeks. Whilst there are some sleep benefits of acute exercise on sleep, these are small and not clinically significant (Kubitz, Landers, Petruzzello, & Han, 1996). King et al (1997) noted that the effects of physical activity on sleep quality in their trial were apparent after 8 weeks. Buman and King (2010) reported on unpublished data from King et al's (2008) trial, and found that increased sleep efficiency in participants at 12 months was greater on nights following physical activity, than on nights with no physical activity. This trend was marginal at 6 months, and statistically significant at 12 months.

Taken together these findings suggest that there is a minimum period of about 8 weeks before the effects of a physical activity intervention can be detected in the self-reported sleep quality of people with moderate sleep complaints. These findings also suggest that changes in sleep structure may take longer time, i.e. up to one year or more; and that the maintenance of such changes is dependent on continuous maintenance and monitoring of the physical activity intervention.

***Level of intervention***

The weekly duration of the physical activity in these intervention trials varied from 100 minutes to 210 minutes, all showing significant effects on sleep quality. The intensity, uniformly chosen, was moderate intensity physical activity. This is consistent with experimental evidence showing that the key health benefits of physical activity mostly occur within this achievable intensity range (CMO, 2011). The two trials with the lowest amount of weekly physical activity (Reid et al, 2010; Irwin et al, 2008) failed to show a significant impact on mood outcomes (however, they were the only two trials to report formal mood assessments, see Table 6). None of the trials tested the minimum recommended level of 150 minutes per week of moderate intensity activity.

It was not established whether increasing the amount of weekly physical activity would result in improved mood outcomes in people with insomnia. A meta-analysis of the effects of exercise on mood outcomes in the general population, and clinical groups with elevated mood dysfunction indicators, showed that the optimal amount of physical activity is around 150 minutes per week, in order to find significant improvement in mood (Guszkowska, 2003). Similarly, the threshold of a minimum of 150 minutes per week has been identified as effecting significant positive changes in mental and physical health of those with chronic disease (CMO, 2011).

The most recent narrative review of evidence of physical activity and sleep quality addresses the question of whether the duration of physical activity, above and below the guidelines, would deliver sleep benefits (Buman & King, 2010). The authors note that in those studies employing the current guideline threshold, there are small to moderate effects on sleep quality. The authors draw their evidence from acute, and chronic physical activity studies, which used a mixture of participants (healthy sleepers, people with primary insomnia, and people with co-morbid insomnia).

***Nature and context of the intervention***

There were no notable differences in outcomes based on modality of physical activity intervention. The modality of interventions in these trials varied between ambulatory movement (walking/jogging) to more static activities (tai chi); some were delivered in supervised classes, and some were performed by participants in their own time, unsupervised. A recent review of exercise effects on depressive symptoms in people with cancer found that wholly or partially supervised exercise interventions showed larger effect sizes of physical activity interventions (Craft, VanIterson, Helenowski, Rademaker, & Courneya, 2012). Supervision and settings of the exercise may also play a significant role in exercise adherence and compliance in randomised clinical trials (Kelley & Kelley, 2013).

***Participants***

All of the trials discussed above, apart from Reid et al (2010), use samples of participants with self-reported mild to moderate sleep complaints. They may have well captured some participants with insomnia disorder, but the inclusion criteria were not stringent enough to allow for such inferences to be drawn. Irwin et al (2008) screened out people with insomnia.

The impact of insomnia symptoms on daytime outcomes (such as health-related quality of life) increases with the severity of insomnia (Leger et al, 2001). People with more severe insomnia symptoms have higher comorbidity of chronic mood-related disorders, higher degree of daytime impairment, and have a higher prevalence of hypnotic daily use, compared to people with mild insomnia symptoms (Hohagen et al, 1993). In addition, people with severe insomnia symptoms differ on psychological variables, such as sleep-related expectations, from people with mild to moderate insomnia symptoms (Montserrat Sanchez-Ortuno, & Edinger, 2010). These findings suggest people with persistent severe symptoms of insomnia (i.e. chronic insomnia disorder) have specific characteristics which may respond differently to treatment, compared to those people with mild or moderate sleep complaints. There is merit in investigating interventions aimed at sub-clinical sleep complaints. As noted in the first chapter, observational data shows people who are physically active are less likely to suffer from insomnia. This suggests a preventative role of physical activity for developing insomnia. Equally, it may be that physical activity may be efficient in preventing the progression of mild to moderate sleep complaints to more severe chronic insomnia. There is a need to test these hypotheses.

However, studies with participants with mild to moderate sleep complaints may mask more significant effects of physical activity in people with insomnia. People with mild to moderate sleep complaints may present 'ceiling effects' in their sleep quality improvement. Such assertion is warranted given that Reid et al (2010), who use an insomnia sample, report the lowest amount of weekly physical activity, yet the most dramatic effects on sleep quality.

***Sleep outcome measures***

As the main outcome measure, all studies reviewed here used the Pittsburgh Sleep Quality Index (PSQI), a self-reported questionnaire, which assesses the quality of sleep over the last month (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989). A PSQI global score higher than 5 shows enough sensitivity and specificity to indicate insomnia (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002). However, the use of a single retrospective measure such as the PSQI would seem more appropriate for estimating prevalence of insomnia, whilst repeated administration of multi-angle measures of insomnia may provide more useful for assessing treatment outcomes (Buysse et al, 2006).

King et al (2008) study also used an objective measure of sleep structure, polysomnography (PSG) as a main outcome measure. However, the use of PSG is not recommended in routine investigation of insomnia (Littner et al, 2003). More convenient, less intrusive and more reliable objective data may be captured through the use of actigraphy: this is recommended for the assessment of treatment effect in insomnia by the American Academy of Sleep Medicine [AASM] (Littner et al, 2003). A multi-instrument assessment approach is recommended, with a mixture of objective and subjective sleep measurements (Buysse et al, 2006).

***Assessment of daytime impairments related to sleep problems***

When diagnosing insomnia, an essential part of the diagnosis is daytime impairment associated with it (DSM-IV-TR, 2000). Yet the emphasis in each of the trials reviewed here was on the night-time characteristics of sleep. A recent NIH consensus statement noted that the importance of insomnia for public health lies in its daytime consequences (Leshner et al, 2005).

In the trials where daytime outcomes related to insomnia/sleep disturbance were measured, physical activity interventions significantly improved the vitality sub-scale of quality of life; whereas the other seven sub-scales of quality of life were not significantly affected by the physical activity intervention (Reid et al, 2010). Li et al (2004) noted significant improvements in the physical sub-scale of quality of life measure used in their trial, but no significant improvement in the mental quality of life sub-scale. Irwin et al (2008) found no significant reduction in depression scores following a physical activity intervention based on their sample of people with mild or moderate sleep disturbance; and nor did Reid et al (2010) in their sample of people with insomnia. These findings suggest that that the daytime benefits of the physical activity interventions were primarily physiological. This view is further supported by the significant improvements noted in physical performance indicators, where these were measured (Li et al, 2004). Reid et al (2010) also showed a trend of improved physical fitness in the group undertaking the physical activity intervention. King et al (1997) noted that the improvement in sleep quality in their experimental group undertaking physical activity was mediated by changes in fitness levels.

None of these studies assessed fatigue, and its response to the physical activity intervention. Where tiredness or fatigue are 'implied' in measures (such as vitality, or daytime dysfunction sub-scales of quality of life measures), there were significant improvements noted (as above). Daytime sleepiness was assessed in two of the trials. Li et al (2004) found a significant improvement in their physical activity intervention group; Reid et al (2010) found a trend of improvement in their sample.

None of the studies tested cognitive processes of attention pre and post intervention, for example via psychomotor tests.

***Confounders***

None of these studies controlled for the role of light exposure in improving sleep quality, though other experimental evidence suggests that increased light exposure arising from physical activity may by itself improve sleep quality (Guilleminault et al, 1995).

The suprachiasmatic nucleus (SCN), the body's internal pacemaker, is a structure in the hypothalamus which regulates the human biological rhythms. The SCN can be entrained to the geophysical 24 hour day/night cycles by zeitgebers. Research has identified entrainment effects of the light/dark cycle, ambient temperature, time of meals, social interactions, and physical activity (Wever, 1989; Aschoff, 1979; Aschoff et al, 1971; Buxton et al, 2003). The SCN integrates these photic and non-photic zeitgebers and produces output signals which regulate the circadian rhythms of the body, such as temperature, hormone levels, metabolic functions, and sleep (Monk et al, 1991).

Light is the most powerful physical zeitgeber (Czeisler, 1995). The availability of sufficient environmental light is critical in the entrainment of the circadian rhythms to the dark/light cycle; most blind people with no, or little, conscious light perception exhibit disturbed circadian rhythms (Skene, Lockley, & Arendt, 1999). The effects of light on the entrainment process depend on its intensity, duration, spectrum, and timing of exposure, relative to the phase of the circadian rhythm (Turner & Mainster, 2008).

The light intensities of most indoor environments are generally below 500 lux. In contrast, midday light intensities outdoors range from 10,000 on an overcast day to 100,000 in bright sunlight (Turner, Van Someren, & Mainster, 2010). In humans, light intensity exposure must probably exceed 1000 lux to optimise circadian rhythms synchronisation of rest/activity over the 24 hours (Middleton, Stone, & Arendt, 2002). In the general population, it is also estimated that middle aged adults receive on average of 58 minutes of daily light exceeding 1000 lux (around 6% of the waking day) (Espiritu et al, 1994).

In terms of light spectrum composition, there is evidence that the blue portion wavelength of light is optimal for photoreception in humans (Provencio et al, 2000). Outdoor daylight has a dominant wavelength in the shorter (blue) spectrum (Gallagher, Beasley, & Gohren, 1996). Indoor lighting is mostly at longer wavelengths (Thorington, 1985), which are less effective for photoreception. Timed optimal light exposure, usually in sessions lasting from 15 minutes to 4 hours, and with light intensities ranging from 2500 lux or 10000 lux has been successfully used for therapeutic purposes in people with circadian rhythm dysfunctions, such as delayed phase sleep syndrome (Terman et al, 1995).

Light supplementation is also useful in improving sleep efficiency in older people with insomnia (Murphy & Campbell, 1996), and in improving sleep duration and continuity in middle aged people with insomnia (Lack, Wright, Kemp, & Gibbon, 2005). Increased duration of exposure, from 20 minutes daily to 45 minutes daily, has been found to lead to long lasting improvement in total sleep duration in older people with insomnia (Kirisoglu & Guilleminault, 2004). Furthermore, early morning light exposure induces immediate changes in alertness levels, underscored by an increase in over 50% in cortisol levels (Leproult, Colecchia, L'Hermite Balériaux, & Van Cauter, 2000). It also induces daytime functioning changes, with shift workers reporting decreases in fatigue and sleepiness when exposed to daylight (Dawson & Campbell, 1991).

The beneficial effects of light therapy on the mood of people with seasonal affective disorder are also well documented (see Glickman, Byrne, Pineda, Hauck, & Brainard, 2006), though evidence for the efficacy of light to improve non-seasonal depression is equivocal (Even, Schröder, Friedman, & Rouillon, 2008). Long term exposure to increased light intensity may improve the ability of the SCN to synchronise hormonal, metabolic and peripheral oscillatory rhythms, which together contribute to an individual's good functioning. However, the re-synchronisation process may be slow, with studies showing that it takes months until effects of increased light exposure on day/night rhythms are observed (Van Someren & Riemersma-Van Der Lek, 2007).

Alternatively, light may act as a mood enhancer, improving subjective alertness and vitality, and leading in turn to a better outlook on the coming day and night (Kirisoglu & Guilleminault, 2004). This in turn may decrease rumination and anxiety over night-time insomnia and its daytime consequences in people with insomnia.

### 3.5.4 Conclusions

All of the above studies have methodological limitations. A recent systematic review of physical activity interventions in people with sleeping problems (to include sleeping problems due to menopause, and mental health problems, alongside insomnia), found a small number of studies, comprising a small number of participants (Yang, Ho, Chen, & Chien, 2012). A Cochrane review, assessing the effects of physical activity on sleep quality in older adults, found only one study which had rigorous enough methodology for inclusion [King et al's (1997) study reviewed above] (Montgomery & Dennis, 2009). The authors of the review noted the need for future trials with appropriate methodology for inferring causal relationships, able to show durable effects of physical activity on sleep. Coupled with the Montgomery and Dennis (2009) conclusions and the findings presented in Chapter 2, the present review provides clear guidance on both the direction and the design of such research. In summary:

1. Trials of relatively low levels (but not 'minimal recommended levels') of physical activity have consistently reported improved sleep outcomes. Since the epidemiological evidence shows that the minimum recommended level of 150 minutes moderate activity/week is significantly associated with a reduced risk of insomnia symptoms (Chapter 2), and since these levels of activity are now widely promoted by public health agencies throughout the world, there is a practical need to investigate the impact of these 'guideline' levels of activity on sleep outcomes.

2. In designing such a study there is an important need to: recognise the confounding impact of light exposure; appropriately characterise participant insomnia using Research Diagnostic/Assessment Criteria; assess both the nighttime (using recommended sleep outcome measures) and daytime (using appropriate assessments of psychomotor performance, cognition and fatigue) consequences of insomnia; assess, and appropriately control for, changes in mood; extend the trial over a period sufficient to allow for the assessment of outcomes at post-treatment and longer-term follow-up; and validate levels of activity change, using instrumental measures.

## 3.6 Research questions for a randomised controlled trial

The trial presented in the next chapter was conceptualised in response to these needs, and was designed specifically to address the following research questions:

When undertaken by previously inactive people reporting symptoms of chronic insomnia, is physical activity which meets the current minimum recommended threshold:

1. Associated with significant improvements in subjective sleep quality?
2. Associated with significant improvement in objective sleep structure indicators?
3. Associated with significant increases in light exposure?
4. Associated with significant improvement in mood indicators?
5. Associated with improvement in psychomotor performance? and
6. Associated with significant improvement in daytime sleepiness, fatigue, and quality of life?

# CHAPTER FOUR

## 4.0 A randomised controlled trial assessing the impact of moderate physical activity (increased to the recommended level of 150 min/week) on sleep, mood and performance outcomes among sedentary people with insomnia

## 4.1 Introduction

The epidemiological studies reviewed in Chapter 1 gave a clear indication that while physical inactivity was a risk factor for insomnia symptoms, higher levels of physical activity were associated with higher levels of sleep quality. However, a minimum level of physical activity likely to mitigate insomnia risk (and which could serve as a target for public health and therapeutic interventions in sleep medicine) had not been evaluated. As a result, it remained unclear whether the internationally recommended level of activity known to be associated with a range of health benefits (≥ 150 minutes of moderate physical activity per week) could also impact insomnia symptoms. This proposition was tested in the secondary analyses reported in Chapter 2, which provided evidence that, independent of comorbid health status, activity at or above the recommended threshold was significantly associated with a reduced risk of reporting insomnia symptoms. The reviews presented in Chapter 3 examined the strengths and weaknesses of the experimental evidence base for a positive impact of physical activity interventions on sleep and insomnia outcomes. The clinical trials included in these reviews showed a variety of limitations, with only a single study qualifying for inclusion in a Cochrane review. This literature then used to inform the research questions presented in the previous chapter, and the trial methodology presented below.

## 4.2 Methods

### 4.2.1 Objective and design

The objective of this study was to assess, in previously inactive people, the impact of increasing activity (to at least the recommended level of 150 minutes of moderate intensity activity/week) on sleep, wellbeing and daytime performance.

The study was designed as a two-arm (activity intervention versus waiting list control) randomised controlled trial. The activity intervention lasted for 6 months, with assessments collected at baseline, 3 months, 6 months, and 12 months (i.e. 6 months after the end of the intervention). Figure 2 shows an overview of the trial procedure.

At baseline, at 3 months, 6 months, and at 12-month follow up, participants were assessed via a battery of standardised self-report questionnaires. In addition, at the baseline and 6 month time points, participants were administered a battery of cognitive (psychomotor) tests. Separate actigraphic measures of sleep (using wrist worn actigraphs) and physical activity (using waist-worn actigraphs) were also initiated for 2-week periods at the baseline, 3 month and 6 month time points.

### 4.2.2 Outcomes and sample size estimation

The primary outcome was self-reported severity of insomnia symptoms, as measured by the Insomnia Severity Index (ISI). Secondary outcomes were changes in depressive symptoms (assessed using the Beck Depression Inventory II), anxiety (using the Spielberger State Trait Anxiety Inventory), and psychomotor performance. Sample size estimation was performed using GPower v.2 (Kiel University, Germany), and adopted the mean treatment effect for behavioural interventions on sleep quality of 0.76 reported from Irwin, Cole, & Nicassio's (2006) meta-analysis of behavioural interventions outcomes for people with insomnia. Setting beta at 80%, and alpha at 0.05, a minimum of 19 persons per group was required in order to detect significant reductions in the severity of insomnia symptoms with adequate power. In order to allow for an attrition rate of approximately 20%, it was intended to recruit 23 participants per arm (though to minimise loss of participants, an attrition management strategy was devised and applied throughout the study period; see Appendix 7).

Ethical approval for the trial was granted by Loughborough University Ethical Advisory Committee (reference number R-11 P67 of 16 May 2011). Recruitment and screening began on 1st June 2011, and ended on 31st March 2012. Data collection was organised so that participants started the trial at intervals, with the last participant ending her 12 month follow up in June 2013. The research programme was staggered in order to optimise quality control and maximise the available research resources. Recruitment, screening and data collection were executed by the author (IH) and involved an average of eight home visits per participant.

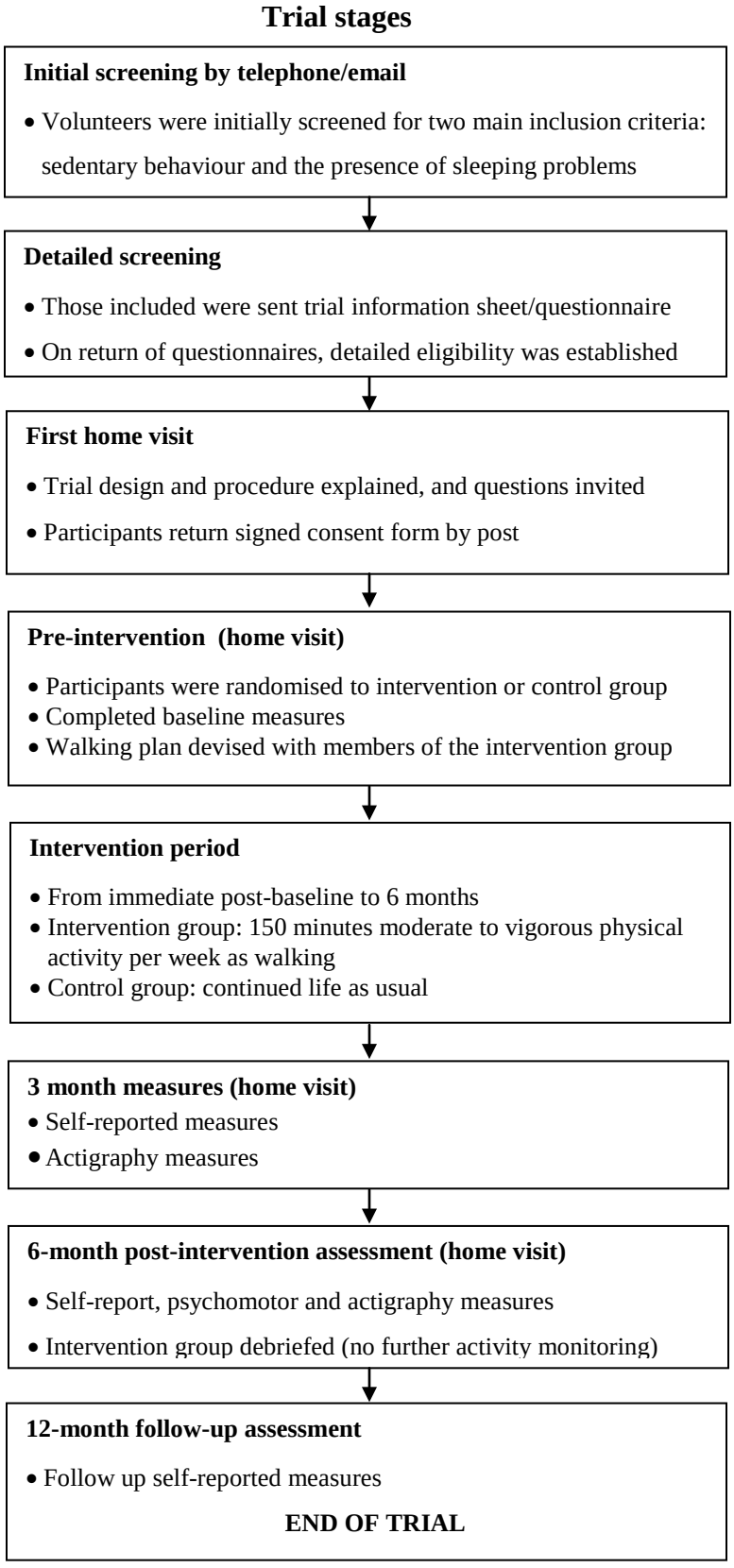


*Figure 2.* Overview of trial procedure

### 4.2.3 Participants

#### *Eligibility*

Participants were inactive[2] men and women who were 40 years or older, who were living in the community and who fulfilled the Research Diagnostic Criteria for insomnia (Edinger et al, 2004; Table 7). The full eligibility criteria are presented in Table 8.

---

[2] **Inclusion criteria** In line with public health research and practice, the initial selection criteria should now be defined in terms of 'physically inactivity', rather than 'sedentary behaviour'. This is because since the design of the study in 2010-2011, research evidence has rapidly evolved to differentiate between concepts of 'sedentary behaviour' and 'physical inactivity'. It is now generally accepted within the research community that sleep, sedentary behaviour, physical inactivity, and physical activity are on a continuum of increasing energy expenditure (Pate, O'Neil, & Lobelo, 2008), with accompanying postural specifics to sedentary behaviours (watching TV, lying down etc).

During 2012, the Sedentary Behaviour Research Network (SBRN) published a definition of 'sedentary behaviour', in contrast to the concept of physical inactivity. According to the SBRN, sedentary behaviour is "…any waking behaviour characterized by an energy expenditure ≤1.5 METs while in a sitting or reclining posture". The group went on to suggest that the term "inactive" is used instead to describe 'those who are performing insufficient amounts of MVPA (i.e., not meeting specified physical activity guidelines) (SBRN, 2012).

The drive to separate these two concepts resulted from accumulating evidence as to the independent predictive role of sedentary behaviours (such as TV viewing) of higher morbidity, even when controlled for daytime levels of physical activity (Wijndaele et al, 2010). Detrimental associations between sedentary time and morbidity outcomes are significant in those adults who are otherwise meeting the recommended physical activity guidelines (the 'active couch potato' phenomenon) (Healy et al, 2008). Going further on energy expenditure continuum, there is evidence that points to incidental, non-purposeful physical activity being beneficial for health (Donahoo et al, 2004; Matthews et al, 2007).

Table 7

*Criteria for establishing insomnia diagnosis for the participants in the present randomised controlled trial**

| **Insomnia diagnosis for participants in the RCT** |
|---|
| A. The individual reports one or more of the following sleep related complaints: |
| 1. difficulty initiating sleep, |
| 2. difficulty maintaining sleep, |
| 3. waking up too early, or |
| 4. sleep that is chronically nonrestorative or poor in quality. |
| B. The above sleep difficulty occurs despite adequate opportunity and circumstances for sleep. |
| C. Significant daytime impairment and distress related to the nighttime sleep difficulty is reported by the individual. |
| D. Insomnia has been present for at least six months. |
| E. If there is a current or past mental or psychiatric disorder, the temporal course of the insomnia shows some independence from the temporal course of the mental or psychiatric condition. |
| F. If there is no current or past sleep-disruptive medical condition, the temporal course of the insomnia shows some independence from the temporal course of the medical condition. |
| G. The insomnia cannot be attributed exclusively to another primary sleep disorder (e.g., sleep apnoea, narcolepsy, or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder. |
| H. The insomnia cannot be attributed to a pattern of substance abuse or to use or withdrawal of psychoactive medications. |

*Based on the Research Diagnostic Criteria for Insomnia Disorder/Primary Insomnia (American Academy of Sleep Research [AASM] 2004; Edinger et al, 2004)

Table 8

*Eligibility criteria for participants in the present randomised controlled trial*

| **Inclusion** | **Exclusion** |
|---|---|
| 40+ years<br>Diagnosis of insomnia; or presenting persistent insomnia symptoms (using the ICD and DSM-IV-TR criteria)<br>Inactive behaviour:<br>• Amount: ≤ 60 min/week of moderate/vigorous exercise; and<br>• Frequency: ≤ twice a week, during the preceding 6 months<br>Stable on all taken medication for at least 3 months<br>Able to speak and understand English sufficiently to provide informed consent<br>Willing to accept random assignment to one of two groups<br>Living within 50 miles of Loughborough University | Presence of other clinically significant sleep disorder e.g. sleep apnoea, Restless Legs Syndrome<br>Shift work<br>Present diagnosed psychiatric or cognitive disorder<br>Severe chronic disease for which moderate-intensity physical activity would be contraindicated<br>Presence or history of myocardial infarct or stroke<br>Taking anti-hypertensive or hypolipidaemic medication<br>Presence of musculo-skeletal impairment which would prevent participation in moderate levels of physical activity<br>Body Mass Index > 35<br>Undergone surgery in the previous 6 months<br>Excessive daily use of tobacco, alcohol, and coffee<br>(for women) Pre- or peri-menopausal status and/or oestrogen replacement therapy (or on such therapy for less than 6 months)<br>Participation in another randomised trial involving an intervention |

***Recruitment***

Participants were recruited by advertising through the local commercial press (Loughborough Echo, Leicester Mercury, East Midlands Gazette); radio stations (BBC Radio Leicester); national TV (BBC community news); local government organisations (the library, neighbourhood offices); local GP and dental practices; local community organisations (U3A, art groups, reading groups); and local major employers (Loughborough University; Brush). A sample of the advertisement used for recruitment is presented in Figure 3.


*Figure 3.* Sample of advert used for trial recruitment

**4.2.4 Procedures**

***Screening***

**<u>Initial telephone/email screening</u>**

Interested members of the public initially contacted the research office by telephone or by email. They were briefed on the study following a standardised script (Appendix 3), and screened to ensure that they were presenting a sleep problem, and that they were inactive.

**Detailed screening**

If they agreed, volunteers were then sent a screening pack in the post, which contained the brief Participant Information Sheet, detailing the study, and the Health Assessment Screening Questionnaire (Appendix 4), to be returned in a pre-paid envelope. All volunteers who were sent the screening questionnaires were allocated a unique identification number, which then remained unchanged through the course of the study.

