The Effect of Cognitive Behavioural Interventions on Sleep Effort

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Thesis Portfolio Abstract

Insomnia is a common sleep disorder distinguished by difficulty with initiating or maintaining sleep. Insomnia both distressing for the individual and costly at a societal level. There are a number of cognitive and behavioural models and interventions developed to treat insomnia. These models propose a variety of mechanisms. Of these, sleep effort (consciously engaging in behaviours that are intended to initiate sleep onset) is emerging as an important maintenance factor. This thesis portfolio aims to explore how sleep effort is affected by cognitive-behavioural treatment. First, a systematic review and meta-analysis is described in which randomised control trials that measure the effect of cognitive-behavioural interventions on sleep effort are identified and relevant data is synthesised to determine the overall effect of these interventions on sleep effort. Second, an empirical research project is reported where an intervention specifically designed to target sleep effort is implemented (paradoxical intention therapy) to examine its effect on both sleep effort and sleep characteristics. A novel aspect of this study is that it utilises an EEG headband to measure objective sleep characteristics. In the systematic review, six relevant studies were identified. The meta-analysis yielded a significant effect of cognitive-behavioural interventions on sleep effort with a medium effect size. In the empirical paper, the intervention was found to have a significant effect on sleep effort, global insomnia symptoms (self-report questionnaire derived) and sleep diary reported sleep onset latency. However, no significant effects were found for any of the other sleep characteristics including all objective sleep parameters. This thesis concludes by noting the significant effect that cognitive-behavioural interventions have overall on sleep effort and considers clinical implications of the research described and future directions.

CHAPTER ONE

Introduction to the thesis portfolio

Introduction to the Thesis Portfolio

Alongside the likes of water and food, Maslow (1943) identifies sleep as among the most fundamental of human needs. It is therefore unsurprising that lack of sleep is associated with a range of adverse psychological, cognitive, and physical consequences. Sleep loss impairs cognitive performance, perception, psychomotor performance, and emotional processing (Goel et al., 2009; Killgore, 2010). Whereas long-term sleep deprivation can increase the risk of chronic diseases (Tobaldini et al., 2017) and contributes to the development of mental health problems (Freeman et al., 2020) and dementia (Irwin & Vitiello, 2019). Clinical guidelines recommend between 7 to 9 hours of sleep per night (Hirshkowitz et al., 2015). However, despite the importance of sleep for both physical and mental wellbeing, polling indicates that only 55% of the British population report getting over 6 hours of sleep per night, on average (Smith, 2020). Lack of sleep is not a localised issue, however. Sleep problems are pervasive across both highincome (van de Straat & Bracke, 2015) and developing countries (Stranges et al. 2012). While the cause of sleep loss is multifaceted, a significant proportion can be attributed to specific sleep disorders (Hillman & Lack, 2013).

Among the sleep disorders, insomnia is one of the most prevalent, although prevalence estimates vary depending on how insomnia is defined (Ohayon, 2002; Ohayon, 2011). The most robust definition of insomnia is identification based on formal diagnostic criteria. The International Classification of Sleep Disorders (3rd Edition; Sateia 2014) requires the presence of a night-time difficulty relating to initiating or maintaining sleep alongside functional impairment (e.g. impaired social, family, occupational or academic performance) or daytime symptoms related to disrupted sleep (e.g. fatigue/malaise) that is not explainable by inadequate opportunity to sleep or another sleep/wake disorder, occurring 3-times per week for at least 3 months. Estimates of the prevalence of insomnia disorder (i.e. insomnia that would meet criteria for diagnosis) has been estimated at between 4.4 and 11.7% (Ohayon, 2002).

The prevalence of insomnia comes with significant societal cost. The rates of absenteeism for insomnia sufferers are twice that of good sleepers (Léger et al., 2002). Moreover, insomnia is associated with greater risk of being involved in a motor vehicle accident (Léger et al., 2002), sustaining an occupational injury (Nakata et al., 2006) and hospitalisation (Léger et al., 2002; Weyerer & Dilling, 1991).

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The economic burden of insomnia in the UK is unknown, but US estimates put the cost of insomnia at over \$100 billion annually (Wickshire et al., 2016).

Insomnia Treatment

The individual and societal costs associated with insomnia underscore the need for effective treatments. Clinical guidelines recommend cognitive behavioural therapy (CBT) as the primary treatment option for insomnia (Morin et al., 2021; Wilson et al., 2019). Indeed, there is now a wealth of data attesting to the effectiveness of CBT for insomnia. A meta-analysis synthesising the treatment outcomes of 20 randomised control trials conducted by Trauer and Colleagues (2015) concluded that CBT achieves clinically meaningful reductions across a range of insomnia symptoms.

However, CBT for insomnia is not a unitary intervention, but an amalgamation of a variety of cognitive (Jansson-Fröjmark & Norell-Clarke, 2018) and behavioural components (Mclaren et al., 2023). These components are derived from several different models of insomnia maintenance which characterise the literature (Bootzin, 1972; Espie et al., 2006; Harvey, 2002; Spielman et al., 1987). While a preponderance of options for formulating and treating insomnia exist and are theoretically interesting, the plurality of treatment approaches raises some practical questions. How should clinicians choose between them? Which of these theoretic conceptualisation(s) provide the most accurate account of insomnia as a construct and should therefore be emphasised in clinical research and future iterations of CBT for insomnia? Harvey and Tang (2003), citing Salkovskis's (2002) model, suggest that interventions for insomnia could be improved by using an empirically grounded approach in which maintaining processes are identified and validated and which then drive the development of theory and clinical interventions. From this perspective, understanding the mechanisms that underpin insomnia should guide both clinical practice and outcome research (Harvey & Tang, 2003).

Sleep effort

There are a number of proposed psychological mechanisms of insomnia (Harvey et al., 2017; Schwartz & Carney, 2012) but the focus of this thesis is on 'sleep effort' (Broomfield & Espie, 2005; Espie et al., 2006). The reason for choosing sleep effort specifically is that it is emerging as an important concept in insomnia research, attracting increasing research interest. Moreover, sleep effort can be studied using a psychometric questionnaire as well as via more experimental methods making it a suitable candidate target for empirically grounded interventions.

Sleep effort as a concept emerged out of the paradoxical intention therapy literature, implicit initially (e.g. Ascher & Efran, 1978) then more explicitly (Broomfield & Espie, 2003; Broomfield & Espie, 2005), and then elaborated fully in Espie and colleagues (2006) Attention-Intention-Effort (A-I-E) model. From the perspective of the A-I-E model, sleep effort is the terminal point in a series of cognitive processes that ultimately inhibit sleep onset. This process begins with selective attention towards sleep related cues. Selective attention is common in a wide range of psychological disorders and is considered a transdiagnostic process, usually driven by threat (Mansell et al., 2008). However, in the A-I-E model, selective attention can be driven by incentive (due to the appetitive nature of sleep), as well as threat (due to the adverse consequences of lack of sleep). Selective attention to sleep related cues is assumed to occur automatically and is not consciously initiated (e.g. Jones et al, 2005; Marcetti et al, 2006).

In the next stage of the pathway, attention is mobilised towards the explicit goal of sleeping. This is the "intention" component of the A-I-E model. The intention to sleep then leads to purposeful, goalorientated action (i.e. sleep effort). Sleep effort describes the behavioural state in which the person takes action with the express purpose of initiating sleep. For example, trying to find an ideal sleeping position so that sleep can occur, or trying to eliminate thoughts to have a "clear mind". Sleep effort is assumed to have an inhibitory effect on sleep, increasing cognitive arousal, leading to frustration and ultimately preventing an otherwise natural, involuntary process (Espie, 2002).

Empirical Support for Sleep Effort

Experimental research supports the proposed role of sleep effort in insomnia. For example, Ansfield and colleagues (1996) either instructed participants to fall asleep as quickly as possible, or whenever they desired. They found that under high (but not low) mental load, those instructed to fall asleep quickly saw a delay in sleep onset latency in comparison to those in instructed to sleep whenever they felt like it. This supports the proposed model of effort, but also indicates that there may be a moderating impact of mental load. More recently, Rasskazova et al. (2014) instructed participants to either relax and rest or to sleep as fast as possible, with the added incentive of a financial reward dependent on the hastiness of sleep onset. They found that explicit instruction to fall asleep quickly resulted in more fragmented sleep.

Moreover, there is some evidence that behavioural sleep effort is associated with insomnia symptoms in clinical samples. For instance, a recent study found that use of 'tricks' to fall asleep was more prevalent and more frequent in insomnia sufferers, in comparison to normal sleepers (Bjorvatn et al., 2023). Further, there is experimental evidence demonstrating the role of effort in insomnia sufferers. For example, Harvey (2001) found that suppression of thoughts before sleeping led to delayed sleep onset in both insomnia sufferers and normal sleepers. Conversely, several studies have demonstrated that distraction (Harvey & Payne, 2002; Haynes et al., 1981; Levey et al., 1991) or non-effortful/passive response to cognition (Lundh & Hindmarsh, 2002) can facilitate sleep onset in insomnia sufferers. The former finding supports the A-I-E model more broadly, demonstrating that not attending to sleep-related stimuli can allay difficulty with sleep initiation, whereas the latter suggests that if sleep disrupting stimuli (i.e. worry) is not responded to with expenditure of effort, then their effect on sleep latency is reduced.

The Glasgow Sleep Effort Scale

Other research on sleep effort has been conducted using the Glasgow Sleep Effort Scale (GSES; Broomfield & Espie, 2005). The GSES is a validated 7-item questionnaire designed to measure sleep effort. In their initial validation study, Broomfield and Espie (2005) demonstrated that the GSES robustly discriminates between good sleepers and insomnia sufferers; with a cut-off score of two identifying 93.3% of insomnia sufferers and 87.3% of good sleepers.

Further research using the GSES has also demonstrated the importance of sleep effort in insomnia, highlighting its association with subjective sleep characteristics (Hertenstein, et al., 2015), change in insomnia symptoms over time (Chung et al., 2023), and a mediating role in the effect of insomnia treatment (Ebert et al., 2015). Moreover, research has shown that sleep effort associates with poor sleep in the context of anxiety and depression (Fairholme & Manber, 2014), suggesting that sleep effort may be a transdiagnostic process underlying poor sleep.

Paradoxical Intention Therapy

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Paradoxical intention therapy (PI) is a psychological treatment designed specifically with sleep effort as the intended treatment target. While instructions vary, in essence PI invites patients to attempt to gently resist sleep onset and try to stay awake and/or to give up trying to sleep (Espie, 2011). In this way, the person's intention is no longer explicitly focused on initiating sleep but is either neutral (i.e. giving up trying) or focused on staying awake. In either case, the inhibitory effect of sleep effort on sleep initiation is neutralised (Espie, 2002; Espie et al., 2006).

There is now an emerging literature demonstrating that PI is an effective treatment for a range of insomnia symptoms (Jansson-Fröjmark, et al., 2022). Moreover, a recent study has demonstrated that PI reduces sleep effort, as measured by the GSES (Ong et al., 2022). However, it is unclear whether PI has any impact on objective sleep. More research is also needed to clarify the impact of PI on sleep effort using a validated measure

This Thesis Portfolio

The focus of this thesis is on evaluating the impact of interventions on sleep effort. In Chapter 2, a systematic review and meta-analysis is described wherein data from randomised control trials are pooled to establish the effect of cognitive behavioural interventions on sleep effort, as measured by the GSES. Chapter 4 presents a piece of primary empirical research, in which the effect of PI on sleep effort (replicating Ong et al., 2022) and insomnia symptoms, is evaluated. This research includes the use of an EEG (electroencephalography) headband to examine the effect of the intervention on objective sleep parameters. Chapter 3 is a 'Bridging Chapter', which aims to clarify the links between the systematic review presented in Chapter 2 and the empirical research described in Chapter 4. In Chapter 5, an overall evaluation and critique of the research and its findings is given, with suggestions for future research set out and reflections on the process of conducting the research provided.

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Chapter Two

Systematic review and Meta-analysis

The effect of Cognitive Behavioural Interventions for Insomnia on Sleep Effort: A Systematic Review and Meta-Analysis

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Abstract

Insomnia is a pervasive sleep disorder for which there are many proposed underpinning psychological mechanisms. Research suggests that sleep effort plays an important role in insomnia. Despite this, no previous meta-analysis has been conducted to examine the effect of psychological insomnia interventions on sleep effort in randomised control trials. To identify randomised control trials examining the effect of a psychological intervention on sleep effort in comparison to a control condition in adults (≥18) with insomnia, searches were conducted across four databases (MEDLINE, CINAHL, PsycINFO, Scopus). A grey literature repository search was also progressed (Open Access Theses and Dissertations and ClinicalTrials.gov) and articles from the seminal paper introducing the Glasgow Sleep Effort Scale were searched by hand (Broomfield & Espie, 2005). Data from six randomised control trials were included in the final meta-analysis. All six trials involved either single component (*k*=2) or multicomponent cognitive-behavioural therapy (*k*=4) for insomnia. Results showed a statistically significant medium effect of the CBT interventions on sleep effort. Five of the six trials finding reductions in sleep effort in favour of the intervention. Explanations for these findings are considered, alongside implications for research and clinical practice.

Introduction

Insomnia is a common sleep-wake disorder estimated to affect between 5-50% of the general population depending on the definition used (Ohayon, 2002). The hallmark symptoms of insomnia are an inability to initiate sleep and/or persistent waking during the night accompanied by psychological distress (Morin et al., 2021; American Psychiatric Association, 2022).

