Improving Sleep for Older Adults: A Feasibility Study

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Thesis Portfolio Abstract

Background: Cognitive Behavioural Therapy for Insomnia (CBT-I) and Brief Behavioural Treatment for Insomnia (BBTI) are recommended interventions for older adults with insomnia. However, adherence to these interventions can be difficult for older adults. One way to increase adherence is to utilise a modified method called countercontrol. Research in this area is lacking despite the negative impact insomnia has on older adults' sleep, wellbeing, and cognition.

Methods: A systematic review explored the effects of CBT-I on cognitive performance for older adults with insomnia. An empirical study explored the feasibility and acceptability of BBTI with countercontrol in older adults with insomnia. Secondary aims of the study explored whether BBTI with countercontrol lead to measurable changes in sleep quality, cognition, and mental wellbeing in older adults with insomnia, and explored how the objective and self-reported measures of sleep compare to each other.

Results: Seven original papers were included in the systematic review. Most found CBT-I improved cognitive performance in one or more domains of cognitive performance: overall cognitive function, memory, executive function, and attention. The empirical study found BBTI with countercontrol to be feasible and acceptable to older adults with insomnia. All participants were retained and adhered to the intervention. Participants in the BBTI group cited countercontrol as one of the most useful elements of the intervention. Results also revealed that BBTI with countercontrol significantly improved self-reported measures of sleep, wellbeing, and cognition. Clear discrepancies were observed between the objective and self-reported measures of sleep.

Conclusions: BBTI with countercontrol is a feasible and acceptable intervention for older adults with insomnia, and leads to improved sleep, wellbeing, and cognition. However further research in this field is required to contribute to the knowledge and clinical practice of older adults with insomnia.

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Chapter One:

Introduction to the Thesis Portfolio

Introduction to the Thesis Portfolio

According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association [APA], 2013) and the International Classification of Sleep Disorders (ICSD-3; American Academy of Sleep Medicine, 2014), insomnia is a condition that causes significant distress or impairment and is characterised by dissatisfaction with sleep quantity or quality as evidenced by one or more of the following symptoms: difficulty initiating sleep, difficulty maintaining sleep, or early-morning awakenings. To meet criteria for insomnia, symptoms must be present for at least three nights per week, for a minimum of three months, despite adequate opportunity for sleep.

Epidemiological studies have highlighted that compared to young and middle-aged adults, older adults are more likely to have clinical levels of sleep difficulties and receive a diagnosis of insomnia (Morin et al., 2006; Klink et al., 1992). Indeed, sleep difficulties are prevalent among older adults, with over 50% reporting difficulty with their sleep (Crowley, 2011). This may be because the structure of human sleep evolves throughout life and becomes shorter, lighter, and more fragmented, with an increased number of awakenings throughout the night (Boselli et al.,1998). Further, the circadian system shows age-related changes, with sleep becoming more desynchronised. This suggests older adults fall asleep earlier in the evening, wake up earlier in the morning, and experience sleepiness during the day (Revell et al., 2006). Other factors which put older adults at an increased risk for insomnia include reduced mobility, nocturia (i.e., waking up to use the bathroom), decreased social interaction, and increased caregiving responsibilities (Patel et al., 2018).

Given that the world's population of older adults is growing with the proportion of those aged ≥60 years 11% in 2010, estimated to reach 22% in 2050, it is therefore likely that the prevalence of insomnia will continue to increase.

The Impact of Insomnia on Older Adults

Insomnia has been linked to a range of negative physical and mental health outcomes in older adults, from reduced quality-of-life to a greater risk of mortality. Insomnia and mental health difficulties, such as depression and anxiety, have a bidirectional relationship (Jansson-Frojmark & Lindblom, 2008). A meta-analysis indicated that 10.6% of older adults have insomnia, depression, and anxiety (Bao, 2017). Further, when insomnia is left untreated

the risk for depression increases and confers an increased risk of suicidal tendencies (Pigeon et al., 2012).

Insomnia has also been linked to several physical health difficulties. A systematic review and meta-analysis revealed insomnia increases the risk of developing diabetes mellitus, hypertension, cardiovascular diseases, coronary heart diseases, obesity, chronic pain, stroke, and cancer (Stoller, 1994).

In addition, insomnia is linked to a decrease in cognitive decline and structural brain changes, including reduced bilateral hippocampal volume and atrophy in the hippocampus compared to individuals without insomnia (Fortier-Brochu et al., 2012). Further, studies have revealed those with insomnia have more than a 1.5–2.4 increased risk of developing Alzheimer's Disease (AD), and those with AD and insomnia experience a faster cognitive decline than those without insomnia (Osorio et al., 2011).

It is worth noting the substantial impact insomnia has on society. Insomnia is a public health concern, and it is estimated to cost the United Kingdom £40 billion per annum (Hafner et al., 2017). Additional costs are also incurred from increased healthcare expenditure and accident risk, with higher healthcare costs for older adults with insomnia and comorbidities (Anderson et al., 2014).

