

Impacts of Cognitive-Behavioural Interventions on Sleep Effort, Objective and Subjective Sleep Quality among Adults with Insomnia.

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Thesis submitted in partial fulfilment of the degree of
Doctorate in Clinical Psychology

Faculty of Medicine and Health Sciences

University of East Anglia

Submission date: 25th July 2022

Thesis portfolio word count: 27, 120

Candidate registration number: 100299102

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Acknowledgments

I would like to start off with expressing my heartfelt appreciation to my research supervisors, Dr Alpar Lazar and Professor Niall Broomfield. My journey of completing this thesis portfolio was not an easy one, and I truly am grateful for their guidance and encouragement which I have received since the very beginning. Alpar, thank you for dedicating your time and having an immense amount of patience in supporting me with developing my research skills and knowledge. Niall, thank you for your invaluable advice and support, especially with your expertise around paradoxical intention.

I am also grateful for my advisor Dr Imogen Rushworth, who has been a huge support to me in many ways throughout the past 3 years. Thank you for your constant availability and graciousness, especially during some very challenging times. I am blessed to have had you as my advisor.

Thank you to my family, who have been regularly checking in on me and cheering for me from all the way back home in Malaysia. I am eternally grateful for each one of them for being my rock, especially my parents. To all my friends, both old friends from Malaysia and new ones I have made in the UK, thank you for keeping me grounded and showing me grace through the highs and lows of this journey.

Finally, I dedicate this achievement to my grandfather, my dearest Gong Gong, who is very much loved and deeply missed.

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Thesis Portfolio Abstract

Background: Insomnia is a highly prevalent sleep disorder that negatively impacts overall health-related quality of life. Cognitive-behavioural interventions including cognitive behavioural therapy for insomnia (CBT-I) and paradoxical intention therapy (PI) have been developed to improve insomnia. Research suggests mixed findings on the impacts of CBT-I on objective and self-reported measures of sleep. Moreover, existing studies examining the effectiveness of PI among adults with high sleep effort are lacking.

Methods: This thesis portfolio aimed to address gaps within current literature around CBT-I and PI. First, a systematic review was carried out to describe and synthesise studies that assessed the effectiveness of CBT-I on both objective and self-reported sleep measures. Second, a two-arm, randomised controlled trial was conducted to determine the feasibility and preliminary efficacy of PI among adults with insomnia and high sleep effort.

Results: The systematic review identified 15 eligible studies. Most studies found significant improvements in sleep diary parameters (e.g., sleep efficiency, sleep onset latency, wake after sleep onset) and subjective sleep-related questionnaires following CBT-I. Conversely, mixed findings were found on objective sleep measures whereby the direction, magnitude and significance of change varied across studies. The empirical study indicated that PI shows good potential as a standalone psychological intervention for adults with insomnia. PI significantly improved sleep effort (primary outcome), self-reported sleep parameters (sleep efficiency, sleep onset latency, wake after sleep onset) and perceived sleep quality. PI also reduced depression symptoms across time, however, no significant effects were observed. Notably, there was a lack of agreement between actigraphy and sleep diary outcomes.

Conclusion: CBT-I and PI show effectiveness in improving sleep effort and self-reported sleep quality. However, there remains scope for future research to investigate the effectiveness of these interventions, with considerations to objective/self-reported discrepancies and severity of

depressive symptoms among adults with insomnia. Implications and directions for future research are discussed.

CHAPTER ONE

Introduction to the Thesis Portfolio

Introduction to the Thesis Portfolio

Insomnia and its theoretical models

Insomnia is a sleep disorder characterised by difficulties initiating and/or maintaining sleep, often resulting in shortened overall sleep duration and poor sleep quality (Roth, 2007). At present, there are three major classification systems that are more commonly used for the diagnosis of insomnia: 1) the Diagnostic and Statistical Manual of Mental Disorders-fifth edition (DSM-5; American Psychiatric Association [APA], 2013), 2) the International Statistical Classification of Diseases and Related Health Problems-eleventh edition (ICD-11; World Health Organisation [WHO], 2019), and 3) the International Classification of Sleep Disorders-third edition (ICSD-3; American Academy of Sleep Medicine [AASM], 2014). Whilst each of these classification systems of insomnia consist of various subcategories of the sleep disorder, primarily, the diagnostic criteria of insomnia include the presence of sleep difficulties and significant impairment of daytime functioning, with DSM-5 and ICSD-3 further specifying that symptoms occur at least three times a week for three months or more.

Over the years, several theoretical models of insomnia have been developed to understand in more depth the aetiology and pathophysiology of this sleep disorder. These models have proposed various conceptualisations of insomnia including those of cognitive, behavioural and neurobiological perspectives. One of the earliest models of insomnia that became widely-recognised and accepted is known as the 3P behavioural model, whereby insomnia is described using a stress-diathesis approach. This approach highlighted the interaction of three factors (predisposing, precipitating and perpetuating) that contributes to insomnia development and maintenance (Spielman et al., 1987). The 3P model considers a broad range of factors including genetic, biological, psychological and environmental factors in influencing one's vulnerability in developing initial sleep disturbances and insomnia symptoms. Whilst insomnia may be triggered by various predisposing factors, the 3P model

explains that insomnia may persist beyond the initial triggers particularly when individuals develop sleep-related habits as attempts to minimise sleep disturbances (e.g., extended time in bed, increased reduced daytime activity; Spielman et al., 1987). This model was later further explored and expanded to include the potential impacts of neurobiological factors on insomnia. Specifically, the neurocognitive model (Perlis et al., 1997) proposed that difficulties in initiating and maintaining sleep are influenced by cortical hyperarousal, in which classical conditioning from repeated pairing of stimuli used to promote sleep (sleep-related stimuli) with arousal (insomnia-related wakefulness) ultimately lead to their experience of insomnia symptoms. This model utilised objective measures of sleep quality including electroencephalography (EEG) and polysomnography (PSG) to evaluate brain activity during sleep, and it was suggested that the conditioned cortical arousal resulted in the occurrence of sleep state misperception, characterised by enhanced sensory processing, information processing and memory formation, thus maintaining insomnia (Perlis et al., 1997).

On the other hand, cognitive models of insomnia emphasise the influence of one's thoughts, emotions and beliefs on the development of maladaptive behavioural patterns that later go on to interfere with the process of sleep. Harvey (2002) proposed that excessive cognitive activity that precedes the initiation of sleep triggers both emotional distress and physiological arousal, thereby disrupting sleep. This model highlighted the vicious cycle of insomnia, whereby one's preoccupation with their sleep is likely to be followed by the engagement in counterproductive sleep-related safety behaviours (Harvey, 2002). For example, individuals who become overly worried about their sleeplessness and poor daytime functioning may have selective attention to perceived sleep-related threats, and they may then manage this by excessively monitoring their behaviours around sleep (e.g. thought control, emotional inhibition). The role of selective attention in insomnia was also emphasised by the Psychobiological Inhibition Model of Insomnia. Developed by Espie (2002), this model

proposed that good sleepers naturally achieve a positive combination of sleep homeostasis and circadian timing, and these are maintained by four interacting subsystems: sleep-related stimulus control, sleep-related physiological de-arousal, sleep-related cognitive de-arousal and daytime attribution of night-time sleep. The Psychobiological Inhibition Model of Insomnia suggested that individuals with insomnia experience an inhibition in one or more of the subsystems following the presence of attentional bias to any sleep-related arousal (e.g. physiological, cognitive) and the subsequent engagement in paradoxical effort to achieve de-arousal (Espie, 2002). This model was further expanded several years later to emphasise the processes that occur after selective attention and how it disrupts normal sleep. Coined as the attention-intention-effort (A-I-E) pathway (Espie et al., 2006), this framework integrated the role of explicit intention and direct effort in initiating sleep, which likely happens after an individual with insomnia selectively attends to potential sleep-related threats or stimuli. Whilst ‘intention’ in this framework refers to the process of combining selective attention with conscious, goal-directed action planning, ‘effort’ is the proactive and responsive process that involves making behavioural changes to initiate sleep (Espie et al., 2006). The Psychobiological Inhibition Model of Insomnia highlighted the role of the A-I-E pathway in disrupting the natural process of sleep, particularly by preventing relaxation and inducing an aroused state of performance anxiety, thus maintaining symptoms of insomnia (Broomfield & Espie, 2003).

Impacts of insomnia on mental health

In recent years, insomnia has been known as a pervasive disorder across demographics and populations (Israelashvili & Romano, 2017), with some studies indicating that the disorder affects approximately 30% of the general population (Bashkar et al., 2016; Roth, 2007) and others showing higher prevalence rates of approximately 50% (Bashkar et al., 2016; Ohayon, 2002). Of those diagnosed with insomnia, various negative impacts have been reported to date.

Individuals with insomnia were found to experience a decreased overall health-related quality of life, in which they had significant complaints of poor cognitive, social, emotional, physical, educational and occupational functioning (Scott et al., 2006; Kyle et al., 2010). A study by Daley and colleagues (2009) evaluated the impacts of insomnia on health and productivity levels, and their findings showed that adults with insomnia were more likely than good sleepers to have greater difficulties with physical and mental health issues (e.g. fatigue and poor daytime functioning, mood and anxiety disorders, alcohol dependency) as well as increased work absenteeism, decreased work productivity and elevated risk of non-motor accidents. These studies therefore suggest that the negative impacts of insomnia can be far-reaching, resulting in potentially crippling effects towards one's personal and/or professional lives. With this in mind, insomnia is undoubtedly a significant public health concern (Israelashvili & Romano, 2017; Mental Health Foundation, 2011).

One of the most commonly associated health-related problems of insomnia is mental health difficulties. A recent meta-analysis conducted by Hertenstein et al. (2019) indicated that insomnia is a significant predictor for the onset of various mental disorders including depression, anxiety, alcohol abuse and psychosis. This association between insomnia and psychiatric disorders is consistent across age groups of the adult population. For example, a longitudinal study conducted among young adults found that insomnia became more prevalent among adults from ages 20 to 40, and this significantly increased their risk of developing depression subsequently (Buysse et al., 2008). Similarly, elderly people with insomnia has been found to have significantly higher risks of developing depression (Cole & Dendukuri, 2003; Perlis et al., 2006). More specifically, Jaussent and colleagues (2011) conducted a longitudinal study to determine the extent to which insomnia was a risk factor of depression among the older adult population, and their findings demonstrated that those with insomnia were 23% more likely those without insomnia to develop depressive symptoms. In addition, there are

extensive supporting evidence highlighting the role of insomnia in perpetuating existing mental disorders. For example, a recent review by Freeman and colleagues (2020) indicated that there was a bidirectional relationship between insomnia and mental disorders such as depression, anxiety, schizophrenia and post-traumatic stress disorder (PTSD). It was suggested that in the context of treatment, the improvement of insomnia symptoms were likely to lessen the severity of mental health difficulties (Freeman et al., 2020). Hence, there appears to be scope for the implementation of sleep-focused interventions to not only improve sleep disturbances but to also potentially benefit one's mental health.

Psychological interventions for insomnia

In England, the first-line of psychological intervention for adults with insomnia is known as cognitive behavioural therapy for insomnia (CBT-I; National Institute for Health and Care Excellence [NICE], 2022). CBT-I comprises of several single-component strategies, typically including stimulus control, sleep restriction, sleep hygiene, relaxation training and a range of cognitive therapeutics (e.g., cognitive restructuring, paradoxical intention), that are administered across a time period to target specific cognitive and behavioural factors of insomnia (Balgioni et al., 2019). For example, whilst stimulus control promotes a learned association between the bed and sleep, and sleep restriction aims to restore homeostatic regulation of the sleep-wake cycle, cognitive therapy focuses on reducing sleep-related thoughts that may be anxiety-provoking (Balgioni et al., 2019).

To date, there has been extensive studies demonstrating the efficacy of CBT-I for adults with insomnia. A review by Davidson and colleagues (2019) indicated that CBT-I was effective in improving sleep quality among both mixed-age adults and the elderly populations, with significant effects found in sleep parameters including sleep onset latency and wake after sleep onset, when delivered in a primary care setting. Similar positive effects were found when CBT-I was administered with adults with insomnia who presented with comorbid psychiatric

disorders including mood disorders, anxiety disorders, PTSD and addictions (Ashworth et al., 2015; Harvey et al., 2015; Smith et al., 2005), whereby CBT-I was effective at reducing the severity of both insomnia and mental disorder symptoms. Moreover, when compared with pharmacological treatments, CBT-I was also reported to be significantly more beneficial in reducing insomnia symptoms and maintaining improved sleep quality across time (Mitchell et al., 2012; Qaseem et al., 2016; Reimann et al., 2017).

One of the strategies delivered as part of the cognitive therapeutic component of CBT-I is paradoxical intention (PI). PI is a cognitive-based intervention that aims to improve sleep quality by reducing pre-sleep cognition such as sleep effort (Broomfield & Espie, 2003; Bagnioni et al., 2019). The rationale of PI is that rather than voluntarily controlling sleep, the act of trying to stay awake in bed is more likely to induce the natural process of sleep because pre-sleep cognitive activities that arouse wakefulness are eliminated (Turner & Ascher, 1979; Espie, 2002). Whilst commonly delivered as part of multicomponent CBT-I, PI is an evidence-based approach that has been included as part of the AASM clinical practice guidelines as a single-component therapy for the treatment of chronic insomnia in adults (Schutte-Rodin et al., 2008). On its own, PI has been found to be useful in managing sleep-onset insomnia across single case studies (Ascher & Efran, 1978; Espie & Lindsay, 1985) and randomised-controlled studies (Espie et al., 1989; Turner & Ascher, 1979; Broomfield & Espie, 2003), in which sleep onset latency and sleep complaints were significantly reduced among people with insomnia following the administration of PI. Nevertheless, apart from the AASM guideline, the use of PI as an intervention for insomnia remains under-recognised and unspecified in most clinical practice guidelines such as the European Sleep Research Society (ESRS) and the NICE guidance, with recognition only given to CBT-I. This suggests that PI may be under-researched despite some indications of it being a promising single-component intervention for insomnia (Jansson-Fröjmark et al., 2021).

The present portfolio

This thesis portfolio aims to address two gaps in sleep literature. Chapter 2 presents a systematic review on the effectiveness of CBT-I on measures of sleep quality among adults with insomnia, focusing on the agreement between objective and subjective measures of sleep. Next, Chapter 4 presents an empirical research paper which investigates the feasibility of PI among adults with insomnia disorder and high sleep effort. Theoretical and conceptual links between these two studies are discussed in Chapter 3. Finally, Chapter 5 integrates the findings across both the systematic review and empirical research paper. Chapter 5 also includes a critical evaluation of the theoretical and clinical implications, strengths and limitations, and areas for future development for this thesis portfolio.

CHAPTER 2

Systematic Review

Comparing the Effectiveness of Cognitive Behavioural Therapy for Insomnia (CBT-I) on

Objective and Self-Reported Measures of Sleep Quality in Adults with Insomnia:

A Systematic Review

Prepared for the Journal of Clinical Sleep Medicine

(see Appendix A for author guidelines for manuscript preparation)

**Comparing the Effectiveness of Cognitive Behavioural Therapy for Insomnia (CBT-I)
on Objective and Self-Reported Measures of Sleep Quality in Adults with Insomnia:
A Systematic Review**

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All authors have seen and approved the manuscript

Conflict of interest: None

Number of tables: 2

Number of figures: 2

Abstract word count: 248

Manuscript word count: 6692

Abstract

Objectives: The aim of this review was to synthesise evidence from studies that evaluated the impacts of cognitive behavioural intervention for insomnia (CBT-I) on objective and self-reported sleep measures when assessed concurrently among adults with insomnia.

Methods: A systematic search was conducted on several electronic databases (MEDLINE, PsycINFO, EMBASE and CINAHL) to retrieve all articles available from inception to March 2022. Of 1949 references that were retrieved, 15 published studies were included in the review.

Results: Self-reported sleep quality in the included studies is often measured using a sleep diary alongside additional sleep-related questionnaires focusing on insomnia severity, daytime functioning, beliefs about sleep and sleep-related quality of life. Conversely, objective sleep quality is more commonly measured using wrist actigraphy, polysomnography and Nightcap. Following CBT-I, self-reported sleep parameters (e.g., sleep efficiency, total sleep time, sleep onset latency, wake after sleep onset) and self-reported sleep quality significantly improved, with moderate to large effect sizes. The magnitude of change in objective sleep measures were less significant compared to self-reported measures, indicating some differences between both measures.

Conclusion: CBT-I shows effectiveness in improving self-reported measures of sleep quality, with mixed findings reported for objective sleep. Future studies should use both measures concurrently and test the association between objective and self-reported sleep quality. More studies with good methodological quality should be conducted to further inform the effectiveness of CBT-I on overall sleep quality and improve current knowledge about sleep-wake misperceptions among adults with insomnia.

Keywords: CBT-I, objective sleep measures, self-reported sleep measures, agreement, insomnia

Introduction

Insomnia is a sleep disorder characterised by difficulties in initiating and maintaining sleep (Roth, 2007). Research suggests that insomnia affects between 30% and 50% of the general population (Bashkar et al., 2016; Ohayon, 2002; Roth, 2007), with most individuals affected reporting decreased satisfaction in aspects of quality of life including daytime functioning, mental wellbeing, and productivity (Baglioni et al., 2011; Daley et al., 2009). To address the negative consequences of insomnia, extensive research has focused on developing and improving psychological interventions for affected individuals. In England, cognitive behavioural therapy for insomnia (CBT-I; National Institute for Health and Care Excellence [NICE], 2022) represents the first-line psychological intervention for adults with insomnia, and it comprises of a range of cognitive and behavioural therapeutic strategies that target key factors of insomnia (Baglioni et al., 2019).

At present, several studies have evaluated the use of CBT-I and found strong evidence of its efficacy in improving sleep quality among adults with insomnia. Okajima and colleagues (2011) conducted a meta-analysis on the effectiveness of multicomponent CBT-I for primary insomnia and found that this approach yielded moderate to large effect sizes as treatment and relapse prevention of insomnia. More specifically, participants who received CBT-I experienced lasting effects of improved quality of night-time sleep and reduced symptoms of daytime depressive mood (Okajima et al., 2011). A recent meta-analysis further examined the long-term efficacy of CBT-I, and whilst results demonstrated a decline in treatment effects over time, the overall impact of the CBT-I remained clinically significant until up to 12 months post-intervention (Van der Zweerde et al., 2019). For example, sleep outcomes such as sleep efficiency and sleep onset latency, as well as insomnia severity, remained considerably better at 12 months follow-up among those who received CBT-I compared to the control group (Van der Zweerde et al., 2019).

Although insomnia disorder is clinically diagnosed based on subjective perception of sleep impairments (American Psychiatric Association [APA], 2013; International Classification of Sleep Disorders [ICSD-3], 2014), research suggests that both objective and self-reported outcomes of sleep quality should be taken into consideration in research trials that measure the assessment of insomnia and effectiveness of treatment (Buysse et al., 2006). Commonly used objective measures of sleep include polysomnography (PSG), which is known as the “gold-standard” quantitative measure of insomnia, and actigraphy (Buysse et al., 2006; McCall & McCall., 2013). Conversely, sleep diaries are considered a “gold-standard” qualitative measure of sleep, and it tends to be used as a standalone self-reported tool and/or alongside self-reported sleep-related questionnaires that measure sleep-wake correlates and consequences such as fatigue, sleepiness, and daytime functioning (Buysse et al., 2006). To quantify sleep quality, sleep parameters such as sleep latency, sleep period, total sleep time, wake after sleep onset and sleep efficiency, among several others, can be derived from both objective and self-reported measures of sleep and further meaningfully interpreted to understand sleep patterns (Ibáñez et al., 2018).

There is a large body of research that supports the effectiveness of CBT-I on self-reported measures of sleep, particularly with sleep diary variables including sleep efficiency, sleep onset latency and wake after sleep onset (Koffel et al., 2016). However, the effectiveness of CBT-I on objective sleep outcomes is less well-known, and findings are mixed. Mitchell and colleagues (2019) recently conducted a meta-analysis to evaluate the impacts of CBT-I on objective sleep measures in 15 randomised controlled trials (RCT). The findings reported that actigraphy outcomes observed small to moderate effects for sleep parameters such as sleep onset latency and total sleep time, and that no significant improvements were found in polysomnography outcomes (Mitchell et al., 2019). Sleep diary outcomes, however, observed robust improvements – namely sleep onset latency (SOL), wake after sleep onset (WASO) and

sleep efficiency (SE; Mitchell et al., 2019). In contrast to this, a meta-analysis by Okajima and colleagues (2011) found moderate to large improvements in objective sleep variables (e.g., SOL, SE), along with sleep diary variables and subjective sleep rating scales.

Overall, it remains unclear the effectiveness of CBT-I on objective and self-reported measures of sleep when both types of measures are compared. Past systematic reviews and meta-analyses have attempted to quantify the impacts of CBT-I on objective and self-reported measures of sleep respectively, however, it should be highlighted that none of these studies have considered the inclusion of studies that employed *both* types of measures concurrently. An exception is the meta-analyses conducted 11 years ago by Okajima and colleagues (2011) which compared the effectiveness of CBT-I on both objective and self-reported measures (sleep-diary and rating scales). As the studies included in this meta-analysis are dated between 1990 and 2009, an update in the review of studies is necessary. Whilst a more recent study by Mitchell and colleagues (2019) evaluated the effects on objective and sleep diary measures in relation to the use of CBT-I, the general emphasis of the work focused on the impacts of CBT-I on objective measures of sleep. Hence, this systematic review aimed to add to existing knowledge by describing and synthesising existing RCTs that evaluated the use of CBT-I on a *combination* of objective and self-reported (e.g., sleep diary, sleep-related questionnaires) measures of sleep quality.

Methods

Protocol and Registration

This review was reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) Statement (Moher, Liberati, Tetzlaff & Altman, 2009) and is registered with PROSPERO: International prospective register of systematic reviews (ID: CRD42022304310).

Search Strategy

A systematic search was conducted by the primary author (GO) to identify all studies that evaluated the effectiveness of CBT-I using both objective and self-reported measures of sleep. Electronic databases MEDLINE, PsycINFO, EMBASE and CINAHL were searched from inception to March 2022, using terms for insomnia, cognitive behavioural therapy, objective, and subjective measures of sleep. The following search terms were used on the electronic databases: objective sleep (measure* OR questionnaire OR assessment) OR actigra* OR polysomnogra* or PSG AND subjective sleep (measure* OR questionnaire OR assessment) OR self-reported sleep (measure* OR questionnaire OR assessment) OR perceived sleep (measure* OR questionnaire * OR assessment) OR “sleep diary” OR “sleep perception” AND “cognitive behavio* therap*” OR “cognitive behavio* intervention” OR CBT OR CBT-I AND insomnia. All searches were limited to human studies that were peer reviewed and published in full in the English language.

Study Selection

Following the initial search, all titles and abstracts were screened by the primary author (GO) to identify studies that provided a CBT-I intervention for adults with insomnia disorder and assessed sleep outcomes using both objective and subjective measures. A second-rater (GB) co-rated 33% of the full-text articles which were randomly selected to ensure included articles were in line with the inclusion and exclusion criteria.

Intervention studies were included in the review if they met the following criteria: 1) the intervention was CBT-I that adopted a multimodal or single-component approach (e.g., training, stimulus control therapy, sleep restriction therapy, paradoxical intention therapy), 2) the study methods included both the use of objective (e.g. polysomnography, actigraphy) and self-reported (e.g. sleep diary, sleep quality questionnaires) sleep measures, 3) an RCT design, and 4) the population sampled were adults (≥ 18 years) who have been diagnosed with insomnia

disorder or presented with insomnia symptoms that met either research diagnostic criteria (RDC; Edinger et al., 2004) or clinical diagnostic criteria such as the Diagnostic and Statistical Manual of Disorders (DSM; American Psychiatric Association [APA], 1980, 1994, 2000, 2013), the International Statistical Classification of Diseases and Related Health Problems (ICD; World Health Organization [WHO], 2016, 2019) or the International Classification of Sleep Disorders (ICSD; American Academy of Sleep Medicine [AASM], 1990, 2005, 2014).

Studies were excluded if they were considered grey literature (e.g., conference abstracts, unpublished data, reports, and theses that have not been peer-reviewed, commentaries without original results, study protocol descriptions). Qualitative studies, narrative reviews, systematic reviews, and meta-analyses were also not included. Research articles that listed co-morbid sleep, psychiatric or medical disorders and shift workers as main focuses of the study or as participant criteria were excluded. However, as patients with insomnia are likely to present with co-morbid conditions in clinical settings, studies were not excluded if the paper reported co-morbid conditions as secondary focus. Moreover, studies that had primary interventions for insomnia other than CBT-I (e.g., CBT-I combined with alternative or pharmacologic treatment) were excluded.

Data Extraction and Synthesis

This review employed the framework for data extraction and synthesis as outlined on the Guidance on the Conduct of Narrative Synthesis in Systematic Reviews (Popay et al., 2006). Empirical data from the included studies were extracted by the primary author (GO) as relevant to the objectives of the review, and findings of each study were interpreted and synthesised narratively. This method of synthesis was used as included studies varied in methodological characteristics (e.g., sample population, CBT-I intervention) and quality, deeming it inappropriate to use other integrative methods including meta-analysis (Dixon-Woods et al., 2004). Following the guidance by Popay and colleagues (2006), this review

involved developing a preliminary synthesis by interpreting the main findings of each included study and exploring associations by evaluating and grouping the studies according to outcomes. The study characteristics for each included study were recorded, including the description of the population, methodological approach, and intervention procedures (Table 1). The outcome measures and summary of the study findings were also reviewed and tabulated (Table 2). Given that the objective of this review was to assess the effectiveness of CBT-I on objective and subjective sleep quality among adults, the post-intervention and follow-up outcomes of sleep quality from both types of measures were reviewed and explored.

Quality Assessment

A risk of bias assessment was conducted for all included studies to assess the reliability and validity of the study outcomes based on their methodological quality. The revised Cochrane risk-of-bias tool for randomized trials (RoB 2; Sterne et al., 2019) was used. This assessment tool was developed as an update to the original Cochrane tool for assessing risk of bias in randomised trials (RoB tool), and it comprised of five domains: 1) bias arising from the randomisation process, 2) bias due to deviations from intended interventions, 3) bias due to missing outcome data, 4) bias in measurement of the outcome, and 5) bias in selection of the reported result. All items of each domain consisted of signalling questions that provided a structured approach to obtaining information relevant to assessing risk of bias. These signalling questions were rated with 'yes', 'probably yes', 'no', 'probably no', 'no information' or 'not applicable', of which specific combinations of ratings in each domain produced an overall risk of bias judgment of 'low', 'high' or 'some concerns' (Sterne et al., 2019).

All included studies were independently appraised by the primary author (GO). To ensure process rigour, 33% of the included studies were randomly selected and co-rated by the second-rater (GB). In the case of any inconsistencies in appraisal of quality, discussions between the two reviewers were held until a consensus was reached.

Results

Search Outcomes

The search strategy yielded 1949 references. After removing duplicates ($n = 595$) and non-English publications ($n = 37$), the titles and abstracts of 1317 records were screened. Following this process, 1259 references were deemed irrelevant and were excluded from the retrieval and screening of full-text articles. Fifty-eight full-text papers were assessed for eligibility, and a total of 15 published studies met the inclusion criteria for this systematic review (see Figure 1).

Study characteristics

Table 1 shows the 15 studies that were included in this review along with their characteristics. The included studies were carried out across the United States of America ($n = 11$), Europe ($n = 3$) and Australia ($n = 1$), and they were published between the years 1993 and 2020. These studies recruited a total of 1317 participants from the community ($n = 11$), a university-based outpatient clinic ($n = 1$), military veterans ($n = 2$) and college students ($n = 1$). Out of all the participants, 2.6% were young adults, 42.7% were middle-aged adults and 51.3% were older adults. One study included 46 participants (3.4%) comprising both middle-aged and older-aged adults (e.g., ≥ 55 years). Across the 15 studies, the mean age of the sample was 57.66, with predominantly female participants ($n = 764$; 58%).