The primary treatment for insomnia is cognitive behavioural therapy (CBT; Morin et al., 2021). Unlike CBT for other conditions which is often offered as a coherent treatment protocol (e.g. Ehlers, 2013), CBT for insomnia is often delivered as a multicomponent treatment consisting of a variety of interchangeable, independent techniques (e.g. sleep restriction therapy, stimulus control, cognitive therapy), each with their own treatment rationale centralised around a particular factor espoused to maintain insomnia (Erdinger et al., 2021). This has to some extent been the impetus for an ever-expanding variety of measures for these proposed mechanisms. Some examples of proposed mechanisms and associated measures include dysfunctional sleep-related beliefs and the Dysfunctional Beliefs About Sleep Scale (DBAS; Morin et al., 2007), pre-sleep arousal and the Pre-Sleep Arousal Scale (PSAS; Jansson-Fröjmark et al., 2012, Nicassio et al., 1985), excessive sleep effort/sleep performance anxiety and the Glasgow Sleep Effort Scale (GSES; Broomfield & Espie, 2005) and poor sleep hygiene and the Sleep Hygeine Index (SHI; Mastin et al., 2006).

The availability of instruments to measure key insomnia processes has some distinct advantages. For example, they can provide clinicians with a direct measurement of the intended targets of therapy. The most well researched of these measures is the DBAS (Morin et al., 2007; Thakral et al., 2020). In a systematic review and meta-analysis of 16 randomised control trials assessing the effectiveness of CBT-I, Thakral and colleagues (2020) found that the DBAS was included in all 16 studies as a measure of sleeprelated cognition, with only two of the trials also including another measure of sleep related cognition. In their review, they found that CBT significantly reduced dysfunctional beliefs about sleep.

While the DBAS can provide valuable insights into the extent that psychological interventions result in a change in dysfunctional beliefs about sleep, it is important not to overlook other psychological processes that data suggest may also be integral to insomnia. One process that warrants attention is 'sleep

effort'. Sleep effort is defined as being the cognition and behaviour associated with actively striving to bring sleep under voluntary control (Broomfield and Espie, 2005). The Attention-Intention-Effort Model (A-I-E) of insomnia (Espie et al., 2006) proposes that sleep effort results from a cascade of cognitive processes, beginning with selective attention toward sleep related stimuli driven by threat (the costs of lacking in sleep) or incentive (craving sleep/restedness), which develops into an explicit intention to fall asleep (e.g. conscious deliberation on how to achieve sleep onset), culminating in sleep effort (the execution of the intention to sleep via cognitive or behavioural means). Some examples of how sleep effort may manifest are shuffling around in bed in an endeavour to attain a position comfortable enough to initiate sleep (behavioural), or 'counting sheep' (cognitive). It is important to qualify that it is not these strategies that reflect sleep effort in and of themselves but do so when they are driven by selective attention to sleep and are motivated by the explicit intention to sleep. Many such behaviours and cognitive strategies may also be employed by good sleepers but under a different motivational context. For instance, a good sleeper may adjust their position in bed if they become uncomfortable quite naturally and with no explicit intention other than to allay discomfort. In contrast, a person who suffers from insomnia may notice the discomfort having been vigilant to threats to sleep onset (selective attention) resulting in the intention to alleviate the discomfort in order to sleep (explicit intention) resulting in tossing and turning (with the express purpose of hastening sleep onset; sleep effort). Sleep effort is thus proposed to be a perpetuating factor in insomnia because sleep is by its very nature an involuntary process and as such, wilful attempts to initiate sleep will inevitably fail, and serve only to interrupt the passive transition to sleep. Failure to sleep is thus perceived as threatening, leading to further anticipatory and performance related anxiety about sleep and therefore continued sleep effort (Broomfield and Espie 2005; Espie, 2023).

The earliest evidence that sleep effort may play an important role in insomnia is derived from the success of paradoxical intention therapy in the treatment of insomnia. While exact instructions vary, paradoxical intention therapy involves directing patients to try to stay awake instead of trying to sleep, with the idea that doing so should overcome the inhibitory effects of effort on sleep (Ascher & Efran; 1978; Jansson-Fröjmark et al., 2022). A recent meta-analysis revealed that paradoxical intention therapy results in moderate-large improvements in several clinically important insomnia domains (Jansson-Fröjmark et al., 2022). In addition, the meta-analysis found large reductions in sleep effort and in the

associated construct of sleep performance anxiety across the two included studies that measured this (Broomfield & Espie, 2003; Buchannan, 1988). This lends provisional support for the role of sleep effort in insomnia, demonstrating that an intervention designed to target and reduce sleep effort, also reduces symptoms of insomnia.

Another avenue of evidence has examined the construct of sleep effort in insomnia directly. The seminal research on sleep effort as a validated, measurable construct was conducted by Broomfield and Espie (2005) in their development and validation of a psychometric instrument to measure sleep effort; the Glasgow Sleep Effort Scale (GSES). In their initial validation study, Broomfield and Espie (2005) demonstrated that a GSES score greater than two, out of a possible 14, was enough to reliably distinguish insomnia sufferers from healthy controls. Further studies have since validated the GSES in Turkish (Uygur et al., 2022), Persian (Doos Ali Vand et al., 2020) and Portuguese (Meia-Via et al., 2016). Distinguishing healthy sleepers from insomnia sufferers is something that GSES shares with other insomnia mechanism measures (e.g. dysfunctional beliefs about sleep; Carney et al., 2010; pre-sleep arousal; Jansson-Fröjmark & Norrell-Clarke, 2012). Moreover, it could be argued that conceptually, sleep effort overlaps with other insomnia mechanisms. For example, pre-sleep arousal could be another way of describing a state of anticipatory anxiety that begets selective attention and which is a precursor to sleep effort, as described in the A-I-E model (Espie et al, 2006). However, further research suggests sleep effort occupies a more niche role in insomnia. Research conducted by Hertenstein and colleagues (2015) compared the exploratory power of the GSES in comparison to the DBAS and the PSAS. Interestingly, the authors found that GSES predicted self-reported insomnia severity, but not polysomnographic sleep characteristics, while the reverse was true for DBAS and PSAS. This suggests that sleep effort may explain particular insomnia symptoms that other processes cannot, for instance sleep state-misperception.

Separately, other research has shown that sleep effort could play a role in maintaining sleeping difficulties when they arise in other conditions. For instance, sleep effort associates with sleep disturbance in the context of depression and anxiety (Fairholme and Manber, 2014). Additionally, recent research conducted by Borges and colleagues (2023) has found that sleep effort mediates the relationship between depression and anxiety, particularly when depression predates the onset of anxiety. In summary, sleep effort may play a transdiagnostic role in sleep problems across disorders and contribute to the considerable

rates of comorbidity between insomnia and common mental health problems such as anxiety and depression (Ohayon et al., 1998).

Despite the above evidence suggesting the important role sleep effort may play in insomnia and poor sleep more generally, it remains unclear the extent to which sleep effort may respond to treatment when assessed in well-controlled studies using a validated measure (for example GSES). Previous reviews have aimed to investigate the effect of paradoxical intention therapy specifically on sleep effort (Jansson-Fröjmark et al., 2022), or the effects of CBT on sleep-related cognition more broadly (Thakral et al., 2020) but have not investigated the effect of CBT on sleep effort. The primary aim of the present systematic review and meta-analysis was to specifically address this evidence gap. We therefore identified randomised control trials in which a cognitive behavioural intervention was used, and sleep effort was included as a treatment outcome, measured by the Glasgow Sleep Effort Scale. We then quantitatively synthesised the data to derive a pooled estimate of the effect of CBT on sleep effort.

Methods

This systematic review was registered on PROSPERO (REF ID: <u>CRD42023429431</u>) and was conducted to identify relevant research which was then synthesised by meta-analysis. Risk of bias was assessed using the Cochrane Tool for Assessing Risk of Bias in Randomised Trials (RoB 2; Sterne, et al., 2019). The review adhered to the guidelines outlined in the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement (Page et al., 2021).

Search strategy

The search was conducted across four electronic databases (MEDLINE, CINAHL, PsycINFO, Scopus) on the 5th of July, 2023. Grey literature was included, and searched via Open Access Theses and Dissertations and ClinicalTrials.gov at the same time. Because the literature of interest to this systematic review is highly specific, it was possible for searches to be comprehensive without returning an unmanageable number of publications. As such, no restrictions were placed on language or date of publication and the search was broad, with few search terms. The search string used was as follows: "Sleep Effort" OR "Sleep performance anxiety" OR "Glasgow sleep effort scale". A hand search of articles citing the original paper in which the GSES was validated was also completed (Broomfield & Espie, 2005). This was conducted because to the author's knowledge the GSES is the only validated measure of sleep effort.

If a study protocol was found, a manual search was also conducted to determine whether the associated publication could be obtained. Where the publication associated with a protocol could be obtained, it was included and screened in the same way as other articles.

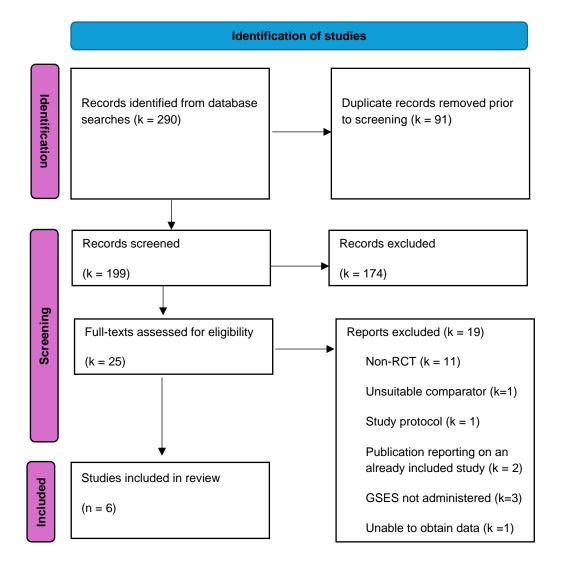
Study selection

The searches were performed with the primary results (k=290) imported into EndNote 20 (Clarivate, 2013), at which point duplicates were removed. The EndNote file containing the remaining records (k=199) were then sent to the third author. The first and third author then independently screened all papers against the inclusion/exclusion criteria. Studies were included if they were [i] randomised controlled trials, [ii] described studies where participants had insomnia identified via diagnosis or self-report questionnaire, and [iii] included a psychological intervention compared against a control condition (active or passive). Note, the initial search was for psychological interventions in general. However, it was determined that if all, or almost all, interventions were of a particular variety (i.e. cognitive behavioural) then the meta-analysis would include only these interventions. This was specified in the protocol. The exclusion criteria were [i] participants under the age of 18 years, [ii] insomnia considered to be of organic origin such as fatal familial insomnia, [iii] non-randomised trials, namely trials that had only a single-arm or which did not randomly allocate participants to groups, [IV] and sleep effort measured using a validated scale.

Included studies were initially screened by review title and abstract. Studies that were not excluded at the initial screening by both authors were then subject to a full text review, also completed by the first and third author. Any discrepancy in decision making was addressed by consulting with the fourth author. A reason for exclusion was noted for each reference removed at this stage. If a study reported measuring sleep effort but did not report sufficient data to enable the planned analyses, authors were contacted in an endeavour to procure the data. If multiple publications reported on the same study, the publication that included the data was kept. If multiple publications included data pertinent to the study, or none of the publications published the data, then the primary research publication was included. Figure 1 is a PRISMA flow diagram which illustrates the process of study selection.

Figure 1

PRISMA Flow Diagram



Data extraction

The first author then extracted data using the Cochrane data collection form (Higgins et al., 2019). Data extracted included the sample size for each study, mean and standard deviation scores for each study group at each time point, the study setting, study population and demographic characteristics, intervention and control condition details, recruitment and study completion rates, outcomes and measurement times, quantity of and reasons for missing data and details relating to risk of bias and study quality. The third author then further assessed one third (k=2) of the studies selected at random (using a random number generator <u>https://www.random.org</u>), to check on data collection accuracy. Unreported data were sought by contacting the authors of the study directly and by searching open-source data repositories (e.g. <u>www.clinicalstudydatarequest.com</u>). Where raw data were provided by study authors following correspondence, mean and standard deviations using the available data were computed without any missing values, i.e. no method of imputation was used.

Risk of Bias Assessment

Risk of bias assessments were conducted using Revised Cochrane Risk of Bias Tool for Randomized Trials (RoB 2;Sterne et al., 2019). The Rob 2 is widely used to assess risk of bias in psychotherapy outcome research (Munder & Barth 2018). The RoB 2 is a structured assessment of studies that assesses risk of bias across five domains (1) bias arising from the randomisation process (2) bias due to deviations from intended interventions, (3) bias due to missing data, (4) bias in measurement of the outcome, (5) bias in selection of the reported result. Risk of bias is identified in studies by systematically evaluating available information against 'signalling questions' for each domain (e.g. "was the allocation sequence random?"). Each domain is then given a risk rating of either 'high, 'medium' and 'low' risk of bias based on the RoB2 algorithm, which can be overridden by author judgement. Domain orientated risk of bias was assessed by the first author. The third author then checked one third of the assessments in the same manner as described for data extraction. Risk of bias was assessed manually without any aid from automated tools. Both risk of bias assessors used training on RoB2 available on Youtube (Cochrane Training, n.d.) and used the full guidance document for reference when performing the risk of bias assessments (Higgins et al., 2019).