The Health Assessment Screening Questionnaire included:

a. General health screening questionnaire (Figure 4)

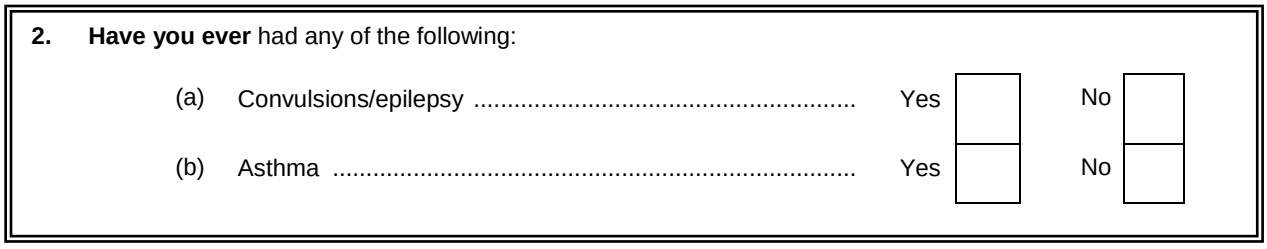


*Figure 4.* Example items from the general health screening questionnaire

b. Physical activity status (Figure 5)

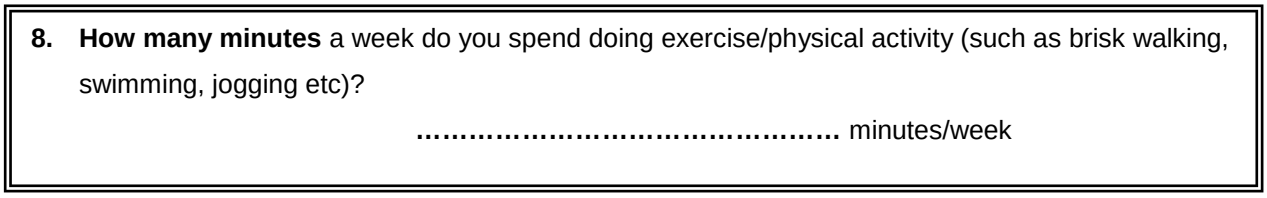


*Figure 5.* Example item from the physical activity status screening questionnaire

c. Insomnia symptoms screening (DSM-IV criteria) (Figure 6)

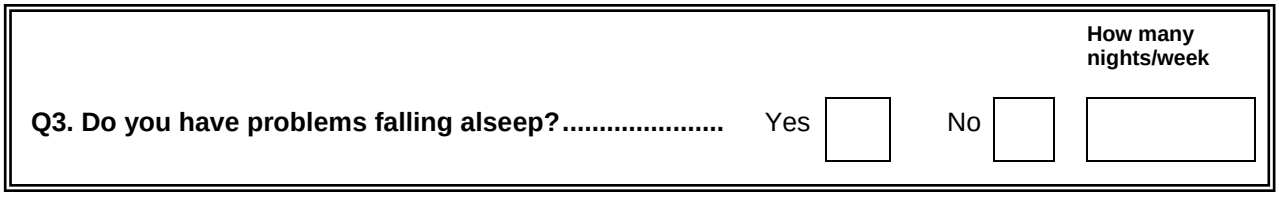


*Figure 6.* Example item from insomnia screening questionnaire

d. Symptoms of Restless Leg Syndrome (Figure 7)

**Q11. Have you ever had unpleasant sensations in your legs, combined with an urge to move your legs?**

Yes ☐ No ☐

*Figure 7.* Example item from Restless Legs Syndrome screening questionnaire

e. Delayed Phase Sleep Syndrome questionnaire: 4-item questionnaire used to identify symptoms of Delayed Phase Sleep Syndrome (Figure 8)

| | | | **How many nights/week** |
|---|---|---|---|
| **Q16. Do you have problems waking up at the desired time?..** | Yes ☐ | No ☐ | |

*Figure 8.* Example item from the Delayed Phase Sleep Syndrome screening questionnaire

f. The Epworth Sleepiness Scale (ESS, Johns, 1991: This 8-item measure assesses the likelihood the individual will fall asleep during different situations (e.g., passenger in a car, sitting quietly after lunch) (Figure 9)

| | I would never doze | I would have a slight chance of dozing | I would have a moderate chance of dozing | I would have a high chance of dozing |
|---|---|---|---|---|
| Sitting & reading | | | | |

*Figure 9.* Example item from Epworth Sleepiness Scale screening questionnaire

Upon return of the completed screening questionnaire eligibility for the study was checked against the full inclusion/exclusion criteria. If necessary, the volunteer was contacted to clarify information. If ineligible for inclusion in the study, volunteers were informed by means of a standardised letter. The letter also invited them to give separate consent for inclusion in a database to be notified of future studies in the Clinical Sleep Research Unit (Appendix 5).

***Randomisation procedure***

Participants were randomised to a moderate-intensity physical activity condition, or a waiting-list control condition (Figure 10). The algorithm for randomisation was stratified by gender (male/female) and age (± 2 years in each group), as these two variables are consistently associated with prevalence and incidence of insomnia symptoms. The randomization was performed by an independent researcher within the University department, who had no involvement in the study, ensuring adequate allocation concealment for the study.

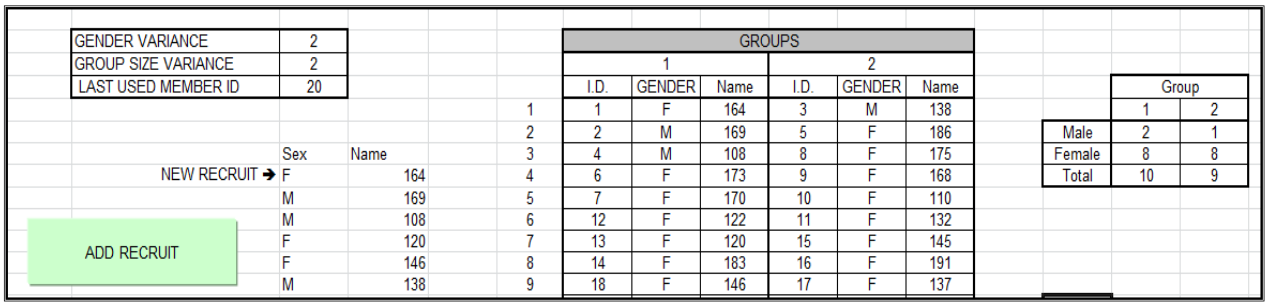


*Figure 10.* Screenshot of Randomization procedure

### 4.2.5 Assessment home visits

**<u>First home visit</u>**

Eligible volunteers were contacted to arrange a home visit by the researcher. The purpose of the visit was to explain the study in more detail, answer any questions, and fully explain the randomization procedure, the consent form, and the University's ethical and legal obligations to study participants. The Researcher left the detailed Participant Information Sheet and Consent Forms (Appendix 6) with the volunteer, to allow them to fully consider the information, before returning the signed Consent Form to the research office (in the pre-paid envelope provided).

If the Consent Form was not received within 10-14 days of the home visit, the researcher contacted the volunteer initially by telephone, or by standardised follow-up letter (if telephoning proved unsuccessful). If the volunteer did not want to take part in the study, they were given the option of being included in the volunteer database for future studies.

If the Consent Form was returned to the Research Office, the participant was entered into the main database against the original identification number given. No identifiable features were included in the main database (name, date of birth, address).

**Second home visit – Administration of baseline measures**

Following randomization, participants were contacted to arrange a home visit for the baseline measures. The visit included: informing of the randomization outcome; explaining group membership procedure; obtaining consent to inform the participant's general practitioner (GP) of study involvement (standard letter to GP enclosed in Appendix 8); administration of objective measures of physical activity and sleep, assessment of subjective measures through the booklet of self-reported questionnaires, and providing all relevant material for the allocated group membership.

In a separate session, the participants were administered the battery of cognitive tests.

**Third home visit – Administration of 3-month measures**

The visit included: administration of objective measures of physical activity and sleep; and assessment of subjective measures through the booklet of self-reported questionnaires.

**Fourth home visit – Administration of 6-month measures (end of intervention period)**

The visit included: administration of objective measures of physical activity and sleep; and assessment of subjective measures through the booklet of self-reported questionnaires.

Separately, the participants were administered the battery of cognitive tests.

**Assessment by postal questionnaire only – Administration of 12-month measures (end of trial)**

At 12 months, all participants were sent the booklet of self-reported questionnaires, to complete and return in the pre-paid envelopes provided.

### 4.2.6 Assessment measures

Data were collected on: 1) participants characteristics; 2) measures of insomnia symptom severity, and sleep quality; 3) sleep structure and light exposure; 4) quality of life and health status; 5) mood, fatigue and daytime sleepiness; and 5) physical activity status.

The self-report questionnaires were administered by a booklet, which participants were asked to complete at baseline (before the intervention), at 3 months, at 6 months (at the end of the intervention) (Appendix 9). And at 12 months (i.e. 6 months after the end of the intervention). Participants were given two weeks to complete the booklet on each occasion.

Actigraphy devices for measuring sleep and levels of physical activity were administered for a period of 14 days at baseline; again at 3 months; and again at 6 months (see Footnote[3] for an explanation of the selection process for these devices).

The cognitive tests were administered separately from the other tests at baseline and 6 months, using a portable laptop. All tasks were administered in participants' home, in a quiet room, in the afternoon (after 1pm and before 7pm).

---

[3] Consideration was given to streamlining the objective outcome measures to be used in the trial. Both devices (Actiwatch 2 for measuring sleep, and GTX3+ for measuring physical activity) incorporate accelerometers. Thus the question was as to whether a single device could be used.

The devices sample at different frequency (32Hz v 30Hz). The data output (counts per minute) from each device uses different equations to summarise movement. No published evidence is currently available as to the comparability of the output data from ActiGraph GTX3+ and Actiwatch 2 accelerometers when used to measure daytime physical activity in adults. Upon investigation, it became apparent that these two devices could not yet accurately measure both daytime physical activity and night-time sleep outcomes (Philips, 2011, email communication).

The manufacturer of the GTX3+ (Actigraph Inc., US) is now in the process of developing a new device, worn at the wrist, which could accurately detect and classify both daytime and night-time movement (Actigraph, 2013, personal communication). Recently (2013), the NHANES study, one of the largest-scale population surveillance programmes, began to use GTX3 at the wrist in order to measure physical activity over 24 hours, on the understanding that equations are currently being developed to validate and accurately classify such movement. Within the research community, work is in progress to use GTX3+ data retrospectively in order to predict sleep variables (Hartescu et al, 2013, conference proceedings). Although it was not possible to streamline the objective measures used in our trial, sleep and physical activity researchers should be able to use a single device for accurate objective measurements over time, in the near future.

Insomnia diagnosis is based on self-reported sleep quality evaluation. The use of self-reported measures of sleep quality was considered essential to capture any meaningful change over time. A combination of self-report and objective measures was used in the trial, for completeness, and accuracy, as recommended in insomnia research (Buysse et al, 2006).

***Physical Activity***

Physical activity was assessed using GTX3+ accelerometer (Actigraph; Figure 11), which measures body accelerations, in epochs of 30 seconds. These are converted into outputs of counts per epoch, then further processed with specialist software (ActiLife 6, 2013) to be expressed as intensity activity per minute. Accelerometers are recognized as a valid and objective tool to assess free-living physical activity. They are worn on a belt at the hip. The GTX accelerometer has been validated against the gold-standard physical activity energy expenditure measures (room calorimetry and doubly-labelled water) (Rothney, Brychta, Meade, Chen, & Buchowski, 2010).


*Figure 11*. Image of GTX3+ accelerometer (Image from http://www.actigraphcorp.com/products/)

Self-reported physical activity was measured with the International Physical Activity Questionnaire-Short Form (IPAQ), a 7-item questionnaire assessing physical activity and sedentary behaviour in adults (Figure 12; Craig et al, 2003). The questionnaire has acceptable concurrent and construct validity, and reliability, when measuring physical activity patterns in the general population (Hagstromer, Oja, & Sjostrom, 2006; Craig et al, 2003).

3. 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? Do not include walking.

_____ **days per week**

☐ No moderate physical activities ***Skip to question 5***

*Figure 12*. Example item from the IPAQ-Short Form

***Primary outcome – severity of insomnia symptoms - Insomnia Severity Index (ISI)***

The Insomnia Severity Index (ISI) is a 7-item self-report questionnaire, designed to assess the nature, severity, and impact of symptoms of insomnia (Morin, Barlow, & Dement, 1993). The usual recall period is 'the last two weeks' prior to administration. The seven dimensions evaluated are: sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by sleep difficulties. A 5-point Likert scale is used to rate responses to each of the 7 items (0 = no problem; 4 = very severe problem), yielding a total score of 0 to 28 points (Figure 13). The total score is interpreted as follows: absence of insomnia (0–7); sub-threshold insomnia (8–14); moderate insomnia (15–21); and severe insomnia (22–28). Three versions of the questionnaire are available - patient, clinician, and others – the present trial used the patient version only. Previous studies have found that the ISI exhibits adequate psychometric properties, both as a screening tool, and as an outcome measure (Bastien, Vallieres, & Morin, 2001).

Recent research shows that internal consistency of the scale is excellent for community and clinical samples (Cronbach α of 0.90, and 0.91, respectively) (Morin, Belleville, Bélanger, & Ivers, 2011). Item response analyses indicate adequate discriminatory capacity for 5 of the 7 items. Convergent validity is demonstrated by significant correlations between the total ISI score, and other measures of daytime impairments associated with insomnia such as fatigue; quality of life; anxiety, and depression. For purposes of detecting cases of insomnia in a community sample, a cut-off score of 10 on ISI is optimal (86.1% sensitivity and 87.7% specificity). In clinical samples, a change in score of -6 to -8 ISI points has been associated with moderately significant clinical improvements in insomnia, as associated with clinically meaningful changes in other health indicators, or as rated by an independent assessor after intervention (Yang, Morin, Schaefer, & Wallenstein, 2009; Morin et al, 2011).

| Insomnia problem | None | Mild | Moderate | Severe | Very severe |
|---|---|---|---|---|---|
| 1) Difficulty falling asleep | 0 | 1 | 2 | 3 | 4 |

*Figure 13.* Example item from Insomnia Severity Index (ISI)

***Secondary outcomes***

**Sleep quality - Pittsburgh Sleep Quality Index (PSQI)**

The PSQI is a 19-item self-report questionnaire evaluating sleep quality and disturbances. The usual recall period is over the past month (Buysse et al, 1989). Of the 19 items, the first 4 items are open questions, whereas items 5 to 19 are rated on a 4-point Likert scale (Figure 14). Scores obtained from individual items yield 7 components. A global score, ranging from 0 to 21, is obtained by adding the 7 component scores. Scores higher than 5 suggest poor sleep quality, and this cut-off score has been used to discriminate people with sleeping problems from good sleepers (Backhaus, Junghanns, Broocks, Riemann, & Hohagen, 2002).

The PSQI has excellent psychometric properties in British samples, and distinguishes people with insomnia from normal sleepers (e.g. Backhouse et al, 2002). The PSQI was used in the present trial because it measures a construct (sleep quality) that is related to insomnia. In addition, the PSQI has previously shown sensitivity to physical activity treatment in people with sleep disturbance (King et al, 1997).

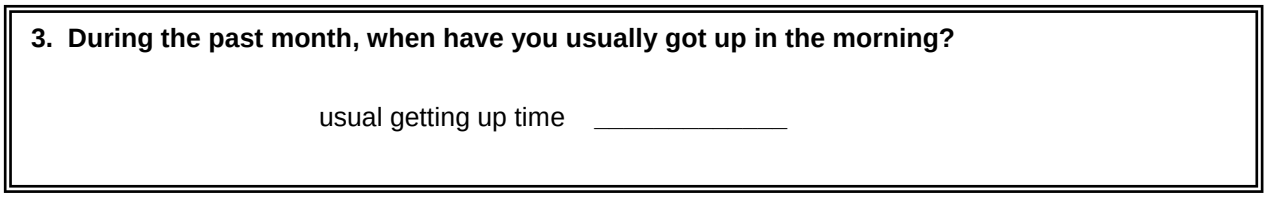


*Figure 14.* Example item from Pittsburgh Sleep Quality index (PSQI)

**Sleep structure / Light exposure**

Sleep structure was assessed using wrist-worn actigraphs (Actiwatch 2, Phillips Corporation) (Figure 15). Comparison of actigraphy with the 'gold standard' assessment of sleep research - polysomnography (PSG) - typically yields agreement rates in the range of 78 to 95% in both community and clinical samples (Sadeh, Hauri, Kripke, & Lavie, 1995). Actigraph devices have been validated to use in insomnia populations (Lichstein et al, 2006), and are sensitive to changes in sleep quality following physical activity (Van Someren, Lijzenga, Mirmiran, & Swaab, 1997).

All participants wore the actiwatches on the wrist continuously for a period of 2 weeks at baseline and 6 months. In addition to measuring movement, the Actiwatch 2 incorporates a light sensor, which records daily photopic whitelight illuminance.

*Figure 15.* Image displaying Actiwatch 2, with the light sensor apparent on its front surface (Image from http://www.healthcare.philips.com/main/homehealth/sleep/actiwatch/default.wpd)

**Quality of life and health status**

The EQ5D-5L (EuroQoL Group, 1990) is a 5-item scale, with an additional visual assessment scale item, which assesses health related quality of life. Self-reported health status captured by EQ-5D-5L relates to participant's quality of life status at the time of completion. The scale contains items on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, which are used to sum up a health profile index value (Figure 16). The additional VAS item rates self-reported health on a scale from 0-100 (worst to best health), and the rates number on the scale is used separately. The EQ-5D-5L has recently been validated in diverse patient populations, including patients with chronic disease: cardiovascular disease, respiratory disease, depression, diabetes, liver disease, personality disorders, arthritis, stroke (Janssen et al, 2012).

| **MOBILITY** | |
|---|---|
| I have no problems in walking about | ❑ |
| I have slight problems in walking about | ❑ |
| I have moderate problems in walking about | ❑ |
| I have severe problems in walking about | ❑ |
| I am unable to walk about | ❑ |

*Figure 16.* Example item from the EQ5D-5L scale

Health service utilisation, as an index of health behaviour, was assessed using 6 independent items developed for economic analyses in previously reported randomised controlled trials (Morgan et al 2004; 2012). Items included the frequency of consuming 'over the counter' sleep aids and the frequency of contact with primary care clinical services (Figure 17).

| | | How often? (enter number of times) |
|---|---|---|
| i | Visited your local surgery for a consultation with a doctor (include 'out-of hours' consultations at special centres)? | |

*Figure 17.* Example item from Healthcare Utilization Index

Body mass index (BMI) was calculated from self-reported height and weight measures, using the NHS BMI Healthy weight calculator for adults, available at http://www.nhs.uk/Tools/Pages/Healthyweightcalculator.aspx. The formula used to calculate it is: BMI=body mass (kg)/(height (m))$^2$.

**Mood, fatigue and daytime sleepiness**

Depression was measured with Beck Depression Inventory-II, a 21-item self-report inventory assessing the intensity of typical symptoms of depression on a 4-point Likert scale, over the past two weeks (Beck, Steer, & Brown, 1996) (Figure 18). The total score ranges from 0 to 63, with a higher score suggesting more severe depressive symptoms. The psychometric properties of the scale show adequate validity and reliability in clinical and non-clinical populations (Beck, Steer, & Carbin, 1988). The scale shows sensitivity to treatment in people with insomnia (Isaac & Greenwood, 2011). The proposed thresholds for clinical severity of depression are below 20 for mild depression, below 29 for moderate, and 30 and up for severe (Beck et al, 1996).

***1. Sadness***

| | |
|---|---|
| I do not feel sad | ◯ |
| I feel sad much of the time | ◯ |
| I am sad all of the time | ◯ |
| I am so sad or unhappy that I can't stand it | ◯ |

*Figure 18.* Example item from Beck Depression Inventory (BDI)

Anxiety was assessed using the State-Trait Anxiety Inventory (STAI – State/Trait), a two part instrument assessing trait (in general), and state (situational), anxiety (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983). Each part contains 20 items, rated on a 4-point Likert scale, indicating the situational intensity of the symptoms (state), or frequency of symptoms (trait) (Figure 19). The scores are summed up separately for each scale, with higher scores indicating greater anxiety. Internal consistency coefficients for the scale range from .86 to .95; test-retest reliability coefficients range from .65 to .75 over a 2-month interval (Spielberger et al, 1983).

The construct and concurrent validity of the scale has been thoroughly tested and evidenced (Spielberger, 1989). Sesti (2000) proposed two cut-off scores: 40 for moderate anxiety, and 60 for clinical anxiety; with scores below 40 being categorised as low anxiety. However, other studies have suggested a higher cut score of 54–55 for older adults, aged 64 and over (Kvaal, Ulstein, Nordhus, & Engedal, 2005).

| | | Almost never | Sometimes | Often | Almost always |
|---|---|---|---|---|---|
| **1.** | I feel pleasant | ○ | ○ | ○ | ○ |

| | | Not at all | Somewhat | Moderately | Very much so |
|---|---|---|---|---|---|
| **1.** | I feel calm | ○ | ○ | ○ | ○ |

*Figure 19.* Example items from STAI-Trait (upper table), and STAI-State (lower table)

Fatigue was assessed with Fatigue Severity Scale (FSS; Krupp, LaRocca, Muir-Nash, & Steinberg, 1989), a 9-item questionnaire assessing symptoms of fatigue over the last 7 days (Figure 20). Scale is a 7-point Likert scale where 1 represents 'Strongly disagree' and 7 'Strongly agree'. The responses are summed up, and the mean of the scale calculated, with a score range from 1-7, with a higher score indicating more fatigue severity. Reliability has proven excellent in both clinical and non-clinical populations, Cronbach's alpha 0.81-0.89 (Krupp et al, 1989), and both construct and concurrent validity are considered very high (Krupp et al, 1995).

A published review of measurements of fatigue in chronic illnesses rated FSS as the highest scorer on robust psychometric properties among other 18 fatigue measurements evaluated (Whitehead, 2009). The mean fatigue severity in normal adults is 2.3 (SD=0.7) (Krupp et al, 1989).

In sleep disordered patients, the FSS averages 4.8 (SD=1.5), whilst specifically in insomnia patients the average score is higher, at an average of 6 (SD=0.5), which is comparable to scores in clinical populations with multiple sclerosis (5.1) and Chronic Fatigue Syndrome (6.1) (Lichstein, Means, Noe, & Aguillard, 1997).

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| My motivation is lower when I am fatigued. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

*Figure 20.* Example item from Fatigue Severity Scale (FSS)

Daytime sleepiness was assessed with the Epworth Sleepiness Scale (ESS, Johns, 1991). The ESS is a self-administered questionnaire that measures daytime propensity (i.e. the likelihood) to fall asleep, in eight real-life scenarios i.e. whilst reading, whilst in a car, etc (Figure 9, above), rating the likelihood on a scale of 0 (unlikely) to 3 (very likely). A total score from 0 to 24 is calculated, with values over 10–11 indicating abnormal or pathological sleepiness (Johns, 2000). The ESS has been shown to have high level of internal consistency and test-retest reliability in healthy subjects (Johns, 1994; Johns, 1992). Patients with insomnia have lower scores on ESS than other sleep disordered patients (Johns, 1991). A recent study found patients with chronic insomnia ESS scores ranging from 4.90-5.91 (above and below age 65), compared to 4.74-4.19 (above and below 65) in normal sleepers (Kim et al, 2013).

## Cognitive Task Design

Several factors were considered when selecting measures for psychomotor performance. The first criteria was to include a task that would reveal the cognitive challenges faced by people with insomnia, and which has proven effective in distinguishing people with insomnia from people with satisfactory sleep. The Simple Vigilance Task was chosen, as protracted reaction time tasks have been reported to differentiate people with insomnia from good sleepers (Shekleton et al, 2010). Vigilance tasks test sustained attention, which is one of the cognitive domains most likely to be affected by daytime insomnia-related impairments.

Second, a comparator task within the same domain was needed, which required, and therefore tested, functions of higher cognitive order, in order to establish whether the complexity as such was driving any observed effect. Thus the Complex Vigilance Task was chosen: this required the use of decision-making and response inhibition cognitive processes. Complex vigilance tasks have been used to show that both lower and higher cognitive load produce observable deficits in people with insomnia (Altena et al, 2008).

Finally, having considered the inclusion of attentional measures, it was then required to control for the possibility of any general gross cognitive differences being responsible for the potential observed effects. A standard working memory task was chosen: this was a forward Digit Span Task. For this task, participants were required to remember a list of numbers that are presented on the screen. The list of numbers was presented for a few seconds before disappearing from view. Participants were required to type on a keyboard the sequence of numbers in the order it previously appeared. The list of numbers increased by one number on every second trial. In the general population, the norm is a maximum digit span of 5 to 7, with a digit span of 3 or lower indicative of gross cognitive deficiency.

The two psychomotor vigilance tasks were obtained from Professor Eus van Someren (Sleep and Cognition Group, Netherlands Institute for Neuroscience), and were the same as those used in the Altena et al (2008) study of effects of chronic insomnia and sleep therapy on vigilance.

The full description of the tasks is quoted from the original paper in full below:

"For the first ‘simple’ vigilance task, 110 asterisks would sequentially appear on the screen on the same location but with variable and random time intervals of between 1 and 10 s. Prior to the task, there was a brief training session of five targets, allowing the subjects to get acquainted with the task and the screen layout. Subjects were instructed to press the left of the two mouse buttons with their dominant hand as quickly as possible whenever they saw the target. They were told that the task had a duration of approximately 13 min and were asked to maintain their concentration as well as they could throughout the task.

In the second task, the ‘complex’ vigilance task, either the target letter ‘p’ or the distracter letter ‘d’ would appear in the middle of the screen. The stimuli were drawn randomly from a list of 10 targets and 10 distracters without replacement, such that the maximum (though very unlikely) number of targets or non-targets appearing consecutively would be 10.

The time intervals between successive stimuli changed randomly between 0.5 and 5 s. This ensured that the average interval between targets, the number of targets and the duration of the task would be the same as for the ‘simple’ vigilance task. The target and distracter letters ‘p’ and ‘d’ were chosen because the shape and size of the letters were the same, whereas they differed only in their orientation. There was a brief training session of 10 stimuli (five targets) preceding the task. Subjects were instructed to respond as accurately *and* as quickly as possible to the targets while ignoring the distracters. A total of 220 stimuli were presented on the screen, of which 110 were target stimuli." (Altena et al, 2008, p.338).

The Digit Span task was obtained from Dr Stephan Bandelow (Applied Cognitive Research Group, Loughborough University). During this task, a sequence of numbers would appear on the screen, one number at a time. The participant was then asked to enter the number sequence using the keyboard, in the order it appeared on the screen. Digits were randomly sampled without replacement up to list lengths of 9 digits in a row (with single digit duplications when participants’ spans surpassed 9), with the additional constraints that successive digits could not occur in regular ascending or descending sequences with equal consecutive step sizes (e.g., 123, 876, 357, 864, or 369). The sequence span length was increased following correct answers and repeated following an incorrect response, up to maximum of 12 trials.

### 4.2.7 Intervention procedure

***Intervention group***

Participants were instructed to engage in brisk walking of moderate intensity. Brisk walking was described for these purposes as: 'walking hard enough to make one breathe more heavily than normal and to become slightly warmer, but not so hard that one is unable to talk and walk at the same time, or become exhausted'. The duration of physical activity was defined as a minimum of 30 minutes of moderate intensity physical activity (PA) on 5 or more days of the week. By the end of the week, participants should have accumulated a minimum of 150 minutes of physical activity.

Prior to the start of the trial, each individual participant had a session with the researcher, in order to discuss present lifestyle, and opportunities for fitting the PA programme within it. During that session, each individual participant was issued with: (i) walking advice booklet, which contained advice on how to begin and sustain moderate intensity walking, (ii) support telephone number for the Research office, to call and text for advice and support (Contact card), (iii) a pedometer with accelerometer (New Lifestyles NL- 2000, New Lifestyles Inc.) for the entire duration of the study, as a monitoring and motivational tool; (iv) pedometer diary for recording daily/weekly steps and moderate-intensity minutes, readings from the pedometer with accelerometer (all in Appendix 2).

The intervention started with a conditioning period of 4 weeks. This started with 10-15 minutes per day of walking on at least 5 days of the week (Weeks 1 and 2), and increased to 20 minutes per day walking on at least 5 days of the week (Week 3), and increased to 25-30 minutes per day walking on at least 5 days of the week (Week 4). After the end of the conditioning period, participants were required to engage in walking on at least 30 minutes per day, on at least 5 days of the week, totalling at least 150 minutes of moderate intensity physical activity at the end of each week. Walking was monitored through readings from the pedometer with accelerometer of minutes in moderate intensity physical activity accumulated at the end of the day/week, self-monitored and noted by participants in the PA diary. Participants engaged in the physical activity programme in their chosen setting in their own time.

Researcher-led contact with participants was effected, on average, on a weekly basis, either by telephone or by email. During the weekly contact, the physical activity target achievement for the current week was discussed. In addition, any adverse reports of physical activity were noted. If the target for the current week had not been achieved, then the discussion included identification of further opportunities to engage in physical activity the following week, e.g. switching mode of transport to work to include more walking, signing up for a local walking group, identifying a supporting friend/relative to engage in the walking programme. Participants were also asked to wear an accelerometer with display screen for the duration of the intervention (see below section on monitoring of adherence for full technical details of the devices worn). Self-monitoring and goal setting have been employed successfully as strategies in increasing physical activity in clinical populations with chronic disease (van Achterberg et al, 2011). The provision of tailored feedback has also been proven successful in adherence to physical activity interventions (de Vries et al, 2008). It was considered that a combination of these strategies to develop a tailored intervention approach would prove successful in ensuring adherence and fidelity of the physical activity intervention for the present trial.