The criteria for insomnia disorder (clinical and research) were ascertained via clinical interview and/or self-reported measures (e.g., sleep diary, questionnaire) for most studies ($n = 11$). The remaining studies used only clinical interview ($n = 3$) and questionnaire ($n = 1$) at baseline to determine the presence of insomnia disorder. A handful of studies also used laboratory-based PSG ($n = 4$) and home-based PSG ($n = 1$) to screen for and exclude sleep disorders other than insomnia, with one study (Edinger et al., 2007) excluding individuals with a PSG measured sleep time ≥ 2 times higher than their subjectively reported sleep time given

the high discordance which suggest unreliable data. Another study (Lovato et al., 2016) also used PSG at screening to classify participants into groups of short- (<6 total sleep time) and long-sleepers (≥ 6 total sleep time).

All included studies employed sleep restriction therapy alongside at least one form of education intervention such as psychoeducation ($n = 7$), sleep hygiene ($n = 6$) or both ($n = 2$). Stimulus control therapy ($n = 13$) was the next most commonly employed component of CBT-I, followed by cognitive therapy ($n = 6$), relaxation ($n = 5$) and cognitive restructuring ($n = 1$). Across the included studies, intervention was delivered on a weekly basis, with only one study (Edinger et al., 2009) delivering intervention biweekly. The duration of intervention ranged between 4 and 8 sessions, with the length of each session lasting between 15 and 90 minutes. CBT-I interventions were administered using several methods including face-to-face individual sessions ($n = 3$), face-to-face group sessions ($n = 3$), a combination of individual and group face-to-face sessions ($n = 1$), a combination of individual face-to-face and phone call sessions ($n = 3$), and a combination of group face-to-face and phone call sessions ($n = 1$). The remaining studies ($n = 4$) had limited information regarding intervention procedures. From the included studies, the control arms included waitlist control ($n = 5$), placebo ($n = 3$), progressive muscle relaxation training control ($n = 1$), treatment as usual ($n = 1$), educational control ($n = 2$), information control ($n = 1$), self-monitoring and attention control ($n = 1$) and time in bed regularisation ($n = 1$).

Outcome Measures of Sleep

Three distinct types of sleep measures were outlined from the included studies in this review: objective measures of sleep, sleep diary and self-reported measures (questionnaire) of sleep (see supplementary tables S1, S2 and S3). All studies administered a sleep diary alongside one or a combination of objective measures of sleep. Moreover, only 4 studies used the sleep diary as the sole self-reported measure of sleep, with most other studies additionally

administering questionnaires relating to perceived sleep quality. Table 2 outlines the summary of findings for all studies included in this review.

Objective Measures of Sleep

The objective measures of sleep that were used in this review included the polysomnography (PSG), the Nightcap sleep monitor and wrist actigraphy. Whilst each measure is commonly employed as a single objective measure of sleep (PSG, $n = 4$; Nightcap, $n = 1$; wrist actigraphy, $n = 8$), some studies used a combination of PSG and wrist actigraphy ($n = 2$). Moreover, PSG was also specified in 4 studies as a screening measure to identify individuals with and without insomnia (Edinger et al., 2001; Edinger et al., 2007; Edinger et al., 2009; Buysse et al., 2011; Lovato et al., 2016). The length of use for each measure ranged across 1 and 14 nights. From the studies that utilised the PSG and Nightcap, data were collected between 1 and 3 nights, and outcomes were calculated by averaging scores from each of the assessment timepoints. As for the wrist actigraphy, studies administered this measure either for 7 or 14 consecutive nights, and a mean outcome was obtained at baseline and post-intervention timepoints.

Sleep diary

All included studies employed the use of a sleep diary, with 3 studies specifying the use of validated sleep diaries: Electronic Sleep Diary (Edinger et al., 2009), Pittsburgh Sleep Diary (Buysse et al., 2011) and Consensus Sleep Diary (Maurer et al., 2020). In all studies, sleep diary data were collected either for 7 or 14 consecutive nights, with scores averaged at each assessment timepoints. The sleep diary was also used in 13 studies at follow-up timepoints which ranged between 1- and 24-months.

Self-reported measures of sleep (questionnaires)

From the included studies, a total of 12 sleep-related questionnaires were administered, this included the Sleep Impairment Index (SII; $n = 1$), Insomnia Symptom Questionnaire (ISQ;

$n = 3$), Pittsburgh Sleep Quality Index (PSQI; $n = 5$), Dysfunctional Attitudes and Beliefs about Sleep Scale (DBAS; $n = 3$), Epworth Sleepiness Scale (ESS; $n = 2$), Insomnia Severity Index (ISI; $n = 5$), Multidimensional Fatigue Inventory (MFI; $n = 1$), Flinders Fatigue Scale (FFS; $n = 1$), Daytime Feeling and Functioning Scale (DFFS; $n = 1$), Sleep Self-Efficacy Scale (SSES; $n = 3$), Sleep Anticipatory Anxiety Questionnaire (SAAQ; $n = 1$), and Glasgow Sleep Impact Index (GSII; $n = 1$). These questionnaires focused on specific aspects of self-perceived sleep which can be categorised into 5 domains: 1) measures of overall sleep quality (e.g., SII, ISQ, PSQI), 2) measures of insomnia severity (e.g., ISI), 3) measures of daytime functioning (e.g., ESS, MFI, FFS, DFFS), 4) measures of beliefs about sleep (e.g., DBAS, SSES, SAAQ) and 5) measures of sleep-related quality of life (e.g., GSII). All questionnaires were administered at baseline, post-intervention, and follow-up timepoints of each study.

Quality Assessment

Figure 2 shows the risk of bias analysis plot for the studies included in this review. Developed using the *robvis* tool (McGuinness & Higgins, 2020), the analysis plot outlines the judgment on each of the five risk-of-bias domains, along with the overall judgment for all included studies. In general, most studies were judged to have a low risk of bias on most domains, however, overall judgment yielded 8 studies (53.3%) with some concerns of a risk of bias and the remaining 7 studies (46.7%) with a high risk of bias. No studies overall had a low risk of bias.

All included studies generated an appropriate randomisation sequence. Allocation sequence concealment was adequate in most studies ($n = 13$; 87%), however, the concealment process was not reported in two studies (13%). In one study, baseline imbalances were observed between the intervention groups. As there was insufficient information to address this imbalance in the study, it was unclear the link between the randomisation process and baseline differences. Moreover, ten studies (67%) reported that participants and researchers were not

blinded. Particularly, authors reported the difficulty of the blinding process due to the implementation of psychotherapy in these trials. Whilst three studies (20%) had insufficient information regarding the blinding process, two studies (13%) reported attempts to minimise the potential bias from unblinded participants by incorporating minimally active control groups. For example, these trials provided the same weekly attention from research personnel to participants in the control group and used structured sleep education sessions. Additionally, 13 studies (86.7%) reported on their outcome data and provided details concerning their attrition rates. Out of 15 studies, 4 studies (26.7%) were unclear regarding the management of missing data. Moreover, there was unclear evidence in relation to selective reporting across all studies to the lack of pre-specified analysis plans.

Relationship between CBT-I and Outcome Measures of Sleep

Comparison of studies with positive, mixed and negative effects

Ten studies out of 15 (66.7%) indicated that CBT-I had overall positive effects on both objective and self-reported measures of sleep (e.g., sleep diary and/or sleep-related questionnaires), whereby both types of outcome measures showed improvements over time. Whilst the direction of change for both measures were similar, 7 of these 10 studies reported that the magnitude of effects over time was greater in sleep diary outcomes compared to objectively measured outcomes. However, it is important to note that none of these studies have good methodological quality scores. Although more than half of the 10 studies ($n = 6$) had only some risk of bias, the remaining 4 studies presented with high risk of bias.

Studies with mixed effects referred to those that reported improvements in some but not all sleep outcomes, and this made up 33.3% of the 15 included studies. Whilst 2 studies with mixed effects were of adequate methodological quality (some risk of bias), the remaining 3 studies yielded a high risk of bias. Finally, none of the included studies reported overall negative effects of CBT-I on either objective or self-reported measures of sleep.

Effects of CBT-I on Objective and Sleep Diary Sleep Parameters

Sixteen sleep parameters were recorded to measure changes in objective and/or self-reported quality of sleep. Sleep efficiency (SE) was found to be recorded on all included studies, followed by total sleep time (TST; $n = 14$), sleep onset latency (SOL; $n = 12$) and wake after sleep onset (WASO; $n = 11$). Other sleep parameters include early morning awakening (EMA; $n = 1$), total wake time (TWT; $n = 4$), total time awake between initial sleep onset and final morning awakening (MWASO; $n = 1$), time between final awakening and rising time (TWASO; $n = 1$), time in bed (TIB; $n = 2$), number of awakening during the night (NWAK; $n = 1$), and terminal wakefulness (TWAK; $n = 1$). One study (Sivertsen et al., 2006) measured slow wave sleep (SWS) using a home-based PSG, whilst other studies (Buysse et al., 2011; Lovato et al., 2016) measured additional sleep parameters such as bedtime (BT; $n = 1$), rise time (RT; $n = 1$) and number of awakenings (NA; $n = 1$) using the sleep diary. Moreover, subjective sleep quality (SQ) was also reportedly assessed based on the sleep diary in three studies (Buysse et al., 2011; Epstein et al., 2012; Taylor et al., 2014).

Sleep Efficiency (SE). Of all the studies that measured the effectiveness of CBT-I on objective and sleep diary SE, thirteen studies (86.7%) reported significant improvements in SE at post-intervention and/or follow-up timepoints. Whilst 7 of these studies were of adequate methodological quality (some risk of bias), the remaining 6 were of high risk of bias that mainly resulted from a combination of randomisation and allocation blinding issues. Two studies (13.3%), however, reported mixed findings between measures that recorded this sleep parameter. Chan and colleagues (2017) indicated that whilst both actigraphy and sleep diary measures of SE improved following the exposure to brief behavioural therapy for insomnia (BBT-I), greater variability was detected on the actigraphy at 3-months follow up. The study by Maurer and colleagues (2020) measured sleep quality using a sleep diary, actigraphy and polysomnography. Results showed significant differences for SE at post-intervention,

however, significant improvements observed on sleep diary and actigraphy SE were not reflected on the polysomnography SE (Maurer et al., 2020).

Total Sleep Time (TST). Seven out of 13 studies that measured both objective and sleep diary TST reported changes in similar directions at post-intervention, whereby five studies observed an increase in TST (Morin et al., 1999; Edinger et al., 2001; Edinger et al., 2009; Taylor et al., 2014; Maurer et al., 2020) and two studies (Buysse et al., 2011; Chan et al., 2017) observed a decrease in TST at post-intervention and/or follow-up. A majority of the studies that observed positive effects of CBT-I on TST ($n=4$) were of adequate methodological quality (some risk of bias), whereas both the studies reporting negative effects were of poor methodological quality (high risk of bias). The remaining six studies observed mixed findings between objective and sleep diary TST outcomes following the exposure to CBT-I interventions. These studies found that whilst sleep diary TST increased at post-intervention, there was conversely a decrease in objective TST (Morin et al., 1993; Jacobs et al., 2004; Sivertsen et al., 2006; Edinger et al., 2007; Epstein et al., 2012; Lovato et al., 2016). Notably, however, 4 of these studies were rated to have a high risk of bias.

Sleep Onset Latency (SOL). Eight studies noted an agreement in both objectively measured and self-reported SOL, in which there was a significant reduction in participants' total time taken to fall asleep after receiving CBT-I sessions as recorded on the actigraphy/polysomnography and sleep diary (Morin et al., 1993; Jacobs et al., 2004; Espie et al., 2007; Edinger et al., 2007; Edinger et al., 2009; Epstein et al., 2012; Taylor et al., 2014; Chan et al., 2017). Of these studies that indicated positive effects, more than half ($n = 5$) were rated to have some risk of bias, suggesting adequate methodological quality. Three studies observed mixed findings when objective and sleep diary measures were compared. Lovato and colleagues (2016) compared the use of CBT-I on short- and long-sleepers and found that whilst long-sleepers achieved consistent reduced outcomes on both sleep diary and actigraphy SOL,

short-sleepers had lowered sleep diary SOL and increased actigraphy SOL. Inconsistent findings were found when SOL was measured on both actigraphy and polysomnography as well as sleep diary. Whilst Buysse and colleagues (2011) found agreement between significantly reduced sleep diary and actigraphy SOL, Maurer and colleagues (2020) observed agreement between significantly increased actigraphy and polysomnography SOL instead.

Wake after sleep onset (WASO). From the studies that compared objective and sleep diary WASO, seven studies reported significant reductions in this sleep parameter following exposure to CBT-I (Morin et al., 1993; Morin et al., 1999; Espie et al., 2007; Edinger et al., 2007; Buysse et al., 2011; Epstein et al., 2012; Lovato et al., 2016). Notably, however, 5 of the 7 studies demonstrating positive effects of CBT-I on WASO had poor methodological quality as they were rated to have a high risk of bias. Conversely, inconsistent findings were found between objectively measured and self-reported WASO between three studies. Specifically for the study by Maurer and colleagues (2020) which measured WASO on the sleep diary, actigraphy and polysomnography, agreement was found between actigraphy and polysomnography outcomes, whereby WASO was significantly increased following CBT-I. However, this was not reflected on the self-reported measure as sleep diary WASO was significantly reduced at post-intervention (Maurer et al., 2020). Similar findings were reported in the studies by Taylor and colleagues (2014) and Chan and colleagues (2017), in which objective WASO was increased and sleep diary WASO was reduced at post-intervention timepoints.

Other sleep parameters. Significant reductions and agreements between objective and sleep diary measures were also observed for the following sleep parameters after CBT-I sessions: EMA (Morin et al., 1993), TWT (Morin et al., 1993; Sivertsen et al., 2006; Edinger et al., 2007), MWASO (Edinger et al., 2001), TWASO (Edinger et al., 2001), TIB (Epstein et al., 2012) and TWAK (Taylor et al., 2014). Conversely, there was inconsistency between

NWAK measures, in which sleep diary NWAK was reduced and actigraphy NWAK was increased at post-intervention (Taylor et al., 2014).

Effects of CBT-I on Self-Reported Sleep-Related Questionnaires

More than half of the included studies ($n = 11$; 73.3%) administered at least one sleep-related questionnaire in the evaluation of CBT-I on self-reported sleep. Notably, positive effects were found for most outcomes of the questionnaires at post-intervention and follow-up timepoints.

Overall sleep quality. This domain of self-reported sleep quality was assessed using the SII (Morin et al., 1999), ISQ (Edinger et al., 2001; Edinger et al., 2007; Edinger et al., 2009) and PSQI (Espie et al., 2007; Edinger et al., 2009; Buysse et al., 2011; Taylor et al., 2014; Alessi et al., 2016). Positive effects were observed on all questionnaires at post-intervention and follow-up, with the exception of the study by Alessi and colleagues (2016) which reported a decline in overall sleep quality as indicated by PSQI scores at 12-month follow-up. Of the 8 studies that included this domain of self-reported questionnaire, a majority (75%) had adequate methodological quality (some risk of bias) with only 2 studies being rated as high risk of bias.

Insomnia severity. The ISI was used to assess insomnia severity in 5 studies (Epstein et al., 2012; Taylor et al., 2014; Alessi et al., 2016; Lovato et al., 2016; Maurer et al., 2020). From these studies, all reported that CBT-I had sustained positive effects on insomnia severity as indicated by the significant reduction of ISI scores at post-intervention and follow-up timepoints. The study by Alessi and colleagues (2016) was the only exception as improvements on insomnia severity was sustained at 6-month follow-up but not at 12-month follow up. Nevertheless, it should be taken into consideration that 2 out of 5 of these studies were rated to be of high risk of bias.

Daytime functioning. This domain was evaluated using the ESS (Buysse et al., 2011; Taylor et al., 2014), MFI (Taylor et al., 2014), FFS and DFFS (Lovato et al., 2016). Whilst

Buysse and colleagues (2011) and Taylor and colleagues (2014) both observed reductions in sleepiness scores on the ESS at post-intervention, only the former study reported yielding significant values. Likewise, scores on all the MFI domains were reduced following CBT-I sessions, with only the improvement on the general fatigue domain was significant (Taylor et al., 2014). Moreover, Lovato and colleagues (2016) reported that CBT-I had sustained positive effects on both FFS and DFFS with scores on both questionnaires observing significant reductions at post-intervention and 3-month follow-up. Importantly, however, the studies by Buysse and colleagues (2011) and Lovato and colleagues (2016) were of poor methodological quality (high risk of bias).

Beliefs about sleep. Three types of questionnaires were used as a self-reported measure of beliefs about sleep: DBAS (Edinger et al., 2009; Taylor et al., 2014; Lovato et al., 2016), SAAQ (Lovato et al., 2016) and SSES (Edinger et al., 2001; Edinger et al., 2007; Lovato et al., 2016). CBT-I was found to have sustained positive effects on all three questionnaires, with all studies reporting significant improvements on DBAS, SAAQ and SSES scores at post-intervention and follow-up timepoints. Only 1 out of 4 studies (Lovato et al., 2016) was rated to have a high risk of bias, with the remaining studies having adequate methodological quality (some risk of bias).

Sleep-related quality of life. Maurer and colleagues (2020) were the only study that administered the GSII which assessed for this domain of self-reported sleep. With adequate methodological quality (some risk of bias), this study indicated that CBT-I significantly improved sleep-related quality of life, with significant positive effects sustained at 12-week follow-up.

Discussion

The aim of this review was to describe and synthesise evidence for the effects of CBT-I on objective and self-reported sleep quality among adults with insomnia. This review

compared the change in objective and self-reported sleep when both types of measures are incorporated concurrently to determine the effectiveness of CBT-I. From 1949 initially identified citations, 15 studies were found eligible for inclusion.

Sleep diary was the most widely used self-report measure of sleep as it was employed in all included studies. Despite being a “gold standard” objective measure of sleep, PSG was more commonly used as a screening tool rather than as an outcome measure. Wrist actigraphy was more widely used to objectively measure treatment outcomes, being included in eight studies alongside sleep diary measures. This is perhaps not surprising as wrist actigraphy is cost-efficient and easy to use. Several studies have also found that actigraphy and PSG produced similar estimates of sleep parameters (e.g., SE, TST, WASO) with high sensitivity (>95%) and high accuracy (>80%), suggesting that actigraphy is a reliable alternative to PSG in measuring treatment outcomes on objective quality of sleep (Lehrer et al., 2022; Kushida et al., 2001; Marino et al., 2013). Moreover, additional self-reported questionnaires were administered in most studies ($n = 11$), with the emphasis of self-reported sleep quality focusing on 4 main aspects: insomnia severity, daytime functioning, beliefs about sleep and sleep-related quality of life.

A majority of studies found agreement in the positive outcomes on both objective and sleep diary measured sleep parameters, particularly SE ($n = 13$), TST ($n = 5$), SOL ($n = 8$) and WASO ($n = 7$). From these studies, significant improvements were found on sleep parameters following exposure to CBT-I, in which SE and TST were significantly increased and SOL and WASO were significantly reduced at post-intervention. Moderate to large effect sizes were observed only in sleep diary SE, SOL, WASO and actigraphy SOL. These findings were in line with past research which suggests that CBT-I is effective in improving subjective sleep parameters with sustaining effects when compared against control groups (Morin et al., 1994; Okajima et al., 2011). Notably, most actigraphy-measured sleep parameters yielded small to

large effect sizes, and only one study (Buysse et al., 2011) that employed PSG and measured effect sizes observed small effect sizes on all sleep parameters. This suggests that whilst self-reported and objective sleep parameters may be in agreement with the direction of change following intervention, the magnitude of change may vary. This could reflect both the way in which individuals estimate their quality of sleep, and that CBT-I has a more positive impact on subjective perception as opposed to objective changes in sleep quality (Okajima et al., 2011, Lund et al., 2013; Mitchell et al., 2019). Importantly, however, caution should be exercised in interpreting these findings as a large number of the evidence of positive effects were derived from studies with a high risk of bias: SE ($n = 6$), TST ($n = 1$), SOL ($n = 3$) and WASO ($n = 5$).

Moreover, there were clear indications that CBT-I was effective in improving outcomes on self-reported psychological sleep-related measures. Most studies were of adequate methodological quality (some risk of bias) and they indicated a significant improvement in all sleep-related difficulties at post-intervention and follow-up timepoints. One study did not find significant reductions in ESS and MFI, with the exception of significant improvement on the general fatigue domain on the MFI (Taylor et al., 2014). Overall, the data suggest that CBT-I has a sustained effect in improving a range of self-reported sleep-related difficulties including insomnia severity, daytime functioning, beliefs about sleep and sleep-related quality of life, particularly when compared to control groups (Okajima et al., 2011).

Implications

Most studies reported an agreement in the direction of change on both objective and self-reported measures, suggesting that CBT-I had a positive effect on overall sleep quality. Despite this, it is worth noting that the magnitude of change in self-reported measures were considerably greater than that of objective measures, in which sleep diary and questionnaire outcomes consistently yielded moderate to large effects whereas objective measures (e.g., actigraphy, PSG) observed mixed effects. Given the similar direction yet varying magnitude of

change between both types of measures, findings of this review suggests that improvements in perceived sleep outcomes may likely indicate some amount of positive objective change. Nevertheless, the discrepancy between objective and self-reported measures of sleep are not uncommon. Previous studies have suggested that sleep-wake misperceptions contribute to the discrepancies between objective and self-reported measures such as the underestimation or overestimation of self-reported sleep quality (Landry et al., 2015; Okajima et al., 2011). Future investigations should explore the mediating factors that may impact the levels of agreement and association between both objective and self-reported measures of sleep. For example, previous research suggests age (Landry et al., 2015; Valko et al., 2021) and intervention type (Lund et al., 2013; Nishikawa et al., 2021) can influence the degree of discrepancy between sleep diary and objective sleep parameters. Specifically, few correlations between self-reported (PSQI) and objective (wrist actigraphy) sleep quality were found among older adults above the age of 55 years, with more than half of the sample ($n = 39$; 51%) reportedly underestimating perceived sleep quality despite having average or good objective sleep quality (Landry et al., 2015). Moreover, a recent study conducted a comprehensive analysis of a large cohort ($n = 2738$) retrospectively and found a significant association between age and subjective sleep-wake perceptions, in which younger adults were more likely to underestimate self-reported TST and WASO and overestimate self-reported SOL when outcomes were compared to polysomnography data (Valko et al., 2021). Conversely, CBT-I was found to be significantly associated with the improvement of self-reported sleep. Particularly, the overestimation of SOL was reduced following exposure to CBT-I, thereby correcting the discrepancy between sleep diary and polysomnography outcomes (Lund et al., 2013). Nevertheless, there remains limited evidence to support the understanding of these associations and other potential factors in influencing the direction and magnitude of objective and subjective sleep. This highlights the need for more studies to incorporate both objective and subjective measures of sleep

concurrently and to explore statistically the association in baseline and post-intervention changes between the two outcome measures.

Similarly, the consideration of using both objective and self-reported measures of sleep quality can be applied within a clinical setting. Whilst self-report measures including the sleep diary and sleep-related questionnaires are commonly used in clinical practice to assess for impairments in night-time sleep and daytime functioning, the use of objective sleep measures can complement the self-reported outcomes to provide further information about overall sleep quality. Natale and colleagues (2009) reported that the use of actigraphy in clinical settings were important because it accurately reflected specific sleep parameters (e.g., SOL, TST, WASO, SE) and had high predictive value (83%) in identifying individuals with insomnia. Furthermore, the additional use of objective sleep measures in clinical practice can improve the assessment of treatment outcomes by measuring the direction and magnitude of change across time following exposure to sleep interventions. Notably, the use of actigraphy has been added to the AASM clinical practice guideline of assessment and management of sleep disorders including insomnia (Morgenthaler et al., 2007). More recently, there has also been an emerging development of ambulatory technologies to measure sleep at home. Specifically, the Dreem headband has been developed as a wearable, reduced-montage dry-EEG device to monitor sleep-related physiological signals (e.g., brain waves, heart and respiration rates) to accurately characterise sleep stages (Arnal et al., 2020). Whilst the Dreem headband is an affordable and accurate alternative to polysomnography as a home-based device to assess sleep (Arnal et al., 2020), future studies need to be conducted to test its usefulness in measuring sleep quality among individuals with insomnia.

Limitations

The intrinsic limitation of a narrative synthesis should be borne in mind when considering the findings of this review. Whilst this method of review is helpful in synthesising

quantitative data at preliminary stages, several concerns have been associated with narrative synthesis including the lack of transparency and accuracy in reporting and interpreting findings (Dixon-Woods et al., 2007; Campbell et al., 2018). To minimise this risk of bias, this review closely followed the guidance on conducting narrative synthesis (Popay et al., 2006), focusing on the process of synthesising evidence to determine intervention effectiveness. Moreover, there is a lack of studies with high methodological quality included in this review. None of the included studies had an overall low risk of bias, making it difficult for this review to draw firm conclusions from findings. This calls for future research to adopt transparent reporting (e.g., fully describing blinding and analysis procedures) to reduce risk of bias and allow for further synthesis of evidence.

Conclusion

Agreements in the direction of change between objective and self-reported measure of sleep quality were found when the effectiveness of CBT-I was measured among adults with insomnia. Whilst the number of research that employs the use of both types of measures concurrently is limited, significant sleep improvements were found from available articles, in which CBT-I had positive effects on self-reported sleep parameters (e.g., SE, TST, SOL, WASO) and sleep-related questionnaires, with minimal to no improvements on objective measures. Moreover, it is important to note that the magnitude of change between objective and self-reported measures varied, with self-reported measures yielding greater improvements compared to objective measures at post-intervention and follow-up. Future studies with good methodological quality should consider concurrently measuring and testing the comparison between objective and self-reported measures of sleep to allow for firmer conclusions to be drawn regarding agreements in CBT-I treatment effectiveness. In turn, this would also help improve our current understandings of sleep-wake misperceptions among adults with insomnia.

Acknowledgments

The authors would like to express their gratitude to George Baldwin for his help as a second reviewer for this systematic review.