Data synthesis

Intervention and control group post-intervention data (sample size, raw mean and standard deviation) were entered into SPSS (citation, version) for analysis. A pooled standardised effect size (Hedge's g; Hedges, 1981) was then calculated by comparison of post-intervention data for each group. Heterogeneity was not assessed as this is unlikely to be meaningful when there are very few studies (Bender et al. 2018)

Results

Study characteristics

Table 1 provides a description of the characteristics of studies included in the meta-analysis. Six trials were included in the meta-analysis. All studies were conducted within the last 8 years, with publication year ranging from 2016-2023. All studies were conducted in western countries, with three conducted in the United States (Manber et al., 2016; J. C. Ong et al., 2018; Tu et al., 2022), two in the United Kingdom (Kyle et al., 2023; G. S. C. Ong et al., 2022), one in Germany (Johann et al., 2020).

In sum, the trials featured 833 participants, 385 of which were in an intervention group and 448 were in a control condition. Overall, studies reported that the majority of participants were female (75.0% of participants) with an average age of 44.1 years (*SD*=13.9). Four of the six studies recruited participants only with insomnia (Johann et al., 2020; Kyle et al., 2023; J. C. Ong et al., 2018; G. S. C. Ong et al., 2022) while one study required participants to have comorbid depression symptoms (Manber et al., 2016) and another also required participants to be diagnosed with sleep apnoea (Tu et al., 2022). In five of the six studies, participants met criteria for diagnosis of insomnia disorder via structured clinical interview (Johann et al., 2020, Kyle et al., 2023; Manber et al., 2016; Tu et al., 2022). Regarding the inclusion criteria for insomnia, two of these studies also required an above threshold score on a self-report

questionnaire for insomnia in addition to meeting the criteria for insomnia on a structured interview (Manber et al., 2016; Kyle et al., 2023). One of the studies (G. S. C. Ong et al., 2022) required only an above threshold score for insomnia on a self-report questionnaire.

Regarding the intervention, three of the studies included multicomponent CBT (Manber et al., 2016; Johann et al., 2020), with one study encompassing a multicomponent intervention combining traditional cognitive behavioural techniques with mindfulness (J. C. Ong et al., 2018) and the two remaining studies featured sleep restriction therapy (Kyle et al., 2023) and paradoxical intention therapy (G. S. C. Ong et al., 2022). The total number of therapy sessions ranged from 2-8 (median =5.5). Although multicomponent CBT-I was the modal intervention by trial, the largest sample (*n*=642) featured in Kyle et al., 's (2023) study, which means that the intervention most frequently received by participants across trials was sleep restriction therapy. None of the studies included any alternative methods of measuring sleep effort in addition to the GSES.

Table 1. Characteristics of trials.

Study, year	N total	Mean age (SD)	Sex (%female)	Comorbidities	Protocol for intervention	Delivery (dose and provider)	Comparator type	Details of comparator	Additional details
Manber et al., 2016	150	46.6(12.6)*	73.3	Depression	Multicomponent CBT-I	7 face-to-face sessions over 12 weeks by psychotherapists naïve to CBT-I	Active	Sleep education and behavioural pseudo intervention	Both groups pharmacotherapy treatment for depression.
J. C. Ong et al., 2018	54	42.9(12.2)	74.1	None required.	Mindfulness-based intervention for insomnia (mindfulness + behavoural sleep interventions)	8 weekly group sessions delivered by the first author who has training in MBSR and CBT-I.	Active	Sleep diary self- monitoring	Study also included mindfulness-based stress reduction group but this was not considered to be a CBT based intervention.
Kyle et al., 2023	642	55.4(15.9)	76.2	None required.	Sleep restriction	A total of 4 sessions delivered over 4 weeks, two online and two face to face delivered by primary care nurses provided with brief training.	Active	Sleep hygiene education + usual care.	Sleep hygiene delivered via a leaflet provided and provided to both groups.
Johann et al., 2020	44	41(15.5)	63	None required.	Multicomponent CBT-I	8-weekly face-to- face sessions delivered by a clinical psychologist.	Active	Sleep diary self- monitoring with contact from	Trial included 3 phases with the latter phases involving treatment with positive

								researchers for review	airway pressure for sleep apnoea, details included only for the first phase.
Tu et al., 2022	121	50.0(13.1)	54.4	Sleep apnoea.	Multicomponent CBT-I	4-sessions over 4 weeks delivered face-to-face by a clinical psychologist	Passive	Waiting list control	
G. S. C. Ong et al., 2022	24	28.9(13.2)	91.7	None required.	Paradoxical intention therapy	2 sessions of paradoxical intention therapy delivered via videoconferencing by a trainee clinical psychologist/ first author.	Active	Sleep hygiene education.	

Note: CBT-I = Cognitive behavioural therapy for insomnia.

Risk of bias assessments

The outcome of the RoB2 assessments are provided in Table 2. Appropriate methods of randomisation were reported in all studies. Additionally, all studies conducted an intention-to-treat analysis, with no indication that study context presented an increased risk of bias. There was some concern that there may be risk of bias in some studies due to significant amounts of missing data (Manber et al., 2016; Ong et al., 2022; Tu et al., 2022). In these cases, it was considered possible that 'missingness' of data was dependent on its true value because missing data was present, but not likely, as the proportion of missing data was similar in each group. In other words, there was no reason to believe that missing data was not missing at random. One study (Kyle et al., 2023) conducted a sensitivity analysis which demonstrated that missing data were not likely to be related to insomnia symptoms. This was taken into account when assessing risk of bias due to missing data, given the known relationship between sleep effort and insomnia symptoms (Broomfield & Espie, 2005). All studies were rated at least as some concern for bias regarding measurement of outcome data, due to the combination of non-blinding of participants and the use of self-report measurements. The exception was Johann et al. (2018) which was rated as a high risk of bias on this domain as participants in the control arm were allocated to a waiting list, as knowledge of being in a 'waiting list' for psychological treatment was deemed to be more likely to influence participants reporting on their symptoms than if they were allocated to a control group with an active component. Risk of bias in the selection of the reported result was rated 'some concerns' due to a lack of a published protocol in which an analysis plan had been specified in all studies other than Kyle et al., 2023). In one case (Manber et al., 2016), the RoB2 algorithm was manually categorised as "low" for the selection of the reported result, because no result for the GSES was published and instead raw data were provided by the authors and analysed for the purposes of meta-analysis.

Table 2

Risk of bias assessments

Author, year	Bias arising from randomisation process	Bias due to deviations from intended interventions	Bias due to missing data	Bias in the measurement of the outcome data	Bias in selection of the reported result	Overall bias
Manber et al., 2016	Low	Low	Some concerns	Some concerns	Low*	Some concerns
J. C. Ong et al., 2018	Low	Low	Low	Some concerns	Some concerns	Some concerns
Kyle et al., 2023	Low	Low	Low	Some concerns	Low	Some concerns
Johann et al., 2020	Low	Low	Low	High	Some concerns	High
Tu et al., 2022	Low	Low	Some concerns	Some concerns	Some concerns	Some concerns
G. S. C. Ong et al., 2022	Low	Low	Some concerns	Some concerns	Some concerns	Some concerns

Post-treatment comparison

Figure 2 displays a forest plot detailing the effect sizes for the included trials. The overall effect was g=-.53 (CI=-1.04 to -.05) favouring the cognitive behavioural interventions. This effect passed the threshold for statistical significance at α =.05 (p=.048). All but one of the studies included found a lower GSES score in the treatment group over the control group, with effect sizes ranging from -.44 to -1.22. The exception was Manber et al.'s (2016) study that found the opposite trend, with significantly lower GSES scores in the control condition relative to the intervention.

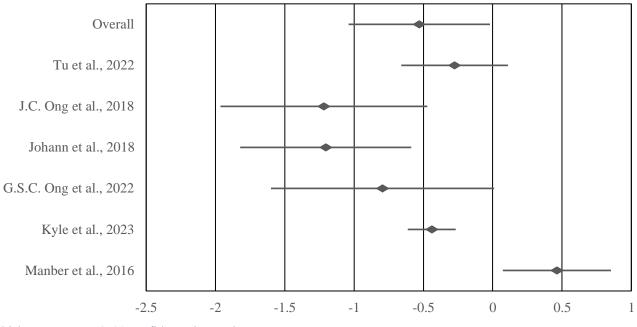
Table 3

Effect Size Estimates for Individual Studies

					95% Confidence Interval			
Study	Effect Size	Std. Error	Z	Sig. (2-tailed)	Lower	Upper	Weight	Weight (%)
Manber et al., 2016	.463	.199	2.325	.020	.073	.853	2.640	18.2
Kyle et al., 2023	440	.088	-4.993	<.001	613	267	2.881	19.9
G.S.C. Ong et al., 2022	795	.410	-1.935	.053	-1.60	.010	1.969	13.6
Johann et al., 2018	-1.21	.315	-3.82	<.001	-1.82	587	2.280	15.7
J.C. Ong et al., 2018	-1.22	.381	-3.20	.001	-1.96	471	2.064	14.3
Tu et al., 2022	275	.197	-1.40	.162	660	.111	2.646	18.3

Figure 2

Forest Plot Displaying Effect Sizes of studies (Hedge's g)



Note: Whiskers represent 95% confidence intervals.

Discussion

The aim of this systematic review and meta-analysis was to synthesise available research to examine the effect of cognitive behavioural interventions for insomnia on sleep effort. Following an exhaustive search of all relevant data bases (MEDLINE, CINAHL, PsycINFO, Scopus) up to July 2023, six randomised control trials were identified that assessed the effect of cognitive behavioural interventions on sleep effort. Relevant data was extracted and pooled to compare post-treatment scores for the intervention groups compared to control groups. The meta-analysis revealed a statistically significant medium effect size for cognitive behavioural interventions on sleep effort. While the majority of the included trials (five out of six) reported reductions in sleep effort favouring the intervention group with an overall pooled effect size of g=.53, one study found the reverse effect (Manber et al., 2016).

This systematic review has several strengths. Namely, a robust approach was taken in only including studies that featured a validated measure of sleep effort (i.e. GSES) and were randomised control trials ensuring methodological rigor and minimising measurement bias. Another strength of this review was employing a narrow focus, examining only a single insomnia process. This allowed a comprehensive

survey of relevant data leading to the identification of trials measuring sleep effort but where sleep effort data were not included as a primary outcome, as was the case in all but one of the included studies (Ong et al., 2022). For one of the identified studies, the relevant data was not in fact reported at all (Manber et al., 2016), and another is yet to be published and currently featured in grey literature only (Ong et al., 2022).

Some of the review features were double edged, also resulting in certain limitations. For instance, stringent inclusion criteria limited the number of studies that were included in the review. This meant this review is necessarily limited in breadth, with studies that included similar concepts to sleep effort such as sleep performance anxiety being omitted. Equally, the review was also limited in quantity of studies because sleep effort is still an emerging domain of inquiry in the insomnia literature. The limited pool of studies presented a challenge for interpreting the results of this meta-analysis. One of the included studies reported greater sleep effort in the intervention group in comparison to the control group (Manber et al., 2016), contrary to the expected direction of effect. The limited number of included studies makes it hard to contextualise this result. For instance, it might be that this finding is an outlier, a consistent trend within a specific population, or sits reasonably within the variation between effect sizes across studies. However, it may still be pertinent to offer the following observations regarding this result. It is important to note firstly that the control condition in Manber and colleagues (2016) study was much more comprehensive than the control conditions in other studies, involving seven sessions of control therapy during which participants paired neutral stimuli with stimuli related to sleep related distress, alongside sleep education and antidepressant medication. It is conceivable that the treatment package provided to the control group did reduce sleep effort. When the first author of the study was contacted to confirm the result, they noted that the control intervention could feasibly have acted to reduce sleep effort, due to participants practicing pairing neutral and distressing sleep-related stimuli at night, despite being told explicitly not to do this. This is supported by other data reported by Manber and colleagues (2016) in that the change in mean Insomnia Severity Index score was greater from pre-post control intervention than it was between the control intervention and treatment group.

There have been two previous reviews which have explored similar research questions to those of the current study. In their meta-analysis, Janson-Fröjmark and colleagues (2022) investigated the effect of paradoxical intention therapy on sleep related performance anxiety across two studies. One included a

measure of sleep effort in a pilot format of the GSES (the 'Sleep Performance Anxiety Questionnaire'; Broomfield & Espie, 2003, pp.318), the other used the "Sleep Performance Anxiety Scale", an unvalidated measure of sleep performance anxiety (Buchanan, 1988). Their analysis revealed a pooled effect size of 1.04, twice as large as that observed in the present study. This difference could be accounted for because Janson-Fröjmark and colleagues (2022) only considered trials of paradoxical intention therapy. PI is a psychological intervention specifically designed to reduce sleep effort and sleep performance anxiety, and thus may have had a more potent effect on these mechanisms. By contrast, the present review included a broader range of psychological interventions which may target insomnia by other processes (e.g. change in dysfunctional beliefs; Lancee et al., 2015). Notably, this review did include one study that utilised paradoxical intention therapy (G. S. C Ong et al., 2022) which, whilst observing a greater effect size (g=.72) than the pooled effect size we report (g=.51), was only the third largest effect and lower than two other studies included here which featured non-PI insomnia treatments (J. C. Ong et al., 2018; Tu et al., 2022). As such, the preferential effects of paradoxical intention therapy on sleep effort remain theoretical.

Another systematic review and meta-analysis conducted by Thakral and colleagues (2020) took a broader approach than the one adopted in this review, including all measures of sleep related cognitions (including the GSES). Thakral et al found that DBAS was used nearly exclusively in randomised control trials that had measured the effect of CBT-I on the mechanisms of insomnia. They found no RCTs that met their criteria and which included GSES as an outcome measure, although of course the majority of studies included here were conducted after the date of the Thakral review (G. S. C. Ong et al., 2022; Johann et al., 2020; Kyle et al., 2023; Tu et al., 2022). Because of the lack of other measures, their meta-analysis was restricted to the effect of CBT-I on the DBAS only, where they found a significant effect of CBT-I on DBAS scores, with a large effect size (g=.91). The effect observed in their meta-analysis is larger than was observed in the present study, although this might be expected given that a change in dysfunctional beliefs is the purported mechanism underlying cognitive therapy of insomnia (Harvey, 2002).