***Control group***

Participants were asked to continue their lifestyle as usual, and maintain their existing levels of physical activity. After 6 months, participants in the control group were offered the same material as had been provided to the intervention group at the start, containing detailed advice on engaging in moderate intensity physical activity.

***Monitoring of adherence during the intervention period***

The participants were asked to wear a pedometer with accelerometer for the duration of the intervention (6 months), in order to monitor adherence to the condition assigned. All participants in the intervention group wore a NewLife NL-1000 Activity Monitor (New Lifestyles Inc., US) (Figure 21), a small hip-worn device which measures vertical acceleration to count steps and accumulate total activity time spent at or above moderate intensity. The participants were asked to record their readings, both in steps and accumulated moderate to vigorous physical activity minutes, in a physical activity daily diary.

To monitor and account for the motivational effect of wearing a physical activity monitoring device, all the participants in the control group were also randomised to wear the same activity monitor, by rotation, for 3 months. The procedure ensured that all participants in the control group wore the activity monitor for at least 3 months during the intervention period.

The research office contacted all participants on a weekly or fortnightly basis, to obtain the readings, and updates on health, physical activity and sleep.


*Figure 21.* Image of New Lifestyles NL-1000 activity monitor

### 4.2.8 Data management

***Data processing***

Data were entered into SPSS version 20.0 (SPSS Statistics v. 20.0, IBM, US). Data were analysed using pre-planned descriptive statistics, t-tests for independent means, analyses of variance and covariance, Pearson correlation and logistic regression. Data were checked for outliers, distribution variance, and missing data. Statistical assumptions of variables' distribution were checked visually and with normality tests. Statistical significance was defined as $p < .05$ using two tailed tests.

The process for handling missing data was set in two stages. Stage 1 included separate bias analyses for data missing from participants who were randomised, but dropped out before the first follow up period, so whole cases were missing. If the analyses revealed no bias effect of the missing data on the outcomes of the trial, analyses proceeded on the remaining data, and no data imputation would be performed. If the analyses at Stage 1 revealed that missing data biased the outcomes of the trial, then Stage 2 would be employed. In Stage 2, statistical procedures for inputting missing data would be used (multiple imputation or last observation carried forward methods). All data was analysed per group allocation, regardless of adherence to intervention, as per 'intent to treat' principles.

**Processing of data from accelerometers**

ActiLife (v.6.5.3 Actigraph, US) software was used for processing the data from GTX3+ accelerometers.

Based on published protocol (Troiano et al, 2008), the following threshold and criteria were used when cleaning up and managing accelerometer data:

- All accelerometers were checked on calibration voltage status before and after being used;
- A valid day was considered a day of 10 or more hours of valid recording;
- Non-wear was defined as a continuous period of at least 60 minutes of 0 counts, with allowance of 2 minutes of counts between 0-100;
- A valid recording unit was considered a minimum of 7 days continuous recording (out of 14 possible days);
- 2020 and above counts was the threshold for moderate to vigorous physical activity (MVPA);
- Time spent in physical activity is presented for every minute where the respective intensity threshold has been met.

The statistical variable resulted from processing accelerometer data is moderate to vigorous physical activity (MVPA) minutes per week.

**Processing of data from Actiwatches**

Respironics Actiware 5 (v.5.71, Phillips Electronics, US) software was used for processing data from Actiwatch 2 monitors.

The statistical variables resulting from processing Actiwatch 2 data were:

- Total sleep time (TST) in minutes per night;
- Time in bed (TIB) in minutes per night;
- Sleep onset latency (SOL) in minutes per night;
- Sleep efficiency (SE) percentage, calculated from TST/TIB x 100;
- Sleep fragmentation index (SFI) which quantifies the degree of fragmentation of sleep-awake pattern during the night. It is calculated as follows: 100 × the number of groups of consecutive immobile 30-s epochs/by the total number of immobile epochs.
- Wake after sleep onset (WASO) in minutes per night.

**Processing of data from psychomotor tests**

The psychomotor tasks were administered using E-prime 1.1, with service pack 3 (Psychology Software Tools, Pittsburgh, PA, USA). All testing was performed on an HP-compatible laptop running Windows XP. During the tasks, stimuli (Courier New bold font size 45) appeared in the middle of a 30.5 × 23cm LCD screen (screen resolution 640 × 480) against a light grey background.

For the attention tasks, for all analyses, the first three target stimuli were discarded, in order to eliminate start-up problems (Altena et al, 2008). Thus, there were 107 target stimuli, for each test, included in the analyses.

As dependent variables for the two vigilance tasks, reaction times (in milliseconds [ms]), lapses and false-positive responses, were used, defined as follows:

- Reaction times (RTs) – these consisted of a single trial RTs to the target stimuli. For purposes of calculating mean RT and all other statistical analyses, the responses scored as lapses were ignored.
- Lapses – the error of omission was scored as a lapse; a lapse was defined as a non-response, or a response slower than 500ms on the 'simple' task (Altena et al, 2008); and slower than 637ms for the 'complex' vigilance task. The complex vigilance task required on average 137ms more than the simple vigilance task.
- False-positive responses – on the complex vigilance task, the errors of commission to the distractor stimuli were scored as false-positives.

As dependent variable for the Digit Span Task, the length of the longest span answered correctly over the 12 trials was used.

**Processing of data from self-reported questionnaires**

All data from questionnaires were entered manually in SPSS. All data were cross-checked for accuracy. Scale sub-scores and total scores were calculated using published algorithms.

***Data analyses***

Analyses of covariance (ANCOVA) models were employed, in which the dependent variable was the change pre-post intervention for each of the primary and secondary outcomes (all scales were coded as continuous variables); and in which group membership (control or intervention) was a fixed factor. The covariates and their coding status were:

- marital status (categorical variable, 2 categories: Married/With partner; and Not married /Widowed/Single)
- education (categorical variable, 2 categories: No formal education/Primary/Secondary; and College/University/Higher)
- Body mass index (BMI) (continuous variable)
- Health index (EQ5D-Visual Analogue Scale - continuous variable)
- Beck Depression Inventory score (continuous variable)
- Light exposure (min/day of light exposure over 1000 lux – continuous variable)
- Baseline value of the primary (or secondary outcome) in the respective model.

Independence of the covariates and intervention effects, and homogeneity of regression slopes was checked.

Logistic regression models were used to characterize the relationship between changes in scores on the Insomnia Severity Index (ISI) (from baseline to 6 months post-intervention) and outcomes/anchors from the Beck Depression Inventory, State-Trait Anxiety Inventory - Trait, and psychomotor tasks.

Effect sizes and confidence intervals were computed using the Effect Size Generator Professional Edition software (v. 4.1, ClinTools Software, Melbourne, Australia), by inputting adjusted means and standard deviations from SPSS for the respective variables.

***Data protection***

All data from the trial was stored according to the current data Protection Act 1998 obligations, and in conformity to Loughborough University's Code of Practice on Investigations Involving Human Participants (available here: http://www.lboro.ac.uk/committees/ethics-approvals-human-participants/additionalinformation/codesofpractice/).

Personal data is as defined by the Act as data relating to a living individual who can be identified from that information or from that data and other information in possession of the data controller. Sensitive data is defined by the Act as data which covers racial or ethnic origin, political opinions, religious beliefs, trade union membership, health, sex life, and criminal convictions.

Personal data (name, address, date of birth) collected from participants was stored in written format, and not transferred into electronic format. The data were stored in a fire-proof locked cabinet, inside a locked office, within Loughborough University. Only the writer (trial main investigator), and the supervisors of the project (Kevin Morgan and Clare Stevinson, both based at Loughborough University), had access to it.

Sensitive data (ethnic origin and health-related data) were stored in electronic format, and were coded and anonymised i.e. devoid of any features which could have led to the identification of the participants. Participants were electronically allocated a number at the beginning of the trial, and all data were entered against the chosen number. The published results of the present research are anonymised, and no information is published that would allow individuals to be identified.

## 4.3 Results

### 4.3.1 Recruitment and selection of participants

The full CONSORT diagram is presented in Figure 22. In response to advertisements, 320 enquiries were received from potential volunteers. After telephone screening, 261 people were sent screening questionnaires. Based on the responses, 93 people were considered eligible for participation in the trial.

Of those potential participants excluded at screening stage, 89% were considered ineligible on the basis that they reported engaging in more than 60 minutes per week of physical activity. The remaining exclusions pertained to present diagnosed psychiatric disorder, or declined randomisation.

Following randomisation to group, six potential participants withdrew or were excluded: three in the intervention group, and 3 in the control group. The reasons given for their withdrawal by the three in the control group were: that they wanted to be in the physical activity condition (n=2), and worsening health (n=1). The reasons given for withdrawal by the three in the intervention group were: unexpected lifestyle demands making time commitment to the trial difficult (n=1); and worsening health (n=2).

One participant from the control group was unavailable for measures within the allocated time at 3 months from baseline.

### 4.3.2 Participants characteristics

Participants' socio-demographic characteristics at baseline are shown in Table 9. Briefly, the sample consisted of 41 adults (of whom 30 were females), with a mean age of 60 years. The mean weekly volume of MVPA was 57 minutes. The sample was just above the normal weight range, with a mean BMI score of 26.

There were no significant differences between the two groups at baseline on any of the variables of interest. None of the variables violated the equality of variance assumption, or normality of distributions assumption (for the t-tests).

Table 10 shows the self-reported sleep and health characteristics within the sample at baseline. The depression and anxiety scores place the sample within the subclinical range. Table 11 presents participants' sleep characteristics from wrist actigraphy at baseline.

At baseline, there were no significant differences between the two groups in these respects. The mean ISI score placed this sample in the moderately severe range of insomnia severity. In terms of the development of the disorder, participants reported an average of 11 years of chronic persistence of insomnia, with a wide range, from 1 year to 25 years.

24% of participants reported present use of non-pharmalogical and of pharmacological treatment to improve sleep. Participants reported on average having one chronic disease in addition to insomnia.

Insomnia duration, medication use and number of other chronic diseases did not significantly differ between groups at baseline.

CONSORT Diagram

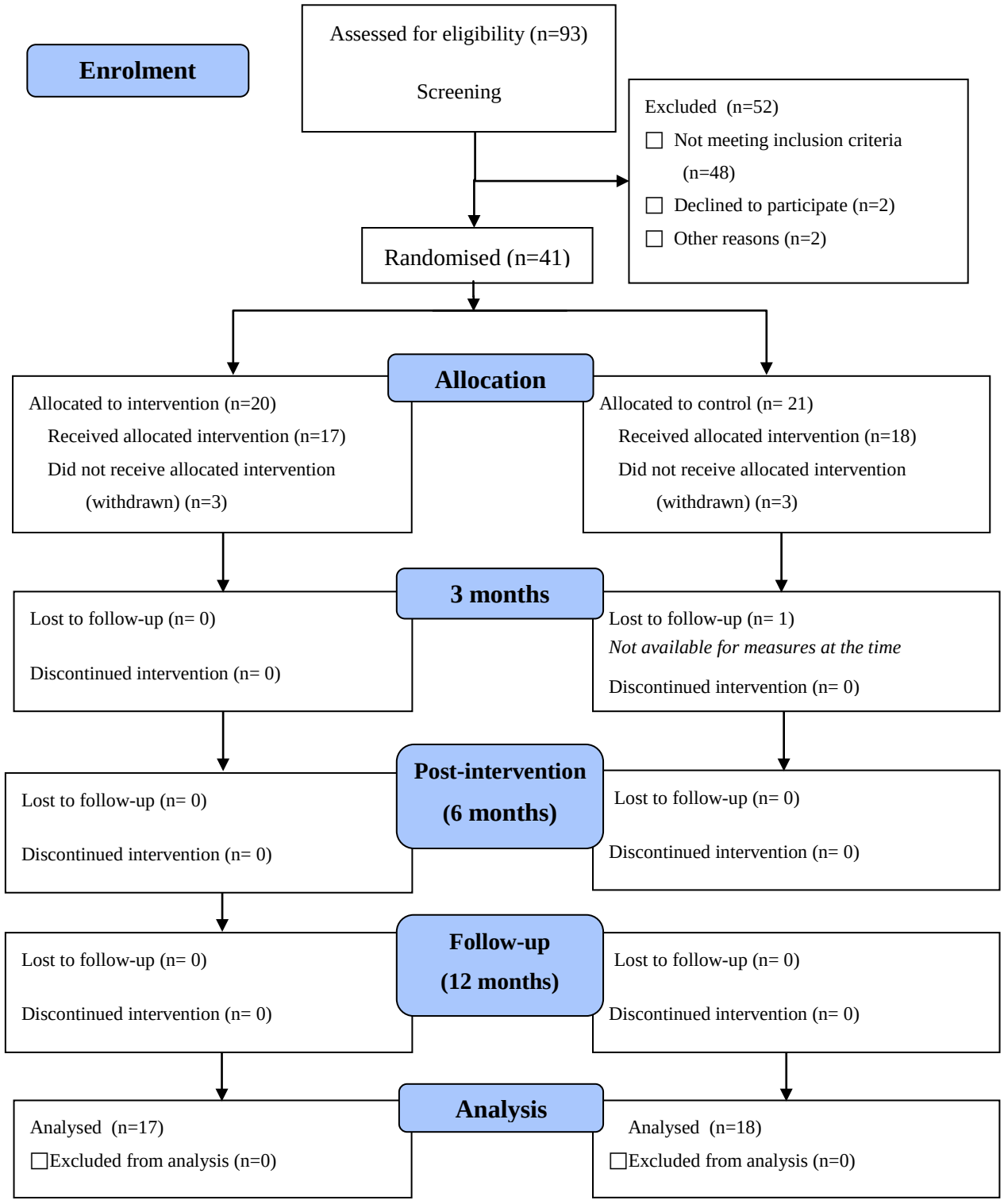


*Figure 22.* Participant flow diagram

Table 9

*Participants' socio-demographic characteristics at baseline*

| Variable | Sample N = 41 | Control group N = 21 | Intervention group N = 20 | p* |
|---|---|---|---|---|
| | | Mean (SD) or frequency | | |
| Age | 59.80 (9.46) | 60.10 (8.51) | 59.50 (10.59) | 0.84 |
| Gender (female/male)† | 30/11 | 15/6 | 15/5 | 0.76 |
| Education (high/low)† | 17/24 | 9/12 | 8/12 | 0.85 |
| Marital status (married/not) † | 36/15 | 12/9 | 14/6 | 0.39 |
| Income groups (median) ‡ | 7.00 | 6.50 | 9.00 | 0.34 |
| Body mass index | 26.29 (4.18) | 26.58 (4.77) | 25.99 (3.55) | 0.65 |
| MVPA§ min/week | 57.50 (30.07) | 48.95 (27.84) | 66.50 (30.37) | 0.16 |

*t-tests between groups; †$\chi$2 between groups; ‡ Mann-Whitney-U; § MVPA= Moderate to vigorous physical activity

Table 10

*Participants' self-reported sleep and health characteristics at baseline*

| Variable | Sample N = 41 Mean (SD)** | Control group N = 21 | Intervention group N = 20 | p* |
|---|---|---|---|---|
| ISI[a] | 16.11 (4.93) | 16.37 (5.58) | 15.82 (4.23) | 0.41 |
| PSQI[b] Global | 10.37 (2.76) | 10.61 (2.94) | 10.10 (2.61) | 0.55 |
| BDI[c] | 11.87 (6.51) | 12.95 (6.84) | 10.75 (6.13) | 0.28 |
| STAI[d]-Trait | 39.95 (8.73) | 40.14 (9.68) | 39.74 (8.09) | 0.88 |
| STAI[d]-State | 34.75 (7.98) | 35.71 (8.52) | 33.68 (7.41) | 0.42 |
| EQ-5D (VAS) | 77.63 (16.53) | 75.24 (20.82) | 80.15 (10.28) | 0.35 |
| FSS[e] | 3.96 (1.51) | 3.88 (1.53) | 4.04 (1.54) | 0.74 |

*t-tests between groups; **Equality of variance tested, all non-significant

[a] ISI= Insomnia Severity Index; [b] PSQI=Pittsburgh Sleep Quality Index; [c] BDI=Beck Depression Inventory; [d] STAI=State/Trait Anxiety Inventory; [e] FSS=Fatigue Severity Scale

Table 11

*Baseline sleep characteristics from sleep actigraphy*

| Variable | Sample N = 41 | Control group N = 21 Mean (SD) † | Intervention group N = 20 | p* |
|---|---|---|---|---|
| Total sleep time – min‡ | 403.58 (59.63) | 405.23 (71.52) | 401.85 (45.79) | 0.85 |
| Time in bed – min | 519.93 (56.62) | 516.04 (66.66) | 524.03 (45.16) | 0.65 |
| Sleep onset latency – min§ | 25.76 (17.26) | 24.96 (15.94) | 26.62 (18.94) | 0.68 |
| Wake after sleep onset – min§ | 67.51 (51.71) | 64.40 (58.81) | 70.79 (44.35) | 0.60 |
| Sleep efficiency (%)§ | 78.01 (8.63) | 79.03 (9.50) | 76.95 (7.71) | 0.22 |
| Sleep Fragmentation Index§ | 17.66 (5.04) | 17.74 (5.41) | 17.58 (4.76) | 0.83 |

*t-tests between groups; †Equal variance tested, all non-significant, apart from ‡.

‡ Equal Variance not assumed, p-value displayed; §Wilcoxon Rank Sum Test

### 4.3.3 Missing data: attrition analyses

Logistic regression was employed to see whether key variables at baseline predicted 'missingness' of data at subsequent follow-up time of 3 months and 6 months. A dichotomous adherence variable was created that represented the status of 'missing' or 'non-missing' data at 3 months follow up, and post-intervention. Predictive relationships were examined between these adherence categories and key independent variables: group allocation, insomnia severity, sleep quality, health status, and mood.

The analyses revealed no significant association between key variables and 'missingness' of data at 3 months and 6 months (Tables 12 and 13).

Table 12

*Logistic regression output for data attrition analyses at 3 months*

| | | | | 95% C.I.for Exp(B) | |
|---|---|---|---|---|---|
| Variables predictors | df | Sig. | Exp(B) | Lower | Upper |
| Group membership (control or intervention) | 1 | 0.96 | 1.07 | 0.10 | 11.45 |
| ISI[a] | 1 | 0.20 | 1.31 | 0.87 | 1.99 |
| PSQI GLOBAL[b] | 1 | 0.41 | 0.72 | 0.33 | 1.57 |
| BDI[c] | 1 | 0.81 | 1.04 | 0.76 | 1.42 |
| FSS[d] | 1 | 0.50 | 1.41 | 0.52 | 3.80 |
| ESS[e] | 1 | 0.22 | 0.74 | 0.46 | 1.20 |
| MVPA[f] min/week | 1 | 0.25 | 0.98 | 0.94 | 1.02 |
| EQ5D-DL Health Index Value | 1 | 0.98 | 1.11 | 0.00 | 4960.80 |
| Body Mass Index | 1 | 0.41 | 0.81 | 0.49 | 1.33 |
| STAI-Trait[g] | 1 | 0.51 | 1.09 | 0.84 | 1.41 |
| STAIT-State[g] | 1 | 0.50 | 0.91 | 0.69 | 1.19 |
| Constant | 1 | 0.73 | 40.18 | | |

[a] ISI= Insomnia Severity Index; [b] PSQI=Pittsburgh Sleep Quality Index; [c] BDI=Beck Depression Inventory; [d] FSS=Fatigue Severity Scale; [e] ESS=Epworth Sleepiness Scale; [f] MVPA=Moderate to vigorous physical activity; [g] STAI=State/Trait Anxiety Inventory.

Table 13

*Logistic regression output for data attrition analyses at 6 months*

| Variables predictors | df | Sig. | Exp(B) | 95% C.I.for Exp(B) Lower | Upper |
|---|---|---|---|---|---|
| Group membership (control or intervention) | 1 | 0.34 | 3.53 | .27 | 46.65 |
| ISI[a] | 1 | 0.34 | 1.23 | .80 | 1.89 |
| PSQI GLOBAL[b] | 1 | 0.42 | .72 | .32 | 1.60 |
| BDI[c] | 1 | 0.79 | 1.05 | .75 | 1.45 |
| FSS[d] | 1 | 0.89 | .93 | .30 | 2.82 |
| ESS[e] | 1 | 0.42 | .83 | .53 | 1.31 |
| MVPA[f] min/week | 1 | 0.40 | .98 | .94 | 1.03 |
| EQ5D-DL Health Index Value | 1 | 0.70 | 5.10 | .00 | 19460.46 |
| Body Mass Index | 1 | 0.61 | .86 | .49 | 1.52 |
| STAI[g]-Trait | 1 | 0.66 | 1.06 | .82 | 1.37 |
| STAIT[g]-State | 1 | 0.71 | .95 | .73 | 1.24 |
| Constant | 1 | 0.86 | 7.04 | | |

[a] ISI= Insomnia Severity Index; [b] PSQI=Pittsburgh Sleep Quality Index; [c] BDI=Beck Depression Inventory; [d] FSS=Fatigue Severity Scale; [e] ESS=Epworth Sleepiness Scale; [f] MVPA=Moderate to vigorous physical activity; [g] STAI=State/Trait Anxiety Inventory.

It was concluded that the missing data was missing at random, thus data left in the analyses would not be biased. No data imputation for missing data was performed.

### 4.3.4 Adherence

***Adherence to intervention***

Over the trial, the participants in the intervention group engaged on average in 219 minutes per week of moderate to vigorous intensity physical activity (MVPA) (SD=99.75). The participants in the control group engaged on average in 74.38 minutes per week of MVPA (SD = 67.36).

During the 6 month period of the intervention, the participants in the intervention group (N=17) were aiming to reach at least 30 minutes of MVPA, over 5 days, per week, leading to at least 150 minutes of MVPA per week. When using this threshold to calculate regular compliance (monitored with continual use of pedometers with accelerometers), out of 442 total reported weeks for the 17 participants, there were 4.75% weeks achieving less than 150 minutes MVPA per week. Thus, there was 95% continuous adherence to the intervention.

Three participants in the intervention group (18%) were found to have achieved less than 150 minutes per week of MVPA per week, at 6-months follow-up. One participant in the control group was found to have engaged in more than 150 minutes per week of MVPA (293 min/week) at 6-month follow up.

The majority of the MVPA reported comprised walking or jogging, with 10% of participants reporting additional swimming sessions, or cycling. Those activities that could not be captured by accelerometers i.e. swimming, or cycling, were not included in the activity figures reported. All the figures reported are from the actigraphy activity monitoring.

***Tolerability to intervention***

There was one adverse event reported due to the intervention (mild sprained ankle). With adequate rest and treatment, the participant returned to her usual walking levels within 2 weeks.

Over the 26 weeks of walking intervention, with participants engaging in an average of 5 walking sessions a week, this represents a 0.03% risk of injury over the course of the study.

### 4.3.5 Effect of intervention on physical activity levels

Independent t-tests between groups separately performed at 3 months follow up, and at 6 months follow up, showed significant differences in physical activity levels, as recorded by accelerometers, between the two groups. The intervention group performed significantly more minutes of moderate to vigorous physical activity per week than the control group (Table 14).

Using multivariate mixed models, there was a significant main effect of group membership on amount of weekly physical activity performed at 6 months, $F(1,32)=19.08$, $p<0.001$. Group membership affected the degree of change in physical activity levels performed over time, ($F(1,32)=15.45$, $p<0.001$), with those participants in the intervention group performing significantly more PA over time than those in the control group (Figure 23).

In the intervention group, participants increased their mean MVPA from 66.50 (SD = 30.37) min/week at baseline, to 213 (SD = 109.31) min/week at 6 months. In the control group, on average participants increased their MVPA from 48.95 (SD = 27.84) min/ week at baseline, to 79.66 (SD = 64.73) at 6 months.

Table 14

*Means and standard deviations for weekly minutes of moderate to vigorous physical activity at 3 months and post-intervention*

| | Control | Intervention | p* |
|---|---|---|---|
| MVPA† 3 months | 66.47 ± 73.72 | 225.62 ± 97.71 | 0.001 |
| MVPA post-intervention | 79.66 ± 64.73 | 213.00 ± 109.31 | 0.001 |

*Independent t-tests; † MVPA=Moderate to vigorous physical activity (min/week)

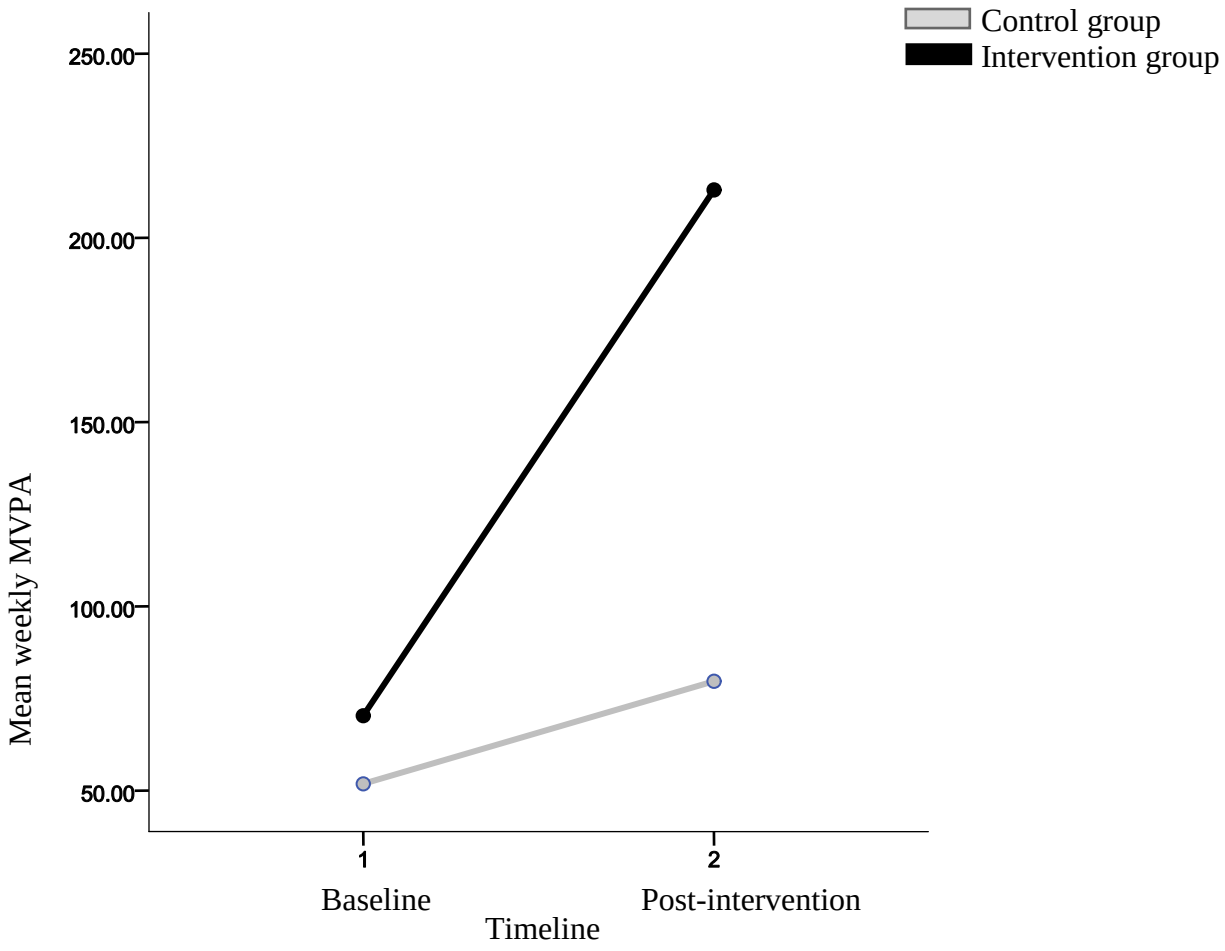


*Figure 23.* Weekly mean physical activity change from baseline to 6-month follow-up

### 4.3.6 Insomnia symptoms severity and sleep quality

The main outcome measure of the trial was severity of insomnia symptoms, as measured by Insomnia Severity Index (ISI). The secondary outcome measures were sleep quality, as assessed with Pittsburgh Sleep Quality Index (PSQI); and sleep structure/quantity, as assessed with actigraphy.