Abbreviations

AASM: American Academy of Sleep Medicine

APA: American Psychiatric Association

BBT-I: Brief behavioural therapy for insomnia

BT: Bedtime

CBT-I: Cognitive behavioural therapy for insomnia

DFFS: Daytime Feeling and Functioning Scale

DBAS: Dysfunctional Attitudes and Beliefs about Sleep Scale

DSM: Diagnostic and Statistical Manual of Mental Disorders

EEG: Electroencephalography

EMA: Early morning awakening

ESS: Epworth Sleepiness Scale

FFS: Flinders Fatigue Scale

GSII: Glasgow Sleep Impact Index

ICD: International Statistical Classification of Diseases and Related Health Problems

ICSD: International Classification of Sleep Disorders

ISI: Insomnia Severity Index

ISQ: Insomnia Symptom Questionnaire

MFI: Multidimensional Fatigue Inventory

MWASO: Total time awake between initial sleep onset and final morning awakening

NA: Number of awakenings

NWAK: Number of awakenings during the night

PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analyses

PSG: Polysomnography

PSQI: Pittsburgh Sleep Quality Index

RCT: Randomised controlled trials

RT: Rise time

RDC: Research diagnostic criteria

REM: Rapid eye movement

RoB 2: Revised Cochrane risk-of-bias tool for randomized trials

SAAQ: Sleep Anticipatory Anxiety Questionnaire

SII: Sleep Impairment Index

SSES: Sleep Self-Efficacy Scale

SE: Sleep efficiency

SQ: Subjective sleep quality

SWS: Slow wave sleep

TST: Total sleep time

TWAK: Terminal wakefulness

TWASO: Time between final awakening and rising time

TWT: Total wake time

SOL: Sleep onset latency

WASO: Wake after sleep onset

WHO: World Health Organization

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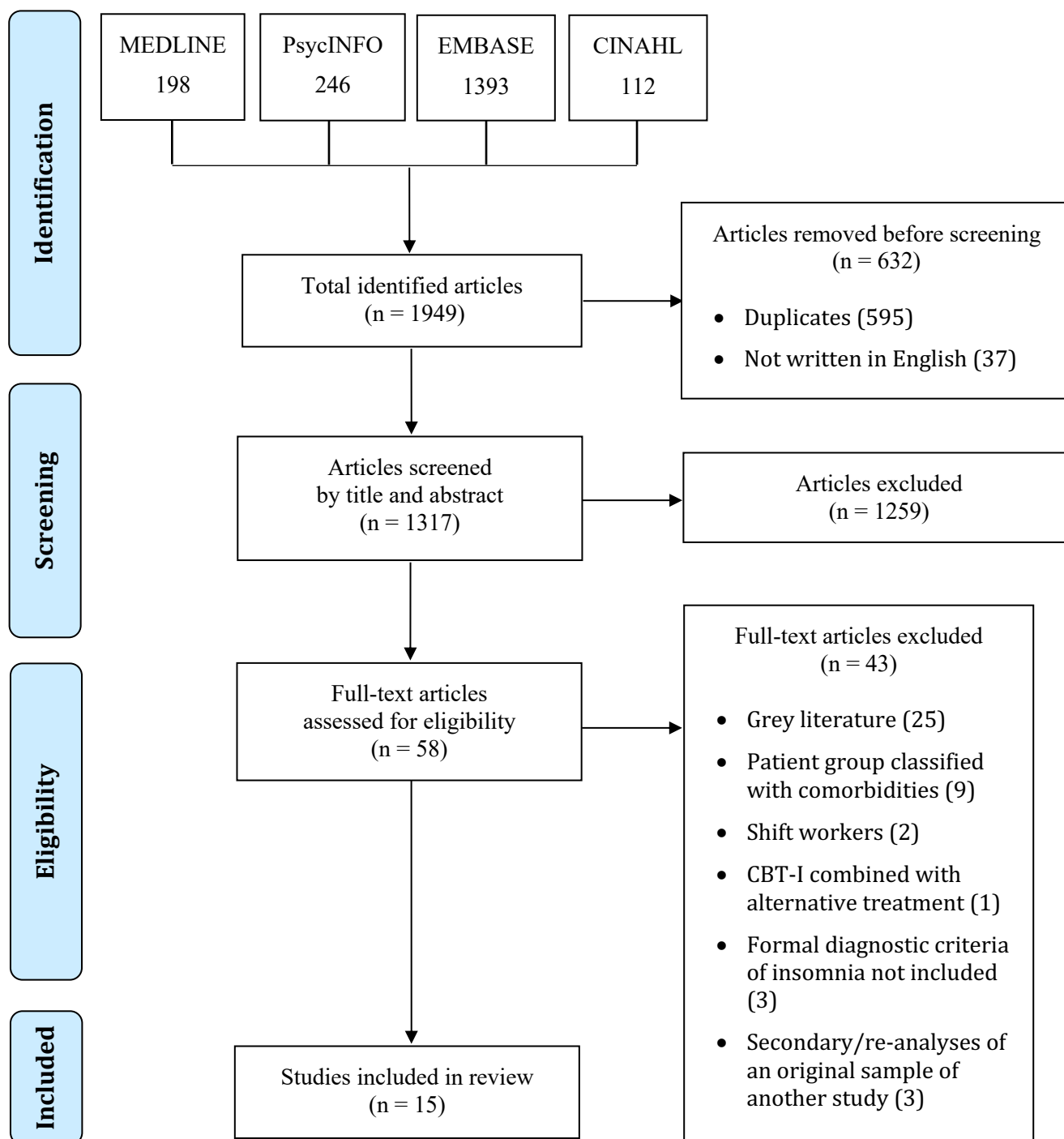
Figure 1*PRISMA flow diagram of selection of studies*

Figure 2*Risk of Bias analysis plot*

		Risk of bias domains					
		D1	D2	D3	D4	D5	Overall
	Morin et al. (1993)	-	-	+	-	-	X
	Morin et al. (1999)	+	+	+	-	-	X
	Edinger et al. (2001)	+	+	+	+	-	-
	Jacobs et al. (2004)	+	+	+	+	-	-
	Sivertsen et al. (2006)	+	+	+	-	-	X
	Edinger et al. (2007)	+	+	+	+	-	-
	Espie et al. (2007)	+	+	+	+	-	-
Study	Edinger et al. (2009)	+	+	+	+	-	-
	Buyse et al. (2011)	-	+	+	X	-	X
	Epstein et al. (2012)	+	-	+	+	-	X
	Taylor et al. (2014)	+	+	+	+	-	-
	Alessi et al. (2016)	+	+	+	+	-	-
	Lovato et al. (2016)	-	+	+	+	-	X
	Chan et al. (2017)	+	+	+	-	-	X
	Maurer et al. (2020)	+	+	+	+	-	-

Domains:

D1: Bias arising from the randomization process.

D2: Bias due to deviations from intended intervention.

D3: Bias due to missing outcome data.

D4: Bias in measurement of the outcome.

D5: Bias in selection of the reported result.

Judgement


 High Some concerns Low

Table 1*Characteristics of included studies*

Author (Year) Location	Sample size (F), Mean age (SD), Recruitment population	Group allocation	Diagnosis/Definition of insomnia (Ascertained by)	Components of the CBT-I treatment arm	Intervention procedure	Intervention provider
Morin et al. (1993) USA	N = 24 (17F) 67.1 (5.3) Older adult community sample	WLC = 12 CBT-I = 12	Persistent Psychophysiological Insomnia (ICSD-1) Sleep maintenance insomnia, WASO >30 minutes per night for ≥3 nights per week (<i>semi-structured interview and sleep diary at baseline</i>)	SR, SC, CT, PE/SH	8 sessions weekly for 90 minutes Group (4-6 per group) Face-to-face	Clinical psychologist
Morin et al. (1999) USA	N = 78 (50F) 65 years Older adult community sample	PB = 20 PT = 20 COT = 20 CBT-I = 18	Sleep onset/maintenance insomnia (ICSD-1/DSV-IV) for ≥6 months SOL ≥30 minutes and/or WASO ≥30 minutes for ≥3 nights per week, ≥1 daytime impairment complaint (<i>clinical interview and sleep diary at baseline</i>)	SC, SR, SH, CT	8 sessions weekly for 90 minutes Group (4-6 per group) Face-to-face	Clinical psychologist or postdoctoral fellow in clinical psychology
Edinger et al. (2001) USA	N = 75 (35F) 55.3 years Adult community sample	PT = 25 PMRT = 25 CBT-I = 25	Persistent Primary Insomnia (DSM-III) Mean WASO >60 minutes for ≥6 months, insomnia age onset after 10, ≥1 sleep disruptive practice (<i>clinical interview and sleep log at baseline</i>)	PE, SC, SR	6 sessions weekly for 30-60 minutes Individual Face-to-face	“Beginning-level” clinical psychologists
Jacobs et al. (2004) USA	N = 63 (44F) 47.05 years Adult community sample	PB = 15 COT = 18 PT = 15 CBT-I = 15	Primary and chronic insomnia (ICSD-1/DSM-IV) for ≥6 months SOL ≥60 minutes for ≥3 times weekly (sleep diary), ≥1 daytime impairment complaint (<i>clinical interview and sleep diary at baseline</i>)	PE, SR, SC, REL	4 sessions weekly First 3 sessions First 3 sessions = 30-minutes, individual, face-to-face 2 weeks after final session = 15 minutes, telephone call	Predoctoral and postdoctoral psychologists
Sivertsen et al. (2006) Norway	N = 46 (22F) 60.8 years Adult and older adults from a Norwegian university-based outpatient clinic	PB = 12 PT = 16 CBT-I = 18	Insomnia (DSM-IV) for ≥3 months Difficulties initiating and maintaining sleep, daytime impairment (<i>clinical interview</i>)	SH, SR, SC, CT, REL	6 sessions weekly for 50 minutes Individual	Clinical psychologists
Edinger et al. (2007) USA	N = 86 (43F) 55.4 years Adult community sample	WLC = 11 CBT-I: (1) = 16 (2) = 18	Primary insomnia (DSM-IV) >6 months with onset after age 10	PE, SC, SR	8 sessions weekly Individual First session = 45-60 minutes	Clinical psychologists

		(4) = 24 (8) = 17	Mean WASO >60 minutes (sleep diary), ≥1 poor sleep hygiene practices (<i>clinical interview and sleep log at baseline</i>)		Subsequent sessions = 15-30 minutes	
Espie et al. (2007) UK	N = 201 (137F) 54 years Adult community sample from GP practices in Glasgow and Edinburgh	TAU = 94 CBT-I = 107	Insomnia (DSM-IV/ICSD) SOL ≥30 minutes and/or WASO ≥30 minutes for ≥3 nights per week, sleep complaints ≥6 months, negative complaint of insomnia (<i>clinical interview and sleep log at baseline</i>)	SH, SR, SC, CT, REL	5 sessions weekly for 1 hour Group (4-6 per group) Face-to-face	CBT-trained health visitors
Edinger et al. (2009) USA	N = 81 (11F) 54.2 (13.7) Outpatients from Veterans Administration	SH = 40 CBT-I = 41	Insomnia disorder (RDC) and/or DSM-IV-TR SOL and WASO ≥60 minutes per night (<i>clinical interview and sleep diary at baseline</i>)	PE, SC, SR	4 sessions biweekly for 30-60 minutes Individual	Clinical psychologists
Buysse et al. (2011) USA	N = 82 (54F) 71.7 years Older adult community sample	IC = 40 BBT-I = 42	Primary insomnia (DSM-IV-TR) without comorbidity criteria/general insomnia (ICSD-2) Sleep complaints >1 month, significant daytime functioning impairment (<i>self-reported questionnaire and structured clinician interview</i>)	PE, SR, SC	4 sessions weekly Individual Initial session = 45-60 minutes, face-to-face Week 1 and 3 = 20 minutes, phone call Follow-up session at 2 weeks = 30 minutes, face-2-face	Master's level nurse practitioner
Epstein et al. (2012) USA	N = 179 (115F) 68.9 years Older adult community sample	WLC = 50 SC = 44 SR = 44 MCI = 41	Chronic primary insomnia SOL ≥45 minutes per night for ≥3 nights per week (14-day sleep diary), insomnia duration for ≥6 months, significant daytime functioning impairment (<i>clinical interview and sleep log at baseline</i>)	PE, SH, SC, SR	6 sessions weekly Weeks 1-4 = group (4-6 per group), 60-120 minutes Weeks 5-6 = telephone call, 15 minutes	Master's level psychiatric mental health clinical nurse specialist
Taylor et al. (2014) USA	N = 34 (14F) 19.71 (2.10) College students from University of North Texas	WLC = 17 CBT-I = 17	Insomnia (DSM-5) SOL or WASO ≥30 minutes for ≥3 months, daytime impairment (<i>clinical interview and sleep log at baseline</i>)	SC, SR, SH, REL, CR	6 sessions weekly Individual Face-to-face	Doctoral-level graduate students
Alessi et al. (2016) USA	N = 159 (5F) 72.2 (7.7) Older adult outpatients at an urban Veteran	SEP = 53 Individual CBT-I = 54 Group CBT-I = 52	Insomnia disorder (ICSD-2) lasting ≥3 months (<i>postal survey assessing for ICSD-2 criteria for insomnia disorder</i>)	PE, SR, SC, CT	5 sessions weekly for 60 minutes Individual or group (3-5 per group) Face-to-face	Master's level non-clinicians, under the supervision of licensed clinical psychologists with

	Affairs healthcare system					behavioural sleep medicine expertise
Lovato et al. (2016) <i>Australia</i>	N = 91 (48F) 63.35 (6.41) Young-old adults (65-74 years) community sample	WLC = 28 CBT-I = 63	Sleep maintenance insomnia WASO >30 minutes for ≥3 nights per week over ≥6 months, daytime functioning impairment (<i>clinical interview</i>)	SR, CT, PE	4 sessions weekly for 60 minutes Group (4-5 per group)	Therapist
Chan et al. (2017) <i>USA</i>	N = 62 (42F) 69.45 (7.71) Older adult community sample	SMAC = 30 BBT-I = 32	Insomnia disorder (ICSD-2) SOL or WASO >30 minutes for >6 months (also measured by sleep diary), daytime functioning (<i>clinical interview</i>)	SH, SC, SR, REL	4 sessions weekly	Therapist
Maurer et al. (2020) <i>UK</i>	N = 56 (39F) 40.78 years Adult community sample	TBR = 29 SRT = 27	Insomnia (DSM-5; <i>Sleep Condition Indicator questionnaire and clinical interview</i>)	SR, SH	4 sessions weekly Individual Sessions 1-2 = Face-to-face, 60 minutes Sessions 3-4 = telephone call, 15 minutes	CBT-I trained doctoral researcher, under the supervision of experts in behavioural sleep medicine

Note. BBTi = Brief Behavioural Therapy for Insomnia; CMI = Comorbid Insomnia; COT = Combination Therapy; CR = Cognitive Restructuring; CT = Cognitive Therapy; DSM = Diagnostic and Statistical Manual of Mental Disorders; F = Female; IC = Information Control; ICSD = International Classification of Sleep Disorders; MCI: Multicomponent Intervention; PB = Placebo; PE = Psychoeducation; PI = Primary Insomnia; PMRT: Progressive Muscle Relaxation Training; PT = Pharmacotherapy; RDC = Research diagnostic criteria; REL = Relaxation; SC = Stimulus Control; SEP = Sleep education program; SH = Sleep Hygiene; SMAC = Self-monitoring and attention control; SOL = Sleep Onset Latency; SQ = Sleep Quality; SR = Sleep Restriction; TBR = Time in bed regularisation; VAS = Visual Analog Scale; WASO = Wake After Sleep Onset; WLC = Wait List Control

Table 2

Summary of findings on objective and self-reported sleep quality for included studies

Author (Year) <i>Location</i>	Objective sleep outcome measure	Number of nights' data at each assessment	Subjective sleep outcome measure	Number of nights' data at each assessment	Follow- up period	Sleep parameter outcomes	Findings	Risk of bias
Edinger et al. (2001) * <i>USA</i>	PSG (home-based)	Number of nights not specified. PSG was used at screening, within 1-2 weeks before treatment and 2 weeks following the end of treatment.	Sleep log, ISQ, SSES	Sleep log: 2-week baseline, 6-week treatment, 2-week post-treatment and 2-week at follow-up	6-months	TST, MWASO, TWASO, SE	The direction of change for both objective and subjective measures were similar for participants who received CBT-I. More specifically, at posttreatment, results showed improved TST and SE, and reduced overall WASO on the PSG and sleep log. However, no significant values were observed. ISQ and SSES scores were significantly improved at posttreatment.	Some
Jacobs et al. (2004) * <i>USA</i>	Home-based Nightcap sleep monitor	3 nights at pre-post intervention	Sleep diary	Daily (2 weeks pre-treatment, 2 weeks during treatment, 2 weeks after treatment, and 1 week at each follow-up)	1-month, 3-6-months, and 12-months	SOL, SE, TST	The direction of change for objective and subjective SOL and SE were similar. There was a significant improvement in SE, however, no significant differences were found for TST at posttreatment. Whilst a large effect size (ES = 1.17) with near significance was found for subjective SOL, there was no significant difference on objective SOL. Overall, CBT-I was found to have the biggest improvement in SOL and SE. Following treatment, the CBT-I group had the highest number of normal sleepers, with long-term therapeutic improvements.	Some
Edinger et al. (2007) * <i>USA</i>	PSG, (home-based), ACT (wrist)	PSG: screening ACT: Nightly (2-week baseline, 8-week treatment, 2-week follow-up at each follow-up)	Sleep log, ISQ, SSES	1-week screening, 2-week baseline, 8-week treatment, 2-week at each follow-up	3-months and 6-months	SOL, TWT, TST, SE	Results from both ACT and sleep log measures favoured 1- and 4-week CBT-I sessions. In these sessions, the direction of change was similar for SE, TWT and SOL, albeit only SE having significant difference for both ACT and sleep log measures. There were significant improvements in both ISQ and SSES scores at post-intervention and follow-up timepoints.	Some
Edinger et al. (2009) * <i>USA</i>	PSG (private hospital or affiliated hotel)	PSG: screening ACT: 2-week baseline, 8-week	Electronic Sleep Diary, ISQ, PSQI, DBAS	2-week baseline, 8-week treatment, 2-	6-months	TST, SOL, WASO, SE	Among the primary insomnia group, similar trends were found for all ACT and sleep diary outcomes: increased TST and SE, and decreased SOL and WASO. Nevertheless, only sleep diary SOL and WASO yielded significant values. Reductions were observed on ISQ, PSQI	Some

	boarding facility), ACT (wrist)	treatment, follow-up		week follow-up			and DBAS scores at post-intervention and sustained at 6-month follow-up.	
Taylor et al. (2014) * <i>USA</i>	PSG (home-based), ACT (wrist)	PSG: screening ACT: Daily for 7 days (pre-post treatment, and during treatment)	Sleep diary, ISI, PSQI, DBAS, ESS, MFI	Sleep diary: Daily for 7 days (pre-post treatment, during treatment, and follow-up)	3-months	SE, TST, SOL, NWAK, WASO, TWAK, SQ (measured with sleep diary only)	Greater improvements were observed for all subjectively reported sleep parameters, with SE, SOL, NWAK, WASO and SE. Sleep diary SOL, WASO and SQ yielded significant values with large effect sizes (ES = 1.09-1.23). Similar improvements were found on ACT SE, TST, SOL and TWAK. However, no ACT data were significant. Significant reductions were observed on ISI, PSQI and DBAS scores (ES = 1.01-1.27). ESS scores were reduced by follow-up albeit no significant values obtained. There was also reduction for all MFI domains, however, only the general fatigue domain was significant (ES = 1.10).	Some
Alessi et al. (2016) * <i>USA</i>	ACT (wrist)	7 consecutive day/night (baseline, post-intervention, follow-up)	Sleep diary PSQI, ISI	Sleep diary: 7 consecutive day/night (baseline, post-intervention, follow-up) PSQI and ISI: (baseline, post-treatment, 6-month and 12-month follow-up)	6-months and 12-months	Sleep diary: SOL, WASO, TWT, SE ACT: SE	Both ACT and sleep diary SE were improved at posttreatment, however, efficacy declined by the 12-month follow-up. No ACT data obtained significant values whereas all sleep diary data was significant and had moderate to large effect sizes (ES = 0.34-0.76). Similar improvements were seen on PSQI and ISI scores at posttreatment, however, efficacy reduced by 12-month follow-up.	Some
Morin et al. (1993) * <i>USA</i>	PSG (sleep laboratory)	2 consecutive nights, within a 2-week period before treatment (baseline) and after treatment	Sleep diary	2-week baseline, 8-week treatment, 2-week at follow-up timepoints	3-months and 12-months	SOL, WASO, EMA, TWT, TST, SE	CBT-I was found to be effective in reducing SOL, WASO and EMA, and increasing SE. The changes seen on the PSG were smaller compared to the sleep diary, however the direction of change for both objective and subjective measures were the same.	High
Morin et al. (1999) * <i>USA</i>	PSG (sleep laboratory)	3-consecutive nights, within a 2-week period before treatment (baseline) and after treatment	Sleep diary, SII	Sleep diary: Daily (2 weeks pre-treatment, 8 weeks during treatment, 2-week at each follow-up)	3-months, 12-months, and 24-months	WASO, SE, TST	At posttreatment, similar results were found for both objective and subjective measures. There was a reduction in WASO, and improvement in SE and TST observed on both the PSG and sleep diary. Self-reported severity of insomnia also decreased over time. Findings indicated that clinical improvements from the CBT-I intervention were sustained at all follow-up timepoints.	High

Epstein et al. (2012) * <i>USA</i>	ACT (wrist)	Daily for 14 days (baseline, post-intervention, and follow-up)	Sleep diary, ISI	Sleep diary: Daily for 14-days (baseline, post-intervention and follow up)	3-months and 12-months	SOL, WASO, TST, TIB, SE, SQ (measured with sleep diary only)	There was a significant reduction in both ACT and sleep diary SOL, WASO and TIB, as well as improvement in SE on all CBT-I groups. Despite improvements in sleep parameters, there was no significant values found for all ACT data among the stimulus control group. Sleep diary data yielded large effect sizes for all parameters at posttreatment: SOL (ES = 1.11-1.44), WASO (ES = 1.04-1.35), TST (ES = 0.63-1.08), TIB (ES = 0.84-1.26), SE (ES = 1.74-2.15), SQ (ES = 0.80-1.06). ACT data yielded small to medium effect sizes for SOL (ES = 0.59-0.93), WASO (ES = 0.38-0.85), TIB (ES = 0.29-0.69) and SE (ES = 0.46-0.80) at posttreatment. Insomnia severity scores significantly reduced over time with large effect sizes found (ES = 1.18-1.24).	High
Chan et al. (2017) * <i>USA</i>	ACT (wrist)	Daily for 2 weeks at pre-post treatment, 4 weeks of treatment, and 2 weeks at follow-up	Sleep diary	Daily for 2 weeks at pre-post treatment, 4 weeks of treatment, and 2 weeks at follow-up	3-months	SOL, WASO, TST, SE	BBT-I was associated with significant reductions in variabilities in sleep diary SOL and ACT TST. Generally, improvements in objective and subjective SOL, WASO and SE were observed across time. However, these self-reported sleep parameters were notably higher than when measured objectively.	High
Espie et al. (2007) <i>UK</i>	ACT (wrist)	14 nights at pre-post intervention	Sleep diary, PSQI	Sleep diary: 14 nights at baseline, post-treatment, and follow-up	6-months	SOL, WASO, SE, TST	CBT-I was associated with improvements in self-reported SOL, WASO and SE. Apart from the objective WASO, no significant treatment effect was found on other sleep parameters. It was noted that actigraphic scores for SOL and WASO were lower when compared to the sleep diary, and SE actigraphic scores were higher than that of the sleep diary. Significant, modest correlation was found between ACT and sleep diary SOL ($r = 0.340$), WASO ($r = 0.182$) and SE ($r = 0.275$). PSQI scores were significantly reduced at post-intervention and follow-up.	Some
Maurer et al. (2020) <i>UK</i>	ACT (wrist), Portable PSG (home-based)	Daily through the 6-week period	Consensus Sleep Diary, ISI, GSII	Sleep diary: Daily for 14 days during baseline and 28 days during treatment GSII: pre-post treatment, and follow-up	12-week	SOL, WASO, SE, TST	Significant differences were found on all sleep parameters on sleep diary, ACT and PSG outcomes. All three measures indicated a significant increase in TST. Discrepancies were observed on the SOL, WASO and SE parameters. There was a significant increase in ACT and PSG SOL and WASO, in contrast to a significant decrease in sleep diary SOL and WASO. On the other hand, there were a significant increase in sleep diary and ACT SE whilst the PSG SE had a significant decrease. Significant improvements were found on both the ISI (ES = -1.36) and GSII (ES = 1.29) at follow-up.	Some

Sivertsen et al. (2006) <i>Norway</i>	PSG (home-based)	2 consecutive nights (pre-intervention), 1 night (post-intervention and follow-up)	Sleep diary	Daily (2-week pre-post intervention and at follow-up)	6-months	TWT, TST, SE, SWS (measured with PSG only).	TWT was significantly reduced on PSG and sleep diary data at post-intervention and follow-up. SWS was also significantly improved. Whilst a similar trend (improvement) was observed on SE, no significant differences were found. Direction of change for TST data was different on both measures.	High
Buysse et al. (2011) <i>USA</i>	ACT (wrist), PSG (home-based)	ACT: 2 weeks at baseline and post-treatment PSG: screening, 2 consecutive nights at baseline and posttreatment	The Pittsburgh Sleep Diary, PSQI, ESS	Sleep diary: 2 weeks at baseline and post-treatment	6-months	Sleep diary: BT, RT, TIB, SOL, WASO, SE, SQ ACT: SOL, WASO, TST, SE PSG: SOL, WASO, TST, SE	Reduced WASO and TST as well as increased SE were found on all measures. However, only ACT and sleep diary WASO and SE had significant values, with moderate effect sizes (ES = 0.59-0.80). Whilst ACT and sleep diary SOL had significant reductions, PSG observed increased SOL. No PSG outcomes were significant. Reductions were observed for both PSQI (ES = 1.10) and ESS (ES = 0.18) scores.	High
Lovato et al. (2016) <i>Australia</i>	PSG (overnight home-based), ACT (wrist)	PSG: 1 night at screening ACT: 7-days (pre-post treatment, during treatment, follow-up)	Sleep/wake diary, ISI, FFS, ESS, DFFS, SSES, DBAS, SAAQ	7 days (screening, pre-post, during treatment, follow-up)	3-months	SOL, WASO, TST, SE, NA (measured with sleep diary only)	Both short and long sleepers experienced reduced WASO (ES = 0.73-1.18) and improved SE (ES = 0.85-1.08) on both sleep diary and ACT outcomes, with significant differences found only for sleep diary outcomes. No significant differences were found for ACT sleep parameters except reduced ACT TST among short sleepers. Discrepancies with found between both groups and measures for SOL and TST. Significant improvements were observed for all sleep-related questionnaire outcomes at post-intervention and follow-up.	High

Note. * = studies reporting positive results; ACT = actigraphy; BT = Bedtime; DBAS = Dysfunctional Attitudes and Beliefs About Sleep Scale; DFFS = Daytime Feeling and Functioning Scale; EMA = Early Morning Awakening; ES = Effect size; ESS = Epworth Sleepiness Scale; FFS = Flinders Fatigue Scale; ISI = Insomnia Severity Index; GSII = Glasgow Sleep Impact Index; ISQ = Insomnia Symptom Questionnaire; MFI = Multidimensional Fatigue Inventory; MWASO = Total time awake between initial sleep onset and final morning awakening; NA = Number of Awakenings; NWAK = Number of awakening during the night; PSG = Polysomnography; PSQI = Pittsburgh Sleep Quality Index; RT = Rise time; SAAQ = Sleep Anticipatory Anxiety Questionnaire; SE = Sleep Efficiency; SII = Sleep Impairment Index; SOL = Sleep Onset Latency; SSES = Sleep Self-Efficacy Scale; SWS = Slow Wave Sleep; TA; Total Awakening; TIB = Time in Bed; TST = Total Sleep Time; TWAK = Terminal wakefulness; TWASO = Time between final awakening and rising time; TWT = Total Wake Time; WASO = Wake After Sleep Onset

Table S1*Description of objective measures of sleep used in the included studies*

Objective measures of sleep	Description of measures	Studies in which the measure was employed
Polysomnography (PSG)	Known as the “gold-standard” objective measure of sleep, PSG measures a range of physiologic parameters related to sleep and wakefulness such as the brain dynamics of electroencephalography (EEG), breathing and heart rates, eye movements and muscle activity (Marino et al., 2013). In sleep research, PSG is commonly used to measure sleep parameters including sleep onset latency, number of awakenings, wake after sleep onset, total sleep time and sleep efficiency (Edinger et al., 2013).	Morin et al. (1993) Morin et al. (1999) Edinger et al. (2001) Sivertsen et al. (2006) Edinger et al. (2007) Edinger et al. (2009) Buysse et al. (2011) Maurer et al. (2020)
Home-based Nightcap Sleep Monitor	The Nightcap uses head and eyelid movement sensors to measure sleep parameters such as sleep onset latency, total sleep time and sleep efficiency. Good interrater reliability (95%) between the Nightcap and laboratory-based PSG was found when used to identify wakefulness, rapid eye movement (REM) and non-REM sleep (Ajilore et al., 1995).	Jacobs et al. (2004)
Wrist actigraphy	The wrist actigraphy provides an objective measure of sleep-wake timings by sensing and recording movement during sleep (Aili et al., 2017). Sleep parameters obtained from actigraphy measures including sleep latency, sleep duration and total wake time have been found to have good correlation with that of PSG (Ancoli-Israel et al., 2003; McCall & McCall, 2012), indicating the effectiveness of actigraphy in assessing overall sleep quality (Martin & Hakim, 2011).	Espie et al. (2007) Edinger et al. (2007) Edinger et al. (2009) Buysse et al. (2011) Epstein et al. (2012) Taylor et al. (2014) Alessi et al. (2016) Lovato et al. (2016) Chan et al. (2017) Maurer et al. (2020)