Historically, sleep effort as a concept has been of interest primarily in relation to treatment by paradoxical intention therapy in the clinical literature (Broomfield & Espie, 2005; Janson-Fröjmark et al., 2022). The results of this meta-analysis suggests, rather interestingly, that sleep effort is responsive to treatment by cognitive behavioural interventions for insomnia more broadly. It is thus possible that CBT

may also achieve some of its effects on insomnia due to its effect on sleep effort. For example, sleep restriction therapy and stimulus control are thought to work by increasing sleep efficiency, thereby strengthening the conditioned association between "sleep" and "bed". However, such treatments also involve abandoning sleeping via any overt effort in favour of preoccupation with another activity (stimulus control) or delaying sleep until there is a biological impetus strong enough that sleep onset occurs quickly. In both of these cases, wilful effort to sleep is arguably systematically sidestepped and a passive attitude towards sleep subtly encouraged (i.e. by relying on biology to result in the initiation of sleep onset). In other words, such treatments can be reformulated as achieving their effects, at least in part, via reduced sleep effort. Indeed, consistent with this argument, one of the studies included in this meta-analysis found that reduction in sleep effort mediated the treatment effect of sleep restriction therapy (Kyle et al., 2023).

This has potential implications for clinical practice. Our findings suggest that cognitive behavioural interventions for insomnia may reduce sleep effort directly, even if they are not explicitly designed to fulfil this purpose. Therefore, it is possible that it may be unnecessary to augment multicomponent psychological interventions for insomnia (e.g. by including paradoxical intention therapy within the treatment package (Espie, 2011)) to address sleep effort specifically in individuals or groups for whom sleep effort is elevated (e.g. individuals with a Type D personality; Uygur et al., 2023).

In terms of recommendations for future research, the most straightforward is that further work is required to clarify the effect of cognitive behavioural interventions on sleep effort. This review identified only six studies, which as noted vary substantially in terms of design and outcome. This makes it difficult to differentiate between signal and noise (i.e. in the case of one study having the reverse effect of the rest; Manber et al., 2016). A larger pool of studies will be required to smooth the heterogeneity in the data.

Beyond this, future research should also consider creative ways of measuring sleep effort to augment psychometric measurement. One of the advantages of sleep effort as a concept compared to certain other insomnia processes (i.e. dysfunctional beliefs about sleep) is that it is a psychological state and by definition involves some form of deliberate cognitive activity or behaviour (Espie et al., 2006). In this sense, there is no reason that psychometric measurement of sleep effort cannot be augmented by collecting data via other indicators that sleep effort is being exerted. For example, adding a question to be answered alongside a daily sleep diary that taps into sleep effort (e.g. "On a scale of 1-5, how hard did you try to fall asleep last night?"). It may also be possible to measure sleep effort by proxy, via objective measurement. For example, it could be assumed that if an individual is exerting deliberate effort to fall asleep that they would be under greater cognitive load. There are a range of physical markers of cognitive load that could be taken during sleep (Vanneste et al., 2021). Such methods of measuring the impact of interrupting natural physiological processes have been previously used in the clinical literature. For example, Wegner and colleagues (1997) found increased skin conductance using an electrodermal measure when participants were asked to apply a relaxation technique under cognitive load. Direct measurement of sleep effort in this way may offer a unique way of evaluating psychological treatments, not possible for many other proposed insomnia mechanisms. A final recommendation for future research is to discern whether interventions designed specifically to target sleep effort (such as paradoxical intention therapy) are more effective at reducing sleep effort than general cognitive behavioural interventions and whether increased success in reducing sleep effort translates to increased effectiveness in reducing insomnia symptoms.

In conclusion, this systematic review and meta-analysis has found that cognitive behavioural interventions are effective in reducing sleep effort, although the pool of randomised control trials including sleep effort as an outcome is currently small.

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CHAPTER THREE

Bridging Chapter

Bridging Chapter

The findings of the systematic review described in Chapter Two suggest that cognitivebehavioural interventions are effective in reducing sleep effort. This insight gives a broadscale account of the effect of treatment on sleep effort. In Chapter four, this is followed up with an empirical research project that takes a more granular approach. The empirical research project was conducted as a preliminary randomised control trial examining the effect of an intervention (paradoxical intention therapy; Espie, 2011) designed to specifically to treat insomnia by reducing sleep effort. In addition, this study will also investigate the effect of variables that are theoretically related to sleep effort, namely sleep characteristics and insomnia symptoms. This study is the first to examine the effects of paradoxical intention therapy on sleep objectively, using new technology that allows ambulatory (home based) EEG readings (the Dreem Headband).

Chapter Four

Empirical Research Paper

Henry Bristowe, University of East Anglia Dr Alpar S Lazar, University of East Anglia Andreas Michaelides, University of East Anglia Professor Niall M Broomfield, University of East Anglia

The Effect of Paradoxical Intention Therapy on Sleep Effort, Subjective and EEG Headband

derived Sleep Characteristics in Adults with Insomnia: A preliminary randomised trial.

Word count: 4181

Written for publication in line in the Journal of Clinical Sleep Medicine. Author guidelines are available in Appendix B.

Abstract

Insomnia is a pervasive sleep disorder defined by difficulties initiating or maintaining sleep. Paradoxical intention therapy is a treatment for insomnia disorder with a growing evidence base. It has been proposed to treat insomnia symptoms by reducing sleep effort; a process that is proposed to inhibit sleep onset. However, few studies have investigated the effect of paradoxical intention therapy on sleep effort using a validated questionnaire. Moreover, previous research has found that paradoxical intention therapy reduces diary reported, but not objectively measured sleep. However, this research measured objective sleep using actigraphy which may not be sensitive enough to detect changes in sleep as a result of a psychological intervention. This study aimed to address these gaps in the literature by examining the effect of paradoxical intention therapy on sleep effort using the Glasgow Sleep Effort Scale (GSES; a validated measure of sleep effort) and by measuring objective sleep

using the Dreem Headband (a dry EEG headband) in a two-armed randomised control trial. In total 26 participants were randomly allocated to receive either two sessions of paradoxical intention therapy or a single session of sleep hygiene educational advice and were asked to implement associated strategies over two weeks. Participants completed a three-day period of sleep measurement and completed psychometric questionnaires at baseline and at the end of the two weeks of implementing the intervention. A significant reduction (p<.01) of sleep effort, global self-reported insomnia symptoms and subjective sleep onset latency was found in the PI group in comparison to the control condition. However, there were no significant effects observed on any objective sleep parameters. These findings suggest that paradoxical intention is effective in reducing self-

reported insomnia symptoms and sleep effort.

Introduction

Chronic insomnia is a widespread sleep-wake disorder (Zhang et al 2019) characterised by self-reported difficulty initiating or maintaining sleep resulting in distress or functional impairment (American Psychiatric Association, 2022; Sateia, 2014). Clinical guidelines advocate cognitive behavioural therapy (CBT) as the first line treatment for insomnia (e.g., Morin et al., 2021; Wilson et al., 2019). CBT for insomnia is generally delivered as a multicomponent therapy comprising a number of interventions employed as part of a broader treatment package (Erdinger et al., 2021). However, there are also a range of evidence based single-component cognitive behavioural insomnia treatments comprising a specific therapeutic technique or set of techniques associated with a specific set of purported maintaining processes (e.g. stimulus control; Bootzin. 1972; sleep restriction; Spielman & Glovinsky, 1987, cognitive therapy; Harvey, 2002).

Paradoxical intention therapy (PI) is one such single-component cognitive behavioural insomnia intervention first introduced by Asher and Efran (1978) nearly half a century ago. In their seminal case series, they instructed patients with insomnia to 'stay awake for as long as they could' instead of trying to fall asleep. They observed substantial reductions in sleep onset latency only three weeks after PI was implemented (Ascher & Efran, 1978). There is now a growing evidence base indicating that PI is effective as a standalone treatment for insomnia, as summarised in recent reviews by Jansson-Fröjmark and Norell-Clarke (2018) and Jansson-Fröjmark and colleagues (2022).

PI was developed on the basis that sleep is an automatic process that cannot be consciously initiated, but attempting to initiate sleep wilfully leads to heightened arousal and curtails the otherwise natural transition into sleep (Ascher & Efran, 1978; Espie et al., 2002; Espie, 2023). By instructing patients with insomnia to intend not to sleep, effort to sleep is reduced and as such, sleep is made more possible. The central therapeutic target for PI is therefore sleep effort; a proactive behavioural state with the express purpose of controlling sleep (i.e. Espie, 2023; Espie et al., 2006). In the literature, sleep effort is measured using the Glasgow Sleep Effort Scale (GSES; Broomfield & Epsie, 2005; Espie, 2023). In their initial validation study, Broomfield and Espie (2005) found that sleep effort reliably distinguishes people with insomnia from good sleepers with a high degree of sensitivity and specificity. Despite reduction of sleep effort being the putative mechanism by which PI works, and the availability of a validated measure (GSES), there have been surprisingly few studies conducted directly examining the specific effect of PI on sleep effort, in people with insomnia (Jansson-Fröjmark et al., 2022).

Another aspect of the theory underpinning PI that has not been tested is the assumption that it influences the psychobiology of sleep (by alleviating the psychological inhibition that effort imposes on sleep initiation; Ascher & Efran, 1978; Epsie, 2002; Espie, 2023; Espie et al., 2006). Research in the broader CBT literature does not support the influence of psychological treatments on objective sleep parameters. A meta-analysis of 16 studies conducted by Mitchell and colleagues (2019) for example, found no effect of CBT on objective sleep parameters when polysomnography was used and only small effects for improvements in sleep onset latency when actigraphy was used. This contrasts with the review's findings on subjective sleep parameters, which indicated robust improvements in sleep as measured via self-report sleep diary.

Research on the impact of PI on objective sleep is limited but has yielded similar results. Broomfield and Espie (2003) found for example no significant effects of PI on objective sleep parameters as measured by actigraphy, despite observing significant improvements in subjective sleep. This finding was also replicated in a study by Ong and colleagues (2022), which also found no effect of paradoxical intention therapy on actigraphy-measured sleep but clear subjective sleep effects.

There are however methodological issues with measuring objective sleep. While polysomnography is considered the gold standard in sleep measurement, it involves highly irregular circumstances (sleeping in a sleep laboratory connected to monitoring equipment) that may influence sleep. Thus polysomnography may be inappropriate for the demonstration of improvements in sleep acquired through application of techniques in a different (i.e. the home) environment.

Actigraphy on the other hand can be used in the person's home and is minimally intrusive. However, while practical, there are issues with the validity of actigraphy measurements also. First, it cannot differentiate between quiet wakefulness and sleep, and as a consequence can over-estimate sleep and underestimate short awakenings (de Souza et al., 2003). Moreover, there are specific limitations associated with actigraphy for insomnia research. Namely, actigraphy is less accurate in differentiating wakefulness from sleep, in populations with poor sleep (Sadeh, 2011). And it has recently been found not to reliably differentiate insomnia sufferers sleep from that of healthy sleepers (Rösler et al., 2023). The latter finding represents a particular issue for clinical trials because it suggests that, even in the most optimistic scenario, where the sleep of insomnia sufferers who received an intervention becomes equivalent to that of healthy sleepers, actigraphy would still be unable to

differentiate between those who had received the intervention and those who had not. Consequently, actigraphy whilst practical, is unlikely to be sensitive enough to denote changes resulting from an intervention.

New technologies have however been developed that allow for more sophisticated, ambulatory (i.e. home based) sleep measurement in naturalistic settings. The 'Dreem Headband' is a wireless headband that combines EEG recorded brain activity and other physiological sleep indicators (heart rate via pulse oximeter, movement and breathing frequency via an accelerometer) to determine sleep state using a machine learning algorithm. The Dreem 3 headband is highly concordant with PSG in identifying sleep stages within the range of discrepancy existing between PSG examiners (Arnal et al., 2020). This new technology thus provides a clear opportunity to gain new insight into the effect of psychological interventions on objective sleep parameters in general and to follow up on previous research testing theories underlying PI and its impact on sleep specifically.

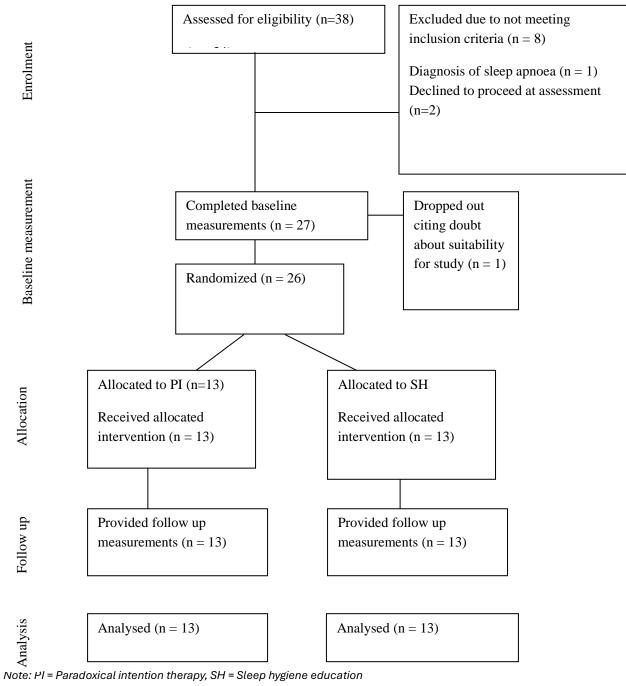
The current research therefore aims to expand on previous research by examining the effect of PI in a naturalistic setting on [i] sleep effort measured using a validated psychometric (Glasgow Sleep Effort Scale), [ii] objective sleep using a measure comparable to PSG (Dreem 3 headband) and [iii] subjective (diary recorded) sleep.