At baseline, the average ISI and PSQI scores in the whole sample were 16, and 10, respectively, placing the sample in the moderate range of insomnia severity.

Changes in insomnia severity symptoms and sleep quality at 3 months, and post-intervention (at 6 months) were assessed using analyses of covariance (ANCOVA) models.

Means and standard deviations on these variables for the groups at baseline, 3 months and post-intervention are presented in Table 15.

Assumptions for the ANCOVA models were checked. Independence of the covariates and treatment effect were ensured through random allocation of participants to the two groups; in addition baseline levels of covariates used did not significantly differ between the two groups (Table 9). Homogeneity of regression slopes was tested through a series of interaction univariate models (controlling for the main effects) between the dependent variable (ISI change score) and the covariates. None of the interaction models were significant, indicating that the homogeneity assumption was met.

Table 15

*Means and standard deviations for self-reported sleep variables at baseline, 3 months and post-intervention*

| | All sample | Control | Intervention |
|---|---|---|---|
| | Mean ± SD | | |
| ISI* (Baseline) | 16.11 ± 4.93 | 16.37 ± 5.58 | 15.82 ± 4.23 |
| ISI (3 months) | 13.24 ± 5.33 | 14.35 ± 5.61 | 12.12 ± 4.96 |
| ISI (Post-intervention) | 13.44 ± 5.60 | 14.95 ± 5.02 | 11.76 ± 5.88 |
| PSQI† Global (Baseline) | 10.33 ± 2.90 | 10.26 ± 3.12 | 10.41 ± 2.71 |
| PSQI Global (3 months) | 9.11 ± 3.15 | 9.47 ± 2.93 | 8.76 ± 3.40 |
| PSQI Global (Post-intervention) | 8.69 ± 3.62 | 9.37 ± 3.93 | 7.94 ± 3.17 |

*ISI=Insomnia Severity Index; †PSQI=Pittsburgh Sleep Quality Index

***3 months sleep variables***

In ANCOVA models, with Insomnia Severity Index difference score as dependent variable (baseline - 3 months score), and marital status, education, body mass index, health index value, Beck Depression Inventory score, light exposure, and baseline value of Insomnia Severity Index, there was a significant effect of group allocation on insomnia severity change, $F(8,25)=4.42$, $p=.04$. Pre-post comparisons within each group revealed that there was a significant improvement in Insomnia Severity Index score in the intervention group, $t(16)=4.68$, $p<0.001$; but no significant change in the control group, $t(16)=2.06$, $p=.06$.

Looking at secondary outcomes, in ANCOVA models with Pittsburgh Sleep Quality Index difference score as dependent variable, and the same covariates as in the model above, there was no significant effect of group membership on change in sleep quality, $F(8,25)=.31$, $p=.58$. Means and standard deviations for actigraphy-derived sleep variables are presented in Table 16; there were no significant changes in any of these sleep variables at 3 month measures.

Table 16

*Means, standard deviations, and ANCOVA models outputs for actigraphy sleep variables at 3 months*

| Variable | Sample N = 34 | Control group N = 17 | Intervention group N = 17 | F(8,24) | p |
|---|---|---|---|---|---|
| Mean ±SD | | | | | |
| Total sleep time – min | 415.80 ± 53.25 | 407.92 ± 63.52 | 423.68 ± 41.00 | .02 | 0.89 |
| Time in bed – min | 510.00 ± 55.88 | 501.76 ± 66.73 | 518.24 ± 42.94 | .02 | 0.90 |
| Sleep onset latency – min | 26.25 ± 17.69 | 22.57 ± 16.09 | 29.94 ± 18.91 | .65 | 0.42 |
| Wake after sleep onset – min | 42.96 ± 19.62 | 44.66 ± 21.32 | 41.26 ± 18.26 | .06 | 0.80 |
| Sleep efficiency (%) | 81.62 ± 7.26 | 81.30 ± 8.10 | 81.94 ± 6.55 | .01 | 0.98 |
| Sleep Fragmentation Index | 19.68 ± 8.11 | 20.95 ± 9.16 | 18.41 ± 6.97 | .08 | 0.77 |

***Post-intervention (6 months) sleep variables***

The covariates were not significantly related to change in the main outcome – insomnia symptoms severity (Table 17). There was a significant effect of group membership on change scores in ISI, after controlling for appropriate variables: $F(8,26)=5.16$, $p=.03$ (Table 18). Pre-post comparisons for each group showed a significant improvement in the ISI score in the physical activity group ($t(16)=3.35$, $p<0.01$), but no significant change in the control group ($t(17)=1.81$, $p=0.21$).

In order to determine the clinical significance of the change in ISI, a series of comparisons were performed within sample groups. The ISI was categorised as subthreshold insomnia (<14) and moderate to severe (15 and over) (Morin et al, 2011). Upon comparing the change in the two categories within the groups over time, there was a reduction of 67% in the moderate to severe category of the intervention group, compared to a 14% reduction within the same category in the control group (Figure 24). Overall, in the intervention group, there was a 4-point reduction in the ISI score.

Considering as responders to physical activity treatment those who improved their insomnia Severity Index score with 4 points or more, 47% of participants in the intervention group were responders at 3 months, and 53% were responders to treatment at 6 months.

Table 17

*Assumptions for covariates significance interaction in the ANCOVA ISI model at 6 months*

| Covariate | F(1,28) | p |
|---|---|---|
| Marital status | 0.30 | 0.58 |
| Education | 0.25 | 0.61 |
| Body Mass Index | 0.54 | 0.46 |
| Health index | 0.003 | 0.95 |
| Light exposure | 0.04 | 0.84 |
| Beck Depression Inventory | 1.28 | 0.26 |
| ISI* (Baseline value) | 1.07 | 0.30 |

*ISI=Insomnia Severity Index

Table 18

*Main models for pre-post intervention outcomes, adjusted means and effect sizes in the RCT*

| Comparison of mean change pre-post intervention | Intervention group | Control group | p | Adjusted mean difference ± SE (95% CI) | Adjusted Cohen d (95% CI) |
|---|---|---|---|---|---|
| | Mean ± SD (n) | | | | |
| **Main outcome: Sleep*** | | | | | |
| ISI[a] | -4.06 ± 4.99 (17) | -1.42 ± 3.42 (19) | 0.03 | 3.67 ± 1.48 (.33–6.4) | .78 (.10–1.45) |
| **Secondary outcomes**[†] | | | | | |
| PSQI[b] | -2.47 ± 3.26 (17) | .89 ± 3.43 (19) | 0.27 | 1.36 ± 1.22 (-1.1–3.87) | .38 (-.27–1.04) |
| FSS[c] | .64 ± 1.48 (17) | -.16 ± .63 (17) | 0.18 | 6.13 ± 4.6 (-.32–1.59) | .49 (-.17–1.15) |
| BDI[d] | -4.35 ± 4.44 (17) | 1.31 ± 9.26 (19) | 0.02 | 5.99 ± 2.52 (.82 – 11.15) | .87 (.19 –1.56) |
| STAI-T[e] | -4.93 ± 5.40 (17) | .38 ± 8.95 (19) | 0.05 | -4.76 ± 2.35 (-9.6 – 0.7) | .72 (.03–1.42) |
| **Attention**[‡] | | | | | |
| Simple RT[f](ms) | -31.98 ± 35.85 | 4.61 ± 31.25 | 0.001 | -33.58 ± 8.68 (-51.47– -15.70) | -1.3 (-2.07 – -0.62) |
| Complex RT(ms) | -13.58 ± 30.56 | -8.18 ± 28.01 | 0.62 | -4.58 ± 9.18 (-23.50–14.32) | -.17 (-0.82–0.48) |
| Ratio SRT/CRT(ms) | .09 ± .12 | -.04 ± .07 | 0.003 | -.11 ± .03 (-.18 – -.04) | 1.09 (0.35 - 1.83) |

[a]ISI=Insomnia Severity Index; [b]PSQI=Pittsburgh Sleep Quality Index; [c]FSS=Fatigue Severity Scale; [d]BDI=Beck Depression Inventory; [e]STAI-T=State-Trait Anxiety Inventory (Trait only); [f]RT=Reaction Time (ms)

*Covariates: Marital status, Education, Body Mass Index, Health Index, Beck Depression Inventory, Light exposure, Baseline value of comparison variable; †Covariates: Marital status, Education, Body Mass Index, Health Index, Beck Depression Inventory, Light exposure, Baseline value of comparison variable; ‡Covariates: Marital status, Education, Body Mass Index, Health Index, Beck Depression Inventory, Fatigue Severity Scale, Baseline value of attention task/ratio (ms)

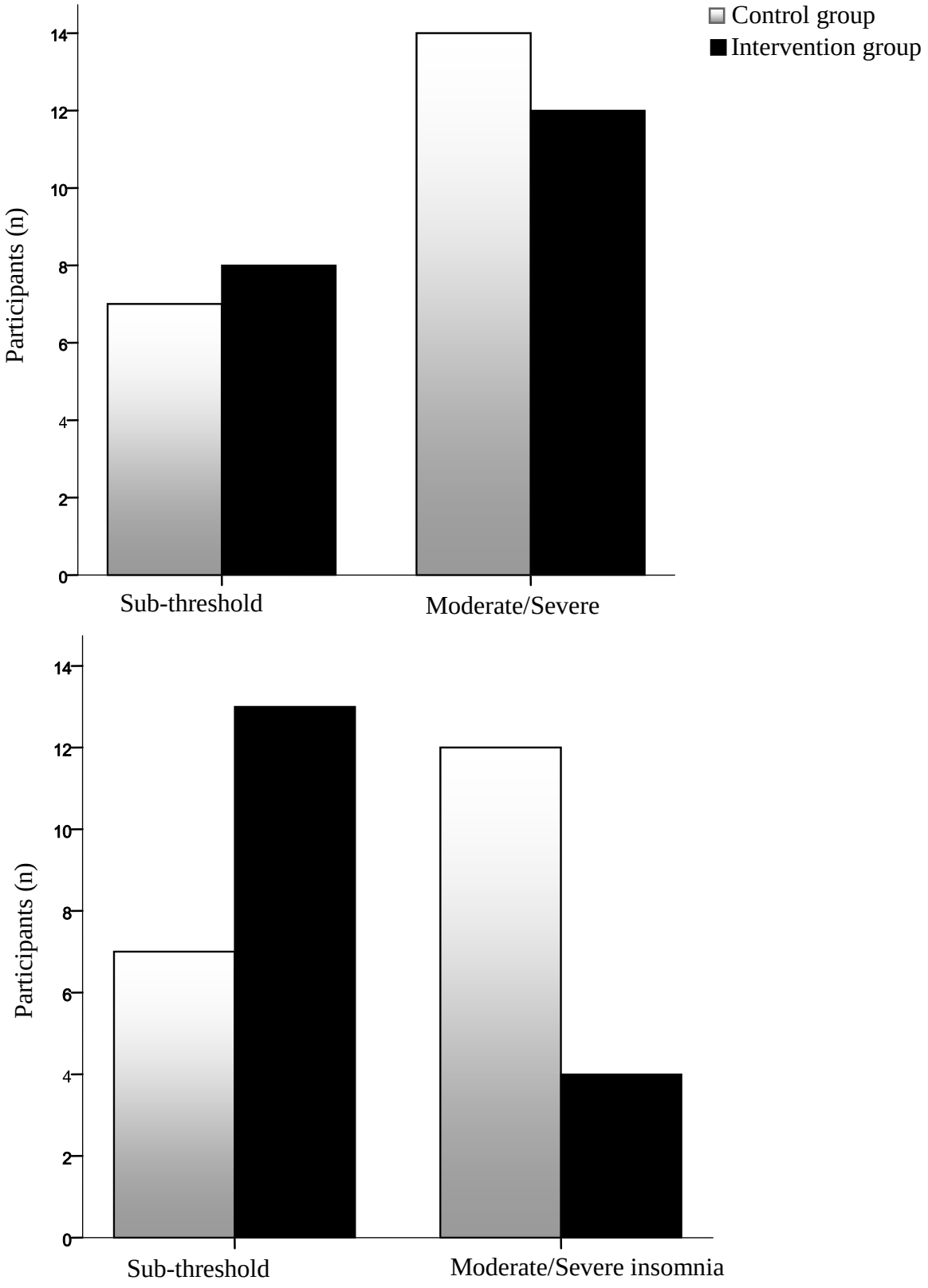


*Figure 24.* ISI categories at baseline (above) and post-intervention (below)

There was no significant effect of group membership on the change score on global PSQI, $F(8,26)=1.24$, $p=.27$. Speculative pre-post comparisons for each group showed significant improvement in the PSQI global score in the intervention group $t(16)=3.12$, $p<0.01$, but not in the control group, $t(17)=1.13$, $p=0.27$ (Figure 25).

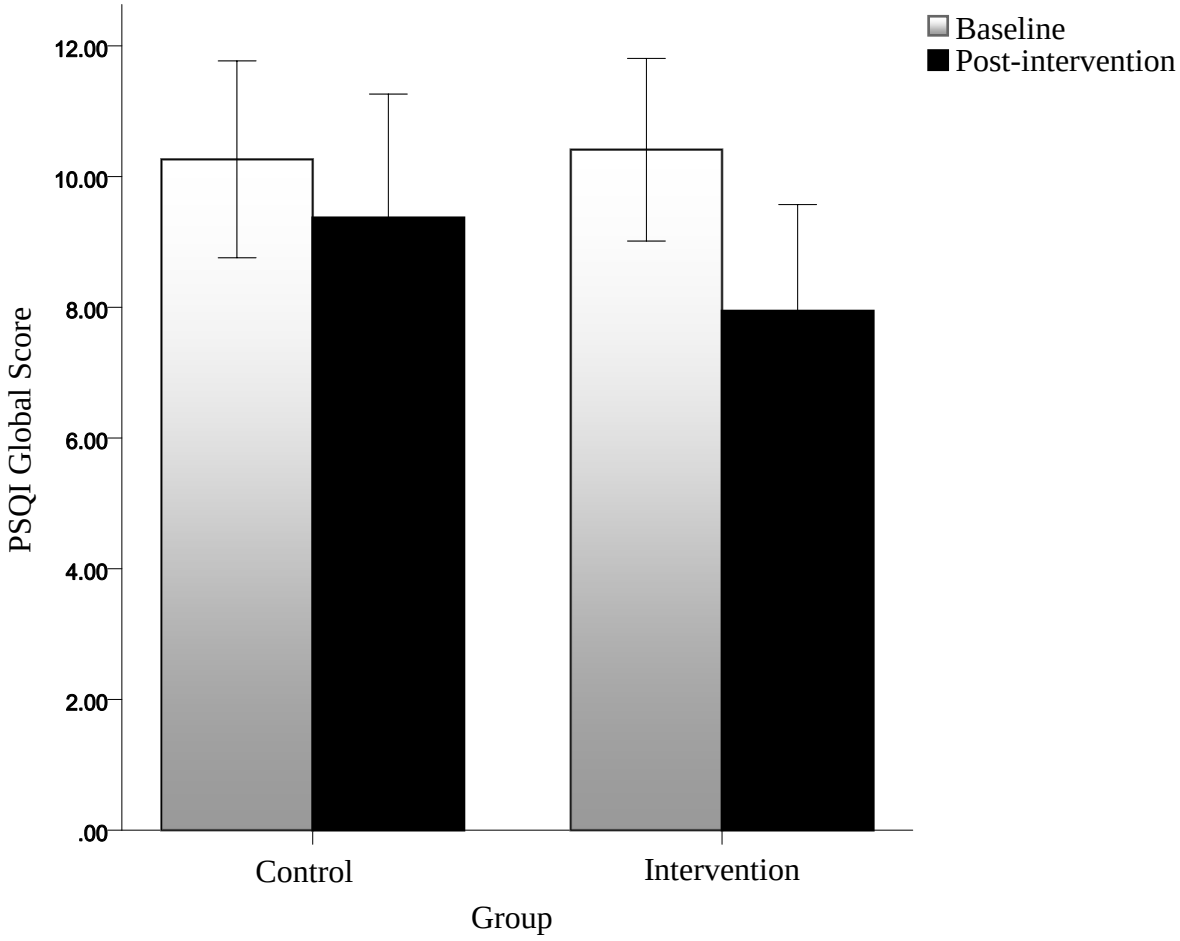


*Figure 25.* Means and standard deviations for PSQI Global scores in the intervention and control groups

Additional analyses on the PSQI subscales change scores revealed a significant effect of group membership on the daytime dysfunction subscale, $F(8,26)=10.83$, $p<0.01$, with follow-up pre-post comparisons for each group showing a significant improvement in the physical activity group, $t(16)=3.05$, $p<0.01$, but no significant change in the control group, $t(17)=-1.75$, $p=0.24$.

Means and standard deviations for the actigraphy-derived sleep variables post-intervention are presented in Table 19. There was no significant effect of treatment condition on the change score post-intervention in any of the actigraphy sleep variables (Table 20).

Table 19

*Means and standard deviations of actigraphy sleep variables post-intervention*

| Variable | Sample N = 35 | Control group N = 18 | Intervention group N = 17 |
|---|---|---|---|
| | | Mean (SD) | |
| Total sleep time – min | 426.35 (41.96) | 418.68 (50.03) | 434.48 (30.74) |
| Time in bed – min | 518.87 (51.66) | 509.74 (58.43) | 528.54 (43.01) |
| Sleep onset latency – min | 26.38 (18.17) | 24.55 (16.73) | 28.32 (19.91) |
| Wake after sleep onset – min | 41.63 (19.84) | 41.96 (18.76) | 41.28 (21.50) |
| Sleep efficiency (%) | 82.61 (7.21) | 82.57 (7.35) | 82.65 (7.28) |
| Sleep Fragmentation Index | 18.99 (7.84) | 19.39 (7.25) | 18.56 (8.63) |

Table 20

*Post-intervention ANCOVA models for actigraphy sleep variables*

| Comparison of mean change pre-post intervention | F(8,26) | p |
|---|---|---|
| Total sleep time | 0.62 | 0.43 |
| Sleep onset latency | 0.14 | 0.71 |
| Wake after sleep onset | 0.06 | 0.80 |
| Time in bed | 1.42 | 0.24 |
| Sleep efficiency | 0.02 | 0.90 |
| Sleep fragmentation index | 0.01 | 0.91 |

### 4.3.7 Mood

***3 months mood variables***

Beck Depression Inventory and STAI-Trait and State were used to measure mood outcomes. In ANCOVA models with depression scores change from baseline to 3 months follow up as dependent variable, and marital status, education, body mass index, health index value, light exposure, and baseline value of Beck Depression Inventory score as covariates; there was a trend towards a significant effect of intervention condition on depression change scores, $F(7,27)=3.66$, $p=0.06$.

Both state and trait anxiety sub-scales showed no significant difference based on group allocation at 3 months measuring point, $F(7,27)=.42$, $p=0.51$, and $F(7,27)=.13$, $p=0.72$, respectively.

***Post-intervention (6 months) mood variables***

At post-intervention, using the same models as above, there was a significant effect of group membership on change in depression scores: $F(6,28)=5.61$, $p=0.02$. In pre-post comparisons for each group, participants in the physical activity group demonstrated significant improvement in the BDI scores, $t(16)=4.03$, $p<0.001$ (Figure 26). Participants in the control group did not show significant improvement, $t(17)=-.61$, $p=0.54$.

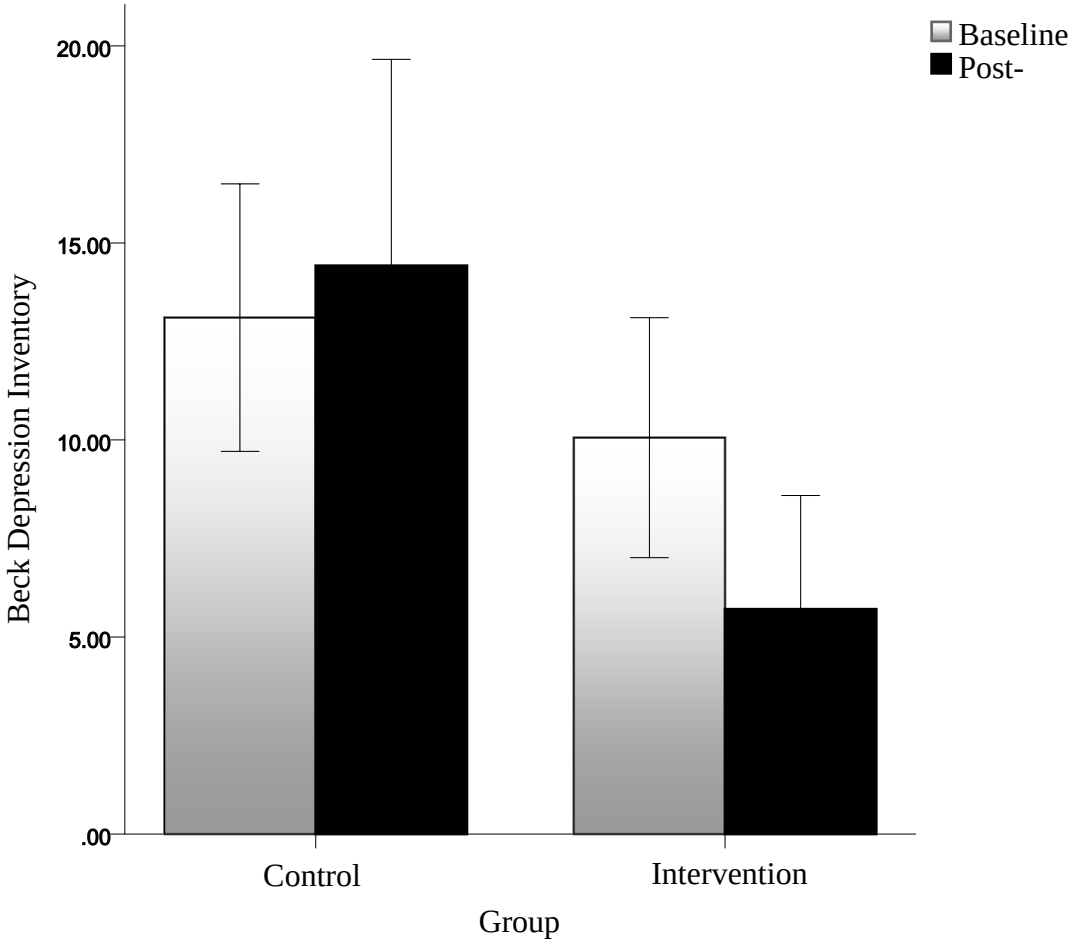


*Figure 26.* Means and standard deviations for BDI scores in the intervention and control groups

Using the same models as at 3 months, but with STAI-Trait change scores, there was a significant effect of group membership on trait anxiety outcomes post-intervention, $F(6,28)=4.41$, $p=0.05$ (Figure 27). Follow-up comparisons for each group revealed that participants in the intervention group had significant improvement in their trait anxiety scores, whilst participants in the control group did not show the same pattern ($t(16)=3.71$, $p<0.01$, and $t(17)=-.18$, $p=0.34$, respectively).

When repeating the models for STAI-State, there was no significant effect of group membership on state anxiety score change, $F(6,28)=0.78$, $p=0.38$.

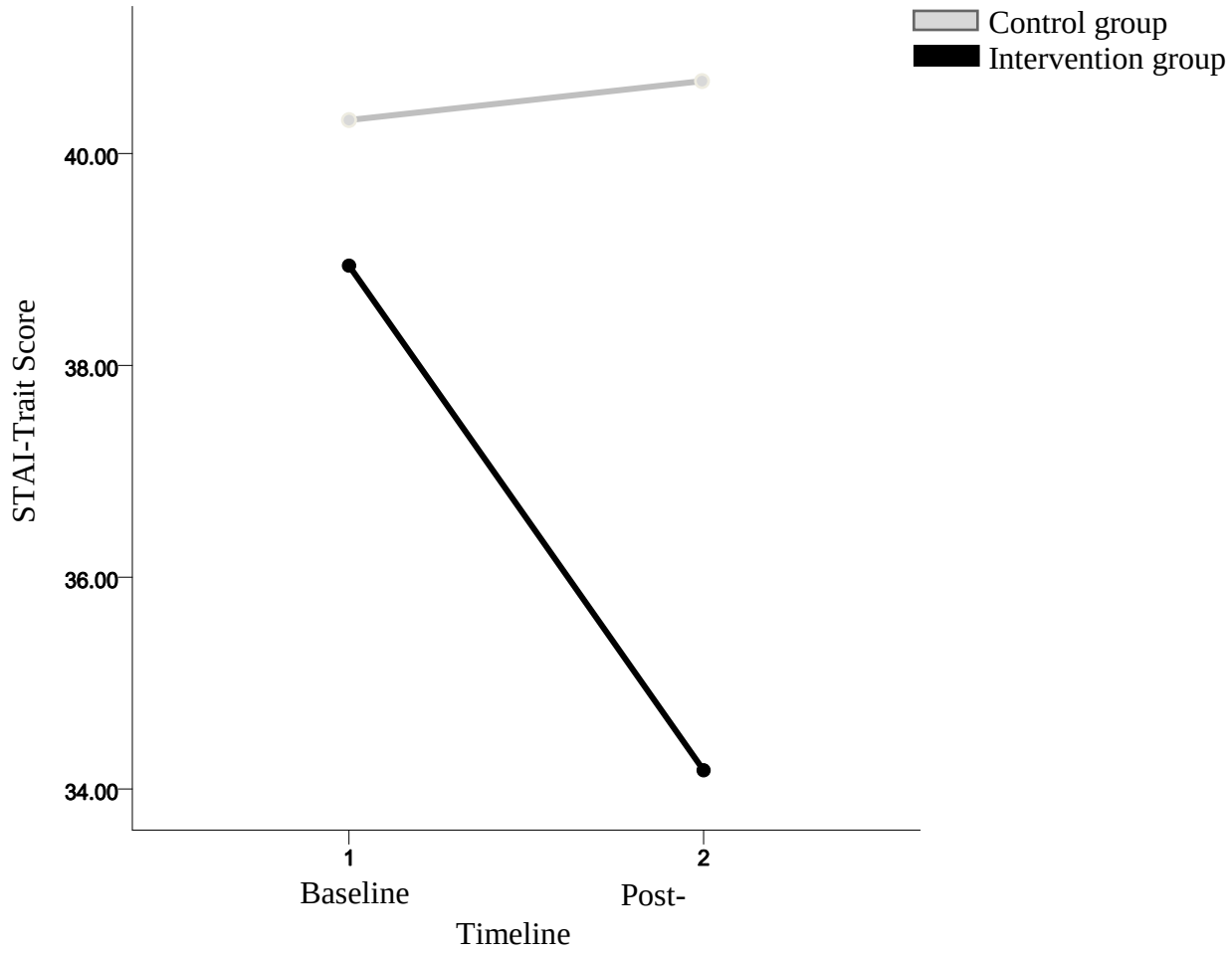


*Figure 27.* Mean STAI-Trait scores at baseline and post-intervention, in the physical activity and control groups

### 4.3.8 Daytime sleepiness and fatigue

There was also no significant effect of group membership on the change score on Fatigue Severity Scale at the two measuring time points, with covariates marital status, education, body mass index, Health Index value, Beck Depression Inventory score, light exposure and baseline values of fatigue F(8,25)=2.83, p=0.10 at 3 months; and F(8,26)=1.84, p=0.18 at post-intervention (Figure 28). Daytime sleepiness followed the same trend, with no significant effect of group membership on change scores at post-intervention, F(8,26)=.04, p=0.83.

Employing an ANCOVA model for the 6-months data only, with fatigue severity scale as dependent variable, group membership as fixed factor, and insomnia severity index as covariate, there was a main effect of ISI on fatigue, F(3,32)=8.54, p=.006, but no significant effect of group membership in this model, F(3.32)=.60, p=0. 44.