Table S2*Description of sleep diaries that were specified in the included studies*

Sleep diary	Description of sleep diary	Study in which the sleep diary was employed
Electronic Sleep Diary	The Electronic Sleep Diary is specially programmed on a hand-held computer and consisted of an interactive program that collects subjective sleep data. The sleep parameters collected on the Electronic Sleep Diary are moderate- to highly correlated to PSG (correlation coefficient, $r = .48-.76$; Edinger et al., 2004).	Edinger et al. (2009)
Pittsburgh Sleep Diary	The Pittsburgh Sleep Diary consists of 'bedtime' and 'waketime' questionnaires that measure factors related to daytime activities and evaluate night-time sleep respectively. Items on the Pittsburgh Sleep Diary uses open-ended responses and ratings on 10cm visual analogue scales. Sleep parameters measures on this diary has high internal reliability (correlation coefficient, $r = .56-.81$; Monk et al., 1994).	Buysse et al. (2011)
Consensus Sleep Diary	The Consensus Sleep Diary is a 9-item diary including 8 subjective questions and 1 question that is scored on a 5-point Likert scale (e.g., very poor to very good; Carney et al., 2012). This sleep diary has high sensitivity (80%) and specificity (90%) in differentiating between individuals with insomnia and normal sleepers (Natale et al., 2015)	Maurer et al. (2020)

Table S3*Description of self-reported measures of sleep used in the included studies*

Self-reported measures of sleep	Description of measures	Studies in which the measure was employed
Measures of overall sleep quality		
Sleep Impairment Index (SII)	The SII is a 5-item scale that measures the quantitative index of insomnia by assessing the perceived severity of sleep onset, sleep maintenance, difficulties with early morning awakenings, impairments in daytime functioning, distress caused by sleep difficulties and satisfaction of sleep quality (Morin et al., 1994).	Morin et al. (1999)
Insomnia Symptom Questionnaire (ISQ)	The ISQ is a 13-item measure that assesses three domains of insomnia symptoms: complaint of difficulties in initiating or maintaining sleep, frequency and duration of symptoms and severity of daytime functioning in relation to sleep complaints (Okun et al., 2009). Items that measure sleep difficulties are measured using a scale ranging from 0 (never) to 5 (always; 5-7 days per week) whereas items that measure impairment of daytime functioning are measured on a scale of 0 (not at all) to 4 (extremely). Open-ended responses are used to record duration of difficulties (e.g., weeks, months, years). The ISQ has good reliability (Cronbach's $\alpha = .89$; Okun et al., 2009).	Edinger et al. (2001) Edinger et al. (2007) Edinger et al. (2009)
Pittsburgh Sleep Quality Index (PSQI)	The PSQI is a 24-item questionnaire that assesses seven components of sleep: sleep quality, sleep disturbances, sleep latency, sleep duration, habitual sleep efficiency, use of sleep medications and daytime dysfunction (Buysse et al., 1989). Items of the PSQI are both open-ended and close-ended, with scores for each item ranging between 0-3. Scores on all domains are added to produce a global score, with the cut-off of >5 indicating severe sleep disturbance. The PSQI has a high degree of internal consistency (Cronbach's $\alpha = .83$; Buysse et al., 1989).	Espie et al. (2007) Edinger et al. (2009) Buysse et al. (2011) Taylor et al. (2014) Alessi et al. (2016)
Measures of insomnia severity		
Insomnia Severity Index (ISI)	The ISI is a 7-item questionnaire that assesses the nature, severity, and impact of insomnia (Bastien et al., 2001). Items on the ISI are scored on a 5-point Likert scale ranging from 0 (no problem) to 4 (very severe problem). The total score ranges from 0-28 and can be interpreted according to four categories: absence of insomnia (0-7), subthreshold insomnia (8-14),	Epstein et al. (2012) Taylor et al. (2014) Alessi et al. (2016) Lovato et al. (2016) Maurer et al. (2020)

moderate insomnia (15-21) and severe insomnia (22-28). Excellent internal consistency was found for ISI when used in both community and clinical samples (Cronbach's $\alpha = .90-.91$; Morin et al., 2011).

Measures of daytime functioning

Epworth Sleepiness Scale (ESS)	The ESS consists of 8 items asking individuals to rate their chances of falling asleep in eight different situations, with each item scoring between 0-3. The total score on the ESS ranges between 0 and 24, and higher scores indicate higher levels of daytime sleepiness. The ESS has a high internal consistency (Cronbach's $\alpha = .88$; Johns, 1992).	Buysse et al. (2011) Taylor et al. (2014)
Multidimensional Fatigue Inventory (MFI)	The MFI consists of 20 items covering five domains including general fatigue, physical fatigue, mental fatigue, reduced motivation, and reduced activity (Smet et al., 1995). Items on the MFI are scored on a 5-point scale ranging from 1 (yes, that is true) to 5 (no, that is not true), with higher total scores indicating higher levels of fatigue. The MFI has been found to have good internal consistency (Cronbach's $\alpha = .84$; Smet et al., 1995).	Taylor et al. (2014)
Flinders Fatigue Scale (FFS)	The FFS is a 7-item scale that measures fatigue based on the severity, frequency, perceived consequences, and relation to insomnia (Gradisar et al., 2007). Six items on the scale are scores on a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely), and the remaining items scored based on multiple-item checklist. The total score on the FFS is between 0 and 31, with higher scores indicating greater fatigue levels. A preliminary study showed that the FFS obtained high internal consistency (Cronbach's $\alpha = .91$; Gradisar et al., 2007).	Lovato et al. (2016)
Daytime Feeling and Functioning Scale (DFFS)	The DFFS is a 12-item scale that measures the frequency of daytime impairment (Gradisar et al., 2006). DFFS items are scores on a scale of 0 (never or seldom) to 3 (frequently or almost all the time), with total possible scores between 0 and 36. The DFFS obtained high internal consistency in discriminating between good sleepers and individuals with insomnia (Cronbach's $\alpha = .89-.94$; Gradisar et al., 2006).	Lovato et al. (2016)

Measures of beliefs about sleep

Dysfunctional Attitudes and Beliefs about Sleep Scale (DBAS)	The DBAS is a 30-item questionnaire designed to identify sleep/insomnia-related cognitions around 5 conceptually derived themes: (1) misconceptions about the cause of insomnia, (2) attitudes around the consequences of insomnia, (3), unrealistic expectations around sleep, (4) appraisal of control	Edinger et al. (2009) Taylor et al. (2014) Lovato et al. (2016)
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and predictability of sleep, and (5) faulty beliefs about sleep-promoting practices (Morin, 1993). DBAS items are rated on a visual analogue scale ranging from 0 (strongly disagree) to 10 (strongly agree). The DBAS has a good internal consistency (Cronbach's $\alpha = .80$; Morin et al., 1993).

Sleep Self-Efficacy Scale (SSES)

The SSES consists of 9 items that requires participants to indicate their level of confidence in accomplishing sleep-related behaviours. Items are scored on a 5-point scale ranging between 1 (not confident) and 5 (very confident), with total scores ranging between 9-45 and higher scores indicating higher self-efficacy. The SSES has obtained a good internal consistency (Cronbach's $\alpha = .71$; Lacks, 1987).

Edinger et al. (2001)
Edinger et al. (2007)
Lovato et al. (2016)

Sleep Anticipatory Anxiety Questionnaire (SAAQ)

The SAAQ is a 10-item scale that assess cognitive and physical arousal during attempts of falling asleep at night (Bootzin et al., 1994). SAAQ items are scored on a 4-point scale ranging from 1 (strongly disagree) to 4 (strongly agree), with higher scores indicating higher levels of negative pre-sleep cognitions. A recent study indicated that the SAAQ has obtained high internal consistency (Cronbach's $\alpha = .88$; Akram et al., 2021).

Lovato et al. (2016)

Measures of Sleep-related Quality of Life

Glasgow Sleep Impact Index (GSII)

The GSII is a sleep-related quality of life measure consisting of four stages: (1) generating three areas of sleep impairment, (2) ranking the impairments from least to most concerning, (3) rating how 'bothered' they are over the past two weeks on a 100mm visual analogue scale from very bothered (0) to not bothered (100), and (4) spending an imaginary £60 on getting rid of the generated impairments (Kyle et al., 2013). The third stage is the only measurable scale, with lower scores reflecting negative impact. All ranks of the GSII have been found to have high sensitivity to change (Cohen's $d \geq .85$; Kyle et al., 2013).

Maurer et al. (2020)

CHAPTER 3

Bridging Chapter

Bridging Chapter

The systematic review in Chapter 2 identified and synthesised evidence from past randomised controlled trials examining the effectiveness of cognitive behavioural therapy for insomnia (CBT-I) among adults. Specifically, the review described and compared the effectiveness of CBT-I on objective and self-reported sleep quality when both types of measures were employed concurrently. Research has suggested that both objective and self-reported measures of sleep should be employed when assessing the efficacy of treatments (Buysse et al., 2006), however, there are currently a limited number of studies that concurrently incorporate the combination of both types of measures.

Among studies that have employed both objective and subjective measures of sleep, it was found that sleep diary was most often used to measure self-reported sleep parameters, alongside sleep-related questionnaires assessing for insomnia severity, daytime functioning, beliefs about sleep and sleep-related quality of life. Conversely, objective sleep quality was most likely to be measured using a wrist actigraphy, followed by polysomnography and Nightcap. A majority of past studies noted agreement in the direction of change in the outcomes of sleep diary and objective sleep parameters, specifically in terms of sleep efficiency (SE), total sleep time (TST), sleep onset latency (SOL) and wake after sleep onset (WASO). Most studies also showed that CBT-I significantly improved SE and TST and significantly reduced SOL and WASO, with treatment effects sustained at follow-up timepoints. Nevertheless, a difference in the magnitude of change was noticeable whereby self-reported measures of sleep yielded moderate to large effect sizes whereas objective measures of sleep produced more mixed findings. Past research has suggested that this discrepancy may have been a result of misperceptions of sleep-wake estimation, which can occur among adults with insomnia (Landry et al., 2015; Okajima et al., 2011).

Despite indications of discrepancy in magnitude between objective and self-reported measures of sleep, overall, the review indicated that CBT-I was effective in improving quality of sleep. Interestingly however, none of the included studies included within the review employed paradoxical intention therapy (PI) or considered the inclusion of participants with high sleep effort. Sleep effort is conceptualised as a perpetuating factor of insomnia (Espie et al., 2006), and PI is an evidence-based cognitive-behavioural sleep intervention that specifically targets sleep effort (Ascher & Efran, 1978). Although PI has been delivered as part of multicomponent CBT-I, it remains under-researched and its effectiveness in improving overall sleep quality is under-recognised. Therefore, the next chapter (Chapter 4) presents an empirical piece of research that examines the feasibility and preliminary efficacy of paradoxical intention therapy among adults with insomnia and high sleep effort.

CHAPTER 4

Empirical Research Paper

Feasibility and Preliminary Efficacy of Paradoxical Intention Therapy among Adults with
Insomnia and High Sleep Effort

Prepared for the Journal of Clinical Sleep Medicine

(see Appendix A for author guidelines for manuscript preparation)

**Feasibility and Preliminary Efficacy of Paradoxical Intention Therapy among Adults
with Insomnia and High Sleep Effort**

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All authors have seen and approved the manuscript

Conflict of interest: None

Number of tables: 5

Number of figures: 1

Abstract word count: 240

Brief summary word count: 108

Manuscript word count: 4996

Abstract

Objectives: The aim of this study was to determine the feasibility and preliminary efficacy of paradoxical intention therapy (PI) among adults with insomnia and high sleep effort.

Methods: A two-arm randomised controlled trial was conducted. Twenty-six adults (18-54 years) were randomly allocated to receive either PI (n = 13) or sleep hygiene instructions (n = 13). PI sessions were delivered across two hour-long sessions over two weeks whereas sleep hygiene instructions sessions were one-off. Participants completed 5 consecutive days of wrist actigraphy and sleep diary, the Glasgow Sleep Effort Scale, the Pittsburgh Sleep Quality Index and Patient Health Questionnaire at baseline, post-intervention (2 weeks) and follow-up (1 month).

Results: Significant reductions were observed on the Glasgow Sleep Effort Scale (primary outcome) indicating the role of PI in reducing sleep effort. Findings also show that PI significantly improved secondary outcomes including self-reported sleep parameters (sleep onset latency, wake after sleep onset, sleep efficiency), and Pittsburgh Sleep Quality Index, yielding moderate to large effect sizes. Notably, there was a lack of agreement between actigraphy and sleep diary outcomes. Unexpectedly, no significant differences were observed in depression scores albeit patterns indicate a reduction over time.

Conclusion: Preliminary findings indicate that PI is a feasible, standalone psychological intervention for insomnia. Future trials are needed to address the sustained efficacy of PI on both objective and self-reported sleep quality, sleep effort and mental health outcomes.

Keywords: Paradoxical intention, feasibility, preliminary efficacy, insomnia, sleep effort, depression

Brief Summary

Current knowledge/Study rationale: Although paradoxical intention therapy (PI) is an evidence-based intervention with several studies indicating its effectiveness in improving insomnia, this approach remains under-researched as a single-component intervention. The purpose of this study was to examine the feasibility and preliminary efficacy of PI among adults with insomnia and high sleep effort.

Study Impact: Preliminary findings indicate that PI is a feasible intervention for insomnia, improving sleep effort and self-reported sleep quality. These findings highlight the importance of further research to test the sustained efficacy of PI as a standalone intervention for insomnia among adults as well as to consider both objective and self-reported measures of sleep.

Introduction

Sleep effort refers to the proactive cognitive and behavioural states of controlling the sleep engagement process (Broomfield & Espie, 2005; Espie et al., 2006). Conceptualised within the attention-intention-effort (A-I-E) pathway, it attempts to explain the perpetuation of insomnia disorder (Espie et al., 2006). Studies suggest that the active control of sleep is likely to extend sleep onset latency because effort disrupts the natural process of falling sleep by preventing relaxation and inducing performance anxiety (Broomfield & Espie, 2003; Broomfield & Espie, 2005). The justification is that sleep is an involuntary behaviour that cannot be controlled intentionally (Broomfield & Espie, 2003).

Clinically, the notion of sleep as an involuntary process can be confirmed by asking what good sleepers 'do' to fall asleep. Typically, good sleepers report doing nothing to fall asleep, indicating that good sleep is effortless. Broomfield and Espie (2003) have demonstrated that among people with insomnia, those allocated to Paradoxical Intention Therapy (PI), which instructs users to abandon all sleep effort, show reduced sleep effort and significantly improved subjective sleep onset latency, relative to a control non-PI condition. In a recent exploratory study, heightened sleep effort was strongly associated with severe self-reported insomnia, demonstrating the role of sleep effort in the aetiology and treatment of insomnia disorder (Hertenstein et al., 2015), and suggesting the significance of targeting sleep effort in interventions for insomnia disorder.

PI is a cognitive-behavioural sleep intervention that specifically targets sleep effort to improve insomnia and sleep quality. Since its inception, the theoretical basis of PI was grounded on the idea that individuals with insomnia were trying too hard to fall asleep, indicating their failure to recognise that sleeping should be involuntary (Ascher & Efran, 1978). The understanding was that those who put effort into falling asleep experienced higher levels of performance anxiety, which was suggested to stimulate the autonomic nervous system, thus

interfering with the physiological ability to initiate sleep onset (Ascher & Efran, 1978). To target sleep effort and subsequently reduce associated sleep-related performance anxiety, PI instructs individuals with insomnia to shift their focus away from trying to fall asleep (Ascher & Efran, 1978) by passively remaining awake for as long as possible and/or giving up explicit intention to fall asleep (Espie et al., 2006).

PI can be delivered as a single-component therapy or as part of multicomponent CBT-I to treat insomnia in adults (Schutte-Rodin et al., 2008). Studies have shown the effectiveness of PI as a single-component therapy in managing sleep-onset insomnia across single cases (Ascher & Efran, 1978; Espie & Lindsay, 1985) and randomised-controlled trials (Espie et al., 1989; Turner & Ascher, 1979), with significant reductions to sleep onset latency and sleep complaints among people with insomnia following PI. Recently, Jansson-Fröjmark and colleagues (2021) conducted a systematic review and meta-analysis to explore the effectiveness of PI on insomnia. Of ten randomised controlled trials (RCT) included in the review, PI yielded moderate to large improvements in insomnia symptoms compared to passive and active comparators, particularly with reductions observed in sleep-related performance anxiety (Jansson-Fröjmark et al., 2021).

In the present study, the objective was to determine the feasibility of implementing PI among adults with insomnia and high sleep effort, with the aim to inform future large-scale RCTs. Feasibility is defined by Eldridge and colleagues (2016) as the overarching concept for research studies that are conducted prior to the main trial and assesses whether a future RCT can be done. Following this framework, this study adopted the randomised pilot study approach in which the main features of acceptability such as eligibility, recruitment and retention rates are explored along with the evaluation of preliminary efficacy of the intervention within a small-scale randomised trial. The acceptability of PI was assessed based on 1) the number of individuals who met inclusion criteria at screening (eligibility), 2) the number of participants

enrolled to interventions (recruitment), 3) session attendance and completion of interventions (adherence), and 4) the number of participants at follow-up (retention). Moreover, this study assessed the preliminary efficacy of PI on reducing sleep effort (primary outcome), as well as improving objective and sleep diary sleep parameters, perceived sleep quality and mental health (secondary outcomes).

Methods

Ethical considerations

Ethical approval for this study was obtained from the Faculty of Medicine and Health Sciences Research Ethics Committee at the University of East Anglia (ref: 2020/21-062; See Appendix B for approval letter).

Design

This study was designed as a two-arm RCT with two phases: screening and intervention. Eligible participants identified from screening were randomly assigned to receive either PI or sleep hygiene (SH) instructions. Randomisation was conducted using an online computer-generated randomisation platform (<https://www.sealedenvelope.com>), with random permuted blocks to ensure groups were balanced and concealment for future allocations were maintained. SH instructions were chosen as the active control condition because they have strong face validity given that they are commonly used in clinical settings for individuals with sleep complaints (Irish, Kline, Gunn, Buysse & Hall, 2015). Moreover, the use of SH as an intervention can entail a similar delivery format, session engagement and level of effort as the sleep intervention, as described by Hauri (1993).

Participants

Participants were recruited between March and July 2021 via electronic and printed advertisements distributed at the host university and word of mouth referrals. Individuals who expressed interest in participating were screened according to the eligibility criteria, which

included those who 1) were aged 18 years and older, 2) met criteria for insomnia by scoring ≤ 16 on the Sleep Condition Indicator (Espie et al., 2014), and 3) reported high sleep effort during night-time sleep with scores of > 2 on the Glasgow Sleep Effort Scale (Broomfield & Espie, 2005). We excluded individuals who 1) were diagnosed with sleep disorders other than insomnia (e.g. sleep-related breathing disorders), 2) had sensorial impairments (e.g. deafness, blindness), 3) used medications that had an effect on sleep, and 4) were receiving any ongoing psychological interventions for insomnia or any other psychological disorders.

Given that this was a feasibility study, no formal power calculation was conducted. Nevertheless, considerations to achieve an adequate sample size were made. As the recommended range of sample size for feasibility and pilot studies were reported to be at least between 24 and 50 (Browne, 1995; Julious, 2005; Sim & Lewis, 2012), this study recruited 46 participants at screening.

Measures

Sleep Condition Indicator (SCI). The SCI is an 8-item screening tool of insomnia disorder based on DSM-5 criteria (Espie et al., 2014). All SCI items are scored on a 5-point scale of 0 to 4, with scores ≤ 2 for each item representing threshold score for insomnia (Espie et al., 2014). Thus, a cut-off score of ≤ 16 reflects putative insomnia disorder (Espie et al., 2014). The SCI has strong construct and concurrent validity in distinguishing individuals with insomnia disorder and normal sleepers (Espie et al., 2014; Palagini et al., 2015), as well as good internal consistency (Cronbach's $\alpha = .83$; Hellstrom et al., 2019).

Glasgow Sleep Effort Scale (GSES). The GSES is a 7-item self-report scale developed by Broomfield and Espie (2005) to measure persistent efforts to sleep. The scale addresses core behavioural and cognitive components of sleep effort such as having the need to control sleep, making voluntary attempts of controlling sleep and experiencing performance anxiety around sleep (Broomfield & Espie, 2005). GSES items are assessed on a 3-point Likert scale (0 = not

at all, 1 = to some extent, 2 = very much), with scores above 2 indicating high sleep effort (Broomfield & Espie, 2005). The GSES has high internal consistency (Cronbach's $\alpha = .77$; Broomfield & Espie, 2005) and there is evidence to support the convergent and criterion validity of the scale (Broomfield & Espie, 2005; Meia-Via, Marques, Espie, da Silva & Gomes, 2016), suggesting GSES is effective in quantifying sleep effort and can adequately distinguish good sleepers from individuals with insomnia (Broomfield & Espie, 2005).

Consensus Sleep Diary (CSD). The CSD is an expert consensus, patient-informed and standardised measurement tool for assessing self-reported night-time sleep (Carney et al., 2012). The 9-item measure includes subjective questions and a 5-point Likert scale (e.g. very poor to very good) covering critical sleep parameters (Carney et al., 2012). Past research supported the validity and sensitivity of CSD in subjectively assessing sleep between good and poor sleepers (Carney et al., 2012; Maich et al., 2018). Furthermore, sleep diaries are “gold-standard” subjective sleep measures (Buysse et al., 2006).

Wrist actigraphy. The wrist-worn actigraphic recording device, MotionWatch 8 (Cambridge Neurotechnology Ltd; Cambridge, UK) estimates sleep quality by sensing and recording motions during sleep (Aili et al., 2017) and provides an objective proxy measurement of sleep-wake timing, sleep duration and sleep efficiency, as computed by the MotionWare Sleep Analysis software. Actigraphy is useful in assessing overall sleep quality in the natural sleep setting (Martin & Hakim, 2011), with actigraphy-measured sleep latency, sleep duration and total wake time being correlated with polysomnography (PSG), the “gold-standard” for objective measurements of sleep (Ancoli-Israel et al., 2003; McCall & McCall, 2012).

Pittsburgh Sleep Quality Index (PSQI). The PSQI is a 24-item questionnaire that assessed seven components of sleep: sleep quality, sleep disturbances, sleep latency, sleep duration, habitual sleep efficiency, use of sleep medications and daytime dysfunction (Buysse et al., 1989). The questionnaire consists of open-ended and close-ended questions, and item

scores are combined to form the seven component scores, each of ranging between 0-3. Total scores are added to yield a global score, with scores >5 indicating severe sleep disturbance. The PSQI is sensitive to clinically meaningful changes across time following intervention to improve sleep (Krakow et al., 2004). Moreover, the PSQI has a high degree of internal consistency (Cronbach's $\alpha = 0.83$; Buysse et al., 1989).

Patient Health Questionnaire (PHQ-9). The PHQ-9 is a 9-item self-report tool used to measure depression severity (Kroenke, Spitzer & Williams, 2001). Each item reflects the nine diagnostic criteria of depression listed in DSM-IV (Zhong et al., 2015). Item scores range from 0 ("not at all") to 3 ("nearly every day") with higher overall scores indicating more severe depression (Kroenke et al., 2001). The cut-off score is set at ≥ 10 , indicating moderate depression. Studies evaluating the psychometric properties of PHQ-9 found that the tool demonstrated good validity as well as high sensitivity and specificity (88% respectively) in detecting symptoms of major depressive disorder (MDD; Kroenke et al., 2001; Rancans et al., 2018). The PHQ-9 also obtained good internal consistency (Cronbach's $\alpha = .85$; Maroufizadeh et al., 2019).

In this study, participants who scored ≥ 1 on item 9 indicating suicide/self-harm risks were signposted to mental health support services.

Procedure

At screening, individuals who expressed interest were given a participant information sheet (see Appendix C) and were required to complete a consent form (see Appendix D). Demographic information, self-reported sleep quality (SCI, GSES, PSQI) and mental health (PHQ-9) outcomes were then collected using an online questionnaire. Adults who were ineligible were signposted to relevant support services and crisis helplines (see Appendix E), whereas adults who met inclusion criteria were invited to participate in the intervention. Participants were given a personal reference code, and they were randomised to either the PI

or control group. Given the limited availability of actigraphic equipment at the host university, interventions took place between August and November 2021.

As the intervention phase was conducted during the COVID-19 pandemic, all sessions were delivered remotely via Microsoft Teams. Eligible participants who were randomised into intervention groups were contacted by email to arrange intervention appointments. A follow-up email consisting of an invitation link to a Microsoft teams meeting was then sent to each participant. Furthermore, in-built platform functions (e.g., share screen, whiteboard) were used during sessions to aid engagement and collaboration between researcher and participant.

Paradoxical Intention (Intervention)

Two sessions of PI lasting 1-hour were delivered individually across two weeks. The sessions introduced the rationale of PI and instructed participants to stay awake without making effort to sleep (Broomfield & Espie, 2003; Espie, 2006; see Appendix H for instruction sheet). PI was delivered following the steps by Espie (2011), including the consideration of sleep normalcy, formulation of insomnia as a sleep effort syndrome, introduction of attentional bias in insomnia and implementation of PI for night-time sleep.

Sleep Hygiene (Control)

Participants received a one-off 1-hour session to understand sleep hygiene. The session followed the guide by Hauri (1993). The session outlined the impacts of lifestyle on night-time sleep, and between two to four well-understood sleep hygiene recommendations were made for each participant. An instruction sheet was developed to include environment and behavioural recommendations (Irish et al., 2015; see Appendix I).

Therapist

All intervention sessions were delivered by the first author (GO) under the supervision of the secondary research supervisor (NB), who is an expert in the field of PI.

Measures of acceptability outcomes

Acceptability outcomes were assessed by participant eligibility, the number of participants enrolled interventions, session attendance and completion of intervention, and the number of participants retained at follow-up.

Measures of preliminary efficacy outcomes

Primary outcome. The GSES was measured at three timepoints: before the intervention (baseline), after the 2-week intervention (post-intervention) and at 1-month follow-up.

Secondary outcomes. Like the primary outcome, perceived sleep (PSQI) and mental health (PHQ-9) were measured at baseline, post-intervention and follow-up.

Participants wore a wrist actigraphy and completed the CSD for 5 consecutive nights at baseline and post-intervention. Both measures recorded sleep parameters including time in bed (TIB), sleep onset latency (SOL), wake after sleep onset (WASO), sleep duration (SD), sleep period time (SPT), sleep efficiency (SE). Actigraphy was worn on non-dominant wrists and participants were instructed to press the event marker on the face of the actiwatch at 'lights out' (night) and 'final awakening' (morning). Participants completed the CSD upon awakening each morning (see Appendix F and G for instruction sheet).

Actiwatch data were downloaded and analysed using the MotionWare Sleep Analysis software. Sleep diary responses were used to confirm the 'lights out' and 'final awakening' times as identified using the timestamped event markers. In cases of disagreements between start and end times of a sleep window on both measures, the light sensor data was used to determine the 'lights out' and 'final awakening' times (cf. Landry et al., 2015: 3). Moreover, objective composite sleep quality was calculated by averaging standardised sleep duration, sleep efficiency and sleep fragmentation scores. The fragmentation score was multiplied by -1

prior to averaging. Higher composite scores represented better sleep quality (Landry et al., 2015).