Methods

Participants

Participants were recruited between February and October 2023 via advertisements displayed around the University of East Anglia campus, university newsletters, and via word of mouth. Upon expressing interest, participants were invited to a brief screening interview during which the Morningness-Eveningness Questionnaire (MEQ; Horne & Ost, 1976) and the Sleep Condition Indicator (SCI; Espie et al., 2014) were administered. Participants with above threshold symptoms of insomnia (SCI score of \leq 16), and reporting they had not been diagnosed with a sleep disorder other than insomnia, were deemed eligible to participate. Participants were excluded if they screened positively for delayed sleep phase syndrome (MEQ \geq 30), if they reported a diagnosis of a sleep disorder other than insomnia (i.e. sleep apnoea), or if they were currently receiving (or planned to receive/commence) a psychological or pharmacological intervention for sleep.

Consort diagram



total of 26 participants were randomly allocated to either a paradoxical intention therapy group (PI) or a sleep hygiene (SH) control condition using a web-based randomisation tool (<u>https://www.randomizer.org</u>). The CONSORT flowchart presented in Figure 1 displays the pathway of participants across the various stages of the study.

Procedure

Participants received study materials (see measures) by collection from the University of East Anglia or via delivery by the first author. Before taking baseline measurements, participants met with the researcher either online or face-to-face at the Sleep and Brain Research Centre at the University of East Anglia. At this initial meeting, participants were taught how to use the Dreem headset device and provided instruction regarding completion of self-report questionnaires and recording of sleep, including via diary. Participants were initially asked to complete measures over three days (the baseline period). On the first of these days, participants were requested to complete the self-report questionnaires and to begin recording with the Dreem headset that night and for the two nights that followed, at the point at which they intended to sleep. On each morning after recording using the Dreem headband, participants completed the Consensus sleep diary (Carney et al., 2012). Participants then met with the researcher remotely via a video call and received either the SH advice or their first of two sessions of PI (marking the beginning of the intervention period). Those in the PI group met with the researcher for a final time one week later for the second PI session. SH allocated participants simply had the one meeting. At the end of the two weeks, participants were instructed to complete the same questionnaires and measure their sleep over three days in the same manner as in the baseline period.

Intervention

PI Group

Participants allocated to the PI group received two weekly sessions of PI lasting around half an hour of PI delivered remotely via a video conferencing platform. The content of PI sessions was in line with the procedures proposed by Espie (2011). Namely, participants were socialised to a formulation of sleep as an automatic process that cannot be consciously initiated (sleep normalcy) and that effortfully attempting to initiate sleep will interrupt the transition into sleep, thereby leading to insomnia symptoms. This principle was introduced by enquiring about the person's own observations of how "good sleepers" manage to fall asleep (generally, without trying) and drawing parallels to analogous situations where excess conscious effort is counterproductive (e.g. in thought suppression). Participants were then encouraged to "give up trying" to sleep by deliberately attempting to stay awake, lying in bed as normal with their eyes open, while gently resisting the urge to sleep. The content of PI sessions closely followed a handout that contained the rationale for the intervention and instructions on how to implement the technique used in previous research (Ong et al., 2022; Appendix C).

SH Group

Participants in the SH group received a standalone half hour session. The SH session consisted of discussion of the participants current sleep practices, and then provision of sleep hygiene education and encouraging implementation of sleep hygiene practices based on Hauri's (1977) recommendations (e.g. increasing evening exercise, reducing caffeine intake). While SH has been historically considered as a treatment for insomnia, current research suggests that it is ineffective as a standalone intervention (Furukawa et al., 2024). Thus the speciousness of SH as an intervention makes it a useful control procedure, giving the allure that it is an intervention for insomnia without any of the treatment effects. In the interest of consistency with the PI condition, the content of sessions were structured around a handout (Appendix D) with clear instructions on SH practices to be maintained during the intervention period.

Therapist

SH and PI sessions were delivered by a trainee clinical psychologist with prior post-graduate training and clinical experience in CBT, with supervision available from a senior clinical psychologist.

Measures

Glasgow Sleep Effort Scale

The Glasgow Sleep Effort Scale (GSES; Broomfield & Espie, 2005) is a 7-item questionnaire designed to assess sleep effort (a=.77). Responses are scored on a scale of 0 to 2 per item and relate to sleep-based performance anxiety or a proclivity to strive for control over sleep (e.g. "I put too much effort into sleeping when it should come naturally") with higher scores denoting a greater degree of sleep effort.

Sleep Condition Indicator

The Sleep Condition Indicator (SCI; Espie et al., 2014) is an 8-item measure of insomnia symptoms (*a*=.86). Items are based on the DSM-V criteria for insomnia disorder (e.g. "Thinking about a typical night in the last month, how many nights a week do you have problems with your sleep?") and responses are scored on a scale between 0 and 4 with lower scores indicating more severe insomnia symptoms.

Sleep Quality Scale

The Sleep Quality Scale (SQS; (Synder et al., 2018) is a single item scale designed to assess sleep quality. The item "During the past 7 days, how would you rate the quality of your sleep?" is scored on a scale of 0-10, with a score of 0 being "terrible" and 10 being "excellent".

Patient Health Questionnaire

The Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) is a 9-item questionnaire used to assess symptoms of depression. Each item is based on one of the DSM-IV criteria for depression (e.g. "Over the past two weeks, have you been bothered by [...] little interest or pleasure in doing things") and scored on a scale between 0 (not at all) and 4 (nearly every day).

Consensus Sleep Diary

The Consensus Sleep Diary (CSD; Carney et al., 2012) was used to assess subjective sleep characteristics (i.e. Wake after Sleep Onset (WASO), Total Sleep Time (TST), Sleep Onset Latency (SOL), Sleep Efficiency (SE)). The CSD was developed as a way of standardising the measurement of sleep characteristics in research. The core diary consists of 8 items (e.g. "what time did you go to bed?") with the option to add additional comments completed on waking.

The Dreem Headband

The Dreem Headband (DH) is a dry electroencephalogic (EEG) headband, that also measures oximetric and actigraphic data and uses this to determine sleep state via a machine learning algorithm (Arnal, et al., 2020). The headband can be operated by the user from the home using an app. The data from the headband is streamed remotely to an data management system where it is analysed automatically via a machine learning algorithm.

The project received full ethical approval from the University of East Anglia's Faculty of Medicine and Health Sciences Ethics Committee prior to initiation. A letter of approval from the ethics committee is included in Appendix E.

Statistical analysis

Analysis was conducted using IBM SPSS Statistics 27 (IBM Corporation, Armonk, NY). Analysis was conducted in two stages. First, a between groups analysis on post intervention scores was conducted for questionnaire outcomes to assess the effect of the intervention. Second, a more sensitive exploratory analysis using a general linear model (GLM) was used to identify trends in the data for objective and subjective sleep parameters. This exploratory approach was chosen given limited statistical power arising from the small participant sample and because some changes in sleep parameters were of a smaller magnitude (particularly objective sleep).

Calculation of sleep characteristics

TST, WASO and SOL were calculated as a median value of the three days that participants recorded their sleep at baseline and at follow up. As the participants were instructed to wear the headband only when they planned to go to sleep, time in bed (TiB) was calculated as the sum of the aforementioned sleep parameters (TST, WASO and SOL) then used as the denominator to calculate SE (with the nominator being TST). This method of calculating SE was chosen because it allows for consistency in the definition of sleep characteristics between subjective- and objective measures.

Between-groups analysis

A Shapiro-Wilke test was conducted to identify variables that violated the normality assumption for parametric testing. For variables for which the Shapiro-Wilk test was not significant, a two-sample T-test was performed. For variables for which data was non-normally distributed the Mann-Whitney U test was used instead.

Exploratory analysis

For the exploratory analysis, a Time by Group interaction was analysed using a GLM analysis to determine whether changes between baseline and follow up differed between each group. Normality was checked visually by examining histograms with residuals plotted.

Results

Demographic and baseline data

All 26 participants provided data sufficient to be included in the analysis. Table 1 provides a breakdown of demographic data, baseline and post-intervention scores for each group. As prescribed in CONSORT guidance (Moher et al., 2010), no statistical test was used to identify baseline differences. Table 2 displays reliability data and that range of responses for each variable.

Table 1

Demographics, mean and standard deviation for the PI and SH group at baseline and follow up.

•		0 1		-		
	PI		SH			
Demographics						
Ν	13		13			
Gender (female)	8		9			
Mean age (SD)	33.6 (17.1)	33.6 (17.1) PI		37.3(13.8)		
				SH		
	Baseline	Follow up	Baseline	Follow up		
Questionnaires						
SCI	8.7(4)	15.8(5.3)	10.4(4.3)	11.0(5.2)		
GSES	8.0(1.8)	3.1(1.8)	6.8(2.7)	5.9(2.3)		
PHQ-9	6.2(3.1)	5.0(2.0)	7.2(2.5)	5.5(2.8)		
SQS	3.7(1.9)	5.5(1.3)	4.2(1.3)	5.1(1.6)		
Subjective sleep parameters						
SOL (mins.)	39.1(20.6)	22.3(16.2)	23.3(14.2)	16.2(16.0)		
TST (mins.)	395(71.0)	435(67.0)	394.3(69.7)	419.4(54.2)		
WASO (mins.)	24.8(17.3)	20(17.4)	28.2(30.3)	22.2(14.3)		
SE (%)	87.6(6.6)	90.9(5.1)	86.9(7.8)	91.7(5.4)		
Objective sleep parameters						
SOL (mins.)	39.1(20.6)	18.7(12.3)	21.8(11.4)	19.0(19.7)		
TST (mins.)	424.7(67.4)	445.8(56.7)	425(76.3)	395.6(124.8)		
WASO (mins.)	28.6(15.1)	18.0(10.1)	25.2(11.0)	25.1(11.6)		
SE (%)	89.6(4.2)	91.6(3.3)	88.1(5.4)	86.7(1.7)		

Note: Questionnaire and sleep parameter scores are provided as means with standard deviation in parentheses. SCI = Sleep condition indicator, GSES= Glasgow Sleep Effort Scale, PHQ-9= Patient Health Questionnaire 9, SQS= Sleep Quality Scale, SOL= Sleep onset latency, TST= Total sleep time, WASO= Wake after sleep onset, SE= Sleep Efficiency, mins.= minutes.

Table 2

Questionnaire reliability data and range scores

	Baseline		Follow up		
	Pre-Intervention Cronbach's Alpha	Range	Post-Intervention Cronbach's Alpha	Range	
Questionnaires					
SCI	.77	3-21	.80	5-23	
GSES	.85	2-12	.66	0-10	
PHQ-9	.70	2-12	.76	2-11	
SQS	-	0-7	-	3-8	
Subjective sleep characteristics					
TST	-	300-520	-	290-550	
WASO	-	0-120	-	0-60	
SOL	-	5-65	-	0-60	
SE(%)	-	70-98	-	82-100	
Objective sleep characteristics					
TST	-	307-530	-	330-542	
WASO	-	8-50	-	7-49	
SOL	-	7-80	-	3-65	
SE(%)	-	78-96	-	50-98	

Note: SCI = Sleep condition indicator, GSES= Glasgow Sleep Effort Scale, PHQ-9= Patient Health Questionnaire 9, SQS= Sleep Quality Scale, SOL= Sleep onset latency, TST= Total sleep time, WASO= Wake after sleep onset, SE= Sleep Efficiency

Between groups analysis

The Shapiro-Wilk test did not indicate that any of the data were non-normal for any of the questionnaires. The two-sample t-test revealed significantly lower post-intervention GSES and SCI scores in the PI group compared to the SH group. Table 2 displays values pertaining to the between group analysis. The effect of PI on GSES ad SCI was "large" according to Cohen's criteria (Cohen, 1988). No significant differences were observed between groups on the PHQ or the SQS.

Questionnaires	df	Т	Cohen's D	<i>p</i> (One-tailed)	<i>p</i> (Two-tailed)
SCI	24	2.31	.91	.015*	.030*
GSES	24	3.49	1.37	<.001**	.002*
PHQ-9	24	.489	.19	.315	.630
SQS	24	.798	.313	.216	.433

Table 2Results of tests of difference

Note: SCI = Sleep condition indicator, GSES= Glasgow Sleep Effort Scale, PHQ-9= Patient Health Questionnaire 9, SQS= Sleep Quality Scale. *p<.05 p<.001**

Exploratory analysis

None of the residuals for sleep characteristics were identified as being non-normal based on histogram plots. Results of the general linear model are displayed in Table 3. No significant time by group interaction effect was observed for any of the variables with the exception of subjective sleep onset latency. In other words, subjective SOL reduced significantly from baseline to follow up in the PI group relative to the SH group, but this was not the case for any of the other sleep characteristics.