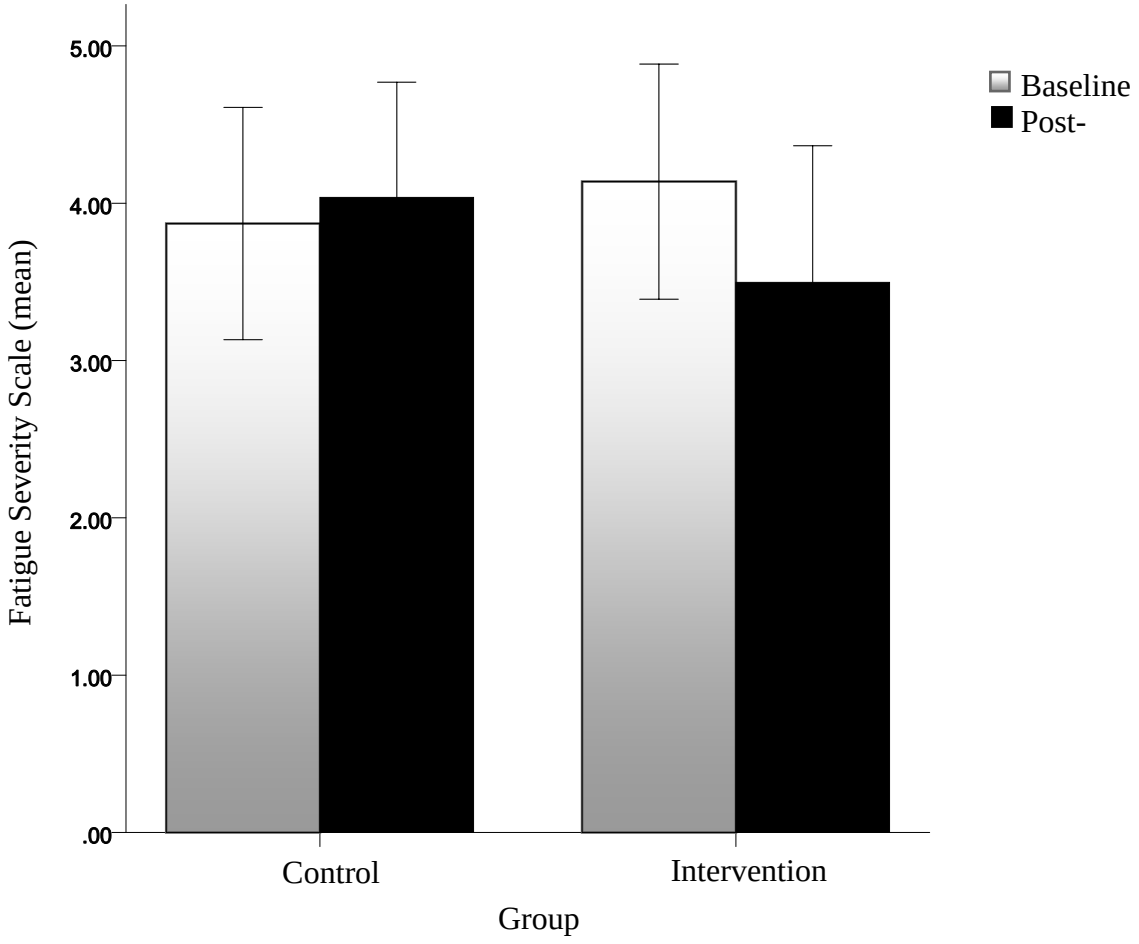


*Figure 28.* Means and standard deviations of Fatigue Severity index at baseline and post-intervention, in the physical activity and control groups

### 4.3.9 Health-related quality of life

The EQ5D-5L was used to measure quality of life. There was no significant condition effect on the health scale change score at 3 months or 6 months, with covariates marital status, education, body mass index , Beck Depression Inventory score, light exposure and baseline values of Health Index, $F(7,26)=2.39$, $p=0.13$, and $F(7,27)=1.28$, $p=0.26$, respectively.

### 4.3.10 Psychomotor performance

The group mean maximum digit span at baseline was 6; this remained unchanged at 6 month follow up. The lowest length of the maximum digit span was 4, both at baseline and post-intervention; therefore none of the participants met the criteria (maximum digit span length of 3) to be eliminated from the analyses. There was no significant effect of group membership on performance on the digit span task, $F(6,25)=.05$, $p=0.82$.

Across all participants and conditions (baseline and post-intervention), the complex vigilance task required approximately 137 ± 12.2ms more than the simple vigilance task to perform. Independent t-tests showed no significant difference between groups at baseline (Table 21).

Table 21

*Means and standard deviations for the psychomotor tests variables at baseline and post-intervention*

| | All sample | Control | Intervention | p* |
|---|---|---|---|---|
| | | Mean ± SD | | |
| Simple Reaction Task (ms) at baseline | 365.97 ± 42.73 | 369.89 ± 70.97 | 362.04 ± 45.12 | 0.56 |
| Simple Reaction Task (ms) post-intervention | 378.38 ± 35.75 | 365.66 ± 29.67 | 389.75 ± 38.92 | |
| Complex Reaction Task (ms) baseline | 487.92 ± 41.23 | 482.42 ± 44.46 | 493.43 ± 38.07 | 0.40 |
| Complex Reaction Task (ms) post-intervention | 499.78 ± 32.86 | 498.39 ± 32.42 | 501.25 ± 34.25 | |
| No. of lapses at SRT at baseline | 7.27 ± 4.04 | 7.05 ± 4.35 | 7.50 ± 3.80 | 0.88 |
| No. of lapses at SRT post-intervention | 8.00 (3.95) | 7.88 ± 3.80 | 8.11 ± 4.22 | |
| No. of lapses at CRT at baseline | 10.42 ± 9.07 | 9.10 ± 7.25 | 11.75 ± 10.62 | 0.68 |
| No. of lapses at CRT post-intervention | 9.11 ± 4.26 | 8.55 ± 3.69 | 9.70 ± 4.83 | |

*Independent t-tests between groups at baseline; equality of variance tested and n/s in all tests

Table 21 (Cont'd/..)

*Means and standard deviations for the psychomotor tests variables at baseline and post-intervention*

| | All sample | Control | Intervention | p* |
|---|---|---|---|---|
| | | Mean ± SD | | |
| No. of false positives at CRT baseline | 2.15 ± 1.29 | 2.30 ± 1.39 | 2.00 ± 1.07 | 0.42 |
| No. of false positives at CRT post-intervention | 1.65 ± 1.23 | 1.16 ± .98 | 2.17 ± 1.28 | |
| Ratio SRT/CRT at baseline | 1.34 ± .14 | 1.31 ± .11 | 1.37 ± .16 | 0.12 |
| Ratio SRT/CRT post-intervention | 1.33 ± .14 | 1.36 ± .11 | 1.29 ± .16 | |

*Independent t-tests between groups at baseline; equality of variance tested and n/s in all tests

There was a significant effect of treatment condition on the change score of the Simple Reaction Task, $F(6,25)=14.96$, $p<0.01$. Further examination of the groups' means revealed that the intervention group had significantly slower reaction time post-intervention, compared to their baseline performance, $t(15)=-3.67$, $p<0.01$. There was no significant effect of treatment condition on the performance on the Complex Reaction Task, $F(6,25)=.24$, $p=0.62$ (Table 18).

When performance was calculated as a ratio between the simple reaction task and the complex reaction task, there was a significant effect of treatment condition on the ratio of performance, $F(6,25)=10.41$, $p<0.01$ (Figure 29). Follow-up comparisons for each group revealed a significant decrease in performance ratio time in the intervention group, $t(16)=-2.74$, $p=0.01$; whilst participants in the control group displayed an increase in their ratio performance time, $t(15)=-2.5$, $p=0.04$. There was no significant differences in ratio performance time at baseline, $F(1,38)=2.25$, $p=0.14$.

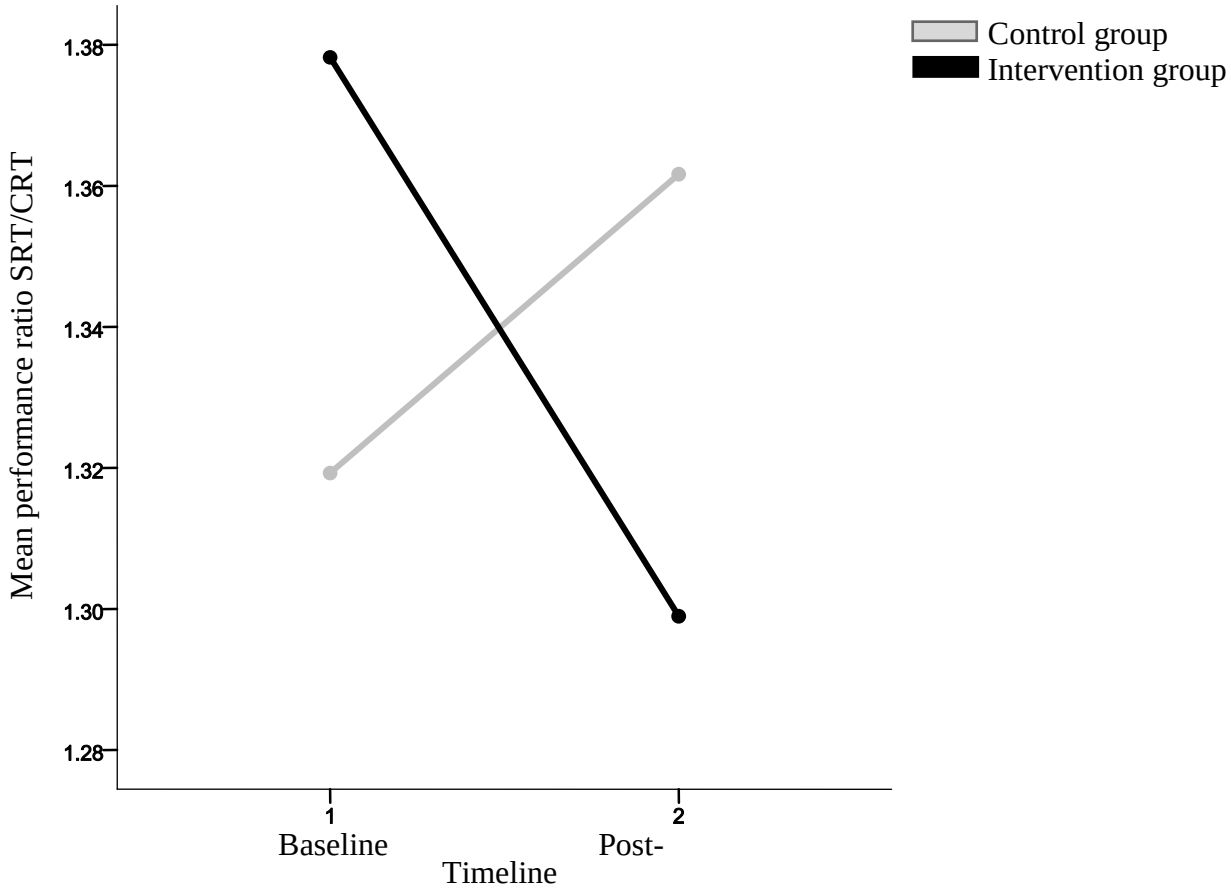


*Figure 29.* Mean performance ratio change between baseline and 6-month follow up in the two groups

### 4.3.11 Light exposure

Using data from wrist worn actiwatches, in ANCOVA models with change scores in average light exposure over 1000 lux as the dependent variable, and health, marital status, BMI, education, and baseline values of light exposure as covariates, there was no significant effect of treatment condition on this outcome at 3 months, or post-intervention: $F(6,28)=.08$, $p=0.77$; and $F(6,28)=.47$, $p=0.49$, respectively (Figure 30).

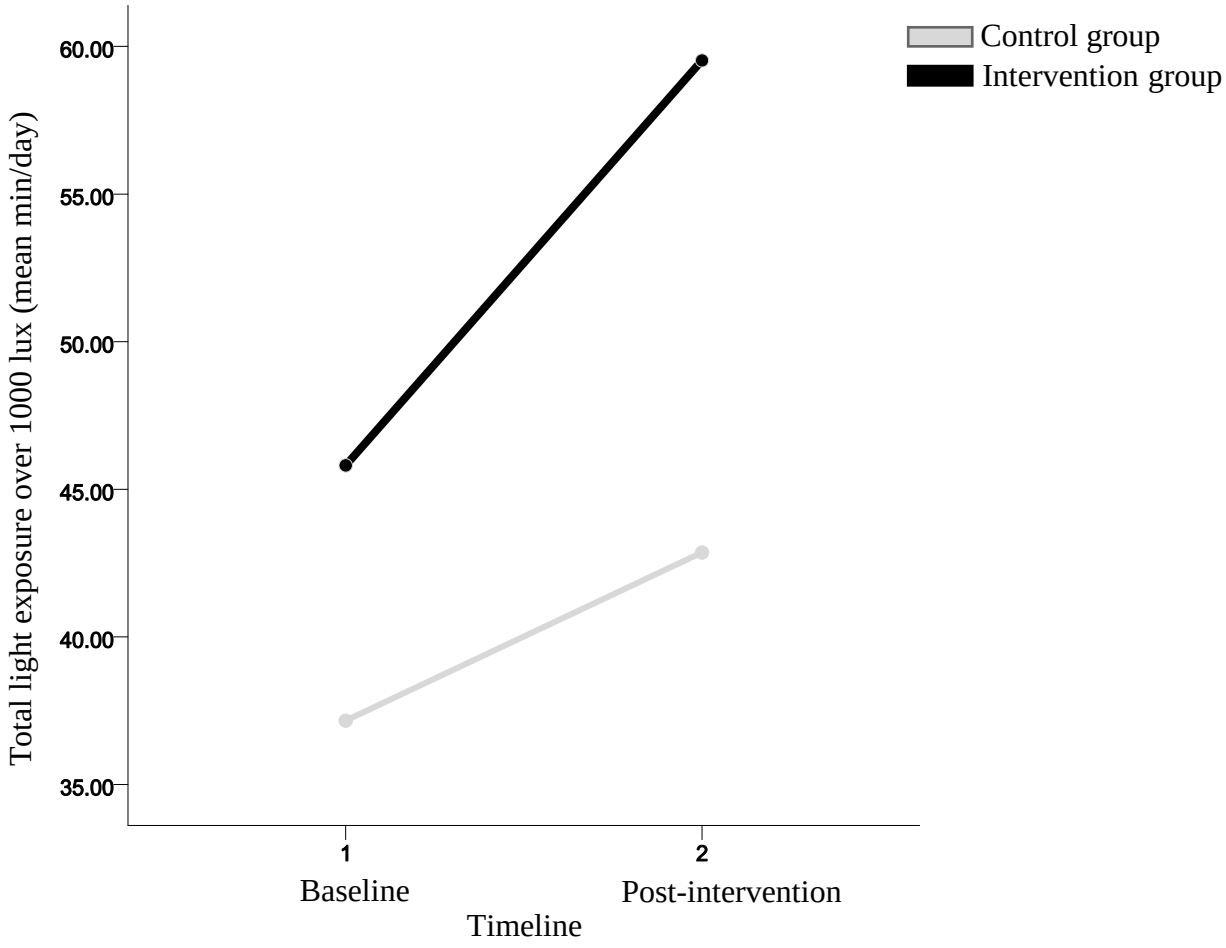


*Figure 30.* Mean light exposure (min/day) at baseline and post-intervention, in the physical activity and control groups

### 4.3.12 Relationship between insomnia severity index and daytime variables post-intervention

For those daytime variables hypothesised to change with the intervention, Pearson-product moment correlations analyses were conducted with the ISI score, for the intervention group. Higher Insomnia Severity Index scores were associated with larger Fatigue Severity Scale scores (r=.58, p=0.01, 2-tailed). Fatigue was also positively correlated with trait anxiety scores (r=.52, p=0.03, 2-tailed). When analysed as change scores (baseline – post-intervention), there was a significant positive association between changes in insomnia severity symptoms and changes in fatigue scores (r=.50, p=0.04, 2-tailed).

A series of stepwise linear regression models for the whole sample was employed, to find the best model predicting the change in ISI scores. The best predictors resulting in a significant model were group membership, depression scores and fatigue scores, $r^2$=.30, F(3,32)=4.48, p=0.01.

### 4.3.13 12-month follow up change

Analyses of self-reported data at the follow up period (12 months since baseline, and 6 months after the physical activity intervention had ceased) were conducted for sleep outcomes (Insomnia Severity Index and Pittsburgh Sleep Quality Index) and mood outcomes (Beck Depression Inventory and State-Trait Anxiety Inventory). Means and standard deviations of these variables are presented in Table 22.

Employing ANCOVA models with Insomnia Severity Index change scores from baseline to 12-month follow up as dependent variable, and covariates: marital status, education, body mass index, Health Index value, Beck Depression Inventory score, light exposure and baseline values of sleep severity index, there was a non-significant trend of improvement in insomnia severity symptoms by group membership, F(8,26)=3.24 , p= 0.08. Similarly, there was no effect of group membership on the change in PSQI score at 12-month follow up: F(8,26)=1.49, p=0.23.

In the self-reported measures of weekly physical activity levels, the intervention group reported a mean of 1796 MET-minutes per week, whilst the control group reported a mean of weekly MET-minutes of 1751 (p=0.07).

Table 22

*Means and standard deviations for self-reported sleep and mood variables at 12-month follow up*

| | All sample | Control | Intervention |
|---|---|---|---|
| | Mean ± SD | | |
| ISI[a] | 11.57 ± 5.40 | 13.06 ± 4.53 | 10.00 ± 5.93 |
| PSQI[b] | 8.71 ± 3.12 | 9.27 ± 2.69 | 8.11 ± 3.49 |
| BDI[c] | 10.28 ± 7.31 | 12.66 ± 7.80 | 7.76 ± 5.97 |
| STAI-S[d] | 33.80 ± 8.96 | 36.05 ± 10.15 | 31.41 ± 7.01 |
| STAI-T[e] | 38.62 ± 9.18 | 42.61 ± 9.03 | 34.41 ± 7.46 |

[a]ISI=Insomnia Severity Index; [b]PSQI=Pittsburgh Sleep Quality Index; [c]BDI=Beck Depression Inventory; [d]STAI-S=State-Trait Anxiety Inventory – State; [e]STAI-T=State-Trait Anxiety Inventory – Trait.

In ANCOVA models with Beck Depression Inventory change scores from baseline to 12-month follow up as dependent variable, and covariates: marital status, education, body mass index, Health Index value, light exposure and baseline values of Beck Depression Inventory score, there was a non-significant effect of group membership, $F(7,27)=2.38$, $p=0.13$. Similarly, there was no effect of group membership on the change in the state sub-scale of the STAI score at 12-month follow up: $F(7,27)=1.07$, $p=0.30$.

When employing the same models with the change in STAI-Trait sub-scale change scores, there was a significant effect of group membership on anxiety score change at 12 months: $F(7,27)=8.16$, $p<0.01$. Subsequent comparisons for each group revealed significant changes pre-post intervention in the intervention group, $T(16)=2.52$, $p=0.02$, but not in the control group, $t(17)=-.97$, $p=0.34$.

## 4.4 Summary

Activity assessments at baseline indicated an inactive sample, and did not differ between the intervention and control group. In addition, self-reported and objective sleep measures, as well as other health-related measures, did not differ at baseline either. At 6 months post baseline the intervention group engaged in 213 min/week of moderate intensity PA, compared to the control group (82 min/week). Following the physical activity treatment, the intervention group showed significant improvement in insomnia severity symptoms score at 6 months $F(1,28) = 5.16$, $p=0.03$), adjusted means difference = 3.37, with an adjusted Cohen's d =.78 (95% CI 0.10–1.45). There were also significant improvements in trait anxiety, and depression outcomes in the intervention group at 6 months, $F(6,28)=4.41$, $p=0.05$, and $F(6,28)=5.61$, $p=0.02$, respectively. These results demonstrate that increasing activity in line with current guidelines could deliver clinically significant improvements in sleep quality, and mood outcomes, among inactive adults with insomnia. These trial results, and the overall thesis conclusions, will be discussed in Chapter 5.

# CHAPTER 5

## 5.0 Discussion and conclusions

## 5.1 Discussion of RCT findings

Using a randomised controlled design, the present trial sought to determine whether a physical activity intervention to the level of the recommended guidelines would reduce the severity of night-time insomnia symptoms, and impact daytime functioning among a sample of physically inactive people aged 40 years or over meeting diagnostic criteria for insomnia.

The results broadly supported the research hypotheses. A 6-month period of increased physical activity (moderate intensity walking for at least 150 minutes per week), monitored objectively by actigraphy, was associated with: a reduction in the severity of insomnia symptoms, as measured by the Insomnia Severity Index (ISI); with a reduction in symptoms of depression and anxiety, as measured by the Beck Depression Inventory (BDI) and the State-Trait Anxiety Inventory (STAI); and with an improvement in daytime function, as measured by selected tests of psychomotor performance. These significant improvements in sleep, mood indicators and psychomotor performance associated with the physical activity intervention were independent of participants' health status, body mass index, marital status, education, light exposure, insomnia severity, mood and psychomotor performance measured at baseline. In interpreting the improvements resulting from the physical activity intervention, there was no confounding effect of increased exposure to light.

Insomnia severity symptoms, as measured by the ISI, showed a significant reduction from baseline to post intervention. The size of this effect (.78) was ‘large’, with the improvement in the intervention group representing an average 4-point reduction on the ISI scale. Over the 6 month period, the majority of participants in the intervention group (67%) reduced the severity of their symptoms by one sub-scale on the ISI. Changes in psychomotor performance were characterised by significant slowing on the simple reaction task among participants in the physical activity intervention group. The ratio of simple to complex reaction times also showed a significant reduction over time in the intervention group, but not in the control group.

In terms of lasting effects of the intervention, analyses of self-reported sleep and mood variables at 12 months (6 months after treatment cessation) showed a continuing trend in the reduction of severity of insomnia symptoms in the intervention group; and still a highly significant improvement in trait anxiety scores in the intervention group.

### 5.1.1 Validity of the findings

Given the known reliability and validity of the measures used, the rigorous procedures employed in sample selection, the power delivered by the sample size, and the relatively high adherence rates obtained at baseline, post intervention and follow up, the present trial offers a robust test of the hypothesis that physical activity at or above the level of the recommended guidelines can positively impact sleep outcomes, and associated daytime experiences in people with insomnia.

The selection of a participant sample typical of health seeking patients with insomnia symptoms is a particular strength of the present trial. All participants in the sample fulfilled the research diagnostic criteria for insomnia disorder[4]. There were no exclusions for present chronic conditions, save where such conditions interfered with informed consent (gross cognitive impairment), or created potential health risks as a result of increased physical activity (for example, uncontrolled heart problems). The mean duration of insomnia symptoms in the sample was 11 years (with a range of 1 year to 25 years).

In the present trial the majority of the sample was female, consistent with the higher prevalence of insomnia among women (Morin et al, 2006). Apart from insomnia, the mean number of existing chronic conditions in the sample was 1.02, with diabetes, arthritis, liver disease, renal disease and asthma among those conditions. These characteristics of the sample are also representative of the national pattern: in the UK almost half of those reporting chronic conditions have more than one such condition, and this rises to 70% in those aged 65 and over (Department of Health, 2012).

Similarly, 14% of participants were taking over the counter sleep aids, or prescribed sleep medication, with some taking medication for other chronic conditions, a proportion in line with other studies of insomnia in older sub-groups. In a nationally representative sample of people aged between 55- 64 years meeting DSV-IV criteria for insomnia, for example, Stewart et al (2006) found that 14.9% were taking anxiolytic or hypnotic medication.

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[4] These subsumed the DSM-IV-TR and ICSD-2 manual criteria, and comprised: predominant difficulties in initiating or maintaining sleep, or non-restorative sleep, whilst having adequate opportunity to sleep, for at least 6 months, accompanied by clinically significant distress and/or impairment in important areas of daily functioning. These criteria are compatible with the updated DSM-V (2013) manual, published after the start of the present research programme).

### 5.1.2 Adherence to the intervention and extent of behaviour change

The trial dropout rate was minimal (equal in both intervention and control groups, at 15%). This is less than the average dropout rate encountered in randomised controlled trials reported in major medical journals, of an average of 20% (Wood, White, & Thompson, 2004). Adherence to the requirements of the intervention was also high, with 95% of those in the intervention group achieving weekly MVPA of 150 minutes or more. Given that adherence rates in physical activity trials have been estimated at between 50% - 78% (Dishman, 2001; Martin & Sinden, 2001), the adherence rate of 95% in the present trial indicates the high quality methodology employed in delivering the intervention. The present trial used a combination of cognitive and behavioural strategies to ensure and enhance individual adherence: goal-setting, self-monitoring, feedback, and support. These strategies have been associated with effective physical activity interventions for health (King, Rejenski, & Buchner, 1998). Previous research has suggested that it takes around 6 months for physical activity change to be realised effectively (Bock, Marcus, Pinto, & Forsyth, 2001). Given this, the results from the present trial indicate that, in public health terms, the sustained behavioural change at 6-month post intervention was particularly remarkable. At the commencement of the trial, participants were habitually physically inactive, yet the intervention group continued to engage in an average of 213 minutes moderate intensity physical activity per week after 6 months, a finding suggestive of a robust lifestyle change.

### 5.1.3 Significance of findings as to the impact of intervention on insomnia symptoms

The baseline characteristics of the sample placed participants in the range of those with moderately severe insomnia symptoms, as scored on the ISI (the average score was 16). The change in sleep severity symptoms was evident at 3 months from the start of intervention, though the magnitude of change on the ISI reached statistical significance at 6 months. The average 4-point reduction in ISI scores found in the present study falls in the lower range of reported ISI outcomes for more specific insomnia interventions.

Lankford et al (2012), for example, report a significant 5-point reduction in ISI scores following 4 weeks of pharmacological treatment, while more recently Gellis, Arigo and Elliott (2013) reported a significant 4-point reduction in ISI scores following a cognitive behavioural intervention.

The clinical significance of changes in scores on the Insomnia Severity Index has been examined in further recent large randomised control trials. One such study examined the probabilities of people with insomnia experiencing significantly better health-related quality of life, increased productivity and reduced fatigue, after a six month pharmaceutical intervention. The study identified that a reduction of 6 points on the ISI was associated with these clinically significant indicators (Yang et al, 2009).

Another such study examined significance of changes in scores on the ISI following intervention with CBT-I, either alone or combined with medication, in people with insomnia (Morin et al, 2011). The clinical meaningful change was determined through global improvement ratings by an independent clinical assessor, who marked those changes as slight, moderate and markedly improved. The authors found that a moderate clinical change was associated with a reduction in ISI scores of 8 points. The reduction in ISI scores by on average 4 points following the physical activity intervention in the present trial corresponds to slight clinical improvement, according to Morin et al's (2011) method.

To put these results in context, the size of effects of interventions can reflect such factors as the characteristics of the sample; the methods of intervention, and the setting of the intervention (Rothwell, 2005). It is important to note that Yang et al (2009) and Morin et al (2011) both used homogeneous clinical samples. They excluded co-morbid chronic diseases, as well as present use of sleeping medication. While such sampling procedures can improve the interpretability of explanatory trials, they also serve to reduce external validity, in that the sample characteristics depart from the heterogeneous insomnia populations routinely found in the community, or in primary care. It is reasonable to conclude, therefore, that in relations to insomnia severity, the present study delivered modest, but clinically significant changes.

### 5.1.4 Changes in psychomotor performance

Trial condition was associated with an interesting pattern of results for psychomotor performance, with those in the intervention group showing a significant post-treatment decrease in simple reaction time, and a reduced ratio of performance between simple and complex reaction tasks when compared with the control group (indicative of a reduced magnitude of difference between simple and complex RT). These results are similar to those reported by Altena et al (2008) who administered the same psychomotor tests to a sample of people with insomnia who then underwent various combined insomnia therapies (CBT, bright light exposure, body temperature manipulation, and physical activity) over a 6 week intervention period.

One possible explanation for the present findings is that a perceived improvement in sleep quality led to a change in task performance strategy post intervention, whereby people feeling more rested took more time to respond to stimuli, in order to increase their precision. If that were the case, those in the intervention group should have recorded significantly fewer lapses (errors) post-treatment. However, the results of the present trial showed no significant difference in lapses pre- and post-treatment. Thus, the changes in performance appear to be independent of any perceived improvement in sleep quality by participants.