Statistical Analyses

IBM SPSS Statistics version 27 was used for all analyses. Descriptive statistics was used to report the demographic data of the sample and acceptability outcomes of the intervention. To assess preliminary efficacy, independent t-tests (continuous data) and Mann-Whitney U tests (categorical data) were used to explore group differences on all outcomes, following the use of Kolmogorov-Smirnov test to check for data normality. Due to a small sample size, an exploratory analysis of Mann-Whitney U test was conducted using the normalised data or data of relative difference to compare individual changes across time on all outcomes (formula = $\text{post-intervention}/\text{baseline} * 100\%$). Moreover, a generalised linear model (GLM) evaluated the main effects and interaction effects across time for all outcomes. Controlling for age, mean values of all outcomes were analysed. Residuals were inspected for normality, and effect sizes (η^2) for each variable were computed. Furthermore, the association between actigraphy and sleep diary parameters was conducted using Spearman correlation (ρ). Additional exploratory analysis on the impacts of PI on self-reported questionnaires from baseline to follow-up were conducted using chi-square analysis and GLM. Statistical significance was set at 0.05 ($p \leq .05$).

Results

Description of the sample

Table 1 shows the characteristics of the overall sample and the intervention conditions. Twenty-four participants (22 females) were included for analysis. The mean age of the sample was 28.88 years, with participants ranging from 18 to 54 years old. There were no significant differences in gender, age, SCI and GSES screening scores between groups.

Acceptability of intervention

Figure 1 outlines the participant flowchart throughout the study. At screening, a total of 46 adults were recruited. Excluding 11 adults who did not complete the screening questionnaire and/or did not meet inclusion criteria of the intervention phase, a total of 35 adults (76%) obtained scores on the SCI and GSES indicating the presence of insomnia disorder and high sleep effort. Twenty-six adults who met inclusion criteria consented to participate in the intervention phase and were randomised, resulting in a recruitment rate of 56.5%. Twenty-four participants of the 26 recruited (92%) completed the study. There were 100% adherence and retention rates within the PI group as participants attended all intervention sessions and were retained at follow-up. Whilst all participants attended scheduled SH sessions, retention rate was at 85% as 2 participants were lost at post-intervention, with 1 participant withdrawing due to medical reasons unrelated to the study, and another dropping out with no further reply to communication attempts.

Preliminary effects of intervention

Findings of all outcomes are outlined in Table 2 (between group analyses), Table 3 (normalised group differences), Table 4 (main effects and interaction of intervention) and Table 5 (association of actigraphy and sleep diary data).

Effects on the primary outcome

PI showed promising effects in reducing sleep effort. The PI group ($M = 3.77$, $SD = 2.42$, $U = 32.50$, $z = -2.05$, $p = .04$) reported significantly reduced sleep effort compared to the control group ($M = 5.60$, $SD = 1.96$) at post-intervention (see Table 2). When normalised to individual baseline, the PI group yielded a large effect ($M = 64.42$, $SD = 36.39$, $U = 23.50$, $z = -2.58$, $p = .01$, $\eta^2 = .30$; see Table 3). Moreover, the age-controlled GLM revealed significant interactions on the GSES favouring the PI group ($F(1, 20) = 4.70$, $p = .04$, $\eta^2 = .19$; see Table

4). The positive effects of PI in reducing GSES scores were also sustained at post-intervention ($F(1, 20) = 9.30, p = .006, \eta^2 = .32$; see Table 4) and 1-month follow-up (see Table S1).

Effects on secondary outcomes

Sleep parameters. No significant outcomes were found on actigraphy data on most analyses. Conversely, sleep diary parameters yielded some significant improvements. The PI group ($M = 15.00, SD = 15.00, U = 37.50, z = -1.97, p = .049$) reported significantly reduced WASO compared to the control group ($M = 32.00, SD = 25.00$; see Table 2). When scores were normalised, moderate to large effect sizes were observed on sleep diary SE ($M = 107.69, SD = 11.81, U = 33.00, z = -2.23, p = .03, \eta^2 = .22$) and WASO ($U = 40.50, z = -1.80, p = .07, \eta^2 = .14$). However, sleep diary WASO was not significant (see Table 3).

Notably, the GLM revealed actigraphy SOL was the only objective outcome that yielded large effect with near significance ($p = .06, \eta^2 = .16$; see Table 4). In contrast, significant main effects were found on sleep diary SOL, SPT and SD. Within group analysis revealed a significant reduction in SOL across time in both groups ($F(1, 21) = 4.57, p = .04, \eta^2 = .18$). Significant improvements were also found among the PI group on sleep diary SPT ($F(1, 21) = 4.89, p = .04, \eta^2 = .19$) and SD ($F(1, 21) = 6.80, p = .02, \eta^2 = .25$).

Spearman correlation revealed some moderate to strong associations between actigraphy and sleep diary measures (see Table 5). However, these were expected, particularly because the sleep parameters involving the ‘lights out’ and ‘final awakening’ of the sleep window between the actigraphy event marker and sleep diary entry were matched prior to data analysis. Conversely, other sleep parameters had weak/non-significant correlations between both measures. Among the PI group, strong correlations were observed in SOL ($\rho = .78, p = .002$) and SPT ($\rho = .75, p = .003$). Similar trends were found among the control group, with strong correlations observed for the objective and self-reported SPT (baseline: $\rho = .85, p = .001$; post-intervention: $\rho = .82, p = .002$) and SD ($\rho = .83, p = .002$).

Perceived sleep quality. No significant group differences were found at post-intervention. However, when normalised to individual baselines, the PI group reported significant improvements in PSQI, yielding a large effect ($M = 57.11$, $SD = 33.18$, $U = 35.00$, $z = -2.13$, $p = .03$, $\eta^2 = .20$; see Table 3). The GLM also revealed a significant interaction of intervention favouring the PI group, with large effect size ($F(1, 20) = 8.33$, $p < .001$, $\eta^2 = .49$). Moreover, sustained improvements were notable as significant reductions were found on PSQI among the PI group at post-intervention ($F(1, 20) = 8.33$, $p = .009$, $\eta^2 = .29$) and follow-up (see Table S1 and S2).

Perceived mental health. No significant group differences were found in PHQ-9 scores. However, when controlled for age, the PI group had significantly lower PHQ-9 scores compared to the control group ($F(1, 19) = 6.09$, $p = .02$, $\eta^2 = .24$; see Table 4). Sustained reductions in depressive symptoms from baseline to follow-up were also found among the PI group (see Table S1).

Discussion

The aim of this study was to assess the feasibility and preliminary efficacy of PI among adults with insomnia and high sleep effort. The present findings indicated that two sessions of PI focusing on the intention to reduce sleep effort along with two weeks of using PI instructions were feasible. There were 100% adherence and retention rates among the PI group throughout the study period. Moreover, findings of the preliminary analysis suggest that PI sessions had positive effects on sleep effort, self-reported sleep parameters including WASO, SOL and SE, and perceived sleep and mental health outcomes.

To the authors' knowledge, this study was the first to demonstrate the effectiveness of PI on improving sleep effort using a validated measure, GSES. Findings showed that there was a significant GSES score reduction among the PI group compared to the SH group at post-intervention, suggesting that participants allocated to PI reported lesser attempts of initiating

night-time sleep, thus having reduced sleep effort. This remained statistically significant across time and when baseline differences were accounted for, yielding large effect sizes. The improvement in sleep effort is further reflected by the decrease in self-reported WASO and SOL. This finding supports the notion that PI alleviates insomnia severity by reducing voluntary attempts at initiating sleep (Ascher & Turner, 1979, Broomfield & Espie, 2003).

Moreover, our findings demonstrated an improvement in both objective and self-reported sleep parameters. At post-intervention, the PI group had reduced WASO and SOL as well as increased SE compared to the SH group. Despite this, only the sleep diary WASO obtained statistical significance. After normalisation to baseline, similar trends were found in which sleep diary WASO and SOL were reduced and SE increased. Although moderate to large effect sizes were found, only the sleep diary SE reached statistical significance. Notably, however, sleep diary WASO and SOL approached near significance. These findings are in line with previous evidence (Ascher & Turner, 1979, Ascher & Turner, 1980, Broomfield & Espie, 2003), supporting the effectiveness of PI on improving self-reported sleep initiation and sleep maintenance. Nevertheless, our findings warrant for further studies to be conducted in a larger group given that preliminary analyses of the effects of PI demonstrated improvement in both objective and self-reported sleep parameters, with near significance and at least moderate effect sizes obtained for sleep diary outcomes.

It is worth noting that our findings demonstrated some discrepancies between objective and self-reported sleep quality. Clear discrepancies were observed between the actigraphy and sleep diary data, particularly SOL and WASO. Interestingly, this discrepancy was observable across both groups, whereby self-reported SOL was overestimated and self-reported WASO was underestimated. A recent study by Valko and colleagues (2021) suggested that this sleep-wake misperception was common among younger people, and this was notable in this study in which a majority of our participants were young adults. Moreover, the sleep-wake

misperception was further confirmed by the weak correlation and non-significant values between objective and self-reported sleep parameters from both groups.

Improvements in PSQI scores were observed among the PI at post-intervention. Although the between group analysis yielded near significant values for the change in PSQI scores, further exploratory analyses indicated that the changes was significant and yielded large effects. The direction of score changes demonstrates that individuals who received PI reported a positive change in self-reported sleep quality, and this finding is in line with past evidence indicating the effectiveness of cognitive-behavioural interventions for insomnia on perceived sleep quality (Espie et al., 2007; Buysse et al., 2011; Taylor et al., 2014). Similar trends were observed in the PHQ-9 scores, whereby the severity of depression among the PI group as indicated by the average scores reduced from mild severity ($M = 9.69$) to none/minimal severity ($M = 4.69$). Like the PSQI scores, significant values with moderate effects were only found in exploratory interaction analysis. Nevertheless, the results indicate that PI may improve depressive symptoms alongside perceived sleep quality. This finding supports the results of past research demonstrating the effectiveness of CBT-I on insomnia and depression (van der Zweerde et al., 2017; Cunningham & Shapiro, 2018).

Implications

This study has both clinical and research implications. Firstly, the acceptability and preliminary efficacy outcomes of the study support the original approach by Ascher and Efran (1978), in which PI can be administered as a brief cognitive-behavioural intervention with the rationale of “trying to stay awake by gently resisting sleep onset” to reduce high sleep effort. Whilst CBT-I remains as the first-line intervention for insomnia, our findings suggest that PI can be used as an alternative standalone approach, particularly for adults with insomnia who also present with high sleep effort and depression. The preliminary efficacy of PI is further

strengthened by the positive, moderate to large effect sizes yielded when outcomes were compared to an active control condition.

Furthermore, these promising findings were a result of the delivery of internet-based PI. Although this delivery format was adopted to adhere to the COVID-19 pandemic restrictions, it had several benefits. For one, our findings support the notion that internet-based interventions including therapist contact and individualised guidance can ensure adherence and therapeutic efficiency (Andersson & Titov, 2014). Session engagements and participant collaboration were also further enhanced by the incorporation of in-built platform functions (e.g., share screen, whiteboard) during sessions. Notably, the use of digital sleep interventions are not uncommon. More recently, CBT-I has also been delivered via the internet. Not only has this improved the accessibility of sleep intervention, internet-based CBT-I is also cost-effective with high treatment efficiency (Soh et al., 2020). A recent meta-analysis of 15 RCTs reported that internet-based CBT-I had significantly positive and sustained effects in reducing insomnia severity and improving sleep parameters including SOL, TST, WASO, SE and NWAK (Ye et al., 2016). Hence, further research should investigate the effectiveness of PI in larger RCTs, adopting both conventional face-to-face and internet-based approaches.

Finally, the lack of agreement between actigraphy and sleep diary data adds to evidence that there may be discrepancies between sleep-wake misperceptions (Lund et al., 2013; te Lindert et al., 2019), in which may be independently associated with age factors (Valko et al., 2021). Both types of measures may reflect varying aspects of sleep quality, and whilst this highlights the importance of utilising both objective and self-reported measures of sleep quality, this also calls for future studies to identify possible factors that may explain the inconsistencies of association between both measures.

Limitations

This study has several limitations. First, all phases of the study were conducted by the primary researcher. As this included intervention delivery and data analysis, double blinding was not achieved. With all intervention sessions being led by the same researcher, there may have been an increased risk of researcher bias in favouring the intervention group. Nevertheless, the inclusion of an active control which involved similar delivery format and engagement as the sleep intervention may have minimised this risk. Moreover, given that full blinding is difficult in psychological intervention studies (Juul et al., 2021), personal reference codes were given to all participants and used throughout the study. Conversely, confirmation bias may have been present as statistical analyses were conducted by the same researcher. However, the primary researcher received regular supervision from the secondary research supervisor (AL) to ensure that all analyses were conducted and interpreted appropriately. In future, studies should consider involving a larger research group with allocation of tasks between randomisation, delivery of intervention and data analyses (Juul et al., 2021).

Another limitation of the study is its small sample size ($n = 24$). With the total number of participants being randomised into two groups, the overall data collected may have negatively impacted the power of the sample to yield significant effects. Nevertheless, PI yielded moderate to large effects in both primary and secondary outcomes, indicating a reasonable degree of practice significance. Notably, this study was designed as a feasibility study, hence, a priori power analysis was not considered to define the sample size. Moreover, baseline differences were observed and there were clear imbalances in participant demographics, whereby most participants were young adults and females. This may make it difficult to draw firm, generalisable conclusions on the preliminary effectiveness of PI. Future studies should recruit a wider population of participants to improve randomisation and to compare potential differences in the effectiveness of PI across different ages and sex.

Conclusion

Findings of this study suggest that PI is feasible and has potential efficacy among adults with insomnia disorder and high sleep effort. To the authors' knowledge, this is the first study to demonstrate the effectiveness of PI on the Glasgow Sleep Effort Scale, which is a validated tool measuring the level of effort an individual employs to fall asleep. Nevertheless, a larger RCT should be conducted in future to further confirm the sustained efficacy of PI on both objective and self-reported sleep quality and mental health outcomes.

Acknowledgements

The authors wish to express their gratitude to those who expressed interest in taking part in the study, and to the participants who took part and committed to the interventions.

Abbreviations

CBT-I: Cognitive behavioural therapy for insomnia

CSD: Consensus Sleep Diary

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

GSES: Glasgow Sleep Effort Scale

PHQ-9: Patient Health Questionnaire

PI: Paradoxical intention therapy

PSG: Polysomnography

PSQI: Pittsburgh Sleep Quality Index

RCT: Randomised controlled trials

SBRU: Sleep and Brain Unit

SCI: Sleep Condition Indicator

SD: Sleep duration

SE: Sleep efficiency

SH: Sleep hygiene

SOL: Sleep onset latency

SQ: Sleep quality

SPT: Sleep period time

TIB: Time in bed

WASO: Wake after sleep onset

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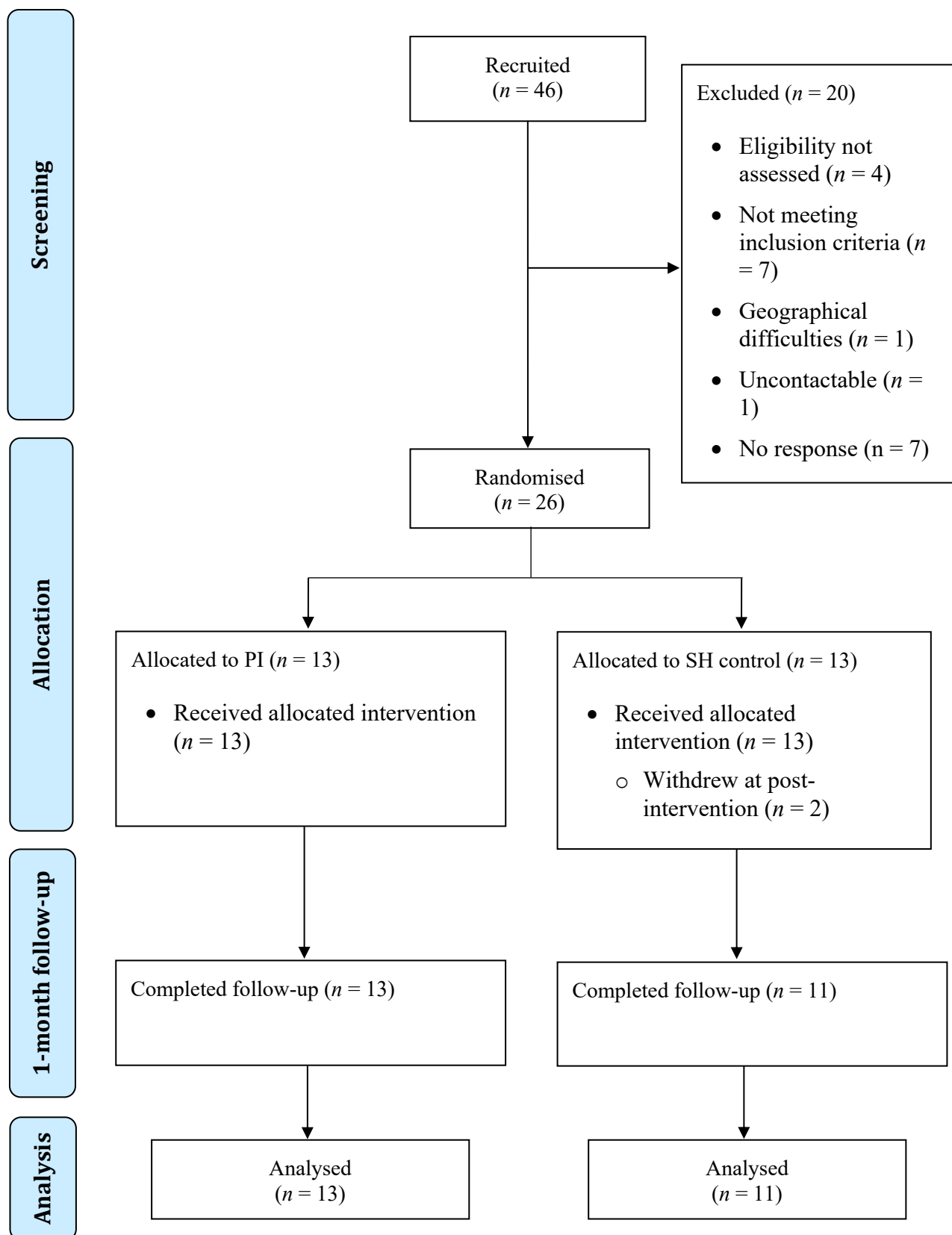
Figure 1*Participant flowchart*

Table 1*Demographic information for the study sample*

Variables	Total sample (<i>n</i> = 24)	PI (<i>n</i> = 13)	SH Control (<i>n</i> = 11)	P value
Age				0.18
<i>M</i> (<i>SD</i>)	28.88 (13.61)	25.85 (12.27)	32.45 (14.81)	
Range	18 – 54	18 – 54	18 – 54	
Gender, <i>n</i> (%)				0.20
Male	2 (8.3)	0 (0)	2 (18.2)	
Female	22 (91.7)	13 (100)	9 (81.8)	
SCI scores (screening)				0.13
<i>M</i> (<i>SD</i>)	10.21 (2.62)	9.39 (2.53)	11.18 (2.48)	
GSES scores (screening)				0.32
<i>M</i> (<i>SD</i>)	8.67 (2.48)	9.39 (1.90)	7.82 (2.89)	

Note. *M* = mean; *SD* = standard deviation; SCI = Sleep Condition Indicator; GSES = Glasgow Sleep Effort Scale; *n* = sample size; PI = Paradoxical Intention; SH = Sleep Hygiene

Table 2

Between group differences in actigraphy data, sleep diary data and self-reported sleep and mental health questionnaires

Variable	Baseline			Post-intervention		
	PI,	SH Control,	P value	PI,	SH Control,	P value
	<i>M (SD)</i>	<i>M (SD)</i>		<i>M (SD)</i>	<i>M (SD)</i>	
Actigraphy						
Lights Out Time (hh:mm)	23:19 (1:01)	23:25 (1:14)	0.25	23:53 (1:12)	23:16 (1:23)	0.79
Final Awakening Time (hh:mm)	8:27 (1:32)	8:14 (1:50)	0.62	8:19 (1:18)	8:05 (5:49)	0.12
Time in Bed (h)	9.27 (1.18)	9.03 (0.85)	0.34	8.65 (0.93)	9.07 (1.00)	0.92
Sleep Onset Latency (min)	31.00 (28.00)	14.00 (13.00)	0.10	22.00 (19.00)	29.00 (49.00)	0.64
Sleep Period Time (h)	8.62 (0.90)	8.55 (0.78)	0.54	8.05 (0.78)	8.55 (0.93)	0.70
Wake After Sleep Onset (min)	66.00 (35.00)	65.00 (29.00)	0.23	55.00 (19.00)	67.00 (30.00)	0.32
Sleep Duration (h)	7.50 (0.75)	7.45 (0.80)	0.73	6.58 (1.87)	7.40 (0.88)	0.15
Sleep Efficiency (%)	81.59 (8.67)	82.59 (6.84)	0.32	76.77 (21.15)	82.07 (5.52)	0.66
Fragmentation Index	31.54 (17.27)	31.80 (11.65)	0.26	29.68 (5.89)	32.67 (13.14)	0.93
Composite Score	-10.14 (5.79)	-10.22 (3.91)	0.25	-9.54 (2.00)	-10.51 (4.40)	0.93

Sleep diary

Lights Out Time (hh:mm)	23:35 (1:04)	23:06 (1:06)	0.71	23:56 (1:14)	23:40 (1:31)	0.91
Final Awakening Time (hh:mm)	8:01 (1:32)	7:59 (2:04)	0.39	7:57 (1:39)	7:59 (5:42)	0.44
Time in Bed (h)	8.45 (1.1)	8.87 (1.82)	0.73	8.38 (2.05)	8.75 (1.42)	0.60
Sleep Onset Latency (min)	56.00 (44.00)	29.00 (13.00)	0.27	31.00 (27.00)	23.00 (13.00)	0.91
Sleep Period Time (h)	7.48 (0.95)	9.20 (4.45)	0.12	7.47 (1.08)	8.37 (1.27)	0.79
Wake After Sleep Onset (min)	37.00 (34.00)	37.00 (30.00)	0.79	15.00 (15.00)	32.00 (25.00)	0.049*
Sleep Duration (h)	6.88 (1.17)	8.98 (4.50)	0.28	7.15 (1.17)	7.82 (1.50)	0.36
Sleep Efficiency (%)	82.09 (10.54)	86.40 (6.98)	0.07	89.11 (7.77)	88.88 (6.26)	0.43
GSES	8.15 (1.63)	7.55 (2.51)	0.50	3.77 (2.42)	5.60 (1.96)	0.04*
PSQI	11.92 (2.57)	9.00 (2.28)	0.01*	5.23 (2.83)	6.50 (2.56)	0.17
PHQ-9	9.69 (4.54)	9.20 (3.89)	0.83	4.69 (0.79)	5.89 (3.98)	0.49

Note. hh:mm = hours and minutes; h = hours; min = minutes; GSES = Glasgow Sleep Effort Scale; PSQI = Pittsburgh Sleep Effort Scale; PHQ-9 = Patient Health Questionnaire; PI = Paradoxical Intention; SH = Sleep Hygiene; *M* = mean; *SD* = standard deviation; * = significant ($p \leq .05$)

Table 3

Between group differences following the normalisation and calculation of relative differences (%) on all sleep and mental health outcomes

Variables	Between group differences		
	<i>M (SD)</i>	<i>ES (η²)</i>	P value
Actigraphy			
Lights Out Time	110.32 (46.83)	0.07 ^M	0.19
Final Awakening Time	100.42 (13.41)	0.004 ^S	0.75
Time in Bed	97.37 (13.18)	0.06 ^M	0.24
Sleep Onset Latency RD	-0.10 (0.48)	0.04 ^S	0.32
Sleep Period Time	97.67 (12.93)	0.12 ^M	0.10
Wake After Sleep Onset	107.21 (59.23)	0.01 ^S	0.66
Sleep Duration	96.95 (11.40)	0.11 ^M	0.11
Sleep Efficiency	101.03 (7.11)	0.001 ^S	0.89
Fragmentation Index	114.35 (47.27)	0.01 ^S	0.66
Composite Score	114.93 (51.43)	0.002 ^S	0.84
Sleep diary			
Lights Out Time	104.27 (23.63)	0.04 ^S	0.35
Final Awakening Time	100.20 (18.73)	0.07 ^M	0.21
Time in Bed	98.76 (11.68)	0.07 ^M	0.20
Sleep Onset Latency RD	-0.13 (0.42)	0.08 ^M	0.17
Sleep Period Time	103.75 (17.50)	0.09 ^M	0.16
Wake After Sleep Onset RD	-0.25 (0.46)	0.14 ^L	0.07
Sleep Duration	107.94 (19.73)	0.04 ^S	0.37
Sleep Efficiency	107.69 (11.81)	0.22 ^L	0.03*

GSES	64.42 (36.39)	0.30 ^L	0.01*
PSQI	57.11 (33.18)	0.20 ^L	0.03*
PHQ-9	61.20 (67.97)	0.06 ^M	0.24

Note. ES = effect size; GSES = Glasgow Sleep Effort Scale; L = large; M = moderate; *M* = mean; PHQ-9 = Patient Health Questionnaire; PSQI = Pittsburgh Sleep Effort Scale; RD = relative difference; S = small; SD = standard deviation; * = significant ($p \leq .05$)

Table 4

Main effects and interaction of interventions on actigraphy data, sleep diary data and self-reported sleep and mental health questionnaires

Variables	Main effect by groups		Main effect of time		Group-by-time interaction	
	P value	ES (η^2)	P value	ES (η^2)	P value	ES (η^2)
Actigraphy						
Lights Out Time	0.54	0.02 ^S	0.85	0.00 ^S	0.15	0.09 ^M
Final Awakening Time	0.85	0.00 ^S	0.21	0.08 ^M	0.52	0.02 ^S
Time in Bed	0.43	0.03 ^S	0.23	0.07 ^M	0.26	0.06 ^M
Sleep Onset Latency	0.98	0.00 ^S	0.29	0.05 ^S	0.06	0.16 ^L
Sleep Period Time	0.22	0.07 ^M	0.19	0.08 ^M	0.23	0.07 ^M
Wake After Sleep Onset	0.37	0.04 ^S	0.27	0.06 ^M	0.45	0.03 ^S
Sleep Duration	0.43	0.03 ^S	0.40	0.04 ^S	0.36	0.04 ^S
Sleep Efficiency	0.66	0.01 ^S	0.62	0.01 ^S	0.53	0.02 ^S
Fragmentation Index	0.61	0.01 ^S	0.16	0.09 ^M	0.91	0.01 ^S
Composite Score	0.62	0.01 ^S	0.16	0.09 ^M	0.92	0.00 ^S

Sleep diary

Lights Out Time	0.88	0.00 ^S	0.63	0.01 ^S	0.93	0.00 ^S
Final Awakening Time	0.64	0.01 ^S	0.98	0.00 ^S	0.87	0.00 ^S
Time in Bed	0.12	0.13 ^M	0.58	0.02 ^S	0.12	0.12 ^M
Sleep Onset Latency	0.34	0.04 ^S	0.04*	0.18 ^L	0.13	0.11 ^M
Sleep Period Time	0.04*	0.20 ^L	0.16	0.10 ^M	0.28	0.06 ^M
Wake After Sleep Onset	0.86	0.00 ^S	0.81	0.00 ^S	0.12	0.11 ^M
Sleep Duration	0.02*	0.25 ^L	0.19	0.08 ^M	0.11	0.12 ^M
Sleep Efficiency	0.26	0.06 ^S	0.46	0.03 ^S	0.27	0.06 ^M
GSES	0.50	0.03 ^S	0.006*	0.32 ^L	0.04*	0.19 ^L
PSQI	0.15	0.10 ^M	0.009*	0.29 ^L	<0.001*	0.49 ^L
PHQ-9	0.48	0.03 ^S	0.54	0.02 ^S	0.02*	0.24 ^L

Note. GSES = Glasgow Sleep Effort Scale; PSQI = Pittsburgh Sleep Effort Scale; PHQ-9 = Patient Health Questionnaire; ES = effect size; S = small; M = moderate; L = large; * = significant ($p \leq .05$)

Table 5*Association between actigraphy and sleep diary sleep parameters between intervention groups across baseline and post-intervention*

Variables	PI				SH control			
	Baseline		Post-intervention		Baseline		Post-intervention	
	Correlation (ρ)	P value	Correlation (ρ)	P value	Correlation (ρ)	P value	Correlation (ρ)	P value
Lights Out Time	0.38	0.20	0.97	<.0001*	0.94	<.0001*	0.58	0.06
Final Awakening Time	0.94	<.0001*	0.96	<.0001*	0.98	<.0001*	0.97	<.0001*
Time in Bed	0.74	0.004*	0.78	0.002*	0.90	<0.001*	0.90	<0.001*
Sleep Onset Latency	0.78	0.002*	0.33	0.28	0.35	0.30	0.02	0.96
Sleep Period Time	0.49	0.09	0.75	0.003*	0.85	0.001*	0.82	0.002*
Wake After Sleep Onset	0.003	0.10	0.44	0.13	0.89	0.80	-0.04	0.91
Sleep Duration	0.36	0.23	0.23	0.45	0.52	0.10	0.83	0.002*
Sleep Efficiency	0.07	0.82	0.10	0.75	0.10	0.77	0.16	0.65

Note. PI = Paradoxical Intention; SH = sleep hygiene; * = significant ($p \leq .05$)

Table S1*Self-reported measures of sleep and mental health outcomes at baseline, post-intervention, and follow-up*

Variable	PI					Control				
	Baseline,	Post-intervention,	Follow-up,	χ^2	P value	Baseline,	Post-intervention,	Follow-up,	χ^2	P value
	<i>Md</i>	<i>Md</i>	<i>Md</i>			<i>Md</i>	<i>Md</i>	<i>Md</i>		
GSES	8.00	4.00	3.00	15.17	<0.001*	7.50	6.00	5.50	0.89	0.64
PSQI	12.00	8.00	4.00	20.67	<0.001*	9.00	7.00	6.00	4.90	0.09
PHQ-9	10.00	5.00	4.00	11.39	0.003*	9.00	8.50	6.00	2.26	0.32

Note. GSES = Glasgow Sleep Effort Scale; PSQI = Pittsburgh Sleep Effort Scale; PHQ-9 = Patient Health Questionnaire; PI = Paradoxical Intention; SH = Sleep Hygiene; *Md* = Median; χ^2 = Chi-square; * = significant ($p \leq .05$)

Table S2*Main effects and interaction of interventions on the GSES, PSQI and PHQ-9*

Variables	Main effect by groups		Main effect of time		Group-by-time interaction	
	P value	ES (η^2)	P value	ES (η^2)	P value	ES (η^2)
GSES	0.32	0.05 ^S	0.01*	0.21 ^L	0.08	0.12 ^M
PSQI	0.09	0.14 ^L	<0.001*	0.33 ^L	0.02*	0.18 ^L
PHQ-9	0.13	0.11 ^M	0.21	0.07 ^M	0.19	0.08 ^M

Note. GSES = Glasgow Sleep Effort Scale; PSQI = Pittsburgh Sleep Effort Scale; PHQ-9 = Patient Health Questionnaire; ES = effect size; S = small; M = moderate; L = large; * = significant ($p < 0.05$)

CHAPTER 5

Extended Discussion and Critical Evaluation

Extended Discussion

The overarching aims of the present thesis portfolio were two-fold: 1) to determine the effectiveness of cognitive behavioural therapy for insomnia (CBT-I) on objective and self-reported measures of sleep by describing and synthesising existing literature that employed both types of measures concurrently, and 2) to examine the feasibility and preliminary efficacy of paradoxical intention therapy (PI) among adults with insomnia disorder and high sleep effort. Both aims were formulated with the expectation to address gaps within extant sleep literature. As such, a narrative synthesis and an empirical study were conducted. The main findings of the two papers presented in Chapter 2 (systematic review) and Chapter 4 (empirical study) are summarised below, followed by an extended critical evaluation and recommendations for future research and clinical practice.