Table 3

General linear model	group by	v time interaction	effects for slee	p variables
	Browp of			p analores

	df	F	Sig.	Partial Eta Squared
Objective sleep parameters				
SOL	1	2.37	0.137	.090
TST	1	1.76	.197	.002
WASO	1	.894	.354	.036
SE	1	.417	.525	.000
Subjective sleep parameters				
SOL	1	7.6	.011*	.240
TST	1	.382	.542	.227
WASO	1	.151	.701	.006
SE	1	.281	.601	.012

Note: SOL= Sleep onset latency, TST= Total sleep time, WASO= Wake after sleep onset, SE= Sleep Efficiency, mins.= minutes. *p<.05

Discussion

The aims of this study were to assess the effect of PI on sleep effort and insomnia symptoms, and examine its impact on sleep characteristics measured objectively, using an EEG headband. The study found that PI significantly reduced sleep effort and insomnia symptoms as measured by SCI. A significant reduction in subjective (diary measured) sleep onset latency was also observed in PI condition in comparison to the SH condition, but no significant change was found for other sleep characteristics.

The reduction in self-reported (i.e. SCI) insomnia symptoms observed in this study is consistent with the one previous randomised study that included a global measure of insomnia symptoms (Ong et al., 2022). Furthermore, findings of this study are consistent with the two previous studies that also observed PI to reduce sleep effort using a validated measure (Broomfield & Epsie, 2003; Ong et al., 2022). Of particular interest is the magnitude of change in sleep effort observed in this study. This was substantial, registering a "very large" effect size (d=1.37), greater than that noted in Broomfield and Epsie's (2003) study. Although it is beyond the scope of this study to make any firm conclusions about causal links between insomnia symptoms and sleep effort, these results lend credence to a proposed theoretical mechanism (e.g. Espie, 2002; Espie, 2023) of PI improving insomnia symptoms by reducing sleep effort. Other mechanisms have been suggested for the effect of PI on insomnia (Jansson-Fröjmark et al., 2022) although these were not measured in this research.

In contrast, no significant reduction in symptoms of depression or significant improvement in sleep quality was observed. This was not unexpected, particularly as depression symptoms were on average below threshold (Kroenke et al., 2001) and neither depression nor sleep quality were direct targets of the intervention.

This study also found that change in subjective sleep characteristics did not differ between the PI and SH groups for almost all of the variables included. In terms of subjective measures of sleep, this contrasts with the findings of Jansson-Fröjmark and colleagues (2022) meta-analysis which found moderate to large effects of PI on several sleep characteristics. It is possible that this was due to the limited power in the present study. The notable exception to this was subjective SOL, which was the only sleep variable to reach statistical significance, with a substantial reduction observed in the PI group compared to a more modest reduction in the SH group. In terms of objective sleep, there were no significant differences in pre-post treatment change between the PI and SH groups in any of the included sleep parameters. This is consistent with previous research measuring the effect of PI on objective sleep using actigraphy which also did not detect statistically significant objective sleep effects, including in sleep onset latency (Broomfield and Espie, 2004; Ong et al., 2022).

One way of interpreting the reduction in subjective but not objective sleep observed is that this result reflects PI reducing sleep-state misperception as opposed to sleep onset latency. It has been demonstrated that people with insomnia underestimate their total sleep time in comparison to polysomnographic measurement (Benz et al., 2023) and this discrepancy can be reduced with treatment (Bensen-Boakes et al., 2022). Moreover, given that a substantial reduction in sleep was observed in this study, a reduction in subjective but not objective sleep onset latency would fit with previous findings that sleep effort is associated with subjective sleep characteristics but not sleep characteristics measured by polysomnography (Hertenstein et al., 2015). However, this does challenge the proposition that PI achieves its effects on insomnia by hastening sleep onset latency (Ascher & Efran, 1978; Epsie, 2002; Espie, 2023). Although, it should be cautioned that these findings are not conclusive and are based on limited statistical power. It might be that the reduction of sleep onset latency is

exaggerated for subjective measures but does reflect a more modest degree of change in objective sleep onset latency that could be detected with a sufficient sample size. The lack of effect observed in many of the variables should also be understood in the context of the intended effects of the intervention. Specifically, it is unsurprising that the only variable that showed significant reduction is SOL because this is the target for PI, whereas other variables such as TST may be affected by other factors (e.g. the person's sleep habits). Moreover, average scores for many of the sleep variables were not particularly poor at baseline, and as such lack of improvement may reflect ceiling effects.

This research has several implications. First, it serves to replicate the findings of previous studies that have indicated that PI is an effective, single-component treatment for insomnia that can reduce insomnia symptoms over a short period with limited therapy time (i.e. 2 sessions). This is particularly important given the prevalence of insomnia and limited availability of resources in healthcare services to treat insomnia.

From a theoretical perspective, this study also demonstrates that PI has a strong effect on sleep effort measured using a validated scale, which provides support for theories that tout sleep effort as the underlying mechanism by which PI may reduce insomnia symptoms (Ascher & Efran, 1978; Epsie, 2002). Moreover, implementing an EEG headband did not detect any significant improvements in objective sleep characteristics above actigraphy. This study is to the best of the authors awareness, the first to incorporate such a device to measure the effect of PI (or in fact any intervention) on objective sleep characteristics in insomnia sufferers.

Strengths and Limitations

It is important to highlight the limitations of this study. First, the sample size was small. This is a problem particularly for detecting the effects of the intervention on sleep characteristics, given that sleep varies so substantially between individuals (Tucker et al., 2007) and the small effects found in previous intervention studies (Jansson-Fröjmark et al., 2022; Mitchell et al., 2019). Moreover, the sample that was recruited was from a community (non-clinical) population, which may not generalise to insomnia sufferers encountered in clinical settings.

Another weakness of this study pertains to confounding factors affecting the control group. First, the control condition received only one session of SH in contrast to the two sessions received in the PI group. As such, it is not possible to discount that differential therapist contact time may be accountable for some of the

differences observed between groups. However, previous research has found that most of the change from PI may occur after the first session (Broomfield and Espie, 2003). Moreover, both the PI and SH were delivered by the first author, who was unblinded. While steps were taken to standardise the delivery of each intervention (i.e. structuring sessions using pre-determined handouts), it is possible that awareness of the intervention being delivered may have resulted in researcher expectations contributing to the observed effects in this study. Additionally, we recognise that there is a risk of false positive results given that we did not perform an adjustment to correct for the use of multiple t-tests.

Finally, the Dreem device is a relatively new innovation in the measurement of sleep characteristics. While research that has investigated the Dreem device as a measure of sleep attests to its validity, to the author's knowledge, this research is scant and is affiliated with the supplier (i.e. Arnal et al., 2020).

One of the major strengths of this study is a 100% retention rate. This may be attributed to the significant effort (learning how to use the headband, recording sleep for three nights) participants had to make in order to complete baseline measurements prior to randomisation and the relatively short window that participants were involved in the study.

Future directions

In terms of future research, an important next step is a definitive RCT investigating the effect of PI on subjective and objective sleep. Moreover, research should examine the mechanisms underpinning PI more closely. For example, by determining whether the effect of PI on insomnia symptoms is mediated by sleep effort. It is also pertinent to investigate the effect of PI on other theoretically related constructs proposed by the A-I-E model (Espie, 2023). For example, by examining whether PI reduces sleep-related selective attention via cognitive tasks (Harris et al., 2015). Clinical research on insomnia should also consider measuring sleep via an EEG headband with sufficient statistical power to examine whether such devices can be used to detect changes in sleep characteristics that actigraphy does not identify.

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CHAPTER 5

General Discussion and Critical Evaluation

General discussion

Broadly, this thesis aimed to contribute to the clinical and theoretic understanding of insomnia and its treatment. Two pieces of research were conducted with this aim in mind. In Chapter 2, a systematic review and meta-analysis was conducted, investigating the effect of cognitive behavioural interventions on sleep effort. This was followed up in Chapter 4 with an empirical study examining the specific effect of paradoxical intention therapy, a single component cognitive behavioural insomnia therapeutic, on sleep effort and insomnia symptoms. In this final chapter, the research will be summarised, critically appraised, and suggestions made for future research. The process of conducting the research will also be reflected upon.

Systematic review and Meta-analysis

Chapter 2 described a systematic review which summarised randomised controlled trials evaluating the effect of a cognitive behavioural intervention on sleep effort in adults with insomnia, in comparison to a control condition. A total of six studies were included and had their outcome data synthesised via meta-analysis. Results showed that those treated with a cognitive behavioural intervention saw a significant decrease in sleep effort, with a medium effect size observed. Five out of the six included studies found a reduction in sleep effort. One study found the converse, instead observing an effect in favour of a control condition which consisted of a sham behavioural intervention with therapy time matched with the treatment condition. This was interpreted tentatively as reflecting the more intensive control condition featured in this particular study.

Empirical Research Project

Chapter 4 reported an empirical research project that aimed to establish the effect of paradoxical intention therapy (PI) on sleep effort, questionnaire evaluated insomnia symptoms, subjective sleep (diary) and objective sleep (Dreem headband). The design of the study was a randomised controlled trial, wherein participants were allocated to receive either PI or sleep hygiene educational advice (SH) acting as a control condition. A total of 26 participants were recruited, completing baseline measurements, including tracking sleep using a sleep diary for three days and wearing an EEG headband to measure objective sleep characteristics. Participants were then randomly allocated to receive either PI, or SH. Those in the PI condition (n=13) received two sessions of PI where they were socialised to the rationale for the intervention and encouraged to gently resist sleep onset. Those in the SH condition (n=13) received one session in which they received advice on good

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sleeping practices (e.g. avoiding caffeine close to bedtime). Participants followed PI or SH instructions for 2 weeks after their first (or only) session. Then, the same baseline measures completed at the beginning of the study were repeated.

The key findings of the study were that PI significantly reduced sleep effort and self-reported global insomnia symptoms (i.e. on the SCI) but did not reduce sleep characteristics measured either using sleep diary or EEG headband.

Critical evaluation

Theoretical Implications

This thesis makes an important contribution to the clinical insomnia research literature. The systematic review highlighted that cognitive-behavioural interventions for insomnia disorder can specifically act to reduce sleep effort. This is a significant finding for the insomnia research literature because historically, sleep effort has tended to be assumed to be an underpinning mechanism specifically of PI (Ascher & Efran, 1978). The finding that cognitive behavioural interventions more generally can act to reduce sleep effort is interesting. It suggests that sleep effort is a more versatile construct that can be treated via a spectrum of cognitive behavioural insomnia interventions, as opposed to a mechanism specific to a particular intervention. This helps progress the research literature by laying the foundation for further research to consider measurement of sleep effort as a relevant variable, regardless of the treatment used and suggesting sleep effort in and of itself may be a relevant psychological maintaining factor, in some cases. Future clinical treatment research will of course be required to determine the extent of any causal relationship.

The empirical research project also has theoretical implications. In the literature, sleep effort is described as having an effect on the physiology of sleep (Espie, 2002; Espie, 2023; Espie et al., 2006). To be specific, the psychobiological inhibition model of sleep (Espie, 2002; Espie, 2023) proposes that sleep is an involuntary process that under most circumstances occurs spontaneously in a suitable environment, if the person is in a relaxed psychological state, if there is sufficient sleep pressure, and if sleep is sought at an appropriate window in the circadian rhythm. Sleep effort is argued to inhibit this involuntary initiation of sleep because actively trying to control the onset of what is by definition an involuntary process will always fail, thereby resulting in heightened physiological arousal and in turn, reduced sleep likelihood.

Sleep effort is also the mechanism by which PI is hypothesised to have its effect (Broomfield & Espie, 2003). Specifically, PI explicitly instructs poor sleeping individuals to give up trying to sleep, and instead to lie eyes awake, gently resisting sleep onset. This is assumed to minimise conscious effort to sleep, and thus hasten sleep onset.

Given the above, it would be expected that PI would have a direct effect on objectively measured sleep. And yet the findings of the study described in Chapter Four do not support this. No effect of PI in this instance was observed on objective sleep parameters measured using a homebased EEG headband. This is the first study of PI to deploy ambulatory home-based objective sleep measurement using an EEG headband system although interestingly, in the only two other studies of PI to deploy objective sleep measures (Broomfield and Espie, 2003; Ong et al 2022), mixed findings were similarly noted. Specifically, both Ong and colleagues (2022) and Broomfield & Espie (2003) noted that, consistent with the present finding, PI improved subjective sleep characteristics in individuals with insomnia relative to a control condition, but not objectively measured sleep (actigraphy). It is hard to draw firm conclusions based on just three studies and further work replicating these will of course be required. However, the present data and those of the two previous studies investigating the effect of PI on objective sleep might suggest that sleep effort may result in the exaggerated sleep-state misperception found in insomnia sufferers (Yoon et al., 2022).

Clinical implications

This thesis portfolio also has clinical implications. In the systematic review, it was found that cognitive behavioural interventions acted to significantly reduce sleep effort, as measured using a valid and reliable psychometric (Glasgow Sleep Effort Scale; Broomfield & Espie, 2005). This is noteworthy, as sleep effort has traditionally been considered as a mechanism of change specifically associated with PI. Given that cognitive behavioural interventions in general also appear to reduce sleep effort, a targeted therapy such as PI may not be necessary to treat individuals presenting in the clinic with insomnia disorder and a high sleep effort score. In clinical practice, it may not be crucial to adjust treatment strategies to specifically target sleep effort in the initial stages of intervention.