An alternative explanation concerns the state of cognitive arousal, a key proposed mechanism in perpetuating insomnia (Harvey, 2002). Espie, Broomfield, MacMahon, Macphee, and Taylor (2006) provide a comprehensive cognitive explanation which builds on the Harvey's (2002) model: the attention-intention-effort (A-I-E) pathway. According to the A-I-E pathway model sleep onset is initially delayed by the automatic processes of hyperarousal selective attention to sleep-related stimuli. When an extended sleep latency is experienced as a consequence, the individual explicitly 'intends' to fall sleep, and deploys a conscious (and counterproductive) 'sleep effort'. Thus, people with insomnia show evidence of both hyperarousal (Harvey, 2002) and an attentional bias towards processing sleep-related, threatening stimuli (Harvey, 2002; Espie et al, 2006). Support for this theory comes from research in other areas of pathological behaviour, such as anxiety-related disorders. People with specific phobias, for example, selectively attend to threat-related stimuli in the environment with a thematic specificity to their disorder (Williams, Watts, MacLeod, & Mathews, 1997).

Levels of performance adopt a U-shaped function in relation to arousal, with hyperarousal often associated with faster reaction times. Given this, a further possibility is that reaction times increased because the exercise intervention reduced levels of hyperarousal arousal in the treated group. The research literature of other conditions in which hyperarousal is a central feature, such as generalised anxiety disorders and Post-Traumatic Stress Disorder, shows that physical activity reduces symptoms commonly associated with hyperarousal (Stathopoulou, Powers, Berry, Smits, & Otto, 2006). The present results are therefore consistent with the hypothesis that the physical activity intervention contributed to the restoration of effective attention regulation mechanisms, resulting in reduced arousal and improved sleep.

While the presents results for simple RT accord with those reported by Altena et al (2008), they differ in that Altena also found a post-treatment improvement for complex RT. That the present study showed no differences in complex RT may be attributable, at least in part, to methodology. Unlike previous studies (e.g. Altena et al, 2008) where testing is conducted under laboratory conditions, in the present study all the psychomotor tests were administered in the participant's own home. While it has been argued that the laboratory environment may lack ecologically validity and, as a result, mask real deficits apparent when cognitive, behavioural and environmental factors interact (Shekleton et al, 2010), it is also the case that less controlled conditions may compromise the sensitivity of the test. It is possible, therefore, that when administered in such an environment, any improvement in a complex reaction task time might have been undetectable.

A final possibility is that the complex reaction time task used may have been too simple to elicit deficits in higher cognitive processes in this heterogeneous sample of people with insomnia (the task required differentiating between letters 'p' and 'd'). Recent reviews of cognitive deficits in people with insomnia suggest that more complex tests may be needed to clearly elicit these impairments in various samples of people with insomnia (Fortier-Brochu et al, 2012). Significant impairment in people with insomnia, for example, is more apparent with tests of working and episodic memory, and problem-solving (Fortier-Brochu, 2012). These impairments better correspond to complaints of daytime performance from people with insomnia: poor concentration, memory difficulties, and inability to maintain attention on tasks (Ohayon & Lemoine, 2004).

### 5.1.5 Changes in mood

The finding that the present physical activity intervention was associated with significant post-intervention reductions in depression and anxiety (as reflected in BDI and STAI scores) is consistent with both the physical activity, and the emerging physical activity and sleep literature. In a systematic review of five RCTs, Stanton & Reaburn (2013) concluded that moderate intensity aerobic activities, continued for at least 9 weeks, can be effective in the treatment of depression. Exercise also acts as a buffer against emotional stressors' negative responses in people who have suffered with depression in the past (Mata, Hogan, Joormann, Waugh, & Gotlib, 2013). Using the CES-D short self-report scale of Radloff (1977), a recent sleep trial (Reid et al, 2010), showed significant reductions in depressive symptoms among sedentary adults with chronic insomnia following a 16 week programme of aerobic activity (although this study lacked sufficient power to demonstrate mood outcomes in its main analyses).

In both activity and sleep studies, effects seem to be dependent on the level of depression present in participants pre-treatment. In studies of the impact of activity on mood, for example, those in the moderate to severe range appear to receive the greatest gain from physical activity interventions (Steffens, 2013). Similarly, Irwin et al's (2008) study of a Tai Chi intervention for insomnia found no change in post-treatment depression scores, but recorded only minimal baseline scores of depression at baseline (the mean baseline BDI score was 4). In contrast, the baseline mean score on BDI of the sample in the present trial was 12, introducing the possibility that the baseline scores in Irwin et al's (2008) sample were such as to have left very little room for improvement.

It is particularly interesting that post-treatment changes in anxiety in the present study were found in the trait anxiety measures, as opposed to state anxiety measures. Trait anxiety is conceptualised as a relatively stable characteristic of an individual (Spielberger et al, 1983). State anxiety, on the other hand, reflects a transitory emotional state that is characterised by subjective, consciously perceived feelings of tension and apprehension, and by heightened autonomic nervous system activity; this may fluctuate and can vary in intensity (Spielberger et al, 1983). Whilst state anxiety generally correlates with trait anxiety, state anxiety is also dependent on situational factors (Endler & Kocovski, 2001). A large number of sleep-related variables could affect an individual's state score at any one time, such as caffeine (Alsene, Deckert, Sand, de Wit, 2003), light exposure (Youngstedt & Kripke, 2007), or circadian timing (Monteleone & Maj, 2008). Nevertheless, changes in trait anxiety are not uncommon.

Only 30-50% of variability in vulnerability to anxiety disorders can be explained by genetic factors, the remainder being attributed to complex environmental and genetic interactions, which are susceptible to change (Clément, Calatayud, & Belzung, 2002). Many forms of behavioural intervention result in a reduction in trait anxiety scores (Jorm, 1989; Manzoni, Pagnini, Castelnuovo, & Molinari, 2008). Physical activity interventions have previously shown a significant effect on trait anxiety when the period of the activity programme is longer than 10 weeks in duration (Petruzzello, Landers, Hatfield, Kubitz, & Salazar, 1991). Indeed, measurements of the effect of such interventions show a larger effect on trait anxiety than on state anxiety (Herring, O'Connor, & Dishman, 2010), as was also found in the present study.

Different mechanisms have been hypothesised as to how depression and anxiety might be affected by increased physical activity. At a physiological level, a number of neurochemical changes occur as a direct result of physical activity which confers neuroprotective and neurotorphic effects (Seifert et al, 2010; Knaepen, Goekint, Heyman, & Meeusen, 2010). Increased physical activity may downregulate the physiological inflammatory response system and increase resilience to stress (Kohut et al, 2006; Starkweather, 2007). Psychological mediational hypotheses include changes in self-efficacy, and the interruption of negative thoughts. These particular mechanisms have resonance in cognitive mechanisms by which insomnia may act (Harvey, 2002; Espie et al, 2006).

### *Self-efficacy*

Self-efficacy has been defined as self-belief in one's abilities to succeed in dealing with prospective situations, and a determinant of how people think, feel and act (Bandura, 1977). A sub-construct of self-efficacy is coping efficacy, which reflects the confidence of a person to perform a task, despite challenges in doing so (Bandura, 1977). People with depression and anxiety often feel inefficacious in dealing with challenges or stress (Sawatzki et al, 2012). Similarly, people with insomnia describe an inability to concentrate, and feelings of fatigue during the day (Ohayon, 2002) and, as a clinical group, show significantly higher levels of depression and anxiety when compared to healthy controls (Taylor et al, 2007).

Craft and Perna (2004) hypothesised that engaging in a physical activity program may provide participants with a meaningful mastery experience necessary to improve perceived ability to cope with depression and stress, and thereby, improve mood. In her quasi-experimental study, Craft (2005) found that women who exercised had significantly lower depression scores, and significantly higher coping self-efficacy, compared to the control group in the study. Significantly higher coping ability and decreased anxiety has also been observed in a randomised controlled trial of physical activity program in anxious inactive participants (Steptoe, Edwards, Moses, & Mathews, 1989).

Using a similar design, Bodin and Martinsen (2004) found that a session of exercise targeting self-efficacy (45 minutes of martial arts) induced significantly greater improvements in positive affect and anxiety compared to exercise that did not target self-efficacy (45 min of stationary bike exercise).

In the present trial, the physical activity intervention (moderately brisk walking) was not designed to target self-efficacy as was the case in Craft's (2005) study. Yet it still required motivation, planning and investment of time from the participants. Whilst self-efficacy was not a variable measured in this study, the hypothesis described above is compatible with the notable improvement in depression scores found.

***Distraction***

An alternative psychological mechanism which might explain the relationship between physical activity and mood is the distraction hypothesis, proposed by Barkhe and Morgan (1978). The hypothesis postulates that physical activity may provide a distraction from accessing, or reduces the perceived intensity of, ruminations, worries and anxieties.

Craft's (2005) study found that exercise was associated with a decrease in rumination throughout the intervention, and greater use of distraction techniques early in the intervention period. Similar distraction techniques, only of cognitive nature, are successfully used as therapeutic strategies in cognitive behavioural therapy for insomnia (Harvey & Payne, 2002).

Harvey (2002) described how people with insomnia constantly monitor the internal and external environment for sleep-related daytime consequences, a key mechanism identified in perpetuating insomnia symptoms (Neitzert Semler & Harvey, 2007). Physical activity may break the vicious cycle of negatively toned daytime cognitive activity, by providing a targeted distraction which may limit accessibility to such thoughts.

***Anxiety sensitivity***

An additional psychological mechanism, which might break constant monitoring and rumination which people with insomnia often experience, is anxiety sensitivity reconditioning. Anxiety sensitivity comprises of the belief that anxiety experiences have negative implications, and at behavioural level of a dispositional tendency to respond fearfully to anxiety-related bodily sensations (Reiss, Peterson, Gursky, & McNally, 1986). Anxiety sensitivity has received a lot of attention in the anxiety literature (for a review, see Naragon-Gainey, 2010). A recent study investigating anxiety sensitivity in people with insomnia found this variable moderated the relationship between insomnia severity and dysfunctional beliefs, and insomnia severity and daytime fatigue (Fairholme, Carl, Farchione, & Schonwetter, 2012). Findings from the anxiety literature suggest that physical exercise programs can result in significant changes in anxiety sensitivity (Broman-Fulks, Berman, Rabian, & Webster, 2004; Smits, Otto, Powers, & Utschig, 2005).

Physical activity intervention can be conceptualized as an interoceptive (internal sensation) exposure procedure, as it provides repeated confrontation with feared bodily sensations (e.g., racing heart, physical fatigue), but, crucially, in the absence of anticipated negative consequences (Stathopoulou et al, 2006). Thus, interoceptive exposure through physical activity may be beneficial in reducing insomnia severity symptoms, at least in those people with insomnia and high anxiety.

***Additional clinical effectiveness***

Physical activity may also act as an adjuvant to other therapies for depression and anxiety. In an augmentation study of participants partially respondent to anti-depressive medication, compared with a health education control group, moderate intensity physical activity (Tai Chi) was associated with greater reductions in depressive symptoms and decreased depression remission after 10 weeks (Lavretsky et al, 2011). Another study looking at the efficacy of physical activity as an adjutant to pharmacological treatment for depression found similar positive results (Mather et al, 2002), shown to extend long-term (Hoffman et al, 2011).

### 5.1.6 Daytime fatigue and sleepiness

***Fatigue*** In the present trial, post-treatment comparisons of fatigue and daytime sleepiness scores showed no significant differences between groups. Nevertheless, additional analyses provided several lines of evidence indicating that changes in sleep quality may have positively impacted fatigue experiences. First, insomnia severity changes were positively and significantly correlated with change scores in Fatigue Severity Scale. Second, multiple regression analyses showed that the physical activity intervention, depression scores and fatigue scores were the best combined variables to predict significant changes in the severity of insomnia symptoms. And third, analyses of PSQI component scores showed a significant improvement on the daytime dysfunction sub-scale following physical activity intervention. This component contains two items: one addressing daytime sleepiness, and the other addressing stamina and enthusiasm through the day. It is interesting, therefore, that this pattern of results, indicative of significant change in daytime experience related to insomnia symptom severity, was not captured by the specific fatigue (FSS) measure employed.

As sleep is usually an effective remedy for fatigue in the healthy population (Aaronson, Pallikkathayil, & Crighton, 2003), it is often assumed that the cause of fatigue lies in the disturbed sleep pattern of people with insomnia, with some cross-sectional studies supporting such a relationship (e.g. Alapin et al, 2000). However, a more detailed consideration of both the fatigue construct, and the assumptions underlying its measurement, can provide insights into the apparent inconsistencies found in the present study. The FSS, for example, was developed to identify common features of fatigue in people with multiple sclerosis and systemic lupus erythematosus (Krupp et al, 1989). The scale measures the impact of fatigue on specific types of functioning, i.e. the behavioural consequences of fatigue, rather than intensity of fatigue symptoms (Taylor, Jason, & Torres, 2000). All but one of the nine items measure physical aspects of fatigue. More recent evidence shows that FSS is not a reliable instrument for measuring cognitive levels of fatigue (Amtmann et al., 2012).

People with insomnia describe difficulties with cognitive, emotional and physical functioning during the day (Kyle, Espie, & Morgan, 2010). And while a central complaint in people with insomnia is 'daytime fatigue' (Carey, Moul, Pilkonis, Germain, & Buysse, 2005), analyses show that people with chronic illness in which fatigue forms a central part of the symptomology describe their present fatigue as qualitatively different from the fatigue they experienced before they became sick (Glause, Crow, & Hammond, 1996). More in-depth analyses of sleep, fatigue and other daytime functioning indicators in people with insomnia also suggest that poorer sleep, as objectively measured by polysomnography, is not systematically associated with more severe fatigue; there are complex interactions between fatigue, subjectively-reported sleep quality, health related quality of life and mood variables (Fortier-Brochu et al, 2012). Collectively, these results indicate that in people with insomnia, disturbed sleep duration and continuity may not be the only pathways leading to high levels of fatigue, and that sleep and fatigue can vary independently. As a result, some daytime experiences of people with insomnia may be best captured by a multidimensional approach, enquiring into the physical, cognitive and emotional domains (Dittner, Wessely, & Brown, 2004).

***Sleepiness*** Daytime sleepiness is one of the criteria (relating to daytime impairments) used for the diagnosis of insomnia in the DSM-5 (APA, 2013) manual and the ICSD-2 (AASM, 2005) manual. Despite this, people with insomnia rarely complain of daytime sleepiness, their complaints relating more to fatigue and exhaustion (Singareddy, Bixler, & Vgontzas, 2010). In the present study, the sample's mean daytime sleepiness scale score was relatively low and stable throughout the trial, with a mean around 6 on Epworth Sleepiness Scale. The mean in the general population without chronic sleep disorder is around 5, and the 'normal' range of sleepiness in the general population has been validated in trials to be from 0 to 10 on the scale (Johns & Hocking, 1997).

Reid et al (2010), in their trial of physical activity and sleep in people with insomnia, found a significant improvement in daytime sleepiness, as measured by the Epworth Sleepiness Scale, in their sample. In Reid et al's study, the baselines values were higher than in the present trial's sample (with a mean of around 10 on the scale). It is a reasonable assumption, therefore, that opportunities for improvement in the present sample were reduced due to ceiling effects (i.e. there was little room for significant improvement).

### 5.1.7 Activity-related sleep outcomes and light exposure

No earlier study of the effects of a physical activity intervention on sleep outcomes has tested, or controlled for increased exposure to light potentially arising from increased time spent outdoors. One of the strengths of the present trial, therefore, is its measurement of, and analysis of the effect of light exposure when interpreting the results of the intervention. While light exposure values did increase within the intervention group (see Figure 30, p137), this increase did not reach statistical significance, and did not significantly contribute to the relationship between physical activity and sleep outcomes in this sample. Furthermore, analyses of the moderating effects of season showed no difference, when looking at all participants spread throughout the year. Thus, in interpreting the improvements resulting from the intervention, there appears to have been no confounding effect of increased light exposure.

Nevertheless, several factors should be considered when interpreting these findings. It is not known, for example, at what point in the day or night participants took their exercise, as these measures were not recorded in the trial. It is also the case that light exposure might only (or mainly) affect those groups of people whose insomnia was related to circadian dysfunction. This has been shown before in people with non-seasonal depression treated with light exposure (Even, Schröder, Friedman, & Rouillon, 2008). The authors of this extensive meta-analytical review on that subject hypothesised that only a defined group of people with depression, whose characteristics relate to circadian dysfunction, would be responsive to light treatment. Given the multi-factorial nature of insomnia, it is possible the same processes apply to insomnia disorders.

It is also possible that the objective means by which light was recorded in this study may not have adequately captured actual light exposure. Illumination was recorded through a light sensor on the actiwatch participants wore at the wrist. Illuminations at eye level and at the wrist are correlated generally at around the 0.76 level (Okudaira, Kripke, & Webster, 1983). The instructions for the participants specified that the actiwatch should be worn on top of clothing i.e. participants to avoid the placement of actiwatches under sleeves. Even so, it cannot be determined whether the device was worn on top or underneath clothing. If the device is worn under clothing, it can underestimate the intensity of light exposure (Figueiro, Hamner, Higgins, Hornick, & Rea, 2012). This may have introduced an unsystematic error into the light exposure data.

### 5.1.8 Changes in sleep quality and sleep quantity

As recommended in international guidelines, a combination of self-report and objective measures (including actigraphy) was used in the design of the present trial (Buysse et al, 2006). The use of multiple methods of assessment maximised the possibility of recording changes of small or moderate magnitude in a sample of those with moderately severe symptoms of chronic insomnia, over the period of the trial.

***Sleep quality*** As measured by the Pittsburgh Sleep Quality Index (PSQI), the baseline sample characteristics of the sample placed the participants in the range of those with ‘clinically disturbed sleep’, with an average global score of 10.33. In contrast to the significant changes in the scores recorded on the ISI, there was no statistically significant change in global scores on the PSQI following the physical activity intervention (with a mean reduction of 2.4 points post-intervention). Earlier randomised controlled studies of physical activity and sleep quality have found statistically significant mean reductions in average PSQI scores post intervention of 1.8 points (Irwin et al, 2008), 3.4 points (King et al, 2008), and 4.8 points (Reid et al, 2010).

A recent systematic review of physical activity interventions in adults with sleeping problems noted a moderate effect of the PA intervention, when measures by the PSQI (Yang et al, 2012). However, none of these earlier studies also used the ISI as an outcome measure.

In explaining the apparent differential sensitivity of PSQI scores to activity interventions it is relevant to note that the samples used in the earlier studies were also differently selected, and of different characteristics, as compared to the present sample. Irwin et al (2008) excluded from their sample people with syndromal insomnia, and only included participants with mild, or moderate sleep complaints. (In addition, their analyses looked at group differences over time between multiple groups, so the changes which they reported may reflect type I error). King et al (1997) included in their sample participants with mild to moderate sleep complaints. Both samples may have captured a few people with insomnia; if so, it is not clear, as the researchers did not employ sufficiently precise selection criteria in their samples. It is possible, then, that those with only mild sleep disturbance, or a sleep disturbance of simple causation, may be more responsive to physical activity interventions. Finally, while Reid et al (2010) used a sample comprising people with thoroughly assessed chronic insomnia, they also augmented their activity intervention with a programme of 'sleep hygiene therapy', which may have amplified treatment effects. Studies looking exclusively at the effects of sleep hygiene education on sleep quality have found significant changes in sleep quality following therapy (Hauri, 1993), and an incremental effect of sleep hygiene when used in conjunction with other sleep therapies (Guilleminault et al, 1995).

The PSQI and ISI scales also show structural differences which help to explain differential sensitivity. For the measurement of self-perceived severity of insomnia, the ISI is the most frequently used disease specific instrument (Morin & Espie, 2003). The seven items on the scale each describe insomnia-related health impairments. The content of the items on the scale yield 3 components: impact, severity and satisfaction. These map onto the DSM-IV-TR criteria for primary insomnia (Bastien et al, 2001). In contrast, the PSQI provides an assessment tool for diverse self-reported sleep disorders (Buysse et al, 1989). The 19 items on the scale assess a broad range of sleep-related domains. These domains include sleep-wake patterns; sleep duration and latency; the frequency of specific sleep problems; other specific behaviours or environmental factors which may contribute to poor sleep (snoring, urinary frequency, temperature change etc). The scale yields a global score, and 7 component scores. Global scores below and above 5 have the main dichotomous application of discriminating between poor and good sleepers.

Due to its wide remit of enquiry, and dichotomous application of its global score, it may be that the global PSQI score does not adequately capture small changes to treatment. This is particularly likely if the change is confined to discrete questions within its many dimensions.

The retrospective nature of the PSQI (over the last 1 month) may also be less sensitive to differences in sleep averaged over such large portions of time, and participants may be weighing up the worst nights over the last 1 month when forming global sleep impressions. The instructions specifically ask for 'usual' sleep patterns, which may not cater for the variability in sleep pattern encountered by the majority of people with insomnia. Anecdotally, several participants in the present study reported difficulties with summing up their sleep pattern over the last month. The ISI, on the other hand, has a recall period of two weeks, and places emphasis on the 'current' perceived insomnia-related impairment.

***Changes in sleep structures*** Wrist actigraphy showed baseline sleep characteristics of the trial participants typical of people with insomnia, with long sleep onset latencies, and long periods of wake after sleep onset. The sample had an average of 78% sleep efficiency. Following the physical activity intervention, there were no significant changes in sleep outcomes as measured by actigraphy. Reid et al (2010) used actigraphy to screen participants at baseline, but did not report actigraphic sleep outcomes following the physical activity intervention.

However, an earlier systematic review of clinical trials of psychological and behavioural treatments for insomnia found that in most trials, actigraphy was insensitive to change following intervention (Morin et al, 2006b). In contrast, polysomnography and self-reporting questionnaires and diaries recorded significant changes following intervention (Morin et al, 2006b). These differences in outcomes probably reflect fundamental differences in the sensitivity and specificity of the two instrumental measures. Studies comparing actigraphy to polysomnography, for example, show that actigraphy tends to underestimate periods of wake time during the night, scoring as 'sleep' those periods when people with insomnia may lie awake but still in bed (Ancoli-Israel et al, 2003; Brooks, Friedman, Bliwise, & Yesavage, 1993). Such studies also show that actigraphy overestimates total sleep time (Hauri & Wisbey, 1992).

Recently, Baron, Reid and Zee (2012) monitored sleep through actigraphy in a group of 11 women with insomnia, and found significant changes in total sleep time as well as in sleep efficiency after 16 weeks of physical activity intervention. That study was not controlled, and the small number of participants precludes firm conclusions as to the ability of actigraphy to capture activity-related changes in sleep structure.

Given that: changes recorded in subjective sleep quality in the present study were modest; actigraphy frequently fails to capture improved sleep quality in clinical trials; and it is also possible that over the 6 month period of the study, changes in subjective sleep quality did not significantly alter underlying sleep structure, the present actigraphy results are not inconsistent with reasonable expectations.

### 5.1.9 Limitations

Whilst successful in answering the hypotheses posed, there are some limitations to the present trial to consider when interpreting these results. The number of participants in the trial was small, which did not allow for more complex analyses of trends of change in insomnia symptoms over the course of the trial, or interaction effects which could have revealed the mechanisms responsible for the change in the main outcome. Further larger trials should be set up to test these additional hypotheses separately. The inclusion criteria test of inactivity was self-reported (less than 60 minutes of moderate intensity activity a week), introducing the possibility of participants over-reporting their physical activity levels, and therefore becoming ineligible for entering the study. Objectively-measured physical activity levels at recruitment stage could maximise the number of participants allowed on the study.

The present trial employed an intervention testing the transition from inactivity, to activity levels to the current guidelines, as this was the state of physical activity in the majority of the adult population. Current evidence indicates that the most significant effects of physical activity on health outcomes is achieved by transitioning from no activity, to activity to the current recommended guidelines. Current evidence also indicates a dose-response relationship between physical activity and health outcomes, with increased doses of physical activity accompanied by increased significant improvements in health outcomes. The present trial did not test for additional higher thresholds of increased activity, to test whether there would be accompanying increased benefits in sleep quality outcomes. It is also not known what the effects on sleep quality would be if existing levels of physical activity in adults already meeting the current guidelines would be increased even further. Future trials should help elucidate the physical activity and sleep quality dose response relationship.

## 5.2 Conclusions: explaining the present results

The literature identifies three plausible mechanisms through which physical activity may impact sleep structure and quality.

1. Physical activity acts upon cognitive processes known to be involved in the normal sleep, such as the effective regulation of attention. Both the internal circadian clock, and the sleep/wake homeostasis can be influenced by conscious decisions and increased levels of vigilance. These may be altered due to the vigilance-induced hyperarousal and/or accompanying altered light exposure. The attention-intention-effort pathway (Espie et al, 2006) attributes the disruption of the automatic process of sleep to dysfunctions of normal attention. This is accompanied by physiological arousal which may interfere with the circadian clock self-regulation, and synchronization with the normal time pattern. There is emerging new evidence pointing to the role of physical fitness and regular physical activity in the maintenance and recovery of cognitive function, by reducing atrophy in critical brain regions (Weinstein et al, 2012). Physical activity may therefore contribute to restoration of effective attention regulation mechanisms, resulting in improved sleep.

2. Physical activity may also act upon sleep quality through alleviating symptoms of depression and anxiety (Youngstedt, 2005). There are numerous studies showing that physical activity has beneficial effects on symptoms of depression and anxiety (Strohle, 2009). There is a strong, bi-directional relationship between depression/anxiety and insomnia; depressed mood and anxiety is associated with risk of developing insomnia (Johnson, Roth, & Breslau, 2006); non-depressed people with insomnia have a two-fold increase in risk of developing depression, compared with people with no sleeping difficulties (Baglioni et al, 2011).
   The study by Reid et al (2010), looking at the effects of physical activity and sleep hygiene on people with insomnia, found that sleep quality improvement was associated with significant improvement in depressive symptoms. Therefore, it is possible that physical activity may improve sleep quality of people with insomnia through improved mood.

3. Finally, physical exercise may influence sleep quality by better entraining the circadian rhythm to the wake/sleep schedule (Van Someren & Van der Lek, 2007). Under natural environments, the internal body clock is synchronized to the geophysical day/night cycle by environmental time cues (Zeitgebers). The most powerful zeitgeber for our bodies is the pattern of light exposure over 24 hours. Indeed, light therapy, which consists of regular light exposure at certain times in the 24 hour period, significantly improves sleep quality in people with insomnia (Guilleminault et al, 1995). Other social zeitgebers are meal times, activity patterns, work schedule etc. When habitual time pattern is disrupted, such as when we travel through time zones, these zeitgebers act upon the body clock to bring it back into synchronization with the new time pattern. Physical activity is one such zeitgeber, shown to have influence upon the entrainment of the circadian rhythm to the environmental time pattern (Youngstedt et al, 2002). Presuming that insomnia results from a disruption in the circadian rhythm, physical activity could contribute to the restoring of sleep quality by entraining the body to the desired sleep/wake schedule.

Results from the present randomised controlled trial are consistent with the view that the physical activity intervention likely improved sleep quality through the restoration of effective attention regulation mechanisms, and through improvements in mood. The evidence from the trial does not support the view that improvements in sleep quality (as measured here) were due to light-dependent improvements in circadian entrainment.

# GENERAL CONCLUSIONS

Large population studies have consistently found that moderate intensity physical activity levels at or above a threshold value of 150 minutes per week reliably deliver cardiovascular, metabolic, psychological and musculo-skeletal health benefits. This threshold value has been widely adopted in public health practice and research as an aspirational, public health goal throughout the world. However, while epidemiological and laboratory studies had established clear links between physical activity and sleep outcomes, the evidence base did not provide guidelines on minimum levels of exercise likely to reduce insomnia symptoms and improve sleep quality. Such guidelines, if evidence based, could have greatly clarified advice, and accelerated the use of physical activity goals to improve sleep outcomes in behavioural sleep medicine and public health.