Systematic Review

In Chapter 2, the review of studies incorporating both objective and self-reported measures of sleep to assess the effectiveness of CBT-I yielded 15 eligible studies. These studies utilised the sleep diary as a self-reported measure of sleep quality alongside at least one type of objective sleep measure including wrist actigraphy, polysomnography and Nightcap. Most of the studies also included the use of additional questionnaires to assess further aspects of self-reported sleep including insomnia severity, daytime functioning, beliefs about sleep and sleep-related quality of life.

Changes in sleep parameters such as sleep efficiency (SE), total sleep time (TST), sleep onset latency (SOL) and wake after sleep onset (WASO) were most commonly measured using both objective methods and sleep diary measures to assess the effectiveness of CBT-I. Additional sleep parameters were also measured in some studies using either or both types of measures, including early morning awakening (EMA), total wake time (TWT), total time awake between initial sleep onset and final morning awakening (MWASO), time between final

awakening and rising time (TWASO), time in bed (TIB), number of awakening during the night (NWAK), terminal wakefulness (TWAK), slow wave sleep, bedtime (BT), rise time (RT) and subjective sleep quality (SQ).

Most studies found an agreement in the direction of change on both sleep diary and objective sleep parameters, in which there were significant improvements in SE and TST, and significant reductions in SOL and WASO among adults with insomnia when CBT-I was compared to control conditions. Notably, however, there was a difference in the magnitude of change between objectively measured and sleep diary reported sleep parameters. Whilst moderate to large effect sizes were produced for sleep diary sleep parameters (e.g., SE, SOL, WASO), mixed findings were observed among objective sleep parameters with effect sizes inconsistently ranged between small and large effects. Moreover, one study (Buysse et al., 2011) which used and measured the effect size of polysomnography outcomes observed small effect sizes on all objective sleep parameters (e.g., SE, TST, SOL, WASO).

Like the sleep diary outcomes, significant improvements were found on all subjective sleep questionnaires at post-intervention and/or follow-up timepoints. An exception to this was one study (Taylor et al., 2014) which observed overall reductions in the Epworth Sleepiness Scale (ESS) and Multidimensional Fatigue Index (MFI), however, only the general fatigue domain on the MFI yielded significant values ($p = .007$, Cohen's $d = 1.10$).

Empirical Study

In Chapter 4, the empirical study investigated the acceptability and preliminary efficacy of PI among adults with insomnia and high sleep effort. Participants were randomised to receive either a brief, two-week session of PI or a one-off sleep hygiene instruction session (control). The acceptability of PI was assessed based on the eligibility, recruitment, adherence, and retention rates of participants throughout the study. The primary outcome of the preliminary efficacy component was on the reduction in severity of sleep effort. Secondary

outcomes included the change in objective and sleep diary sleep parameters, and perceived sleep quality and mental health.

Findings of the study indicated that the administration of PI across two weeks was feasible. From the 35 adults who met the eligibility criteria for insomnia disorder and high sleep effort by scoring ≤ 16 on the Sleep Condition Indicator (SCI; Espie et al., 2014) and > 2 on the Glasgow Sleep Effort Scale (GSES; Broomfield & Espie, 2005), 26 participants consented to take part and were randomised to the intervention groups. Compared to the control group, all participants in the PI group completed the study and were retained at follow-up.

PI was found to have promising effects in reducing the severity of sleep effort among individuals with insomnia. Significant improvements in GSES scores were found between intervention groups, indicating that the participants in the PI group reported that they engaged in lesser voluntary attempts at initiating night-time sleep. This positive effect was sustained across time, with a large effect size observed at post-intervention and significant values yielded for the change from baseline to 1-month follow-up.

Improvements were also found on both actigraphy and sleep diary outcomes. Particularly, there was an increase in sleep efficiency (SE) and a decrease in sleep onset latency (SOL) and wake after sleep onset (WASO) among the PI group as compared to the control group at post-intervention, on both measurement types. Notably, however, no changes in objective sleep parameters reached significance, whereas sleep diary WASO demonstrated significant differences between groups and sleep diary SE yielded significant values when individual differences in baseline outcomes were accounted for. The trends in the direction of change for the SE, SOL and WASO estimates are in line with past research (Ascher & Turner, 1979; Ascher & Turner, 1980; Broomfield & Espie, 2003), supporting the preliminary efficacy of PI in improving sleep quality, specifically sleep initiation and sleep maintenance among adults high in sleep effort.

Similarly, improvements were observed across time on the self-reported sleep and mental health outcomes. There were significant differences between the PI and control groups in the improvement on perceived sleep quality (Pittsburgh Sleep Quality Index [PSQI]; Buysse et al., 1989), indicating that the participants in the PI group reported experiencing better overall sleep at night. The severity of depression which was measured using the Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001) also observed a significant decrease across time between both groups, suggesting that the participants who received PI reported an improvement in depression symptoms compared to the control group. Moreover, the preliminary effectiveness of PI on the self-reported measures of sleep and mental health outcomes were sustained at the 1-month follow-up timepoint.

Critical Evaluation

This section presents an extended evaluation of the methodology and findings of the thesis portfolio along with the implications for relevant research and clinical practice, and strengths and limitations. Additional areas for future development are also discussed.

Theoretical and Clinical Implications

The systematic review suggests that there are currently a limited number of studies with good methodological quality that assessed the effectiveness of CBT-I on both objective and self-reported measures of sleep. Given the varying magnitude of change between outcomes of objective and self-reported sleep estimates found in the review, this highlights the need for future trials to consider employing and comparing *both* types of measures concurrently. This is in line with past research that recommended for research trials to include both objective (e.g., polysomnography, actigraphy) and self-reported (e.g., sleep diary, subjective insomnia and sleep-wake quality questionnaires) measures when assessing sleep among individuals with insomnia (Buysse et al. 2006; Landry et al., 2015).

Findings of the systematic review also has important implications for clinical practice. First, the positive effects on the direction of change in both objective and self-reported measures of sleep may suggest a likely association between both forms of sleep measures. As CBT-I was found to have a greater magnitude of change in self-reported sleep parameters and sleep-related questionnaires compared to objective sleep measures, this suggests that large improvements in perceived sleep quality may indicate some level of change in objective sleep quality. Given that the diagnosis for insomnia disorder solely depends on the assessment of perceived sleep impairments in clinical settings (American Psychiatric Association [APA], 2013; International Classification of Sleep Disorders [ICSD-3], 2014), this review supports that a large improvement in self-reported sleep quality can give reasonable indication that there are positive changes in overall sleep quality, including objective change. This is particularly important because whilst the use of both objective and self-reported measures in clinical assessments may provide a more representative understanding of sleep, the practicalities of employing both measures simultaneously in clinical settings may be challenging. Sleep diaries and self-administered questionnaires, which are now commonly used by healthcare professionals to assess for key domains of sleep quality including sleep complaints, usual sleep-wake schedule, sleep hygiene and daytime functioning among individuals with sleep difficulties (Schutte-Rodin et al., 2008), are easier to employ compared to objective sleep measures. For one, the use of home-based polysomnography is costly, and may interfere with sleep if not administered properly (Blackwell et al., 2008). Conversely, the use of actigraphy is less costly and invasive, and a good level of correlation of actigraphic sleep parameters has been found when the estimates are compared to polysomnography (Lehrer et al., 2022; Kushida et al., 2001; Marino et al., 2013). However, the scope of administering actigraphy in clinical settings is not yet known. Notably, some factors that may need to be considered include the access to actigraphy measures in clinics, the time availability of clinical professionals and

training opportunities for professionals to understand the technical use of actigraphy tools as well as extraction and interpretation of outcomes. Moreover, the recent emergence of wearable ambulatory technologies such as the Dreem headband allows sleep-related physiological signals and classification of sleep stages to be accurately assessed (Arnal et al., 2020). As preliminary evidence demonstrates that the Dreem headband outcomes correlate to the “gold-standard” polysomnography outcomes, there is potential for the Dreem headband to be used in clinical practice for assessment and treatment of sleep disorders (Arnal et al., 2020). Nevertheless, further studies are needed to examine its use among individuals with insomnia.

The empirical study highlights the feasibility and preliminary efficacy of administering PI as a brief, two-week intervention to improve sleep quality and reduce sleep effort by encouraging individuals with insomnia to “try to stay awake by gently resisting sleep onset”. As the current literature and use of PI continues to be in development, it is still unclear the ideal approach and administration of delivering the sleep intervention in a standardised manner. Particularly, a recent meta-analysis (Jansson-Fröjmark et al., 2021) identified three rationales of staying awake as part of the PI instructions: 1) moving the emphasis away from voluntary attempts to fall asleep (Ascher & Turner, 1979), 2) desensitising individuals to anxiety-provoking thoughts whilst waiting to fall asleep (Ascher & Turner 1980), and 3) paying close attention to any thoughts and writing them down the next morning (Ott et al., 1983). Findings of the empirical study here lend support to the original approach (Ascher & Turner, 1979) by demonstrating preliminary efficacy for PI instructions to be used as a cognitive-behavioural intervention that focuses individuals with insomnia away from attempts to initiate sleep voluntarily.

Participants who received PI instructions reported improvements on both actigraphy- and sleep diary-reported sleep parameters, including reduced SOL and WASO, and improved SE compared to the control group. Whilst trends in the direction of change were observed for

both objective and self-reported measures of sleep parameters, only the sleep diary measures reached significant values. This indicates a discrepancy between the two types of measures, a common occurrence among individuals with insomnia (Lund et al., 2013; te Lindert et al., 2019). The discrepancy between the actigraphy- and sleep diary-reported sleep parameters was further reflected in the magnitude of change. Particularly, the improvements in SE, SOL and WASO on sleep diary produced moderate to large effect sizes whereas actigraphy yielded mixed findings ranging from small to large effects in the same sleep parameters. Recent studies have suggested that sleep-wake misperceptions among individuals with insomnia may have a role in contributing to discrepancies between objective and self-reported measures of sleep quality. Particularly, younger and older adults are likely to report greater objective/self-reported discrepancies (Landry et al., 2015; Valko et al., 2021).

Nevertheless, there were clear indications of the positive sustained effects of PI on self-reported sleep and mental health outcomes, and these effects were sustained at the 1-month follow-up timepoint. When compared between groups and across time, the PI group obtained significant lower scores on the GSES and PSQI, indicating that those who received PI instructions experienced lesser voluntary attempts at initiating sleep and improved self-reported sleep quality. Similarly, PHQ-9 scores were significantly reduced among the PI group compared to the control group over time, suggesting that PI may also have contributed to the improvement of depressive symptoms among individuals with insomnia. This is in line with past research that found a significant association between insomnia and depression, particularly in which the management of insomnia may play an important role in preventing and improving depressive symptoms (Jindal & Thase, 2004; Li et al., 2016). Overall, the preliminary efficacy found for the use of PI instructions reflected past research that evaluated the effectiveness of cognitive-behavioural interventions for insomnia on self-reported sleep quality (Espie et al., 2007; Buysse et al., 2011; Taylor et al., 2014) and severity of depression (van der Zweerde et

al., 2017; Cunningham & Shapiro, 2018). This suggests preliminary effectiveness of PI as a standalone psychological therapeutic for insomnia (Jansson-Fröjmark et al., 2021). Moreover, findings of the empirical study suggests the suitability of using PI among adults with insomnia who may also present with high sleep effort and/or depressive symptoms. Thus, clinicians who work with adults with insomnia may benefit from additionally screening for sleep effort using the GSES and depressive symptoms.

Strengths and Limitations

The research presented in this thesis portfolio has several strengths and limitations. A major strength is that findings from both papers add to the current evidence in the sleep literature by addressing gaps within research informing clinical practice of cognitive behavioural interventions for insomnia. The systematic review highlighted the need for more robust studies using objective measures alongside self-reported sleep measurement methods, to investigate the effectiveness of CBT-I. Despite CBT-I being a first-line psychological intervention for adults with insomnia in England (National Institute for Health and Care Excellence [NICE], 2022), it is surprising that there remains few studies of good methodological quality investigating the effectiveness of CBT-I on both objective and self-reported measures of sleep, as recommended by Buysse and colleagues (2006), with further explorations on the impacts of factors including sleep-wake perceptions and age on the discrepancies between outcomes. Moreover, the methodology of the narrative synthesis may be seen as a strength. By following the guidance on conducting narrative synthesis (Popay et al., 2006), this allowed for the development of the review to be completed systematically with more rigour and transparency (Snilsveit et al., 2012).

The empirical study adds to the growing literature of using PI as a standalone psychological therapeutic to improve sleep quality and reduce sleep effort among adults with insomnia. One strength of the empirical study is that the paper demonstrated the feasibility of

administration and preliminary outcomes of delivering PI instructions with the rationale of de-emphasising voluntary attempts at sleep initiation (Ascher & Turner, 1979; Broomfield & Espie, 2003). Specific to the primary outcome of the preliminary efficacy component, the significant and sustained effects of PI on GSES scores over time supports the theoretical rationale of PI in improving sleep quality and sleep initiation by targeting sleep effort (Ascher & Efran, 1978; Jansson-Fröjmark et al., 2021). Given that this study was the also first to test the preliminary efficacy of PI on GSES since it was validated as a measure for assessing sleep effort (Broomfield & Espie, 2003), the positive effects further strengthen the role of PI in reducing sleep effort. Moreover, PI was found to have sustained improvements on secondary outcomes including actigraphy- and sleep diary-measured sleep parameters (e.g., SE, SOL, WASO), self-reported sleep quality (e.g., PSQI) and mental health outcomes (e.g., PHQ-9). Notably, the improvements in both primary and secondary outcomes yielded moderate to large effect sizes when compared to an active control condition, which further enhances the preliminary efficacy of PI in improving sleep parameters, perceived sleep, and mental health among adults with insomnia.

In addition, the empirical study contributes to the understanding of PI when used as an internet-based sleep intervention. Whilst the remote delivery of intervention was adapted to follow COVID-19 pandemic safety restrictions, the feasibility and preliminary outcomes of internet-based PI were promising. Digital functions (e.g., interactive whiteboard) within the online platform allowed for sustained engagement and collaboration from participants, which may have been helpful in improving adherence and therapeutic efficiency.

A limitation of the systematic review was that only a relatively small number of studies were found, and none of these studies had an overall low risk of bias. This limited the ability for firm conclusions to be drawn and generalised from the findings. Another potential limitation is that the review restricted the inclusion of studies to those written fully in English

only. This may have excluded relevant evidence published in different languages, limiting the knowledge and insights on the external validity of the effectiveness of CBT-I on objective and self-reported sleep quality across cultures.

The empirical study also has several limitations. One is that the size and heterogeneity of the overall sample was restricted. Whilst the study was designed as a feasibility study, considerations regarding the sample size were made following research recommendations (Julious, 2005). However, diversity in age and sex were lacking among the sample, with most of the participants young adults (e.g., 18 to 25 years) and female (92%). Moreover, the empirical study may have been predisposed to risks of researcher bias and confirmation bias as all intervention sessions and statistical analyses were conducted by a single author (GO). Whilst the inclusion of an active control condition may have minimised the risk of researcher bias during the intervention phase, it remains clear that double blinding was not achieved. Moreover, further efforts were put in place to minimise the risk of confirmation bias during the analysis phase (e.g., regular supervision, use of personal reference codes).

Areas for Future Development

Cognitive behavioural interventions for insomnia show good efficacy in improving self-reported sleep quality among adults with insomnia, however, mixed effects are observed in the direction and magnitude of change in objective sleep quality (Okajima et al., 2011, Lund et al., 2013; Mitchell et al., 2019). Whilst findings of the systematic review support this notion, the paper also revealed the lack of high-quality research available which has evaluated the effectiveness of CBT-I using both objective and self-reported measures of sleep, concurrently. Considering that past research has suggested discrepancies between objective and self-reported measures of sleep quality, this is surprising and future studies should aim to explore and address potential factors that impact on the discrepancy.

The preliminary efficacy of PI in improving sleep effort was strengthened with the reduction in the GSES scores, which was validated as a measure in assessing sleep effort (Broomfield & Espie, 2005). Particularly, this finding reflects the usefulness of PI when the rationale of instructions are to de-emphasise voluntary efforts to initiate sleep. Moreover, the significant differences in improvement produced from both objective and self-reported measures of sleep parameters as well as self-reported sleep and mental health questionnaires in the empirical study demonstrates the promising effectiveness of PI as a standalone psychological therapeutic for insomnia. Given that the overall sample size was small, significant values along with moderate to large effect sizes in sleep measures were unexpected. Nevertheless, this suggests that PI may have the potential to improve both sleep and mental health outcomes among adults with insomnia. Future studies with a larger sample size consisting of more diverse populations (e.g., age, sex) should be conducted to produce a more generalisable conclusion of the effectiveness of PI among adults with insomnia. It would be beneficial for bigger trials to also consider the effectiveness of PI among those who may also present with high sleep effort and/or depressive symptoms, as well as the effectiveness of PI when delivered face-to-face and/or via the internet.

Reflections on the Research Process

My journey of completing this thesis portfolio has been an interesting and valuable one. Although I have had some involvement with research in the past, I acknowledged that my experience and skills in research were limited, with much room for development. Given that this was my first experience with developing a thesis portfolio and leading a number of studies, especially research that focused specifically on insomnia and sleep intervention, this journey has been a steep learning curve. Upon reflection, completing this portfolio has provided me with meaningful and novel experiences, allowing me to grow as both a researcher and clinician throughout the process.

It has been a privilege for me to have been a part of a research team consisting of experts in the field of sleep research. Not only did this feed my growing interest in sleep research, I have also learnt so much in shaping and improving research methodologies, as well as implementing sleep interventions and interpreting findings of sleep-wake analysis. Moreover, I am grateful to have had the opportunity of working with adults suffering from insomnia disorder. It has been an invaluable experience for me to learn and understand their difficulties with the sleep disorder, and to support them in managing their difficulties. In hindsight, it has truly been inspiring to get to know these individuals and to watch them commit and stay actively involved in improving their sleep. I sincerely hope that my present and potentially future research will be able to compensate for their support towards this thesis portfolio and be meaningful to others who go through similar experiences.

Overall Conclusion

Insomnia is a highly prevalent sleep disorder that has been associated with negative reports of overall health-related quality of life. Over the years, extensive research has been conducted to develop greater understanding regarding the development and maintenance of the disorder as well as to reduce the severity of insomnia disorder among those who experience them. This thesis portfolio investigated the impacts of cognitive-behavioural interventions on sleep quality among adults with insomnia, focusing on the aspects of objective and self-reported sleep, and sleep effort. A systematic review found discrepancies between objective and self-reported sleep parameters and highlighted the concern that current available literature assessing both types of measures remained lacking and without good methodological quality. An empirical study then found preliminary efficacy in administering PI as a brief, single-component cognitive-behavioural intervention, with positive and sustained effects observed mainly on self-reported sleep effort, sleep quality and depressive symptoms. Importantly, these

are promising indications that may improve the current knowledge and clinical practice of cognitive-behavioural sleep interventions for adults with insomnia.

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Appendix A

Author Guidelines for the Journal of Clinical Sleep Medicine



Manuscript Submission Guidelines

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About Journal of Clinical Sleep Medicine

Journal of Clinical Sleep Medicine is the official, peer-reviewed journal of the American Academy of Sleep Medicine. This monthly, online publication features papers with direct applicability and/or relevance to the clinical practice of sleep medicine, including original scientific investigations, reviews, case reports and commentaries.

Since 2005, sleep specialists have turned to JCSM for the information they need to remain proficient in the diagnosis and treatment of the broad spectrum of sleep disorders. Each issue addresses concepts and questions that are of critical importance to the practice of sleep medicine.

It is distributed to nearly 11,000 AASM members and journal subscribers, who have access to all new and archived articles. All articles are available to the public as free to access 12 months after publication.

Increase exposure to your research by publishing in JCSM:

- Accepted papers are available on the JCSM website 7 days after acceptance for viewing by all AASM members and subscribers.
- Abstracts of accepted papers are deposited to PubMed as ahead of print listings upon acceptance.
- The full text of all articles are automatically deposited into PubMed Central and are made freely available on PubMed Central and the JCSM website 12 months after publication.
- Noteworthy manuscripts are promoted to various national and local media via the journal's public relations staff.

Journal stats:

- 2018 Impact Factor: 3.456
- 5-year Impact Factor: 3.951
- Google Scholar h-5 index of 48 and an h-5 median of 59
- Visitors: More than 20,000 monthly, including 62,500 page views.

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Manuscript Submission Instructions

All materials are submitted and edited electronically. To submit a manuscript, please go here: <http://editorialmanager.com/jciinsleepmed>.

The AASM is not responsible in the event that any manuscript, or any part thereof, is lost.

Articles cannot be concurrently submitted or published by any other publication, print or electronic. Accepted manuscripts become the permanent property of the AASM and may not be published elsewhere without written permission from the AASM. All accepted manuscripts and supporting documents are subject to manuscript copyediting for conciseness, clarity, grammar, spelling, and JCSM journal style.

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Submission Fee

Beginning May 1, 2019, JCSM requires a nonrefundable submission fee of \$50. This fee is applicable to the following article types: Original Articles, Review Articles, Emerging Technologies Section, Durable Medical Equipment Section, and Case Reports. (No fee is required for Editorials; Commentaries; Letters to the Editor; Sleep Medicine Pearls; Global Practice of Sleep Medicine section; or REM submissions by medical students, residents and fellows.) The fee is collected during the manuscript submission process and is charged regardless of the final decision reached on your manuscript.

The submission fee is waived if the corresponding author of a manuscript is a current member of the American Academy of Sleep Medicine. When you reach the payment screen during the submission process, request a waiver and include in the comments field the email address used when you log in to your membership account and your telephone number. Optionally, you may also include your membership number.

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Categories of Manuscripts

The following types of manuscripts are accepted:

Original Articles

Original articles are reports of scientific investigations or case series of direct relevance to the clinical practice of sleep medicine. Below are some guidelines:

1. Typically, original articles will contain new data derived from a series of patients or subjects.
2. There are no minimum length requirements for original articles. In general, original articles should not exceed 5,000 words.
3. A structured abstract of no more than 250 words is required.
4. A brief summary is required. This should be no more than 120 words. It includes two parts:
 - a. Current Knowledge/Study Rationale: two sentences summarizing why the study was done
 - b. Study Impact: two sentences summarizing how the study impacts the field.
5. References should be limited to no more than 50 citations.
6. The structured abstract, brief summary, references, tables and figures are not included in the 5,000-word limit.
7. Original articles should include no more than eight tables/figures.
8. The submission of methodology papers, incomplete data sets, partial cohorts or pilot data is discouraged.

Review Articles

Review articles usually bring together important information on a topic of general interest to a clinical sleep medicine practitioner. Authors who have ideas for such articles are advised to contact the Editor-in-Chief at jcsmeditor@aasm.org to ensure that a similar work has not already been submitted. Below are some guidelines:

1. Reviews are not intended to be a forum for the presentation of new data.
2. The main text of the review should not exceed 7,500 words.
3. A structured abstract of no more than 250 words is required.
4. The structured abstract, references, tables and figures are not included in the 7,500-word limit.

Case Reports

Case reports present unique, unusual or important clinical observations of interest to clinical sleep medicine practitioners. Below are some guidelines:

1. Case reports should be organized with the following sections: Introduction, report of case, discussion, references and table/figure.

2. Case reports should be brief.
3. An unstructured abstract of no more than 150 words is required.
4. References should be limited to no more than 10 citations.
5. Tables should be limited to no more than one and figures should be limited to no more than two.

Durable Medical Equipment

The Durable Medical Equipment (DME) section focuses on reviewing rules and regulations for prescribing and managing patients utilizing DME. Its main purpose is to educate clinicians in the terminology and appropriate use of DME. Examples of possible topics include: Overview of Medicare system for DME; DME and Stark Rules; CPT codes for sleep testing; Billing for home sleep apnea testing; RAD LCDs for chest/wall neuromuscular disorders, central apnea/complex; RAD LCDs for hypoventilation/COPD; NPPV for patient's going home after being hospitalized for respiratory failure; Oxygen LCDs; Oxygen use in OSA; DME and mask issues; DME replacement rules for devices; Required documentation in EMR for adherence; Rules if patient does not meet adherence requirements. Below are some guidelines:

1. Manuscripts should be organized with the following sections: Introduction, description of the rules/regulations/policy, a clinical example to demonstrate how the rule works in an individual patient scenario and conclusions. If applicable, regional or insurer-based differences should be pointed out.
2. In general, manuscripts should be 1,500 to 2,000 words in length.
3. References should be limited to no more than 25 citations.
4. The references are not included in the 2,000-word limit.