Moreover, in the empirical research project, it was found that PI reduced global self-reported insomnia symptoms when delivered in a brief format over the course of two sessions, when compared to sleep hygiene education (SH). This finding holds significant clinical implications, considering the limited resources currently seen within the UK National Health Service (NHS). Specifically, offering PI as a brief intervention could be an efficient way to address insomnia in primary care. Particularly given that the intervention featured in this study was straightforward and based around standardised instructions. Moreover, it could be advisable on the basis of these present findings to simply exchange sleep hygiene education for PI directives, given that sleep hygiene is already delivered routinely within primary care settings (Aziz & Titova-Chaudhry, 2017). SH is typically what people reporting poor sleep usually receive, despite no evidence in favour of its utility as a single component therapy (Furukawa et al., 2024). Notably, GSES was designed specifically to measure sleep effort, and has been shown to reliably discriminate people with insomnia disorder from good sleepers (Broomfield & Espie, 2005). This lends weight to the hypothesis that the presence of sleep effort may signal insomnia disorder beyond any doubt (i.e. that effort is pathognomonic of insomnia disorder) and in turn, that PI may present an ideal candidate for insomnia management in the primary care setting. It is important to note that the present research recruited participants from a community dwelling (non-clinic presenting) sample, and therefore may not generalise to patients who present in primary care settings with insomnia disorder. Future research should replicate these findings in a clinical sample first, before implementing roll out of PI in primary care as a generalist treatment approach.

Strengths and Limitations

There are several strengths of this thesis. Firstly, the work relied on robust methodologies that aimed to minimise the impact of bias on the data. In the systematic review and meta-analysis, this took the form of the inclusion of only high-quality evidence (i.e. randomised control trials) and a systematic approach to the identification and appraisal of evidence. The characteristics of the empirical paper that reflected this robust approach were the use of randomisation to allocate participants to independent groups and the use of an intention-to-treat analysis, alongside literature standard PI and SH instruction sets and delivery format, and the use of established, validated questionnaires. These approaches minimised selection bias and the imposition of the researcher's values on the results of the study, thereby increasing the external validity of the research and adding credibility to the findings.

A further strength of the empirical research project is that it incorporated a novel method of measuring sleep characteristics (i.e. with an EEG headband). Previous research (Broomfield & Espie, 2005; Ong et al., 2022) investigated the effect of PI on actigraphy, however recent research has brought the validity of actigraphy into question, particularly for the purposes of insomnia research based on the fact that actigraphy cannot reliably distinguish between healthy sleepers and insomnia sufferers (Rösler et al., 2023). The empirical research project took an innovative approach to measuring objective sleep parameters in making use of new technologies to confirm previous research findings.

A strength of the systematic review and meta-analysis was the narrow focus, on a single insomnia process. This allowed for a comprehensive search for relevant data. This is particularly advantageous in this case, because sleep effort was not included as a primary outcome in most of the studies identified and in some cases was not even reported in the primary publication for papers. Indeed, meta-analysis examining the effect of CBT published recently did not find any randomised control trials where sleep effort was included as an outcome (Thakral et al., 2020). However, in some cases, relevant data were either not reported at all, as seen in this study, or are yet to be published and currently only available in grey literature. The approach used here therefore provides a number of advantages. First it made maximum use of the data available, increasing statistical power. Secondly, it reduced the influence of bias due to selective publishing of studies (and the data/results therein) in academic journals in favour of positive results (Thornton & Lee, 2000).

There are limitations to this thesis portfolio. Firstly, both research projects included a limited quantity of data. The systematic review and meta-analysis included only six studies and the empirical paper contained only 26 participants. For the systematic review, specifically, this meant that heterogeneity could not be examined. This made it challenging to have confidence about the source of heterogeneity in the studies and in drawing conclusions about the variability of effect sizes. For example, one of the studies in the review found significantly greater sleep effort in the control group over the intervention group. The lack of studies made it difficult to tell whether this was an outlier, due to the specific characteristics of the study, or whether this could have been expected given the variability of effect sizes between the studies. In terms of the empirical research project, the small sample size limited statistical power. This presented an issue, because almost all of the subjective and objectively measured sleep characteristic effects were non-significant. A lack of statistical power meant that it

was not possible to rule out the possibility that PI had an effect on those variables but not large enough to be detected.

A further limitation of the research contained within this portfolio is that all research activities were conducted by a single researcher (albeit under the supervision of two experienced researchers). Broadly, this may have increased the possibility of bias or error effecting the research practices. For instance, in the empirical study, both the intervention and control conditions were delivered by the same person. This may have unintentionally affected the way in which the sessions were delivered, impacting the results (e.g. due to imparting the expectations of the researcher on the direction of the effect onto participants).

This contrasts substantially with research with similar aims in the insomnia research literature. For example, Manber and colleagues (2016) conducted a research trial investigating the effect of cognitive behavioural therapy for insomnia in conjunction with antidepressants in participants who had comorbid depression and insomnia. In their trial, both pharmacotherapy, and CBT-I, were delivered by clinicians who were not a part of the research team. Because the pharmacotherapy was delivered to both groups, this made it possible to blind psychiatrists to the group assignment of participants. Similarly, outcome measurements were taken by raters who were blind to the condition of participants. This was addressed in the systematic review to some extent, with the inclusion of a second rater to independently screen articles, and to check one third of the papers regarding risk of bias and data extraction. However, other reviews in the relevant literature include independent raters throughout the screening, data extraction and risk of bias assessment stages (Jike et al., 2018). Consequently, the reliability of the work done in this thesis may be less than that of other research conducted and there is a greater risk that the researcher's values may have had an impact on the results than in similar, albeit better resourced research.

Directions for Future Research

Considering the findings described in this thesis portfolio, several directions for future research can be suggested. First, there are few studies that measure sleep effort. Further research is clearly needed to provide additional insight into the effect of cognitive behavioural interventions on sleep effort. For example, by comparing different interventions to others (i.e. PI compared to multicomponent CBT). This would clarify how clinicians could most effectively target sleep effort in cases where this is a significant feature of a client's

presentation. Similarly, the empirical research project described here was a small-scale study, similar to others that have investigated the effect of PI on sleep characteristics and sleep effort (Broomfield & Espie, 2003; Ong et al., 2022). A definitive randomised control trial would seem a suitable and required next step in the PI literature. Moreover, future research should trial the delivery of PI in primary health settings to examine the feasibility of incorporating it as a more effective alternative to sleep hygiene educational advice. Finally, future research should elucidate the relationship between change in insomnia symptoms as a result of treatment and change in sleep effort. Namely, by investigating whether change in sleep effort is a process that underpins change in insomnia symptoms, or whether the two reduce independently of each other.

Reflections on the Process of Conducting Research

I had very limited exposure to research prior to conducting the research for this portfolio, although I had read a lot of it. The part of the process that I enjoyed the most was designing a system that dealt with the logistics of the practical elements of the empirical project (e.g. advertising, enrolling participants, providing them with materials etc). I found it rewarding to consider where the limiting factor was and relished the opportunity to creatively tackle these problems within the constrained resources available. I believe that through this process, I have developed skills in appraising, designing and adjusting processes. I hope to apply this to my future work as a psychologist in NHS services. I also learnt that even with the best planning and preparation, research does not always go to plan. The biggest unanticipated setbacks throughout the process were losing a systematic review after an unregistered review on the same topic was published, which resulted in the loss of several months of work. And also the rights for the EEG headband being sold to another company, which resulted in unanticipated disruption to research activities and premature ceasing of data collection due to the new company requesting a significant financial sum for continued use of the EEG headbands. Finally, it was hard to predict many of the factors that I relied upon for the research to be a success (e.g. the willingness of people to take part). However, I also learnt a lot from this. In particular, that it is important to be adaptable when a plan cannot be executed.

Conclusion

Among the many processes proposed to underpin insomnia, sleep effort is an emerging, under researched yet important one. This thesis portfolio is constituted of two parts. First, in a systematic review and meta-analysis, relevant studies were identified and data synthesised to investigate the effect of cognitive

behavioural interventions on sleep effort. This research found that cognitive behavioural interventions have a moderate effect on sleep effort. In the empirical research project, primary data was collected to examine the effect of paradoxical intention therapy on insomnia symptoms, sleep effort and subjective (diary) and objective (EEG headband) sleep. Significant reductions in global self-reported insomnia symptoms and sleep effort were found, although there were no significant effects observed for sleep characteristics. This research has important clinical and theoretical implications.

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Appendix A

Author Guidelines: Sleep Medicine Reviews

INSTRUCTIONS FOR AUTHORS

Sleep Medicine *Reviews*

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Aims and scope

The aim of this journal is to review all aspects of sleep medicine. It will provide in-depth and up-to-date Clinical Reviews of sleep disorders, including their aetiology, diagnosis, treatment and implications for related conditions at an individual and a public health level, as well as Physiological Reviews, Theoretical Reviews and Historical Notes.

Clinical and (patho)physiological information about sleep disorders published in peer-reviewed journals devoted to the many disciplines involved in sleep medicine are reviewed. These disciplines include cardiology, dentistry, endocrinology, general medicine, geriatrics, neurology, ORL, paediatrics, pharmacology, physiology, psychiatry, psychology and pulmonology.

The journal intends to be an international forum for opinion within the field of sleep medicine, covering areas of controversy and debate as well as areas of future research. It publishes narrative reviews, systematic reviews and editorials primarily for the clinician. Submission of systematic or meta-analytic reviews following validated guidelines is encouraged.

Submission of papers

Articles are invited from recognised experts. Individuals who wish to submit an article should initially contact the Editor-in-Chief at the (e-mail) address above.

Manuscripts will only be accepted on the strict understanding that they are original publications that have not been published previously or are not under consideration for publication by other journals.

Please note that the readership of this journal comprises many different medical disciplines. Please ensure that your article will be accessible to all readers.

The final section of each article should highlight the important points raised in the article, summarise the current state of knowledge in the area and outline future avenues of research.

Presentation of papers

Submitted manuscripts must be written in Standard English - Times New Roman 'Font 12'. American or British usage is accepted, but not a mixture of these. If the authors are not native English speakers, it is strongly suggested that before submission they have their manuscript reviewed by a native English speaker or that they utilize a professional editing service.

English language service is also provided via the Elsevier WebShop at http://webshop.elsevier.com/languageediting/

The submitted manuscript should be typed double-spaced (i.e. a full line space between every typed line). Margins of at least 25 mm (1 inch) should be left on all sides.

Key Points for Authors

1. Unless otherwise directed, articles should be **a maximum of 8000 words long** including figures, tables and references.

(As a guide for conversion, a half-page illustration or table is equivalent to 250 words of text.

2. Include a **Summary** and **Keywords** for each article.

3. The results reported in the Results section should not duplicate the table(s), but rather comment and synthesize the results reported in the table(s).

The discussion should not be a summary of the results, but rather should put them into perspective and discuss their implications.

4. The **final section** of each article should highlight the important points raised in the article, summarise the current state of knowledge in the area and outline future avenues of research. This should be presented in boxed format as **Practice Points** and **Research Agenda**. However, wherever these summary points are necessarily extensive, the author may prefer to break them up and group them at the end of relevant sections within the text. *It is very important that these items are included with all clinical, physiological and theoretical reviews.*

5. Conflicts of interest and Acknowledgements should be noted on the title page and should be set off by specific headings.

6. **References** should be presented according to the Vancouver numbered style 3 (including figures and tables).

(See page 5 for more information)5. All **Abbreviations** must be explained in full when first used; a full alphabetically ordered list of abbreviations and definitions used in your review should be provided.

7. **Text and tables** should be double spaced and clearly laid out with suitable headings. Abbreviations used in tables and figures should be defined in their legend, even if they were defined elsewhere in the text

8. **Illustrations and tables** should be used wherever appropriate. They should be clear and precise. All tables, figures including supplementary ones should be numbered and referred to in the body of text

The title page of the article should include the title of the paper and full name (First Name, Middle initial (if any), Last Name) and affiliation of each author. Please indicate who is to be the corresponding author with a full address including with email address, telephone and fax numbers. A shortened version of the title should also be included for use in running heads.

Please avoid footnotes where possible.

Your article should include:

Summary The second page of your article should contain the summary (which should not exceed 200 words). This should be comprehensible to readers before they have read the paper. References, illustrations and tables should not be mentioned; acronyms and abbreviations should be avoided in the summary . Sleep Medicine Reviews does not publish research papers and therefore the summary should not be structured

Keywords. Three to ten key words should be given below the summary, to be used for indexing purposes.

Glossary of terms. Please include an explanatory list of uncommon or difficult terms used in the text following the Summary. This list should be clear and concise.

Capitalization, Capital letters should only be used for proper names and any references to things such as scores, indexes, syndromes etc. (e.g., Epworth sleepiness score, quality index, restless legs syndrome). In figures, too many capitals make it difficult to identify separate items. Only the first letter of each item should be capitalized (e.g., "Systemic hypertension" rather than "Systemic Hypertension"; "Lack of control Separation from parents" rather than "Lack Of Control Separation From Parents")

Abbreviations. All abbreviations and acronyms used in a manuscript must be explained in full when first used in the Summay, again when first used in the body of a manuscript or in a table. Authors should try to restrict the use of abbreviations/acronyms to the most commonly used terms. Abbreviated expressions should not be capitalized: It should be "restless legs syndrome (RLS)" and not "Restless Legs Syndrome (RLS)".

All abbreviations will be listed following the Summary and Keywords in alphabetical order either as a footnote (< 10 abbreviations), or in an abbreviation box (> 10 abbreviations). The list of abbreviations should include only the abbreviations used in the body of the text. Abbreviations used only in tables and figures should be defined *in alphabetical order* in the respective legends of tables and figures. Abbreviations used both in the body of the text and tables and figures should be defined again in the respective legends of tables and figures.

Units. Spell out all numbers under ten; numbers 10 and over should appear as digits. Please note, numbers should appear as numerics if part of a formula or as an expression of units (e.g. 2kg)."The International System of Units (SI) should be applied (e.g. mm, kg etc.); use s for second, min for minute, d for day, wk for week, mo for month and y for year

Drugs. Generic names should be used. Proprietary names may follow in parentheses (include both English and American names if different). Great care should be taken in describing the use of drugs and details of the regimen should be thoroughly checked.