This thesis examined the current public-health recommendation of 150 minutes of moderate intensity activity per week in relation to sleep outcomes. First, it established a population-level pattern describing the relationship between levels of physical activity and sleep quality by reviewing relevant epidemiological evidence. Exploratory analyses were then conducted using data from a longitudinal study of physical activity and health outcomes among older people (age = 65+), the Nottingham Longitudinal Study of Active Ageing (NLSAA). Respondents in the study were classified as walking at or above, or below the recommended threshold of 150 minutes per week. In regression models controlling for health and demographic factors, these analyses showed that higher levels of walking were significantly and independently associated with a lower likelihood of either reporting insomnia symptoms (OR = 0.67 (95% CI = 0.45 – 0.91) $p<0.05$), or experiencing poor sleep efficiency (OR = 0.70 (95% CI = 0.52 – 0.94 $p<0.05$). Using the same data, the predictive validity of this activity threshold was then confirmed in a 27-year survival analysis. The analysis showed a significantly decreased all-cause mortality risk associated with the higher level of walking (HR = 0.75 (95% CI = 0.65 - 0.86) $p<0.01$). These findings offered ‘proof of concept’ that physical activity and sleep relationships operate on a continuum, with sleep benefits evident at relatively low levels of activity.

Experimental evidence on the acute and sustained effects of physical activity on sleep quality were then analysed and discussed. Outcomes from the review of evidence, together with the NLSAA preliminary analyses, were then used to inform the design of a randomised controlled trial to investigate the effects on sleep quality of increasing physical activity to currently recommended levels among sedentary people with insomnia. A total of 41 sedentary adults meeting DSM-IV criteria for insomnia (30 female; mean age 59.8±9.5) were randomised to a physical activity group (≥150 minutes moderate intensity activity/week) or a waiting list control group. The principal outcome was Insomnia Severity Index (ISI) change 6 months post baseline; secondary outcomes were anxiety (using the State Trait Anxiety Inventory; Spielberger et al, 1983) and depression (Beck Depression Inventory II; Beck et al, 1996). Sleep and physical activity were objectively measured. Outcomes were assessed in univariate general linear models, adjusted for baseline confounders.

Results of the RCT showed that activity and sleep assessments did not differ at baseline. At 6 months post baseline the intervention group engaged in 213 min/week of moderate intensity PA, compared to the control group (82 min/week). Compared to the control group, the intervention group showed significant improvement in the ISI score at 6 months $F(1,28) = 5.16$, $p<0.05$), adjusted means difference = 3.37, with an adjusted Cohen's d =.78 (95% CI .10–1.45). There was a significant improvement in trait anxiety, and depression outcomes post-intervention, $F(6,28)=4.41$, $p=0.05$, and $F(6,28)=5.61$, $p=0.02$, respectively. The results showed that increasing activity in line with current guidelines could deliver clinically significant improvements in sleep quality and mood outcomes among sedentary people with insomnia, independent of possible confounders.

The pattern of results reported here allow for two conclusions with clear implications for public health: 1) measures to increase levels of physical activity above the currently recommended threshold of 150 minutes per week could usefully be added to the other tools available for insomnia management; and 2) the likelihood of improved sleep quality should be routinely added to those evidence-based cardiovascular and metabolic benefits most frequently associated with increased physical activity in behaviour change initiatives.

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# LIST OF APPENDICES

**Sear strategy: Key words**

| **SLEEP** | **PHYSICAL ACTIVITY** |
|---|---|
| Insomnia* | Exercise |
| Sleep* disorder* | Physical Activity |
| Sleep* problem* | Recreational activity |
| Sleep* pattern* | Occupational activity |
| Sleep* disturbance* | Walking |
| Sleep initiation | Personal maintenance |
| Sleep maintenance | Social activity |
| | Leisure activity |
| | Fitness |
| | Training |
| | Movement |
| | Physical exertion |
| **METHODOLOGY** | **MeSH** |
| Clinical trial | Sleep |
| Controlled trial | Sleep disorder |
| Evaluation study | Sleep disorder* [therapy] |
| Meta-analysis | Exercise |
| Randomised controlled trial | Exercise movement technique |
| Validation Study | |

**Search strategy**

Sleep (MeSH)

Sleep disorder (MeSH)

Sleep (title)

Insomnia (truncation) – tile + abstract; all text

Exercise (MeSH)

Exercise movement technique (MeSH)

Exercise or resistance or strength or endurance adj 6 (train$ or program$) – title or abstract

Physical adj activity + therapy

Clinical trial + random$ - title + abstract

## Jadad Scale for scoring methodology quality of randomised controlled trials (Jadad et al, 1996)

| Item | Maximum points | Description | Examples |
|---|---|---|---|
| Randomization | 2 | 1 point if randomization is mentioned | "The patients were randomly assigned into two groups" |
| | | 1 additional point if the method of randomization is appropriate | The randomization was accomplished using a computer-generated random number list, coin toss or well-shuffled envelopes |
| | | Deduct 1 point if the method of randomization is inappropriate (minimum 0) | The group assignment was accomplished by alternate assignment, by birthday, hospital number or day of the week |
| Blinding | 2 | 1 point if blinding is mentioned | "The trial was conducted in a double-blind fashion" |
| | | 1 additional point if the method of blinding is appropriate | Use of identical tablets or injectables, identical vials<br>Use of tablets with similar looks but different taste |
| | | Deduct 1 point if the method of blinding is inappropriate (minimum 0) | Incomplete masking |
| An account of all patients | 1 | The fate of all patients in the trial is known. If there are no data the reason is stated | "There were 40 patients randomized but the data from 1 patient in the treatment group and 2 in the control were eliminated because of a break in protocol" |

Methodological Quality Assessment of RCTs of physical activity and sleep quality in populations with mild to severe insomnia complaints, using the Jadad Scale (Jadad et al, 1996)

| **Trial** | **Randomisation** | | **Blinding** | | **Participants** | **Total Score** |
|---|---|---|---|---|---|---|
| | Randomisation mentioned | Randomisation appropriate | Blinding mentioned | Blinding appropriate | All participants accounted for | |
| Reid et al, 2010 | 1 | 0 | 0 | 0 | 1 | 2 |
| King et al, 1997 | 1 | 1 | 0 | 0 | 1 | 3 |
| Li et al, 2004 | 1 | 1 | 1 | 1 | 1 | 5 |
| Irwin et al, 2008 | 1 | 1 | 1 | 1 | 1 | 5 |
| King et al, 2008 | 1 | 1 | 1 | 1 | 0 | 4 |

## Appendix 2: Intervention group material

### *2.1 Walking advice booklet*

### *2.3 Pedometer diary*

# Walk your way to health and better sleep

Whatever your age, size or physical condition, you are likely to benefit from being more active. The people who can benefit the most are inactive people who start to take regular, moderate activity.

Walking is one of the best ways to get your dose of healthy activity: just 30 minutes of walking spread throughout the day (in bouts of at least 10 minutes) will help to keep you healthy. It's easy, and you can do it anywhere, at any time and either alone or with friends. Physical activity doesn't have to mean exhausting runs, buying fancy equipment or joining an expensive health club.

We've produced this walking guide, adapted from the British Heart Foundation's 'Put Your heart Into Walking' booklet, with practical tips and a personal walking plan to help you succeed in living your life as actively as possible, for the rest of your study.

## What walking can do for you

Regular walking can help reduce your risk of coronary heart disease. It can also reduce your risk of stroke, diabetes, obesity and osteoporosis (thinning of the bones). Walking can also help lift your mood, increase energy levels, improve your sleep quality, manage your weight and enjoy the environment.

## How much should I do?

You should aim to be active daily. To keep your heart, lungs, muscles and bones in good working order, you should do a total of ***at least 30 minutes of at least moderate-intensity physical activity a day, on five or more days a week.***

Moderate-intensity physical activity means working hard enough to make you breathe more heavily than normal and become slightly warmer, but not so hard that you are unable to talk and exercise at the same time, or that you become exhausted. Brisk walking is a good example of moderate-intensity activity.

## If 30 minutes a day sounds a lot, don't worry

You can split the 30 minutes up into two bouts of 15 minutes, or three bouts of 10 minutes. If you're not used to walking, start slowly and build up gradually. To receive the health benefits, the activity needs to be continuous for at least ten minutes.

## Taking the first step

The first step towards being more active is the most important one. Don't be over-ambitious. Just set yourself small achievable goals to start with.

## Start slowly

If you're not used to walking 30 minutes a day, start slowly and at a level that suits you. Below are some examples of simple changes you could make to get into a healthy habit:

- Get off the bus a stop earlier and then walk.
- Walk up the stairs. If you're going up or down fewer than three flights, walk instead of using the lift, or walk up or down the escalator.
- Reduce the time you spend sitting down. Get up and move around during television advert breaks.

## Build up gradually

Once you're used to taking the stairs and reducing the time you spend sitting down, it's time to gradually build up your activity. Vary the time you spend walking and how often you go for a walk.

For example, you could start by walking for five minutes, three times a day, on three days a week. Walk at a slightly faster pace than usual, without it being uncomfortable. As you get fitter, you'll be able to do more.

After a few weeks, you can gradually increase your walking, by adding a few more minutes to each walk and going out for a walk on more days of the week.

**You should aim to build up to doing brisk walking for at least 30 minutes a day in bouts of ten minutes or more on at least five days a week.**

## Build more walking into your daily routine

If you're not used to walking every day, look into ways of building walking into your daily life. It's easier than you think. Make sure your goals are measurable. For example, it's better to say 'I'll walk to the shop to get a newspaper on Saturday and Sunday instead of taking the car,' rather than 'I'll walk to the shop more often.'

## Tips to get you started

- Walk to your local shop instead of taking the car or the bus.
- Build a walk into your journey to work. Try different routes to add variety.
- Make walking part of your social life. Go for a walk at lunchtime with colleagues instead of staying at work. Walk to the cinema or library, or walk round to see friends.
- Plan a walk with a friend instead of just meeting for a chat. Keeping each other company can keep you both motivated. Arrange regular walks so that they become a habit.
- Involve the whole family so you can support each other. Walking is good for children too, and a great way of exploring your local area or the countryside.
- Walk the children to school and save the expense of driving or going on the bus.
- Try letting something go. Are there any low-priority ‘in-activities’ that you can stop doing to make time for your health?
- Take your children, grandchildren, neighbours children, or your partner or siblings, for a walk in the park at the weekend. It will give you quality time with a loved one, and an opportunity to keep active.

## Take care – be safe

You will want to make sure that your first steps are safe and enjoyable.

Here’s how you can achieve this:

- Stop exercising if you feel pain, discomfort or dizziness, or if you feel unwell or very tired, and get advice from your doctor.
- Choose comfortable, supportive shoes, such as running, walking, or cross-training shoes.
- Practise correct posture – head upright, arms bent at the elbow and swinging as you stride.
- If you’re going for a longer walk, start slowly for the first few minutes and build up gradually. At the end, spend some time slowing down gradually.
- Drink plenty of water before, during and after your walk, to keep your body hydrated.
- Tell others if you are walking alone and take a mobile phone with you in case of emergencies.
- Walk in well-lit areas where it is fairly busy.
- Be careful of traffic and wear reflective clothing in the dark.

## Take the pedometer challenge

One way of helping you to achieve the recommended 30 minutes a day is to aim to take 10,000 steps a day. On average, people only take between 3,000 and 5,000 steps a day.

You can use a pedometer to count the number of steps you take each day. A pedometer is fun, and easy to use. It's a small device that you clip onto your waistband. Set it at zero at the beginning of the day, and at the end of the day it tells you how many steps you have taken.

A person who walks 10,000 steps a day burns between 1,750 and 2,450 extra calories a week (about 250 to 350 calories a day), compared with the average person who takes between 3,000 and 5,000 steps a day. This is the energy equivalent of gaining or losing half a pound (0.25 kilo) each week.

## Walk 10,000 steps a day

When you begin walking, to avoid feeling the strain of a new routine, start out slowly and build up gradually. You can keep a Pedometer record sheet (attached) to see the progress you are making.

## Tips to keep you going

- Try to walk every day and build a healthy habit.
- Plan a time in your day when you will walk. Use your diary or calendar if it helps.
- Use reminders. Put a note where you will see it – by the front door, on the fridge or by the kettle – to remind you to do some walking. And keep your walking shoes by the door.
- If you're struggling for motivation, think of how walking makes you feel: fitter, energised, relaxed, self-confident, toned and happy.
- Don't give up. If you miss a day – just start again tomorrow. Your health is worth working for.

## PEDOMETER DIARY

| TIMELINE | STEPS | MINUTES |
|---|---|---|
| **Week 1** | | |
| **Week 2** | | |
| **Week 3** | | |
| **Week 4** | | |
| **Week 5** | | |
| **Week 6** | | |
| **Week 7** | | |
| **Week 8** | | |
| **Week 9** | | |
| **Week 10** | | |
| **Week 11** | | |
| **Week 12** | | |

Email: sleepstudy@lboro.ac.uk
Telephone: 01509 223 021
Text: 07977 790 622

## Appendix 3: Telephone screening standardised script

**Telephone Script (First time contact)**

Greeting. Do you have 15 minutes now, I can call you back and we can discuss the study in detail.

No – send information in the post? Get address, and post information sheet and screening questionnaire.

Yes – proceed with script as below.

This is a 1-year study looking at the relationship between sleep problems and lifestyle habits. In the course of the study, two approaches will be compared: regular physical activity, and continuous health monitoring whilst not engaged in physical activity. We need to find out if either of these two approaches makes any difference to sleep. To make sure the comparison is fair, each participant is allocated to the two groups by chance (randomly).

During the study, we will monitor your sleep, and will give you health-related tests and questionnaires (none of them invasive, uncomfortable or requiring any bodily fluids from you. For example, we will give you a computerised task involving you watching a screen and pressing a key as symbols appear on a screen).

However, the study will involve some of your time. You will complete a brief questionnaire booklet four times during the year, at regular intervals. You will also receive brief computerised tasks at the beginning and at the end of the study.

Depending on what group you are allocated by chance, one group may need to engage in a regular walking activity. If you are in the second group, you will have your sleep and health monitored for a year, at regular intervals.

The study will include men and women who:

1. Are aged over 40 years,
2. have problems with their sleep (for example, cannot go to sleep, or wake up too early),
3. and who are not engaged in regular physical activity.

There are other criteria, but these are the main requirements.

Do you think you fulfil these basic criteria?

If you would like to, I can send you some further information in the post. I will also send you a screening questionnaire for you to complete, to see whether you can participate in the study. The screening asks more questions about your sleep and lifestyle habits. If you think you may want to join, please complete the screening questionnaire and send it back to me in the envelope provided. We will then assess your answers, and contact you further.

Please be aware that just because you send us the screening questionnaire back, it does not mean that you signed up for the study. You will only be signed up for the study once you sign a Consent Form, which we will send you at a later stage. You can change your mind at any time.

Do you have any other questions now?

No – take address and contact number. Ask if it possible to call back in a couple of days to check whether they received the information.

Yes – refer them to the information they will be receiving in the post. Then take address and contact number. Ask if it possible to call back in a couple of days to check whether they received the information.

**Input details in the telephone enquiries booklet.**

## Appendix 4: Detailed screening material

### *4.1 Brief Participant Information Sheet*

### *4.2 Health Screening Questionnaire*

# Loughborough University Sleep and Lifestyle Study

# Information Sheet

**What is this study all about?**

The aim of this study is to find out how much sleep patterns change over time, and whether lifestyle factors (like physical activity) can influence these changes. To do this, we are monitoring the sleep of 2 groups of people with sleep problems. One group will be asked to go about their lives as usual, and the other will be asked to walk regularly every week (in line with Government guidelines). Although regular physical activity can offer benefits, it is not known whether regular physical activity can help people with sleep problems. To find out, we will closely monitor the sleep of both groups.

During the study we will ask you to complete some brief questionnaires and health- related tests. These questionnaires will be completed at the start of the study and then again, 3 months, 6 months and 12 months later. At periods throughout the study we will also ask you to wear special electronic devices which record your activity and sleep patterns. We cannot promise that the study will benefit you personally, but the information from this study will help us to better understand disturbed sleep. At the end of the study, however, we will provide all the participants with a detailed personal sleep profile and expert sleep advice.

**What happens next?**

If you are willing to participate, please complete the enclosed screening questionnaire. Your answers to these questions will help us to include the most appropriate people for this study. If, on the basis of your questionnaire results, you are eligible to participate, we will arrange to visit you at home and explain the trial. Or we could arrange for you to come to our research office and explain the trial. If, on the other hand, you are not eligible to participate, we will explain why.

**If you have any queries or would just like to discuss the project further please telephone Iuliana in the research office on: 01509 223 021 (or please leave a message on the answerphone and we will call you back at a convenient time to you).**

Name/Number .....……

## Health Screen Questionnaire for Study Volunteers

As a volunteer participating in a research study, it is important that you are currently in good health and have had no significant medical problems in the past. This is (i) to ensure your own continuing well-being and (ii) to avoid the possibility of individual health issues confounding study outcomes. All answers will be kept in strict confidence.

**Please complete this brief questionnaire to confirm your fitness to participate**

**Source**

| | |
|---|---|
| How did you find out about the study?<br>(e.g. advert in the library) | |

**Personal Details**

| | |
|---|---|
| Your Name: | Date of birth: Age: |
| Telephone(s): | Address: |
| Usually available to talk: | |
| Distance from Lboro University (please approximate): | |

How much do you weigh? _____ (kg/stones/pounds)
*Delete as applicable.*

How tall are you? _____ (feet/metres/cm)
*Delete as applicable.*

**1. At present,** do you have any health problem for which you are:

| | | | | | |
|---|---|---|---|---|---|
| (a) | on medication, prescribed or otherwise ..... | Yes | | No | |
| (b) | attending your general practitioner ..... | Yes | | No | |
| (c) | on a hospital waiting list..... | Yes | | No | |

**If Yes,** please give details (e.g. name of medication, for how long have you been taking medication etc):

**……**

**……**

**……**

**2. Have you ever** had any of the following:

| | | | | | |
|---|---|---|---|---|---|
| (a) | Convulsions/epilepsy ..... | Yes | | No | |
| (b) | Asthma ..... | Yes | | No | |
| (c) | Eczema ..... | Yes | | No | |
| (d) | Diabetes ..... | Yes | | No | |
| (e) | A blood disorder ..... | Yes | | No | |
| (f) | Head injury ..... | Yes | | No | |
| (g) | Digestive problems ..... | Yes | | No | |
| (h) | Heart problems ..... | Yes | | No | |
| (i) | Problems with bones or joints ..... | Yes | | No | |
| (j) | Disturbance of balance/coordination ..... | Yes | | No | |
| (k) | Numbness in hands or feet ..... | Yes | | No | |
| (l) | Disturbance of vision ..... | Yes | | No | |
| (m) | Ear / hearing problems ..... | Yes | | No | |
| (n) | Thyroid problems ..... | Yes | | No | |
| (o) | Kidney or liver problems ..... | Yes | | No | |
| (p) | Allergy to nuts ..... | Yes | | No | |

**3.** **Have you ever** had any of the following:

| | | | | | |
|---|---|---|---|---|---|
| (a) | Anxiety disorder ..... | Yes | | No | |
| (b) | Bipolar disorder ..... | Yes | | No | |
| (c) | Delirium ..... | Yes | | No | |
| (d) | Dementia ..... | Yes | | No | |
| (e) | Depression, dysthymia ..... | Yes | | No | |
| (f) | Schizophrenia ..... | Yes | | No | |
| (g) | Substance abuse ..... | Yes | | No | |

**If YES to** any question, please describe briefly if you wish (e.g. to confirm problem was/is short-lived, insignificant or well controlled.)

**.....**

**.....**

**……..**

**4. Do you** regularly consume:

| | | | | | | How much/day? |
|---|---|---|---|---|---|---|
| (a) | Caffeine ..... | Yes | | No | | |
| (b) | Alcohol ..... | Yes | | No | | |
| (c) | Nicotine ..... | Yes | | No | | |
| (d) | Excessive fluid in the evening ..... | Yes | | No | | |

**5**. **Has any,** otherwise healthy, member of your family under the age of 35 died suddenly during or soon after exercise? ..... Yes ☐ No ☐

**6**. **Allergy** Information

| | | | | | |
|---|---|---|---|---|---|
| (a) | are you allergic to any food products? | Yes | ☐ | No | ☐ |
| (b) | are you allergic to any medicines? | Yes | ☐ | No | ☐ |
| (c) | are you allergic to plasters? | Yes | ☐ | No | ☐ |

**If YES** to any of the above, please provide additional information on the allergy**:**

**……**

**7**. **Additional questions** for female participants

| | | | | | |
|---|---|---|---|---|---|
| (d) | are you taking hormone replacement therapy (HRT)? | Yes | ☐ | No | ☐ |

**If YES,** please state when you commenced the hormone replacement therapy:

**……**

**8. Are you** currently involved in any other research studies at the University or elsewhere?

Yes ☐ No ☐

If yes, please provide details of the study

**……..**

**……..**

**9. How many minutes** a week do you spend doing exercise/physical activity (such as brisk walking, swimming, jogging etc)?

**……** minutes/week

**10. On an average week,** on how many days a week do you exercise/are physically active?

**……** days per week

**Sleep problems**

**Q1. Have you been told that you have a sleep problem/condition by your GP or another healthcare professional?.....** Yes ☐ No ☐ **If No, go to Q3.**

**If Yes**, please describe the diagnosis

**……..**

**Q2**. **Please** tell us when you were diagnosed

**……..**

**Q2. Are you currently taking medication/any other treatment for this condition? .....** Yes ☐ No ☐

**If yes**, please provide details – what medication/treatment are you taking, when have you started

**……**

**……**

| | | | **How many nights/ week** |
|---|---|---|---|
| **Q3. Do you have problems falling alseep?.....** | Yes ☐ | No ☐ | |
| **Q4. Do you have problems staying alseep?.....** | Yes ☐ | No ☐ | |
| **Q5. Do you wake up in the morning before the desired time?.....** | Yes ☐ | No ☐ | |
| **Q6. Do you wake up feeling unrefreshed, despite adequate opportunity to sleep?.....** | Yes ☐ | No ☐ | |
| **Q7. Do you consider your sleep problems interfere with your daytime functioning, for example memory, concentration, ability to work/daily chores, mood?.....** | Yes ☐ | No ☐ | |
| **Q8. Are you concerned about your sleep problems? ....** | Yes ☐ | No ☐ | |

**Q9**. **How long** have you been having these sleep problems?

**……**

**Q10. Are you currently taking medication, prescribed or over the counter, for your sleep problems? .....** Yes ☐ No ☐

**If Yes**, please provide details – what medication/treatment are you undertaking, when have you started

**……**

**……**

**Q11. Have you ever had unpleasant sensations in your legs, combined with an urge to move your legs?**

Yes ☐ No ☐

**Q12. Do/did these feelings occur mainly or only at rest and do/did they improve with movement?**

Yes ☐ No ☐

**Q13. Are/were these feelings worse in the evening or night than in the morning?**

Yes ☐ No ☐

**Q14. How often do/did these feelings occur?**

- ☐ **Less than one time per year**
- ☐ **At least one time a year but less than one time/month**
- ☐ **2–4 times per month**
- ☐ **2–3 times per week**
- ☐ **4–5 times per week**
- ☐ **6–7 times per week**

| | | | **How many nights/week** |
|---|---|---|---|
| **Q15. Do you have problems falling asleep at the desired time? .....** | Yes ☐ | No ☐ | |
| **Q16. Do you have problems waking up at the desired time?.....** | Yes ☐ | No ☐ | |
| **Q17. Do you feel very sleepy during the daytime?.....** | Yes ☐ | No ☐ | |

**Q18**. **How long** have you been having these sleep problems?
**.....……**

**Q19.** How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you.

| | I would never doze | I would have a slight chance of dozing | I would have a moderate chance of dozing | I would have a high chance of dozing |
|---|---|---|---|---|
| Sitting & reading | | | | |
| Watching TV | | | | |
| Sitting, inactive in a public place (e.g. cinema) | | | | |
| As a passenger in a car for an hour without a break | | | | |
| Lying down to rest in the afternoon when given the chance | | | | |
| Sitting and talking to someone | | | | |
| Sitting quietly after lunch without alcohol | | | | |
| In a car, while stopped for a few minutes in traffic | | | | |

**Q20.** Please tick (✓) the most appropriate response to the questions below. Please answer all questions.

***1. Sadness***

| | |
|---|---|
| I do not feel sad | ◯ |
| I feel sad much of the time | ◯ |
| I am sad all of the time | ◯ |
| I am so sad or unhappy that I can't stand it | ◯ |

***2. Pessimism***

| | |
|---|---|
| I am not discouraged about my future | ◯ |
| I feel more discouraged about my future than I used to be | ◯ |
| I do not expect things to work out for me | ◯ |
| I feel my future is hopeless and will only get worse | ◯ |

**3. *Past Failure***

| | |
|---|---|
| I do not feel like a failure | ◯ |
| I have failed more than I should have | ◯ |
| As I look back, I see a lot of failures | ◯ |
| I feel I am a total failure as a person | ◯ |

**4. *Loss of Pleasure***

| | |
|---|---|
| I get as much pleasure as I ever did from things I enjoy | ◯ |
| I don't enjoy things as much as I used to | ◯ |
| I get very little pleasure from the things I used to enjoy | ◯ |
| I can't get any pleasure from the things I used to enjoy | ◯ |

**5. *Guilty Feelings***

| | |
|---|---|
| I don't feel particularly guilty | ◯ |
| I feel guilty over many things I have done or should have done | ◯ |
| I feel quite guilty most of the time | ◯ |
| I feel guilty all of the time | ◯ |

**6. *Punishment Feelings***

| | |
|---|---|
| I don't feel I am being punished | ◯ |
| I feel I may be punished | ◯ |
| I expect to be punished | ◯ |
| I feel I am being punished | ◯ |

**7. *Self-Dislike***

| | |
|---|---|
| I feel the same about myself as ever | ◯ |
| I have lost confidence in myself | ◯ |
| I am disappointed in myself | ◯ |
| I dislike myself | ◯ |

**8. *Self-Criticalness***

| | |
|---|---|
| I don't criticise or blame myself more than usual | ◯ |
| I am more critical of myself than I used to be | ◯ |
| I criticise myself for all of my faults | ◯ |
| I blame myself for everything bad that happens | ◯ |

**9. *Suicidal Thoughts or Wishes***

| | |
|---|---|
| I don't have any thoughts of killing myself | ◯ |
| I have thoughts of killing myself, but I would never carry them out | ◯ |
| I would like to kill myself | ◯ |
| I would kill myself if I had the chance | ◯ |

**10. *Crying***

| | |
|---|---|
| I don't cry anymore than I used to | ◯ |
| I cry more than I used to | ◯ |
| I cry over every little thing | ◯ |
| I feel like crying, but I can't | ◯ |

**11. *Agitation***

| | |
|---|---|
| I am no more restless or wound up than usual | ◯ |
| I feel more restless or wound up than usual | ◯ |
| I am so restless or agitated that it's hard to stay still | ◯ |
| I am so restless or agitated that I have to keep moving or doing something | ◯ |

**12. *Loss of interest***

| | |
|---|---|
| I have not lost interest in other people or activities | ◯ |
| I am less interested in other people or things than before | ◯ |
| I have lost most of my interest in other people or things | ◯ |
| It's hard to get interested in anything | ◯ |

**13. *Indecisiveness***

| | |
|---|---|
| I make decisions about as well as ever | ◯ |
| I find it more difficult to make decisions than usual | ◯ |
| I have much greater difficulty in making decisions than I used to | ◯ |
| I have trouble making any decisions | ◯ |

**14. *Worthlessness***

| | |
|---|---|
| I do not feel I am worthless | ◯ |
| I don't consider myself as worthwhile and useful as I used to | ◯ |
| I feel more worthless as compared to other people | ◯ |
| I feel utterly worthless | ◯ |

**15. *Loss of Energy***

| | |
|---|---|
| I have as much energy as ever | ◯ |
| I have less energy than I used to have | ◯ |
| I don't have enough energy to do very much | ◯ |
| I don't have enough energy to do anything | ◯ |

**16. *Irritability***

| | |
|---|---|
| I am no more irritable than usual | ◯ |
| I am more irritable than usual | ◯ |
| I am much more irritable than usual | ◯ |
| I am irritable all of the time | ◯ |

**17. *Concentration Difficulty***

| | |
|---|---|
| I can concentrate as well as ever | ◯ |
| I can't concentrate as well as usual | ◯ |
| It's hard to keep my mind on anything for very long | ◯ |
| I find I can't concentrate on anything | ◯ |

**18. *Tiredness or Fatigue***

| | |
|---|---|
| I am not more tired or fatigued than usual | ◯ |
| I get more tired or fatigued more easily than usual | ◯ |
| I am too tired or fatigued to do a lot of the things I used to do | ◯ |
| I am too tired or fatigued to do most of the things I used to do | ◯ |

**19. *Loss of Interest in Sex***

| | |
|---|---|
| I have not noticed any recent change in my interest in sex | ◯ |
| I am less interested in sex than I used to be | ◯ |
| I am much less interested in sex now | ◯ |
| I have lost interest in sex completely | ◯ |

**20. *Changes in Appetite***

| | |
|---|---|
| I have not experienced any change in my appetite | ◯ |
| My appetite is somewhat less than usual | ◯ |
| My appetite is somewhat greater than usual | ◯ |
| My appetite is much less than before | ◯ |
| My appetite is much greater than usual | ◯ |
| I have no appetite at all | ◯ |
| I crave food all the time | ◯ |

**21. *Changes in Sleeping Pattern***

| | |
|---|---|
| I have not experienced any change in my sleeping pattern | ◯ |
| I sleep somewhat more than usual | ◯ |
| I sleep somewhat less than usual | ◯ |
| I sleep a lot more than usual | ◯ |
| I sleep a lot less than usual | ◯ |
| I sleep most of the day | ◯ |
| I wake up 1-2 hours early and can’t get back to sleep | ◯ |


**THANK YOU FOR COMPLETING ALL QUESTIONS**

**PLEASE RETURN THE SCREENING QUESTIONNAIRE IN THE FREEPOST ENVELOPE PROVIDED**

## Appendix 5: Standardised letter for ineligibility for the RCT

**PRIVATE & CONFIDENTIAL**
Volunteer

15 February 2012

Dear Mr/Mrs …,

**Re: Loughborough University Sleep and Lifestyle Study**

Thank you for returning the screening questionnaire to the Clinical Sleep Research Unit. We are very grateful for taking the time to do it.