Emerging Technologies

The Emerging Technologies section focuses on new tools and techniques of potential utility in the diagnosis and management of any and all sleep disorders. As such, the intent is not to be limited to technology applied to sleep-disordered breathing. New technologies for the assessment or treatment of insomnias, parasomnias, and other sleep disorders will be considered for the section. The technologies should be already in existence, at least in prototype form (not a hypothetical idea), but may not yet be marketed. Some preliminary evidence of efficacy should be available. Examples of possible topics include: Smartphone apps for sleep disorders; Consumer-level wearable devices; Applying telemedicine to the care of patients with sleep disorders; Novel uses of mandibular advancement devices: titratable appliances and combined appliance and PAP therapy; Electrical stimulation for treatment of obstructive sleep apnea; Phototherapy for uses other than in patients with circadian rhythm disorders or seasonal affective disorders; Transcranial stimulation devices to treat insomnia (electrical and magnetic); and software and hardware to modify the light spectrum of computer displays to prevent disruption of circadian rhythm. Below are some guidelines:

1. In general, manuscripts should be 1,500 to 2,000 words in length.

2. References should be limited to no more than 25 citations.
3. The references are not included in the 2,000-word limit.
4. Tables and figures are encouraged; the latter in particular might be of great utility in presenting new technologies that involve equipment.
5. If FDA approval (when/if appropriate) has not yet been received, a suitable disclaimer should accompany the article.

Global Practice of Sleep Medicine

The Global Practice of Sleep Medicine section introduces readers to the worldwide scope and practice of sleep medicine. It is hoped that by sharing information about sleep medicine structure and practice in countries around the world, commonalities and barriers are better identified, paving the way for global collaboration. Below are some guidelines:

1. It is recommended that authors include the following headings in their manuscript:
 - a. Introduction: size of the country, country population and demographics (adult and pediatric census data), healthcare system (single payer, employer-based, etc.), physician to patient ratio, use of general practitioners as gatekeepers.
 - b. Sleep Medicine Training: Is a formal sleep fellowship a requirement? The number of training programs and fellowship positions available.
 - c. Practice and Structure of Sleep Medicine: Including but not limited to the following: the number of sleep physicians practicing in the country, the number of sleep labs available (how many sleep labs per 100,000 populations), type of testing available (home sleep apnea testing, in-lab, both), the role of primary care in testing and prescribing treatment for sleep apnea, treatment of insomnia with medication, the use of cognitive behavioral therapy/presence of trained personnel to do this, country specific sleep apnea prevalence (if that data is available), number of specialized centers engaged in sleep research, availability of pediatric sleep, surgical and dental specialists.
 - d. Barriers to the Practice of Sleep Medicine: Discuss any barriers noted to the practice of sleep medicine. Are there any nationwide advocacy groups for sleep medicine? Are there any government-sponsored research or organizational support/initiatives?
 - e. Costs of Sleep Medicine: Is there any data on the costs of practicing sleep medicine or prescribing therapies? Are there certain sections of society that are precluded from obtaining optimal sleep health due to barriers or costs?
 - f. Conclusion
2. Use of original surveys or existing nationwide databases to provide a better picture of the status of sleep medicine in a specific country is encouraged.
3. In general, manuscripts should be 1,500 to 2,000 words in length.
4. References should be limited to no more than 30 citations.

5. The references are not included in the 2,000-word limit.

Sleep Medicine Pearls

Sleep medicine pearls are brief descriptions and discussions of interesting polysomnographic, actigraphic or other laboratory findings, or brief descriptions of a case with significant teaching value. Below are some guidelines:

1. Sleep medicine pearls should include a patient history, the results of any laboratory findings and end with a summary of the treatment strategy.
2. The pearl should conclude with two to three significant teaching points.
3. Sleep medicine pearls should not exceed 500 words in total length.
4. References should be limited to no more than 10 citations.
5. Tables should be limited to no more than one and figures should be limited to no more than three.

Letters to the Editor

Brief letters (maximum of 500 words, including references; no tables or figures) will be considered if they include the notation "for publication." A letter must be signed by all of its authors. Case reports should not be submitted as letters, but rather as formal case reports. Letters commenting on an article published in JCSM must be received within 10 weeks of the article's publication. Letters received after the deadline will not be considered for publication. Accepted letters will be sent to the authors of the original manuscript for reply. Such letters must include the title and author of the manuscript and the month and year of publication. Letters that do not meet these specifications will be returned unreviewed. JCSM will notify authors about the disposition of their letters.

Special Articles

JCSM will consider for publication manuscripts in other areas as special articles. These include medical, political or economic commentary; perspectives on the history of medicine; technical considerations in polysomnography; and sleep medicine practice issues. Authors are advised to contact the Editor-in-Chief at jcsmeditor@aasm.org to discuss their concepts for these manuscripts before submitting.

Solicited Articles

On occasion, the Editor-in-Chief will solicit commentary, pro/con debate, and journal club articles. Should you have a suggestion for these article types, please contact the Editor-in-Chief at jcsmeditor@aasm.org.

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Essential Elements of Manuscript Submissions

Each submitted manuscript must address the following elements:

Clinical Trial Registration

JCSM requires that all clinical trials, regardless of when they were completed, and all partial and secondary analyses of original clinical trials must be registered before submission of a manuscript based on the trial. Trials must have been registered at or before the onset of patient enrollment for any clinical trial that began patient enrollment on or after February 1, 2007. The trial name, URL, and identification number should be included at the end of the manuscript abstract.

The following trial registries are acceptable:

- Australian New Zealand Clinical Trials Registry: <http://anzctr.org.au/>
- Chinese Clinical Trial Register (ChiCTR): <http://www.ChiCTR.org.cn>
- Clinical Trials (service of NIH): <http://www.clinicaltrials.gov>
- Clinical Trials Registry India (CTRI): <http://ctri.nic.in/Clinicaltrials/login.php>
- German Clinical Trials Register (DRKS): <http://www.germanctr.de>
- ISRCTN Register: <http://isrctn.org>
- Nederlands Trial Register (NTR): <http://www.trialregister.nl>
- UMIN Clinical Trials Registry: <http://www.umin.ac.jp/ctr>

Ethics of Investigation

Authors should specify within the manuscript whether ethical standards were used in their research. If results of an experimental investigation in human or animal subjects are reported, the manuscript should describe the approval by an institutional review board on human or animal research and the appropriate informed consent procedures for human subjects. If approval by an institutional review board is not possible, then information must be included indicating that clinical experiments conform to the principles outline by the Declaration of Helsinki.

Privacy and Informed Consent

Authors must omit from their manuscripts, figures, tables and supplemental material any identifying details regarding patients and study participants, including patients' names, initials, Social Security numbers, or hospital numbers. If there is a possibility that a patient may be identified in text, figures, photos or video, authors must obtain written informed consent for use for in publication of print, online, and licensed uses of JCSM, from the patient or parent or guardian and provide copies of the consent forms to JCSM. In such cases where the patient may be identified, authors must indicate that they have obtained informed consent in their manuscript. In addition, all authors are responsible for ensuring that their manuscript, figures, tables and supplemental material comply with

the Health Insurance Portability and Accountability Act (HIPAA) (www.hhs.gov/ocr/hipaa).

Authorship

All authors listed on the manuscript should have participated sufficiently in the work and analysis of data, as well as the writing of the manuscript to be listed as a co-author. All authors should have read and approved the final version. All authors will be required to attest to their involvement and approval of the final version prior to publication of the manuscript. The title page should state that all authors have seen and approved the manuscript.

For guidelines on authorship, please refer to the [Uniform Requirements for Manuscripts Submitted to Biomedical Journals](#), formulated by the International Committee of Medical Journal Editors. More than one corresponding author is permitted for each manuscript, and both authors will appear on the correspondence line on the final article. However, only one can be considered the corresponding author in the manuscript submission system; thus, only the author entered in the system as the corresponding author will receive automated messages, such as editors' decisions and page proofs.

Originality

By submitting a manuscript to the journal, the authors affirm that it is an original manuscript, is unpublished work, and is not under consideration elsewhere.

Authorship and "Umbrella" groups

Many large collaborative studies are organized under a group name that represents all the participants. All articles must have at least one named individual as author. Authors who wish to acknowledge the umbrella group from which the data originated should list the authors of the article, followed by "on behalf of the [GROUP NAME]". The members of the group should be listed individually in the acknowledgments section.

Conflict of Interest

On the manuscript's title page, all authors must disclose any financial interests or connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated—including pertinent commercial or other sources of funding for the individual author(s) or for the associated department(s) or organization(s), personal relationships, or direct academic competition. When considering whether a conflicting interest or connection should be disclosed, please consider the conflict of interest test: Is there any arrangement that would embarrass you or any of your co-authors if it was to emerge after publication and you had not declared it?

If the manuscript is published, conflict of interest information, including if none was declared, will be communicated in a statement in the published paper.

Any changes made to the list of conflicts after the paper is accepted must be submitted in writing, signed by the appropriate authors (that is, the corresponding author and the author for whom the conflict exists), to the JCSM editorial office.

Continuing Medical Education Credit

During the submission process, the corresponding author will be required to indicate whether or not the manuscript should be considered for continuing medical education (CME) credit. Should the manuscript be accepted and selected for CME credit, all authors will be required to submit a separate conflict of interest disclosure document. The corresponding author will be required to submit a learning objective and five multiple choice questions. Instructions will be provided approximately two to three months prior to an article being published.

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In order to reproduce any third-party material (including tables, figures, or images) in an article authors must obtain permission from the copyright holder and be compliant with any requirements the copyright holder may have pertaining to this reuse. When seeking to reproduce any kind of third-party material authors should request the following:

- non-exclusive rights to reproduce the material in the specified article and journal;
- print and electronic rights, preferably for use in any form or medium;
- the right to use the material for the life of the work; and
- world-wide English-language rights.

It is particularly important to clear permission for use in both the print and online versions of the journal. JCSM is not able to accept permissions which carry a time limit because articles are retained permanently in the online journal archive.

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Manuscript Format

All manuscripts must be created in Microsoft Word, double spaced, have one-inch margins (top, bottom, and sides), and include page numbers. Figures should not be included in the manuscript, but should be uploaded separately.

Manuscripts should be structured using the following components:

Title Page

The title page must include the following:

- Title and Subtitle (if applicable)
- Authors (first name, last name, degrees and affiliations)
- Corresponding author's full address and corresponding author's current Email
- Institution where work was performed
- A statement that all authors have seen and approved the manuscript
- Declarations for each author:
 - Financial support (presence or absence)
 - Off-label or investigational use (if applicable)
 - Conflict of interest (presence or absence) defined as any financial interests or connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated--including pertinent commercial or other sources of funding for the individual authors or for the associated departments or organizations, personal relationships, or direct academic competition for each author.
- Declare if the manuscript reports on a clinical trial, and if so, provide the necessary clinical trial registration information: The trial name, URL, and identification number. See [Essential Elements of Manuscript Submissions](#).
- Number of tables
- Number of figures
- Abstract word count (if applicable)
- Brief summary word count (if applicable)
- Manuscript word count

Abstract

Each original or review article must be preceded by a structured abstract. The abstract is limited to 250 words. The components of this format are (start each on a new line): Study Objectives, Methods, Results, Conclusions and Keywords.

Conclusions should not simply restate results, but should address the significance and implications of the findings. Abstracts should include as few abbreviations as possible. Please provide no fewer than three but no more than ten keywords that reflect the

content of your manuscript. For guidance consult the Medical Subject Headings - Annotated Alphabetic List, published each year by the National Library of Medicine.

Brief Summary

Each original manuscript requires a brief summary. The brief summary will appear on the first page of the manuscript just below the abstract. This should be no more than 120 words. It includes two parts:

1. Current Knowledge/Study Rationale: two sentences summarizing why the study was done
2. Study Impact: two sentences summarizing how the study impacts the field.

The brief summary must NOT contain references and should avoid numbers, description of methods and acronyms unless necessary.

Introduction

State the object of research with reference to previous work.

Methods

Describe methods in sufficient detail so that the work can be duplicated, or cite previous descriptions if they are readily available.

Results

Describe results clearly, concisely, and in logical order. When possible give the range, standard deviation, or standard error of the mean, and statistical significance of differences between numerical values.

Discussion

Interpret the results and relate them to previous work in the field. Include a paragraph near the end of the discussion that briefly lists the limitations of the study.

Abbreviations

Please provide on a separate page an alphabetical list of all abbreviations used with their full definition. Within the manuscript, each should be expanded at first mention and listed parenthetically after expansion.

Acknowledgments

The minimum compatible with the requirements of courtesy should be provided.

Reference List

See [Details of Style](#) for references and citation formatting guidelines.

Figure Titles and Captions

Provide a short title for each figure included with the manuscript. This title should be no more than 20 words. Include the figure number in the title (eg, Figure 1—Flow chart of patient care). Provide a caption for each figure included with the manuscript. Give the meaning of all symbols and abbreviations used in the figure in the caption. For further guidelines see [Figure Guidelines](#).

Tables

Include tables at the end of your manuscript. Each table should have a short title and caption. The title should be no more than 20 words. Include the table number in the title (eg, Table 1—Results of first night polysomnogram). For further guidelines, see [Table Guidelines](#).

Supplemental Material

See [Supplemental Material Guidelines](#).

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Details of Style

References and Citation Formatting

JCSM uses the AMA Manual of Style, 10th Edition. A brief summary of the formatting requirements follow, but please reference this source for specific detail.

- Each reference should be cited in the text, tables, or figures in consecutive numerical order by means of superscripted Arabic numerals placed outside periods and commas and inside colons and semicolons.
- When three or more references are cited at one place in the manuscript, a hyphen should be used to join the first and last numbers of a series; commas should be used without spaces to separate other parts of a multiple-reference citation.
- A standard bibliography program such as EndNote or Reference Manager may be used.
- JCSM uses abbreviated journal names in references; for abbreviations of journal names, refer to listings in the Pubmed database. Exclude periods following each abbreviated journal name word. Include a period at the end of the full journal name. See the Journal Article example below.
- Provide all authors' names when fewer than seven; when seven or more, list the first three and add et al.
- Provide journal article titles in sentence case, and provide inclusive page numbers.

Accuracy of reference data is the responsibility of the author. We cannot guarantee that citation/reference software will match all JCSM author guidelines. Failure to initially comply with JCSM's style requirements may result in manuscripts returned to authors for correction and may potentially delay publication.

Sample Citations within the Body of a Paper

- According to our previous work,^{1,3-8,19}
- The patients were studied as follows^{3,4}:

Sample References

Journal article:

1. Rainier S, Thomas D, Tokarz D, et al. Myofibrillogenesis regulator 1 gene mutations cause paroxysmal dystonic choreoathetosis. *Arch Neurol.* 2004;61(7):1025-1029.

Book:

2. Modlin J, Jenkins P. *Decision Analysis in Planning for a Polio Outbreak in the United States*. San Francisco, CA: Pediatric Academic Societies; 2004.

Chapter of a book:

3. Solensky R. Drug allergy: desensitization and treatment of reactions to antibiotics and aspirin. In: Lockly P, ed. *Allergens and Allergen Immunotherapy*. 3rd ed. New York, NY: Marcel Dekker; 2004:585-606.

Website:

Include as many of the following elements that are available. Author(s); Title of the specific item cited (if not given, give the name of the organization responsible for the site); Name of the website; URL (verify that URL is active and working); Published date; Updated date; and Accessed date.

Example:

4. International Society for Infectious Diseases. ProMED-mail website. <http://www.promedmail.org>. Accessed April 29, 2004.

Sleep Medicine Terminology

Follow the terminology usage recommendations in the AASM Style Guide for Sleep Medicine Terminology. Authors should use respiratory event index (REI) instead of using apnea-hypopnea index (AHI) when using home sleep apnea testing (HSAT) to diagnose obstructive sleep apnea (OSA). The abbreviations are acceptable on second use within a document, after the abbreviation has been previously defined.

Drug Names

Use generic names in referring to drugs; trade names may be given in parentheses after the first mention, but the generic name should be used thereafter.

People-Centered Language

The *Journal of Clinical Sleep Medicine* endorses the use of inclusive and “people-centered” language. When reporting clinical research, please be mindful that study participants are not defined by their condition. You should ensure that your word choice is precise, neutral, and respects the autonomy of everyone involved. Words and phrases that impart bias or imply negative connotations on a person or group must be avoided. Below are some commonly used words and phrases that can be improved by being mindful of these principles.

Avoid	Use Instead
OSA patients	patients with OSA
narcoleptics	people with narcolepsy
suffers from	experiences
burden	effect
subjective data	self-reported data
subjects	participants
compliance	adherence

For more guidance, read "[People-Centered Language Recommendations for Sleep Research Communication](#)" by Rebecca E. Fuoco, MPH.

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Figure Guidelines

Submitted figures that do not meet journal guidelines may result in delays to the publication of a manuscript. The AASM reserves the right to modify figures in order to meet journal guidelines. Include the number of figures on the title page of the manuscript submission.

1. Figures must be a useful visualization of data that could not otherwise be accomplished in a few lines of text.
2. The following graphics can be submitted as figures: charts, graphs, illustrations, and photographs.
3. Figures must be numbered consecutively in the order in which they are cited in the manuscript. Figures should be numbered using Arabic numerals (eg, 1, 2, 3). Include the figure number in the figure's filename.
4. Each figure must have a corresponding short title and caption included in the manuscript text.
5. All figures must make economical use of space. Large areas of white space are not acceptable (eg, axes of graphs extending beyond the relevant points needed to display data).
6. The resolution of all figures must be a minimum of 300 dpi.
7. Figures must be submitted in their final size. One-column figures have a maximum width of 3.3 inches and a maximum height of 8 inches. Two-column figures have a maximum width of 7 inches and a maximum height of 8 inches. Lengthy figure captions may require that the height of the figures be reduced.
8. All figures must fall within the maximum height and width values and must be viewable without rotation.
9. Figures must be submitted as .tif, .eps, or .pdf files. Figures embedded as images in a Word document are not acceptable for publication. PowerPoint files are not acceptable for publication. Charts and graphs that are built in a Word document or an Excel spreadsheet can be submitted as a Word .doc file or an Excel .xls file provided that a .pdf version accompany these files.
10. Each figure must be self-contained and comprehensible without referring to the manuscript. This includes the following requirements:
 - a. All symbols used in a figure must be defined for that figure (eg, *, †). If a symbol is used in multiple figures, the definition of the symbol must also be repeated for every figure in which it appears. Symbols may be defined in a key within the figure or in the figure caption.
 - b. All abbreviations used in a figure (including those used in the figure's title and caption) must be defined in the figure caption. This includes abbreviations defined in the manuscript. If the same abbreviation is repeated in multiple figures, the definition of that abbreviation must be repeated for every figure in which it appears. Only the most widely recognized abbreviations are the exception to this rule.
11. Type within figures must be consistent and legible when viewing the figure at its final size. The preferred font is Arial 9 pt. The use of italic and bold styling should

- only be used when meaningful (eg, differentiating between gene and protein names).
12. Charts and graphs must be two-dimensional unless the data require a third dimension.
 13. Illustrations must be professionally drawn. Use color where appropriate. There is no charge for color.
 14. Visual representation of animal subjects through the use of illustrations is preferred to photographs.
 15. Photographs of subjects in which the individual is identifiable require a signed model release.
 16. Authors are responsible for obtaining full permission to publish figures for which they do not hold the copyright. Proof of this permission is required prior to publication. See [Third-Party Copyright](#).
 17. The use of clip art and stock photography is not allowed.

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Table Guidelines

Submitted tables that do not meet journal guidelines may result in delays in publication. The journal reserves the right to modify tables in order to meet journal guidelines. Include the number of tables on the title page of the manuscript submission.

1. Tables must not duplicate data reported in the manuscript text or figures.
2. All tables must be created using the table function in Microsoft Word. Tables created in PowerPoint are not acceptable. Tables submitted as images are not acceptable.
3. Tables must be numbered consecutively in the order in which they are cited in the manuscript.
4. Each table must have a corresponding short title above the table and caption below.
5. Authors are responsible for obtaining full permission to publish tables that have been previously published. Proof of this permission is required prior to publication. See [Third-Party Copyright](#).
6. Tables can be no more than 10 columns wide. Lengthy column headings may require that the number of columns be reduced.
7. Tables can be no more than 45 rows tall. Lengthy captions may require that the number of rows be reduced.
8. Each table should fit on one, letter-sized page in portrait orientation. If necessary, large datasets can be submitted as supplemental material.
9. Each table must be self-contained and comprehensible without referring to the manuscript. This includes the following requirements:
 - a. All symbols used in a table must be defined for that table (eg, *, †). If a symbol is used in multiple tables, the definition of the symbol must also be repeated for every table in which it appears. Symbols should be defined in the table caption.
 - b. All abbreviations used in a table (including those used in the table title and caption) must be defined in the table's caption. This includes abbreviations defined in the manuscript. If the same abbreviation is repeated in multiple tables, the definition of that abbreviation must be repeated for every table in which it appears. Only the most widely recognized abbreviations are the exception to this rule.
10. Footnotes are acceptable in tables. Footnotes should clearly be marked with superscript lowercase letters or symbols in the table. Do not use numbers (Arabic or Roman numeral) to indicate a footnote. All footnotes should be fully expanded in the table caption.

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Supplemental Material Guidelines

Supplemental material can provide additional detail on study methods, or on data that are informative, but not critical to the aims of the study. However, indiscriminate or excessive use of supplemental material can also undermine the concept of a self-contained research paper by providing a place for critical material to get lost. It is the author's responsibility to make sure that the main manuscript can be read and understood without reference to supplemental materials. Information that is essential to understanding the article must NOT be provided as supplemental material. While discouraging indiscriminate use of supplemental materials, some forms of data (videos and large datasets, explanations of data sources, details of computational algorithms) may be appropriately presented as supplemental material. All supplemental material must be succinct, organized carefully, and labeled appropriately.

Reviewers are instructed to review supplemental materials of reasonable length (eg, typical figures and tables) at the same level as the content of the main manuscript. Reviewers cannot reasonably be expected to review large supplemental data formats (eg, large databases). Reviewers are also asked to comment on the appropriateness of supplemental materials, including if they contain essential information that belongs in the main article and if they sufficiently enhance the presentation of the main article to justify inclusion. Readers are expected to communicate directly with the corresponding author about supplemental material, not with the Editor-in-Chief. No comments or critiques of supplemental material will be considered for publication in JCSM.

General Formatting Guidelines for Supplemental Material

Supplemental materials are not copyedited or formatted by JCSM, and therefore authors must ensure that all files are checked carefully before submission and that the style of figures and tables conforms to the recommendations spelled out in the manuscript submission guidelines for figures and tables. Refer to each piece of supplemental information within the text of the main manuscript using the file name and the term "supplemental material," (eg, see Video 1 in the supplemental material).

Supplemental Figure and Table Guidelines

A maximum of four supplemental figures of no more than 5 MB in total are permitted per manuscript. Figures and tables should be numbered sequentially using the prefix "S" to differentiate them from figures and tables presented in the main manuscript (eg, see Figure S1 and Table S3 in the supplemental material).

Video Guidelines

Videos should be provided in .mp4 format. Videos submitted in alternate formats will be converted. File names should be as short as possible (eg, Video 1). Please provide a separate Microsoft Word file containing a description of the videos. Please keep the description as short as possible and ensure that the description is necessary for the

comprehension of the videos. Releases signed by persons who appear in any video must be provided with the submission of videos. JCSM will not publish any video where persons can be identified without suitable permission forms on file.

Dataset Guidelines

Large datasets should only be submitted when necessary to support a manuscript's conclusions, when solicited by JCSM's Editors/Reviewers, or if the authors feel that the publication of the dataset is critical to advancing research in the field. These should be submitted as an Excel spreadsheet, which will be made available for download. The dataset will not be copyedited or formatted in any way by JCSM. It is the author's responsibility to carefully check and correct any errors in the content or formatting of the dataset. Authors have the option of providing a link to large data sets and hosting them on their own website.

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Review Process

The Editor-in-Chief and/or an Associate Editor first determines if a submitted manuscript is suitable for review and publication. Manuscripts are then sent for peer review to reviewers who are selected based on their expertise related to the particular manuscript. After reviews are submitted, a recommendation of accept, reject or revise (for further consideration) is made by the Associate Editor to the Editor-in-Chief, who makes the final decision.

Manuscripts are reviewed with due respect for the author's confidentiality. At the same time, reviewers also have rights to confidentiality, which are respected by the editors. The editors ensure both the authors and the reviewers that the manuscripts sent for review are privileged communications and are the private property of the author.

When submitting a manuscript for consideration for publication, authors may suggest the names of potential reviewers to invite and/or exclude.

Resubmissions

If a manuscript is returned to the author(s) for revisions, all resubmissions must follow the instructions for submitting a manuscript and include the following:

- Both a clean copy and a redlined copy of the revised submission. NOTE: If the redlined copy was created using "track changes" mode in Word, please create a PDF file of the redlined version and upload the PDF file. If you are not able to create a PDF file of your redlined version, please use alternative font colors or highlighting tools in Word to show the redlined changes – not "track changes" mode.
- The corresponding author must also upload a letter (Corresponding Author's Rebuttal) responding to each of the points made by the reviewers.

The deadline for submission of a revised manuscript needing major revisions is two months from the date of the notice. For minor revisions, the deadline for resubmission is one month. There is no guarantee that a revised manuscript will be accepted for publication.

Plagiarism Review

The editorial office carefully monitors papers submitted to JCSM for plagiarism. All accepted manuscripts will be compared to published papers using similarity checking software. Plagiarism includes literal copying - reproducing a work word for word, in whole or in part, without permission and acknowledgment of the original source; paraphrasing - reproducing someone else's ideas while not copying word for word, without permission and acknowledgment of the original source; substantial copying - copying images, or data from other sources; text-recycling - reusing substantial amounts of text from your own previous publications.

Any text contained in a manuscript that is directly copied from another source must be placed within quotation marks and the original source must be properly cited. If a paper captures the essence of a previously published work, that work should be cited. If any paraphrasing is included, the source must be properly referenced and the meaning intended by the source must not be changed. All works that may have inspired a study's design or manuscript structure must be properly cited.

If plagiarism is detected during any part of the peer-review process, the manuscript may be rejected. For published papers where plagiarism is detected, the journal reserves the right to issue a correction or retract the paper, whichever is deemed appropriate. The journal reserves the right to inform authors' institutions about plagiarism detected either before or after publication.

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After Acceptance

Author Agreement Letter – Required Upon Acceptance

Upon acceptance, all authors of an accepted manuscript will receive an email informing them that their paper has been provisionally accepted and will be accepted upon the receipt of an “Author Agreement Form” from all authors within seven business days. The Author Agreement Form requires authors to assign copyright to the American Academy of Sleep Medicine, declare their involvement in the development of the manuscript and attest to their review and approval of the final manuscript. The corresponding author will be responsible for disseminating this form to all authors, collecting the completed forms and uploading the forms into the manuscript submission system. Should ALL forms not be returned within the specified time frame, the manuscript will be automatically rejected.

Copyediting and Proofreading

All accepted manuscripts are subject to manuscript editing for conciseness, clarity, grammar, spelling and JCSM style. After acceptance all manuscripts will be copyedited and page proofs will be developed. The page proofs will be sent to the corresponding author for review and approval. These proofs will be expected to return their corrections or approval of these proofs within the timeframe given in the correspondence. It is the authors' responsibility to keep their account in Editorial Manager current and to notify the JCSM Editorial Office (publications@aasm.org) of any changes in contact information after a paper has been accepted.