Genetics. All genes should be underlined to indicate italicization. Proteins should be left as Roman.

Text. Underline only the words or letters that should appear in italics. Clearly identify unusual hand-written symbols and Greek letters. Differentiate between the letter "O" and zero and the letters I and L and the number 1.

Lists of items may be numbered 1) ... 2) ... 3) ...but NOT (1) ... (2) ... (3) ... to avoid confusion with references.

Practice Points. Present the important points for readers to remember in clearly indicated box(es), e.g.:

Practice Points

- Sleep apnea clinical prediction rules may be useful to:
- 1. exclude the diagnosis when the probability is low and the patient has insignificant symptoms;
- 2. establish an *a priori* probability before considering the utilization of a non-PSG diagnostic method;
- 3. prioritize patients for polysomnography according to the probability that they will have a positive result.

Research Agenda. Please indicate points which you feel would repay further research in box(es), e.g.:

Research Agenda

In the future we need to be able to not only predict those with sleep apnea, but also which patients:

1. are at highest risk of morbidity and mortality and whether this risk can be modified by treatment;

- 2. obtain the most significant improvement in their quality of life as a result of treatment;
- 3. are most likely to be compliant with therapy.

It is recommended not to use acronyms or abbreviations in the Research Agenda and the Practice Points.

Please note that *Practice Points and Research Agenda* are standard features of reviews published in *Sleep Medicine Reviews* and we ask that authors to pay particular attention to incorporating these into their reviews before submitting the article.

Acknowledgements for personal and technical assistance should be indicated on the title page. Financial support and any conflict of interest are also to be stated in the acknowledgements (see above). The source of equipment and drugs may be included here as well.

Authors are actively encouraged to use tables and other forms of illustration where appropriate. Tables and Figures must however be fully self-explanatory; all abbreviations and acronyms used should be defined in their legends, even if defined elsewhere in the manuscript.

Tables should be quoted in the text (e.g. "See table 1"). Tables should be numbered consecutively using Arabic numerals in the order in which they are cited in the text. Each table should be typed in double spacing on a separate page and given a brief explanatory caption. Please us a simple lay out for tables, it is recommended **not** to use vertical lines or boxes

Tables with a systematic overview of the included studies should be ordered either on the first author name, or on year of publication. With author names in the first column please use the same format as used in the text (author names if one or two authors, first author followed by et al. if more than 2 authors). In the latter case, the year of publication should be mentioned in the first column of the table, together with the first author name and reference number of the study. Studies should be alternatively (lightly) shaded and not shaded, in order to clearly separate them.

Authors, reference number	Study type	Type of patients	# SUDEP	# SUDEP during sleep	In bed	% of SR- SUDEP
Antoniuk SA et al 2001 ⁴¹	Uncontrolled descriptive study	Unselected epileptic patients	20	2/8 witnessed deaths	13	25%
Donner EJ et al 2001 ⁴²	Uncontrolled descriptive study	Children	27		16	59%
Hitiris N et al 2007 ²⁹	Case-control study §	Medically refractory epilepsy	62	-	59	95%

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References: The references should represent the most recent and pertinent literature available. It is essential that the references are thoroughly checked by the author as inaccuracies cannot be detected by the publisher. **A maximum of 100 references should be included**.

Whenever a study is cited, it should be followed by the respective reference number in the body of the text, but also in the tables and in the figures.

- References should follow the Vancouver numerical style 3. Indicate references in the text by number(s) in square brackets [1] to [100] in line with the text.

- The actual authors can be referred to, but the reference number(s) must always be given.

- Number the references (numbers in square brackets) in the list at the end of the paper in the order in which they appear in the text.

- In the reference list supply all author names up to 6 author names, then use "et al." In Endnote use style 3a like in: comp thera clin pract.ens (Complementary Therapies in Clinical Practice

Examples

1. Barnes P, Holgate ST. Pathogenesis and hyperreactivity: In Brewis RAL, Gibson J, Geddes DM (eds) *Respiratory Medicine*, 3rd Edition. London: WB Saunders 1994: 558-9

2. Shepard JW Jr, Buysse DJ, Chesson AL Jr, Dement WC, Goldberg R, Guilleminault C, et al. History of the development of sleep medicine in the United States. *J Clin Sleep Med* 2005; **1:** 61-82.

Papers that have already been accepted but not yet published, should be indicated in the reference list followed by ("in press"). Papers in preparation, including those already submitted for publication, personal communications and unpublished observations should be referred to in the text only.

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- Ensure that your files are not saved as read only

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Summary

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- 2. Use clearly indicated headings throughout.
- 3. Use double line spacing throughout.
- 4. Leave margins of at least 25 mm (1 inch) all around the page.

5. Present the article in the following order: title page, summary, key words, glossary of terms, text, acknowledgements, references, (figure legends and captions), figures, tables

6. Tables can be part of the Word document with the text or can be uploaded as a separate Word or as separate spreadsheet-files. Figures are to be uploaded in one or more separate files using the original format of the program that produced the figure. Preferred formats for figures are eps and tiff; jpg, ppt, xls and pdf are also acceptable for production purposes

- 7. Include **Practice Points** and a **Research Agenda** in separate boxes.
- 8. Spelling should be English throughout; be consistent in American or British usage.
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Appendix B

Journal of Clinical Sleep Medicine Author Guidelines



Manuscript Submission Guidelines

Quick Links

- About Journal of Clinical Sleep Medicine
- Manuscript Submission Instructions
- Submission Fee
- Categories of Manuscripts
- Essential Elements of Manuscript Submissions
- Manuscript Format
- Details of Style
- Figure Guidelines
- Table Guidelines
- Supplemental Material Guidelines
- <u>Review Process</u>
- <u>After Acceptance</u>
- <u>REM: A Publication for Residents and Fellows</u>

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:

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- 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.
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Journal stats:

- 2022 Impact Factor: 4.3
- 5-year Impact Factor: 5.3
- Google Scholar h-5 index of 56 and an h-5 median of 82
- Visitors: More than 60,000 monthly, including 125,000 pageviews

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Manuscript Submission Instructions

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

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, Durable Medical Equipment, Research Epochs and Case Reports. (No fee is required for Editorials; Commentaries; Letters to the Editor; Sleep Medicine Pearls; Global Practice of Sleep Medicine; 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 theemail 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

All manuscripts, unless otherwise stated in the particular manuscript category, must follow JCSM's guidelines for <u>Essential Elements of Manuscript Submissions</u>, <u>Manuscript Format</u>, <u>Details of Style</u>, <u>Figure Guidelines</u>, and <u>Table Guidelines</u>. 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 participants.
- 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:
 - 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.
- 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 <u>icsmeditor@aasm.org</u> to ensure that a similar work has not already been submitted. A completed PRISMA checklist and flow diagram are required when reporting findings from a systematic review or meta-analysis. Templates for these can be on the PRISMA website, which also describes several PRISMA checklist extensions for different designs and types of data beyond conventional systematic reviews evaluating randomized trials (<u>https://www.prisma-statement.org/</u>). At minimum, your article should report the content addressed by each item of the checklist. Meeting these basic reporting requirements will greatly

improve the value of your review and may enhance its chances for eventual publication. 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. No more than a total of 5 tables and figures are permitted. Additional tables and figures can be submitted as <u>supplemental material</u>.
- 5. The structured abstract, references, tables and figures are not included in the 7,500-word limit.
- 6. If a meta-analysis is part of the review, it must follow PRISMA reporting guidelines or MOOSE reporting guidelines and a PRISMA-style flow diagram should be included as **supplemental material**. It is strongly encouraged to provide a table with ratings of the quality of the studies/evidence.

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 assessmentor treatment of insomnia, 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 affectivedisorders; 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. 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.
- 2. In general, manuscripts should be 1,500 to 2,000 words in length.
- 3. References should be limited to no more than 30 citations.
- 4. The references are not included in the 2,000-word limit.

In addition, it is recommended that authors include the following headings in their manuscript:

1. Introduction: size of the country, country population and demographics (adult and pediatric census data), health care system (single payer, employer-based, etc.), physician to patient ratio, use of general practitioners as gatekeepers.

- 2. Sleep Medicine Training: Is a formal sleep fellowship a requirement? The number of training programs and fellowship positions available.
- 3. 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.
- 4. 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?
- 5. 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?
- 6. Conclusions

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.

Research Epochs

Research epochs are short reports of research findings. This type of publication is appropriate when there is insufficient data for a full manuscript, but the clinical research is of high quality, novel, or has the potential for significant impact. Research epochs should be no more than 1,200 words and 10 references. One figure and/or one table are permitted, but they should be of critical importance to the publication. A brief unstructured abstract is required (no more than 150 words). Supplemental material are not permitted for this article type.

Letters to the Editor

Brief letters (maximum of 500 words, including references; no tables or figures) will be considered. A signed author agreement form is a requirement for all authors listed on a letter. 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 issuestimate. Authors are advised to contact the Editor-in-Chief at issuestimate. Authors are advised to contact the Editor-in-Chief at issuestimate. Authors are advised to contact the Editor-in-Chief at issuestimate. Authors are advised to contact the Editor-in-Chief at issuestimate.

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 (ANZCTR): 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
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- ISRCTN Register: http://isrctn.org
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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.

Third-Party Copyright

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 the first night polysomnography.). For further guidelines, see <u>Table Guidelines</u>.

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 choreathetosis. *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.

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 <u>AASM Style Guide for Sleep Medicine</u> <u>Terminology</u>. Authors should use respiratory event index (REI) instead of using apneahypopnea 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 <u>People-Centered Language Recommendations for Sleep Research</u> <u>Communication</u> by Rebecca E. Fuoco, MPH.

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Figure Guidelines

All figure files must follow the <u>JCSM digital art guidelines</u>. Images created by generative artificial intelligence technology are not permitted. Submitted figures that do not meet these 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 total number of figures on the title page of the manuscript submission.

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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 <u>Third-Party Copyright</u>.
- 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

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:

- **Response to reviewers**: a letter that lists all comments made by reviewers and a response to each.
- **Redlined version**: a version of the manuscript that shows all edits made from the prior version. Please note that our manuscript submission system cannot accept Word DOC files that include tracked changes. Authors must convert the Word DOC file to PDF and upload the PDF if using Word's track changes mode to show revisions. If authors are not able to create a PDF file of the redlined version, they can use alternative font colors or highlighting tools in Word to show edits.
- Manuscript: a clean copy of the revised manuscript.
- Please ensure all **figures**, **tables** and **supplemental material**, if separate from the manuscript file, are included with every resubmission.

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 submitted 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); and 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 issuea 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 Form

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. Before publication in an issue, 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 (<u>publications@aasm.org</u>) 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. When an article appears in an issue, it is removed from the Accepted Papers page.

All papers appearing in JCSM, including online Accepted Papers, are copyright of the American Academy of Sleep Medicine and may not be used in any form without written permission from the American Academy of Sleep Medicine.

Ahead of Print Abstracts

All accepted papers will be deposited to the PubMed website as an ahead of print (AOP) listing. The AOP listings include only the manuscript's abstract. 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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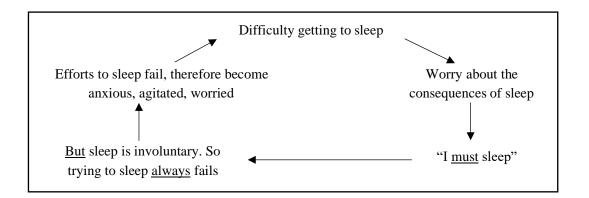
Last updated 9/1/2023

Appendix C

Paradoxical intention instructions.

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. <u>Do not purposefully make yourself stay awake</u>, 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 D

Sleep hygiene instructions

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. 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. 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!

Appendix E

Confirmation of ethical approval.

Henry Bristowe (MED - Postgraduate Researcher)

University of East Anglia

Study title: The Effect of Paradoxical Intention Therapy on Objective Sleep and Effort in Insomnia Sufferers: A randomised control trial

Application ID: ETH2122-2245

Dear Henry,

Your application was considered on 12th January 2023 by the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee).

The decision is: **approved**.

You are therefore able to start your project subject to any other necessary approvals being given.

If your study involves NHS staff and facilities, you will require Health Research Authority (HRA) governance approval before you can start this project (even though you did not require NHS-REC ethics approval). Please consult the HRA webpage about the application required, which is submitted through the IRAS system.

This approval will expire on **1st June 2024**.

Please note that your project is granted ethics approval only for the length of time identified above. Any extension to a project must obtain ethics approval by the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) before continuing.

It is a requirement of this ethics approval that you should report any adverse events which occur during your project to the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics

Subcommittee) as soon as possible. An adverse event is one which was not anticipated in the research design, and which could potentially cause risk or harm to the participants or the researcher, or which reveals potential risks in the treatment under evaluation. For research involving animals, it may be the unintended death of an animal after trapping or carrying out a procedure.

Any amendments to your submitted project in terms of design, sample, data collection, focus etc. should be notified to the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) in advance to ensure ethical compliance. If the amendments are substantial a new application may be required.

Please can you send your report once your project is completed to SIRG (<u>student.survey.request@uea.ac.uk</u>).

Approval by the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee) should not be taken as evidence that your study is compliant with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. If you need guidance on how to make your study UK GDPR compliant, please contact the UEA Data Protection Officer (dataprotection@uea.ac.uk).

Please can you send your report once your project is completed to the FMH S-REC (<u>fmh.ethics@uea.ac.uk</u>).

I would like to wish you every success with your project.

On behalf of the FMH S-REC (Faculty of Medicine and Health Sciences Research Ethics Subcommittee)

Yours sincerely,

Paul Linsley

Ethics ETH2122-2245 : Mr Henry Bristowe

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