Your screening questionnaire indicates that you engage in moderate to vigorous physical activity of 250 to 300 minutes per week. This specific trial is aimed at people who are currently engaged in less than 60 minutes of physical activity in a week. We are sorry therefore that you cannot participate in this study.

We understand sleep problems are very distressing, and we hope our research leads to better understanding of sleep-related conditions, and expand the knowledge base on treatment options. Whilst it is disappointing that you cannot participate in this study, we can keep your contact details on our database, with your express permission. Should suitable future sleep-related studies take place in our department, we can invite you to take part.

If you would like to discuss this further, please do not hesitate to contact me.

I thank you for the time taken to write to us, and complete the screening process.

Kind regards,

**Iuliana Hartescu**

Sleep Research Centre
Tel: 01509 223021 (direct line)
Fax: 01509 223940
i.hartescu@lboro.ac.uk

Clinical Sleep Research Unit:
http://www.lboro.ac.uk/departments/ssehs/research/behavioural-medicine/sleep/clinical-sleep-search-unit/index.html.

## Appendix 6: Full Participant Information Sheet and Consent Form

**Number:**

**Date:** **May 2011**

# Information Sheet

**Our invitation to you**

Thank you for expressing interest in participating in our study. We are currently running a study on monitoring lifestyle, health and sleep quality. We would like to invite you to take part in this research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish, or call the number provided at the bottom of this sheet.

**What is this study all about?**

The aim of this study is to find the best way of helping people with sleep problems to get the most out of their sleep. In the course of this study, two approaches to physical activity habits are being compared: regularly walking to the prescribed governmental guidelines; and continuous health monitoring whilst not engaged in regular physical activity. While regular physical activity can offer benefits, it is not known whether physical activity habits can help people with sleep problems. To find out, we need to compare these two approaches.

To do this we invite people to join different groups and give each group a different treatment. In the present study we are calling these groups the 'Regular Walking' group and the 'Regular Health Monitoring' group. At the end of the study results from both groups are compared to see if one is better. To try to make sure the comparison is fair, each participant is allocated to a group by chance (randomly). In this case you have a 50-50 (evens) chance of joining one of the two groups. We cannot promise the study will help you, but the information we get from this study will help to improve the treatment of people who cope with long-term health conditions, and experience disturbed sleep. This trial is financially supported by Government funded Research Councils, and is being managed by Loughborough University's Sleep Research Centre.

**What will happen to me if I take part?**

**If you are being invited to participate in the Regular Walking group**. This means that we will support you in engaging in regular walking (of 30 minutes per day, on at least 5 days of the week).

**If you are being invited to participate in the Regular Health Monitoring group**. This means that we will regularly monitor your health and sleep, whilst you continue your lifestyle as usual.

**For all participants**. We will give you a booklet of questionnaires, monitor your sleep and conducts health tests at the beginning of the study. We will give you the same questionnaires and tests after 3 months, 6 months, and one year later.

And that's it; all together you will be involved in the study for approximately 12 months.

**What do the questionnaires ask?** In order to assess your regular health and sleep, we need to ask you for information on your health, your sleeping patterns, and the amount of fatigue you experience. These questionnaires take approximately half an hour to complete. You can take breaks whilst completing the questionnaires. You will be provided with pre-paid envelopes to return the questionnaires to Loughborough University.

**What do other tests involve?** In order to assess the contribution of other factors to your sleep problems, we will also test your attention. There are two computerised attention tests, each lasting approximately 15 minutes. The tests involve watching a screen, and pressing a button when certain targets appear on the screen. You will be given ample opportunity to first familiarise yourself with the tests. We can conduct these tests either in the comfort of your home, or you can visit our University (your choice). After that, we will repeat the same tests after 6 months, and one year later.

**What happens to this information?** All the questionnaires and tests are anonymous (we will place a number on the form). The information will also be stored anonymously and securely, and only people with correct authority will have access. If you decide to withdraw from the study we will destroy your personal (contact) information, but we will need to use the questionnaire data collected up to your withdrawal. At all times we will follow strict codes of ethical and legal practice.

**What if I want to complain?**

If you have concerns about any aspect of this study, you can bring this to the attention of the researchers (office number below) who will do their best to address the matter. If you remain unhappy and wish to complain formally, you can do directly to the University authorities. The person to contact for complaints is Mrs Zoë Stockdale, Secretary to the Ethical Avisory Committee, Research office, Loughborough University, Tel: 01509222423, email: z.c.stockdale@lboro.ac.uk.

**Do I have to take part?** Participation is, of course, entirely voluntary. If, after reading this information, you decide to participate, we will ask you to sign a consent form to show you have agreed to take part. We will then inform your GP so that they know what is going on. You are also free to withdraw at any time, without giving a reason.

**Full contact details of the Investigators:**

| | | |
|---|---|---|
| Ms Iuliana Hartescu<br>Clinical Sleep Research Unit<br>Loughborough University<br>Leicestershire<br>LE11 3TU<br>Tel: 01509223021<br>Email: i.hartescu@lboro.ac.uk | Professor Kevin Morgan<br>Clinical Sleep Research Unit<br>Loughborough University<br>Leicestershire<br>LKE11 3TU<br>Tel: 01509222472<br>Email: k.morgan@lboro.ac.uk | Doctor Clare Stevinson<br>School of Sports, Exercise and Health Scien<br>Loughborough University<br>LE11 3TU<br>Tel: 01509222472<br>Email: C.D.Stevinson@lboro.ac.uk |

If you have any queries, or would just like to discuss the project further, please telephone the project office on: 01509 223 021.

**Number:**

**Date:** **May 2011**

# CONSENT FORM

Title of Project: Sleep and lifestyle factors

Name of Researcher: IULIANA HARTESCU

**Please initial box**

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at anytime without giving any reason, without my legal rights being affected. ☐
3. I agree to take part in the above study ☐

_____ _____

Name of Participant Date Signature

**Iuliana Hartescu**

_____ _____

Name of Person Date Signature

taking consent

## Appendix 7: RCT Attrition Management Strategy

**RCT Attrition management**

1. **Offer incentives**
    a. Sleep profile
    b. A free personal consultation with a sleep specialist at the end.
    c. Pedometer

2. **Offer attention and support**
    a. Weekly reminder text
    b. Monthly progress letter
    c. Mobile number for continuous support
    d. Monthly update on local walking opportunities

3. **Run procedure**
    a. Identify personal walking opportunities
    b. Have milestones set (3 months, 6 months, one year) and agreed with participants

4. **Exit interview**
    a. Have early exit interview ready
    b. Try and identify, and overcome, obstacles to continuing
    c. Test participants at whatever point they wish to terminate

5. **Get specialist support from the Department**
    a. Clare Stevinson
    b. Stacy Clemes

## Appendix 8: Standard letter to General Practitioner, for intervention and control groups

Surgery

10 December 2011

Dear Sir or Madam,

**Re: Participant, DOB, Address:**

I am writing to inform you that Mr/Mrs ..  has volunteered to participate in a research study at Loughborough University. The study is examining the relationship between lifestyle factors and insomnia symptoms, and has been approved by Loughborough University Ethics Committee Reference Number R11-P68.

During the 12-month study, participants will undertake regular physical activity (brisk walking) to governmental guidelines (150 minutes per week), and wear an accelerometer. They will also complete cognitive tests, questionnaires on their lifestyle habits, perceived physical and mental health, and sleep, on four occasions.

If you require any more information, or if you have any comments or concerns about the study, please do not hesitate to contact me.

Kind regards,

**Iuliana Hartescu**

Sleep Research Centre
Loughborough University

Direct line: 01509 223 021
Email: i.hartescu@lboro.ac.uk

**Appendix 9: Booklet of self-reported questionnaires, administered at baseline, 3 months, 6 months and 12 months**

# Loughborough University Sleep and Lifestyle Study

**Please complete ALL questions**

**THANK YOU**

**School of Sport, Exercise and Health Sciences**
**Loughborough University**
**Loughborough**
**Leicestershire LE11 3TU**

**Please answer the following questions about you and your health**

**All responses will be kept confidential.**

# About you

Please tick (✓) the appropriate boxes where indicated :

1. Are you :

Male ☐ Female ☐

2. What is your age? _____

3. What is your ethnic background?

i) White – British, Irish, Other White background ☐

ii) Mixed – White and Black Caribbean, White and Black African, White and Asian, other mixed background ☐

iii) Asian or Asian British- Indian, Pakistani, Bangladeshi, other Asian background ☐

iv) Black or Black British – Caribbean, African, Other Black background ☐

v) Chinese or other ethnic group – Chinese, any other ☐

4. Would you describe your work as:

Day time work (e.g. 9am – 5pm) ☐

Shift work – day time only ☐

Shift work – including nights ☐

I am currently unemployed/retired ☐

# About your health

By placing a tick (✓) in ONE box in each group below, please indicate which statements best describe your own health state TODAY.

**1. MOBILITY**

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

**2. SELF-CARE**

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

**3. USUAL ACTIVITIES** *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

**4. PAIN / DISCOMFORT**

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

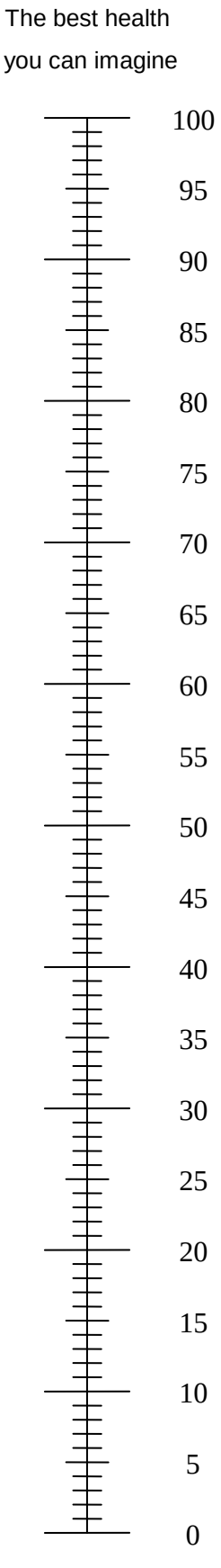
**5. ANXIETY / DEPRESSION**

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

**6.** We would like to know how good or bad your health is TODAY.

- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



**7.** Over the past 4 weeks, how often have you:

| | | How often? (enter number of times) |
|---|---|---|
| i | Visited your local surgery for a consultation with a doctor (include 'out-of hours' consultations at special centres)? | |
| ii | Visited your local surgery for an appointment with a nurse, a counsellor, or any other member of the team? | |
| iii | Visited an Accident and Emergency department in a hospital? | |
| iv | Taken sleep medicine prescribed by your doctor (please enter the name of the medicine below)?<br><br>_____ | |
| v | Taken sleep medicine that you bought yourself from a chemist or health shop (please enter the name of the medicine below)?<br><br>_____ | |
| vi | Contacted NHS direct? | |

**What is your current weight?**

_____**stone/ lb / kg**

**How tall are you?**

_____ **ft/ cm**

**What is your annual household income, before taxes?**

☐ £5,000 - £9,999
☐ £10,000 - £14,999
☐ £15,000 - £19,999
☐ £20,000 - £24,999
☐ £25,000 - £29,999
☐ £30,000 - £34,999
☐ £35,000 - £39,999
☐ £40,000 - £44,999
☐ £45,000 - £49,999
☐ £50,000 - £54,999
☐ £55,000 - £59,999
☐ £60,000 - £64,999
☐ £65,000 - £69,999
☐ £70,000 – £74,999
☐ More than £75,000

# About your sleep quality

**Instructions:**

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all the questions.

**1.** During the past month, when have you usually gone to bed at night?

usual bed time _____

**2.** During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

number of minutes _____

**3.** During the past month, when have you usually got up in the morning?

usual getting up time _____

**4.** During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spend in bed).

hours of sleep per night _____

**5.** During the past month, how often have you had trouble sleeping because you…

For each of the remaining questions, tick (✓) the most relevant response. Please answer all questions.

| | Not during the past month | Less than once a week | Once or twice a week | Three or more times a week |
|---|---|---|---|---|
| Cannot get to sleep within 30 minutes | | | | |
| Wake up in the middle of the night or early morning | | | | |
| Have to get up to use the bathroom | | | | |
| Cannot breathe comfortably | | | | |
| Cough or snore loudly | | | | |

| | Not during the past month | Less than once a week | Once or twice a week | Three or more times a week |
|---|---|---|---|---|
| Feel too cold | | | | |
| Feel too hot | | | | |
| Had bad dreams | | | | |
| Have pain | | | | |

If there are any other reason(s) you have had trouble sleeping please describe:

| |
|---|
| |

**6.** If you provided other reasons for having trouble sleeping in the box above, please indicate how often this has affected your sleep over the past month.

| Not during the past month | Less than once a week | Once or twice a week | Three or more times a week |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

**7.** During the past month, how would you rate your sleep quality overall?

| Very good | Fairly good | Fairly bad | Very bad |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

**8.** During the past month, how often have you taken medicine (prescribed or "over the counter") to help you sleep?

| Not during the past month | Less than once a week | Once or twice a week | Three or more times a week |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

**9.** During the past month, how often have you had trouble staying awake while driving, eating meals or engaging in social activity?

| Not during the past month | Less than once a week | Once or twice a week | Three or more times a week |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

**10.** During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

| No problem at all | Only a very slight problem | Somewhat of a problem | A very big problem |
|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ |

**11.** Over the past month have you consumed any of the following to help you sleep? Please tick all that apply.

| | |
|---|---|
| Alcohol | ☐ |
| Medicines purchased from a pharmacy e.g. Nytol | ☐ |
| Medicines purchased from the internet | ☐ |
| Herbal tablets or compounds e.g. valerian, Nytol Herbal | ☐ |
| Herbal teas e.g. camomile | ☐ |
| Milk drinks e.g. Horlicks, milk, hot chocolate | ☐ |

Is the anything else you consume to help you sleep? (Please specify)

**12.** Over the past month have you consumed any of the following to reduce feelings of sleepiness? Please tick all that apply.

Caffeinated drinks e.g. tea, coffee ☐

"Energy" drinks, e.g. Red Bull ☐

High sugar drinks e.g. cola ☐

Sugary snack e.g. chocolate, sweets ☐

Over the counter stimulants e.g. Pro Plus ☐

Is the anything else you consume to reduce daytime sleepiness? (Please specify)

| |
|---|
| |

**13.** For each question, please CIRCLE the number that best describes your answer.

*Please rate the CURRENT (i.e. LAST 2 WEEKS) SEVERITY of your insomnia problem(s).*

| Insomnia problem | None | Mild | Moderate | Severe | Very severe |
|---|---|---|---|---|---|
| 1) Difficulty falling asleep | 0 | 1 | 2 | 3 | 4 |
| 2) Difficulty staying asleep | 0 | 1 | 2 | 3 | 4 |
| 3) Problems waking up too early | 0 | 1 | 2 | 3 | 4 |

4) How satisfied/dissatisfied are you with your current sleep pattern?

| Very satisfied | Satisfied | Moderately satisfied | Dissatisfied | Very dissatisfied |
|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 |

5) How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

| Not at all noticeable | A little | Somewhat | Much | Very much noticeable |
|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 |

6) How WORRIED/DISTRESSED are you about your current sleep problem?

| Not at all worried | A little | Somewhat | Much | Very much worried |
|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 |

7) To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood etc) CURRENTLY?

| Not at all interfering | A little | Somewhat | Much | Very much interfering |
|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 |

# About your daytime functioning and mood

**Instructions:**

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. 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? Do not include walking.

_____ **days per week**

☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

**Instructions:**

Read each statement and circle a number from 1 to 7, based on how accurately it reflects your condition during the past week and the extent to which you agree or disagree that the statement applies to you.

• A low value (e.g., 1) indicates strong disagreement with the statement, whereas a high value (e.g., 7) indicates strong agreement.

• It is important that you circle a number (1 to 7) for every question.

| **During the past week, I have found that:** | **Disagree <--------> Agree** | | | | | | |
|---|---|---|---|---|---|---|---|
| My motivation is lower when I am fatigued. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Exercise brings on my fatigue. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| I am easily fatigued. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Fatigue interferes with my physical functioning. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Fatigue causes frequent problems for me. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| My fatigue prevents sustained physical functioning. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Fatigue interferes with carrying out certain duties and responsibilities. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Fatigue is among my three most disabling symptoms. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Fatigue interferes with my work, family, or social life. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

**Instructions:**

How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you.

| | I would never doze | I would have a slight chance of dozing | I would have a moderate chance of dozing | I would have a high chance of dozing |
|---|---|---|---|---|
| Sitting & reading | | | | |
| Watching TV | | | | |
| Sitting, inactive in a public place (e.g. cinema) | | | | |
| As a passenger in a car for an hour without a break | | | | |
| Lying down to rest in the afternoon when given the chance | | | | |
| Sitting and talking to someone | | | | |
| Sitting quietly after lunch without alcohol | | | | |
| In a car, while stopped for a few minutes in traffic | | | | |

**Instructions:**
Please tick (✓) the circle that best indicates how you feel right now, that is, at this moment. There are no right or wrong answers.

| | | Not at all | Somewhat | Moderately | Very much so |
|---|---|---|---|---|---|
| **1.** | I feel calm | ○ | ○ | ○ | ○ |
| **2.** | I feel secure | ○ | ○ | ○ | ○ |
| **3.** | I am tense | ○ | ○ | ○ | ○ |
| **4.** | I fell strained | ○ | ○ | ○ | ○ |
| **5.** | I feel at ease | ○ | ○ | ○ | ○ |
| **6.** | I feel upset | ○ | ○ | ○ | ○ |
| **7.** | I am presently worrying over possible misfortunes | ○ | ○ | ○ | ○ |
| **8.** | I feel satisfied | ○ | ○ | ○ | ○ |
| **9.** | I feel frightened | ○ | ○ | ○ | ○ |
| **10.** | I feel comfortable | ○ | ○ | ○ | ○ |
| **11.** | I feel self-confident | ○ | ○ | ○ | ○ |
| **12.** | I feel nervous | ○ | ○ | ○ | ○ |
| **13.** | I am jittery | ○ | ○ | ○ | ○ |
| **14.** | I feel indecisive | ○ | ○ | ○ | ○ |
| **15.** | I am relaxed | ○ | ○ | ○ | ○ |
| **16.** | I feel content | ○ | ○ | ○ | ○ |
| **17.** | I am worried | ○ | ○ | ○ | ○ |
| **18.** | I feel confused | ○ | ○ | ○ | ○ |
| **19.** | I feel steady | ○ | ○ | ○ | ○ |
| **20.** | I feel pleasant | ○ | ○ | ○ | ○ |

**Instructions:**

Now please tick (✓) the circle that best indicates how you generally feel.

| | | Almost never | Sometimes | Often | Almost always |
|---|---|---|---|---|---|
| **1.** | I feel pleasant | ○ | ○ | ○ | ○ |
| **2.** | I feel nervous and restless | ○ | ○ | ○ | ○ |
| **3.** | I feel satisfied with myself | ○ | ○ | ○ | ○ |
| **4.** | I wish I could be as happy as others seem to be | ○ | ○ | ○ | ○ |
| **5.** | I feel like a failure | ○ | ○ | ○ | ○ |
| **6.** | I feel rested | ○ | ○ | ○ | ○ |
| **7.** | I am “calm, cool and collected” | ○ | ○ | ○ | ○ |
| **8.** | I feel that difficulties are piling up so that I cannot over them | ○ | ○ | ○ | ○ |
| **9.** | I worry too much over something that really doesn’t matter | ○ | ○ | ○ | ○ |
| **10.** | I am happy | ○ | ○ | ○ | ○ |

| | | Almost never | Sometimes | Often | Almost always |
|---|---|---|---|---|---|
| **11.** | I have disturbing thoughts | ○ | ○ | ○ | ○ |
| **12.** | I lack self confidence | ○ | ○ | ○ | ○ |
| **13.** | I feel secure | ○ | ○ | ○ | ○ |
| **14.** | I make decisions easily | ○ | ○ | ○ | ○ |
| **15.** | I feel inadequate | ○ | ○ | ○ | ○ |
| **16.** | I am content | ○ | ○ | ○ | ○ |
| **17.** | Some unimportant thoughts runs through my mind and bothers me | ○ | ○ | ○ | ○ |
| **18.** | I take disappointments so keenly that I can’t put them out of mind | ○ | ○ | ○ | ○ |
| **19.** | I am a steady person | ○ | ○ | ○ | ○ |
| **20.** | I get in a state of tension or turmoil as I think over my recent concerns and interests | ○ | ○ | ○ | ○ |

Please tick (✓) the most appropriate response to the questions below. Please answer all questions

***1. Sadness***

| | |
|---|---|
| I do not feel sad | ◯ |
| I feel sad much of the time | ◯ |
| I am sad all of the time | ◯ |
| I am so sad or unhappy that I can't stand it | ◯ |

***2. Pessimism***

| | |
|---|---|
| I am not discouraged about my future | ◯ |
| I feel more discouraged about my future than I used to be | ◯ |
| I do not expect things to work out for me | ◯ |
| I feel my future is hopeless and will only get worse | ◯ |

***3. Past Failure***

| | |
|---|---|
| I do not feel like a failure | ◯ |
| I have failed more than I should have | ◯ |
| As I look back, I see a lot of failures | ◯ |
| I feel I am a total failure as a person | ◯ |

***4. Loss of Pleasure***

| | |
|---|---|
| I get as much pleasure as I ever did from things I enjoy | ◯ |
| I don't enjoy things as much as I used to | ◯ |
| I get very little pleasure from the things I used to enjoy | ◯ |
| I can't get any pleasure from the things I used to enjoy | ◯ |

***5. Guilty Feelings***

| | |
|---|---|
| I don't feel particularly guilty | ◯ |
| I feel guilty over many things I have done or should have done | ◯ |
| I feel quite guilty most of the time | ◯ |
| I feel guilty all of the time | ◯ |

***6. Punishment Feelings***

| | |
|---|---|
| I don't feel I am being punished | ◯ |
| I feel I may be punished | ◯ |
| I expect to be punished | ◯ |
| I feel I am being punished | ◯ |

**7. *Self-Dislike***

| | |
|---|---|
| I feel the same about myself as ever | ◯ |
| I have lost confidence in myself | ◯ |
| I am disappointed in myself | ◯ |
| I dislike myself | ◯ |

**8. *Self-Criticalness***

| | |
|---|---|
| I don't criticise or blame myself more than usual | ◯ |
| I am more critical of myself than I used to be | ◯ |
| I criticise myself for all of my faults | ◯ |
| I blame myself for everything bad that happens | ◯ |

**9. *Suicidal Thoughts or Wishes***

| | |
|---|---|
| I don't have any thoughts of killing myself | ◯ |
| I have thoughts of killing myself, but I would never carry them out | ◯ |
| I would like to kill myself | ◯ |
| I would kill myself if I had the chance | ◯ |

**10. *Crying***

| | |
|---|---|
| I don't cry anymore than I used to | ◯ |
| I cry more than I used to | ◯ |
| I cry over every little thing | ◯ |
| I feel like crying, but I can't | ◯ |

**11. *Agitation***

| | |
|---|---|
| I am no more restless or wound up than usual | ◯ |
| I feel more restless or wound up than usual | ◯ |
| I am so restless or agitated that it's hard to stay still | ◯ |
| I am so restless or agitated that I have to keep moving or doing something | ◯ |

**12. *Loss of interest***

| | |
|---|---|
| I have not lost interest in other people or activities | ◯ |
| I am less interested in other people or things than before | ◯ |
| I have lost most of my interest in other people or things | ◯ |
| It's hard to get interested in anything | ◯ |

**13. *Indecisiveness***

| | |
|---|---|
| I make decisions about as well as ever | ◯ |
| I find it more difficult to make decisions than usual | ◯ |
| I have much greater difficulty in making decisions than I used to | ◯ |
| I have trouble making any decisions | ◯ |

**14. *Worthlessness***

| | |
|---|---|
| I do not feel I am worthless | ◯ |
| I don't consider myself as worthwhile and useful as I used to | ◯ |
| I feel more worthless as compared to other people | ◯ |
| I feel utterly worthless | ◯ |

**15.** ***Loss of Energy***

| | |
|---|---|
| I have as much energy as ever | ◯ |
| I have less energy than I used to have | ◯ |
| I don't have enough energy to do very much | ◯ |
| I don't have enough energy to do anything | ◯ |

**16.** ***Irritability***

| | |
|---|---|
| I am no more irritable than usual | ◯ |
| I am more irritable than usual | ◯ |
| I am much more irritable than usual | ◯ |
| I am irritable all of the time | ◯ |

**17.** ***Concentration Difficulty***

| | |
|---|---|
| I can concentrate as well as ever | ◯ |
| I can't concentrate as well as usual | ◯ |
| It's hard to keep my mind on anything for very long | ◯ |
| I find I can't concentrate on anything | ◯ |

**18.** ***Tiredness or Fatigue***

| | |
|---|---|
| I am not more tired or fatigued than usual | ◯ |
| I get more tired or fatigued more easily than usual | ◯ |
| I am too tired or fatigued to do a lot of the things I used to do | ◯ |
| I am too tired or fatigued to do most of the things I used to do | ◯ |

**19.** ***Loss of Interest in Sex***

| | |
|---|---|
| I have not noticed any recent change in my interest in sex | ◯ |
| I am less interested in sex than I used to be | ◯ |
| I am much less interested in sex now | ◯ |
| I have lost interest in sex completely | ◯ |

**20.** ***Changes in Sleeping Pattern***

| | |
|---|---|
| I have not experienced any change in my sleeping pattern | ◯ |
| I sleep somewhat more than usual | ◯ |
| I sleep somewhat less than usual | ◯ |
| I sleep a lot more than usual | ◯ |
| I sleep a lot less than usual | ◯ |
| I sleep most of the day | ◯ |
| I wake up 1-2 hours early and can't get back to sleep | ◯ |

**21.** ***Changes in Appetite***

| | |
|---|---|
| I have not experienced any change in my appetite | ◯ |
| My appetite is somewhat less than usual | ◯ |
| My appetite is somewhat greater than usual | ◯ |
| My appetite is much less than before | ◯ |
| My appetite is much greater than usual | ◯ |
| I have no appetite at all | ◯ |
| I crave food all the time | ◯ |

**Thank you for completing the questionnaires.**