Accepted Papers Repository

In order to provide readers with access to accepted papers as early as possible, all manuscripts accepted will be available online prior to being published in an issue. Accepted manuscripts are posted as received - without editing or formatting by the publisher. The layout and appearance of each article will change when published in an issue of JCSM.

All papers appearing in JCSM, including online Accepted Papers, are copyrighted by the American Academy of Sleep Medicine. No paper in whole or in part may be used in any form without written permission from the American Academy of Sleep Medicine. When an article appears in an issue, it is removed from the Accepted Papers page.

Ahead of Print Abstracts

All accepted papers will be posted to the PubMed website as ahead of print (AOP). The AOP listings include only the manuscript's abstract and are citable. These listings will update after the manuscript is published in an issue of JCSM.

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REM: A Publication for Residents and Fellows

About

REM is the resident and fellow section of the *Journal of Clinical Sleep Medicine*. Its mission is to provide relevant, high-quality, peer-reviewed articles to medical students, residents and fellows in the sleep medicine pipeline. Where possible, every step in the manuscript submission and review processes for this section are completed by medical students, residents, fellows and those who have recently completed their fellowship.

General

Ideally submissions to REM are from current medical students, residents, fellows and those who have recently completed their fellowship. Faculty can be listed as coauthors for manuscripts submitted for the REM section. Manuscripts must follow JCSM's guidelines for [Manuscript Submission Instructions](#), [Essential Elements of Manuscript Submissions](#), [Details of Style](#), [Figure Guidelines](#), [Table Guidelines](#) as well the specifics below for each article type. To submit a manuscript, go to [JCSM's Editorial Manager website](#), and choose "REM: Resident Fellow" as the article type. Add the specific article type to your manuscript's title, followed by a colon. Example: "Media Review: The Role of Sleep in Colson Whitehead's *The Underground Railroad*."

Review Process

Manuscripts are first evaluated for essential elements by JCSM staff. Acceptable manuscripts are assigned to Resident/Fellow Editors who oversee the peer review process. Reviewers are selected from a pool of Resident/Fellow Reviewers. Following peer review, the Resident/Fellow Editor submits a recommendation to one of the JCSM Associate Editors that supervise this section. The JCSM Associate Editor then recommends a decision to the Editor-in-Chief of JCSM, and the Editor-in-Chief of JCSM makes the final decision.

Publication

If selected for publication, articles in the REM section will be published within an issue of JCSM. This means the article will be assigned a DOI and will be submitted to PubMed/PubMed Central for indexing.

Article Types

The following article types will be considered for REM.

Board Review

Board review articles highlight a topic relevant to the sleep medicine board examination. Board reviews must include a challenging multiple choice question and answer that highlight a topic likely to be on sleep medicine board examination. If necessary, a brief case report or description of a clinical scenario may precede the multiple choice

question. Following the correct answer, a discussion section that explains why the correct answer is correct and the other answers are incorrect is required. The discussion should also highlight what is important to remember about the topic.

Specifications:

- Multiple choice question, answer, and discussion section are required
- A brief case report or description of a clinical scenario is optional
- Maximum of 1250 words (not including the multiple choice question, figure legends, table legends, and references)
- No more than 15 references (less than 5 years old)
- Maximum of 3 tables and/or figures

Perspective

Perspective articles are editorials that express the author's opinion about a topic related to the current practice and science of sleep medicine. For REM, opinions directly related to the medical student, resident, and fellow experience are encouraged.

Specifications:

- Maximum of 1000 words (not including table legends, figure legends, and references)
- No more than 20 references
- Only one table and/or figure is permitted

Shift Work

Shift work articles are personal perspectives from medical students, residents and fellows working long or irregular hours. It is recommended that these articles begin with a relevant story or example and then discuss how the author's personal perspective fits with current understanding of shift work, fatigue and well-being.

Specifications:

- Maximum of 1000 words (not including table legends, figure legends, and references)
- No more than 15 references
- Maximum of 3 tables and/or figures

Media Review

Sleep disorders, normal sleep phenomena, habits related to sleep, and the impact of sleep on health have all been subjects of multiple media pieces and deserve attention from the sleep medicine community. We invite medical students, residents and fellows to review movies, books, music, television, and podcasts that reference sleep themes.

Reviews should focus on the accuracy and relevance of the sleep information presented in the media. The content should be organized as a description of the media piece: the name and author(s), format (movie, book, music, etc), and where featured or available. This should be followed by an unstructured text discussion of how the sleep topic was depicted, the accuracy of this information and the relevance and potential impact of media piece.

Specifications:

- Maximum of 500 words
- No more than 10 references
- Maximum of 2 figures and/or 1 table

Images

Diagnostic testing provides relevant ancillary information to the physician caring for the sleep disorders patient. Medical students, residents and fellows with a video or image that highlights an important teaching point that is best depicted visually may submit this material along with a description of the case. In addition to content from the sleep laboratory, radiological or physical exam images are welcome. In most cases, it is preferred that all information that may lead to the identification of a patient be removed or obscured. In instances where this is not possible, and a patient is identifiable from the image or video used, a signed release form is required from the patient or guardian.

The article should be organized as follows: introduction, report of the case, associated video(s) or image(s), and discussion.

Specifications:

- Maximum of 750 words
- No more than 10 references
- Minimum of 1 image or 1 video required
- Maximum of 3 images and/or 2 videos

To the Editor

Brief letters precipitated by articles published in REM or brief commentaries on a timely topic that are relevant to medical students, residents and fellows will be considered for publication. The letter should address the editors and cite the article or state the topic they are addressing in the first sentence. The letter should otherwise be unstructured.

Specifications:

- Maximum of 500 words
- No more than 10 references
- Maximum of 1 figure and/or 1 table

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Last updated 1/14/20

Appendix B

Ethical Approval Letter for the Empirical Research Paper

Faculty of Medicine and Health Sciences Research Ethics Committee



Glenneze Ong
Norwich Medical School
University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

NORWICH MEDICAL SCHOOL
Bob Champion Research & Educational
Building
Rosalind Franklin Road
University of East Anglia
Norwich Research Park
Norwich NR4 7UQ
Email: fmh.ethics@uea.ac.uk
www.med.uea.ac.uk

17th February 2021

Dear Glenneze

Title: Feasibility of Paradoxical Intention Therapy among adults with insomnia and high sleep effort

Reference: 2020/21-062

Thank you for your email of 5th February 2021 notifying us of the amendments you would like to make to your above proposal. These have been considered and I can confirm that your amendments have been approved.

Please can you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance, and that any adverse events which occur during your project are reported to the Committee.

Approval by the FMH Research Ethics Committee should not be taken as evidence that your study is compliant with GDPR and the Data Protection Act 2018. If you need guidance on how to make your study GDPR compliant, please contact your institution's Data Protection Officer.

Please can you arrange to send us a report once your project is completed.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Jackie Buck', is written over a light blue horizontal line.

Dr Jackie Buck
Chair
FMH Research Ethics Committee

COVID-19: The FMH Research Ethics Committee procedures remain as normal. Please note that our decisions as to the ethics of your application take no account of changes in Government measures and UEA guidelines relating to the coronavirus pandemic and all approvals granted are, of course, subject to these.

Appendix C

Participant Information Sheet



Participant Information Sheet

Feasibility of Paradoxical Intention Therapy among Adults with Insomnia and High Sleep Effort

Why have I been sent this document?

You have received this document as you have either expressed an interest in taking part in our study in response to one of our advertisements, or we have contacted you because you have registered an interest in taking part in future research studies.

What is the purpose of the study?

The primary objective of this study is to explore the feasibility of Paradoxical Intention Therapy (PI) among adults with insomnia disorder and high sleep effort. Insomnia is a highly prevalent sleep disorder that affects at least a third of a population. One reason why insomnia may persist is due to an individual having high sleep effort, whereby one actively tries to control their sleep. Consistently having poor sleep can negatively impact various aspects of life, particularly one's mental health. As PI is an intervention that targets sleep effort, we want to find out whether it is feasible to use PI as an intervention for adults with insomnia and high sleep effort. There will be two phases to this study: screening phase and intervention phase. The screening phase will be used to identify adults with insomnia and high sleep effort, whereas a 2-week intervention to improve your sleep will be introduced in the intervention phase.

Do I have to take part?

No, your participation is voluntary. If you do agree to take part, you can withdraw at any time and without giving any reason. Please be assured that no penalty will be imposed should you decide not to take part or to withdraw from the study.

If you decide to withdraw from the online survey, you can stop taking part at any point by simply closing the internet browser tab or window. For those who participated in the intervention phase, if you wish to withdraw your participation, you can let the researcher know verbally that you do not wish to continue the intervention. However, if you decide to withdraw from the study at any point, any anonymised data already obtained from you up to the point of your withdrawal will be retained and used in the research.

What will I be required to do if I want to take part?

You will first need to provide your written consent which can be electronically signed. The consent form has been attached along with this information sheet.

Once you have provided consent, you will receive a personal reference code and a link to an online survey containing screening questionnaires that will collect your demographic information and assess your sleep quality and mental health. Each one takes approximately 1-10 minutes and it shouldn't take you longer than 20 minutes to complete all of them. However, this will also depend on your reading speed. Do note that you will not be timed for filling in the online questionnaires.

If you do not meet the inclusion criteria for the intervention phase, you will be contacted and informed. If you meet the inclusion criteria, you will be invited to take part in the intervention phase where you will need to commit to two weeks of using the sleep intervention and to monitor your sleep experiences using a sleep diary and actiwatch that will be posted directly to you. You will be randomly allocated to either receive PI or sleep hygiene instructions. Participants in the PI group will learn to understand the process and instructions used in PI whereas participants in the sleep hygiene instructions group will receive behavioural and environmental recommendations to improve sleep. You will also be asked to fill in a similar series of online questionnaires as you did in the screening phase before and after the intervention period, as well as one month after the end of the intervention. The research study will fully be completed online.

Are there any risks in taking part?

There are no foreseen risks associated with this study. If you have any concerns about risks, please contact the study team for more information.

Who are we initially looking for?

We are looking for adults aged above 18 years who meet the criteria for insomnia and report high sleep effort during night-time sleep. This study is open to both staff and students at the University of East Anglia who have capacity to consent to the study prior to taking part.

You will unfortunately not be able to take part in the intervention phase of the study if you:

- Have common sleep disorders other than insomnia (e.g. sleep-related breathing disorders)
- Have sensorial impairment (e.g. deafness, blindness)
- Use medication for sleep or other chronic conditions that may affect your sleep
- Are currently receiving ongoing psychological interventions

If I decide to take part in the study, what will happen to the data I provide?

All information collected during the study will be anonymised, indexed by personal references codes and stored according to the General Data Protection Regulation (GDPR). If you consent to this study, your anonymised data might also be used in other ethically approved studies being conducted in collaboration with this study.

If you consent to this study, you give permission for the principal investigator to contact you in future to follow up with you the outcomes of the screening and/or intervention phase. Your personal identifiers and allocated personal reference codes will be stored in a separate document and retained until the completion of this study. Any information discussed during the intervention phase will be kept confidential, with mutual agreement from you and the principal investigator that no audio/visual recordings are to be made. All hardcopy and electronic files collected will be stored securely in a locked cabinet and in a highly secured password-protected database respectively. All data will only be accessible to the study team, as authorised by the principal investigator. In accordance with good research practice, all data will be kept for up to 10 years following the completion of the study. Your data might be disseminated anonymously and collectively as part of a journal publication describing the results of this study.

Only in circumstances where there is an immediate threat of harm to the participant, others or other safeguarding issues, the study team will be required to break confidentiality and inform the relevant emergency services as appropriate.

Your anonymised data may also be shared with researchers from the School of Health Sciences at UEA who are conducting relevant research studies. These data will be stored securely in a password-protected shared drive and managed by the primary research supervisor of this study, Dr Alpar Lazar.

Who has reviewed this study?

This study has been reviewed and granted ethical approval by the UEA Faculty of Medicine and Health Sciences Research Ethics Committee.

Who do I contact if I have any questions or concerns about this study?

If you have any further questions or concerns about this study, please contact the principal investigator, Gleneze Ong (S.Ong@uea.ac.uk). You may also contact the research supervisors, Dr Alpar Lazar (A.Lazar@uea.ac.uk) or Professor Niall Broomfield (N.Broomfield@uea.ac.uk). If you would like to contact an independent person who is not directly involved in this study, please contact Associate Professor Joanne Hodgekins (Senior Research Tutor responsible for research projects on the Doctoral Programme in Clinical Psychology) at J.Hodgekins@uea.ac.uk.

Thank you for your interest in this study.

Appendix D

Consent Form



Consent Form

Study title: Feasibility of Paradoxical Intention Therapy among Adults with Insomnia and High Sleep Effort

Principal Investigator: Glenneze Ong

Research supervisors: Dr Alpar Lazar (HSC) and Professor Niall Broomfield (MED)

Please read the following statements carefully and only initial the boxes if you have understood and agree to the corresponding statements. Please ask the study team if you are unsure about the following statements.

	Please initial as appropriate
I confirm that I have read, understood and accept the conditions contained in the participant information sheet for this study.	
I have had the opportunity to ask questions and that any questions have been answered to my satisfaction.	
I understand that my participation is voluntary and I can withdraw from the study at any time without resulting in any penalty.	
I understand that all anonymised data already obtained about me up to my withdrawal will be retained and used in the research.	
I agree to comply with the instructions given to me during the research study to provide accurate information to the best of my knowledge.	
I understand that all information collected as part of the study will be kept confidential and that data will only be accessible to the study team.	
I give permission for other ethically approved studies being conducted in collaboration with this study which I have consented to participate in to access and share my anonymous results across studies.	
I agree for the study team to contact me in the future in respect of other research opportunities or follow up to this study and securely store my contact details for that purpose.	
I confirm that I would like to take part in this study.	

Signed declaration:

Name of participant:	Researcher name:
Participant signature:	Researcher signature:
Date:	Date:

Appendix E

Crisis Contact List

Crisis Contact List

If you are in crisis and need support urgently, the following numbers are available 24 hours a day, seven days a week, 365 days a year:

Samaritans

Samaritans offers a safe place for you to talk about your difficulties at any time you like. Calls made to Samaritans are free, confidential and non-judgmental.

Contact number: 116 123

NHS

Calls can be made to receive urgent medical help or advice.

Contact number (for non-life-threatening situations): 111

Contact number (for immediate, life-threatening situations): 999

Other helpful contacts:

UEA Student Support Services

The Wellbeing team in Student Services offer one-to-one support, workshops and group session, talking therapies and online resources and self-help materials for students require support.

Contact number: 01603 592651

Email: studentwellbeing@uea.ac.uk

Your General Practitioner (GP) (contact details vary)

Your GP will be able to offer support and advice on possible treatment options for any mental health difficulties. It can be helpful to take someone with you if you are not used to talking to them.

Mind

Mind provides a wide range of mental health support such as talking therapies, support programmes, and advice to individuals with mental health difficulties.

Contact number: 0300 330 5488

Email: enquiries@norfolkandwaveneymind.org.uk

NHS Wellbeing services

The Wellbeing service offers talking therapies for self-referring individuals experiencing low mood, stress or anxiety.

Contact number (Norfolk): 0300 123 1503

Self-referral website: www.wellbeingnands.co.uk

Email: admin@wellbeingnandw.co.uk

Appendix F

Instruction Sheet for Actigraphy and Sleep Diary Use (PI group)

Instructions for sleep diary and actiwatch use

You have received this pack consisting of a sleep diary and an actiwatch because you volunteered to take part in the research study entitled 'Feasibility of Paradoxical Intention among Adults with Insomnia and High Sleep Effort'.

Please complete the sleep diary and wear the actiwatch for five consecutive nights at baseline and post-intervention. The five nights for baseline will begin on _____ up until the first session; the five nights for post-intervention will begin on _____ which is the day after the second session. At the end of the baseline five days/nights, you will need to return the actiwatch and sleep diary. You will receive a new set of actiwatch and sleep diary in time for post-intervention five days/nights. We can arrange the logistics of returning the actiwatch and sleep diary as this could be by prepaid tracked special delivery (if you live outside of Norwich) and in person (if you live in or near Norwich).

Please follow the instructions below to use the sleep diary and actiwatch.

- **Consensus Sleep Diary (CSD)** – Adapted from “The Consensus Sleep Diary: Standardizing Prospective Sleep Self-Monitoring,” by C. E. Carney et al., 2012, *Sleep*, 35(2), 287-302.)

This sleep diary worksheet is to help us gather information about your daily sleep pattern. It is necessary for you to complete your sleep diary every day for the duration of five consecutive nights. If possible, you should complete the sleep diary within one hour of getting out of bed in the morning. If you forget to fill in the diary or are unable to finish it, please leave it blank for that day rather than trying to complete it from memory at a later time when you are not sure about the details. Please answer the questions to your best estimate.

1. *What time did you get into bed?*
Record the time that you got into bed. This may not be the time that you were ready to fall asleep.
2. *What time did you try to go to sleep?*
Record the time that you were ready to fall asleep.
3. *How long did it take you to fall asleep?*
Beginning at the time you wrote in question 2, record how long it took for you to fall asleep.
4. *How many times did you wake up, not counting your final awakening?*
Record the number of times you woke up between the time you first fell asleep and your final awakening.
5. *In total, how long did these awakenings last?*
Record the total time you were awake between the time you first fell asleep and your final awakening. For example, if you woke up 3 times for 20 minutes, 35 minutes, and 15 minutes, add them all up ($20+35+15=70$ minutes or 1 hour 10 minutes).

6. *What time was your final awakening?*
Record the last time you woke up in the morning. This may not be the time that you were ready to get out of bed.
7. *What time did you get out of bed for the day?*
Record the time you got out of bed with no further attempt at sleeping. This may be different from your final awakening time. For example, you may have woken up at 6.35am but did not get out of bed to start your day until 7.20am.
8. *How would you rate the quality of your sleep?*
'Sleep quality' is your sense of whether your sleep was good or poor.
9. *Comments.*
If you have anything that you would like to say that is relevant to your sleep, feel free to write it in this column.

- **Actiwatch**

1. *Wearing the watch*
You should wear the actiwatch continuously (day and night) on your non-dominant wrist during the five nights. You can take it off occasionally for a short time but please do not forget to put it back on afterwards. The actiwatch is waterproof.

The actiwatch should be fastened as you would a normal wristwatch. You can adjust the strap to ensure this is comfortable on your wrist.
2. *Precautions*
Actiwatchers are not designed to be worn on irritated or damaged skin. In the event that you experience any discomfort or irritation, please try to wear the watch on your other wrist. Ideally, the actiwatch should stay on your non-dominant wrist. Nevertheless, if you do need to change the wrist on which you wear the actiwatch, please make a note in your sleep diary. If you continue to experience discomfort, please notify the study team.

As with similar devices you should also ensure the actiwatch is kept out of reach of children as it contains a coin cell battery that can be a potential swallowing hazard if the casing were to be opened. Please do not open the actiwatch whilst it is in your possession.

If you have any questions or concerns, please get in touch with me (Glennze Ong) at S.Ong@uea.ac.uk. Thank you.

Appendix G

Instruction Sheet for Actigraphy and Sleep Diary Use (control group)

Instructions for sleep diary and actiwatch use

You have received this pack consisting of a sleep diary and an actiwatch because you volunteered to take part in the research study to test the feasibility of a sleep intervention.

Please complete the sleep diary and wear the actiwatch for five consecutive nights at baseline and post-intervention. The five nights for baseline will begin on _____ up until we meet for our session; the five nights for post-intervention will begin on _____ which is one week after our session. Once you complete the first five nights, we will arrange for you to return the set of actiwatch and sleep diary. You will receive a new set of actiwatch and sleep diary in time for the post-intervention five nights.

At the end of the baseline five days/nights, you will need to return the actiwatch and sleep diary. You will receive a new set of actiwatch and sleep diary in time for post-intervention five days/nights. We can arrange the logistics of returning the actiwatch and sleep diary as this could be by prepaid tracked special delivery (if you live outside of Norwich) and in person (if you live in or near Norwich).

Please follow the instructions below to use the sleep diary and actiwatch.

- **Consensus Sleep Diary (CSD)** – Adapted from “The Consensus Sleep Diary: Standardizing Prospective Sleep Self-Monitoring,” by C. E. Carney et al., 2012, *Sleep*, 35(2), 287-302.)

This sleep diary worksheet is to help us gather information about your daily sleep pattern. It is necessary for you to complete your sleep diary every day for the duration of five consecutive nights. If possible, you should complete the sleep diary within one hour of getting out of bed in the morning. If you forget to fill in the diary or are unable to finish it, please leave it blank for that day rather than trying to complete it from memory at a later time when you are not sure about the details. Please answer the questions to your best estimate.

1. *What time did you get into bed?*
Record the time that you got into bed. This may not be the time that you were ready to fall asleep.
2. *What time did you try to go to sleep?*
Record the time that you were ready to fall asleep.
3. *How long did it take you to fall asleep?*
Beginning at the time you wrote in question 2, record how long it took for you to fall asleep.
4. *How many times did you wake up, not counting your final awakening?*
Record the number of times you woke up between the time you first fell asleep and your final awakening.
5. *In total, how long did these awakenings last?*
Record the total time you were awake between the time you first fell asleep and your final awakening. For example, if you woke up 3 times for 20 minutes, 35

minutes, and 15 minutes, add them all up (20+35+15=70 minutes or 1 hour 10 minutes).

6. *What time was your final awakening?*
Record the last time you woke up in the morning. This may not be the time that you were ready to get out of bed.
7. *What time did you get out of bed for the day?*
Record the time you got out of bed with no further attempt at sleeping. This may be different from your final awakening time. For example, you may have woken up at 6.35am but did not get out of bed to start your day until 7.20am.
8. *How would you rate the quality of your sleep?*
'Sleep quality' is your sense of whether your sleep was good or poor.
9. *Comments.*
If you have anything that you would like to say that is relevant to your sleep, feel free to write it in this column.

- **Actiwatch**

1. *Wearing the watch*
You should wear the actiwatch continuously (day and night) on your non-dominant wrist during the five nights. You can take it off occasionally for a short time but please do not forget to put it back on afterwards. The actiwatch is waterproof.

The actiwatch should be fastened as you would a normal wristwatch. You can adjust the strap to ensure this is comfortable on your wrist.

Please press the event marker (button on the face of the actiwatch) when you go to sleep at night and again when you wake up in the morning. This is to help accurately record your time at 'lights out' and again at your 'final awakening'.
2. *Precautions*
Actiwatches are not designed to be worn on irritated or damaged skin. In the event that you experience any discomfort or irritation, please try to wear the watch on your other wrist. Ideally, the actiwatch should stay on your non-dominant wrist. Nevertheless, if you do need to change the wrist on which you wear the actiwatch, please make a note in your sleep diary. If you continue to experience discomfort, please notify the study team.

As with similar devices you should also ensure the actiwatch is kept out of reach of children as it contains a coin cell battery that can be a potential swallowing hazard if the casing were to be opened. Please do not open the actiwatch whilst it is in your possession.

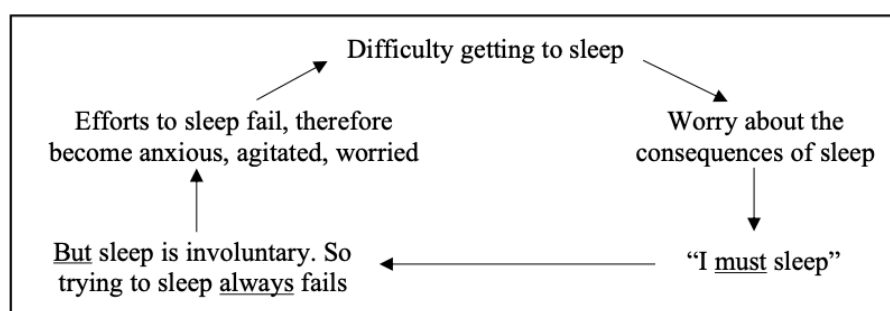
If you have any questions or concerns, please get in touch with me (Glennze Ong) at S.Ong@uea.ac.uk. Thank you.

Appendix H

Instruction Sheet for Paradoxical Intention Therapy

Instructions for Paradoxical Intention

Sleep is a natural process which happens involuntarily. This means that you cannot make yourself fall asleep, rather, sleep must occur naturally. And if you try to switch sleep on, you could switch it off. People who actively try to control their sleep often find it difficult to fall asleep because their aroused state of mind disrupts the natural sleep process. Not being able to sleep, people may start feeling worried about losing sleep, which in turn urges them to try even harder to fall asleep. This can put them in a cycle of struggling to sleep and eventually worsen their sleep problem.



The more you try to control your sleep, the less likely you are able to fall asleep. By giving up trying to sleep, your sleep pattern should improve. This is what we would like you to do in this study.

For the next 14 nights, test giving up trying to sleep when you go to bed at night. Instead, we want you to try staying awake. Paradoxically, staying awake should help you get to sleep more quickly because it stops you from trying hard to fall asleep and worrying about losing sleep. Here's how you can try to stay awake:

1. As you go to bed tonight, lie down comfortably in your bed with the lights off, but keep your eyes open.
2. Give up any effort to fall asleep and any concerns about still being awake.
3. When your eyelids feel like they want to close, say to yourself gently "***Just stay awake for another couple of minutes, I'll fall asleep naturally when I'm ready.***"
4. If at any stage you feel worried or irritable at not sleeping, remind yourself "***Staying awake will help me get to sleep quicker***" and "***The plan is to remain awake so I'm doing fine.***"
5. Try to stay awake for as long as you can.
6. Do not purposefully make yourself stay awake, but if you can shift the focus off attempting to fall asleep, you will find that sleep comes naturally.

The above instructions may take time to have an effect on your sleep. Continue to have patience and perseverance as you follow the instructions to stay awake for the next 14 nights.

Good luck!

Appendix I

Instruction Sheet for Sleep Hygiene Recommendations

Sleep Hygiene Instructions

“Sleep hygiene” refers to healthy sleep habits. Having good sleep hygiene helps you to fall asleep at night and improve your sleep quality. Here’s how you can develop good sleep hygiene:

1. Avoid caffeine.
 - Caffeinated beverages and food (e.g. coffee, tea, soft drinks, chocolate) can cause difficulty falling asleep, night awakenings and poor sleep. Try to cut down on all caffeine products as even caffeine in the day can disrupt night-time sleep.
2. Avoid nicotine.
 - Nicotine is a stimulant which can disrupt sleep. Try to avoid smoking, especially during the night, if you have trouble with your night-time sleep.
3. Avoid alcohol.
 - Try to refrain from drinking alcohol, especially during the night. Although alcohol can help people fall asleep more easily, it increases arousal during the second half of the night which induces overnight awakenings.
4. Exercise regularly.
 - Exercises makes it easier to initiate sleep and deepen sleep. However, schedule exercise times so that they do not occur within 2 hours of going to bed which may make it more difficult to fall asleep.
5. Manage stress.
 - Worrying can keep you up at night, which makes it difficult for you to fall asleep and achieve deep sleep. Avoid taking your worries to bed. You may find it useful to assign a “worry time” earlier in the evening to address any problems or create a “worry diary” to write down your problems.
6. Have a comfortable sleeping environment.
 - A comfortable, noise-free sleep environment will reduce the likelihood that you will wake up during the nights. Although it is possible to get used to background noises, it may disturb the quality of your sleep.
7. Maintain a regular sleep timing.
 - Only sleep as much as you need to feel refreshed the next day. Excessively long periods in bed can result in fragmented sleep.
 - Have a regular wake time in the morning, no matter how little you slept the night before, seven days a week. This helps you have a regular sleep timing at night.
8. Avoid daytime naps.
 - Sleeping a lot during the day will affect your ability to fall asleep at night. If you do need a nap, try to limit it to 15 minutes. This should prevent you from going into deep sleep which would usually make it more difficult for you to wake up.

For the next 14 nights, try incorporating these healthy sleep habits to improve your sleep. It may be difficult to do all changes immediately and at the same time. They may also take time to have an effect on your sleep. Continue to have patience and perseverance as you follow the instructions (as relevant to you).

Good luck!