A Conceptual Model of Insomnia

Insomnia in older adults has long been considered the result of aging biological processes and thus an inevitable fate of older age. However, accumulating evidence points to a multifactorial origin, where health, psychological, situational, and environmental factors play an important role in the initiation and maintenance of sleep difficulties. Spielman et al. (1987) demonstrated a three-factor model for understanding the etiology and persistence of insomnia. This model identifies several predisposing, precipitating, and perpetuating factors.

Predisposing factors include demographic, biologic, psychological, and social characteristics. For instance, research has evidenced that females are 1.7 times more likely to have insomnia than men. Those divorced, separated, or widowed are also more likely to have insomnia than married individuals. Lower levels of education or income may contribute to

insomnia, and smoking, alcohol use, and reduced physical activity are other factors associated with higher rates of insomnia in older adults (Patel et al., 2010).

Precipitating factors include stressful life events or medical conditions that may affect sleep (Bastien et al., 2004). For most individuals, sleep is normally restored after the stressful event, however for others sleep disturbances will develop a chronic course. Older adults with respiratory symptoms, physical disability, and poor perceived health are at increased risk of insomnia. Medication such as beta blockers, glucocorticoids, nonsteroidal anti-inflammatory drugs, decongestants, and antiandrogens may be one of the factors contributing to insomnia. Several studies have demonstrated that older adults with depression and anxiety have higher rates of insomnia (Foley et al., 1999; Brenes et al., 2009).

Perpetuating Factors consist of behavioural or cognitive changes that arise because of sleep difficulties and insomnia. This includes spending excessive time in bed, frequent naps, and conditioning (e.g., anxiety before sleep onset due to fear of another sleepless night, alongside heightened sleep effort).

According to this model, behavioural and psychological factors are often involved in perpetuating insomnia over time, regardless of the nature of the precipitating event (Morin, 1993; Spielman et al., 1987). In older adults, this may include poor sleep habits, irregular sleep-wake schedules, and misconceptions and unrealistic expectations about normal sleep which interplay to maintain sleep difficulties in a vicious cycle (Morin et al., 2006). Thus, treatment should focus on these maintaining factors.

Treatment of Insomnia

Despite the high prevalence of insomnia and its negative impact among older adults, only 5% seek treatment (Ancoli-Israel & Roth, 1999). Instead, many will self-medicate using alcohol as a sedative, taking over-the-counter drugs, dietary supplements, and natural products (Morin et al., 2006). This can cause adverse effects (e.g., drug interactions) and can exacerbate insomnia (Sproule et al., 1999).

The first line of treatment for insomnia tends to involve medication. However, for older adults' significant risks are associated with its long-term use, including memory impairment, falls, and accidents (Glass et al., 2005).

An alternative to medication is Cognitive Behavioural Therapy for Insomnia (CBT-I). CBT-I is an effective and first-line treatment option for older adults with insomnia (Irwin et al., 2006). CBT-I is a multi-component treatment that consists of sleep education, sleep hygiene, stimulus control, sleep restriction, cognitive restructuring, and relaxation training (Morin et al., 2006). However, despite cognitive difficulties featuring in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association [APA], 2013) and the International Classification of Sleep Disorders (ICSD-3; American Academy of Sleep Medicine, 2014), there has been little evaluation of the impact of CBT-I on cognitive performance. This is important since impairments in cognitive abilities are among the most reported symptoms of insomnia (Fortier-Brochu et al., 2012). Older adults report deficits in attention, concentration and memory which impacts on their decision making, social functioning and daily activities (Carey et al., 2005). Difficulties in cognition negatively impacts older adults through decreasing their quality of life, increasing their costs of care, and putting them at an increased risk of accidents and mortality (Klepac et al., 2008). Thus, CBT-I should aim to improve not only sleep, but also the cognitive difficulties that contribute to the effect of the disorder (Wade, 2010).

Further, whilst studies have demonstrated the efficacy of CBT-I as a multicomponent treatment package, research has not yet determined the most effective single components (Vitiello et al., 2002; Schwartz & Carney, 2012). This would provide useful insights, given that despite its efficacy CBT-I, is often overlooked as a treatment for older adults with insomnia, due to limited resources, mobility difficulties, and financial constraints (Buysse et al., 2006). Thus, modifications of CBT-I may achieve the same level of effectiveness while enhancing efficiency and feasibility within real world clinical practice.

Brief Behavioural Treatment for Insomnia (BBTI; Buysse et al., 2011) for example offers fewer sessions than CBT-I and focuses on the behavioural components of CBT-I (e.g., sleep education, sleep restriction and stimulus control; Troxel et al., 2012). Studies have found BBTI to be a feasible and effective treatment among older adults (Buysse et al., 2011). However, implementation of the stimulus control procedure warrants special attention when working with older adults.

Stimulus Control

The stimulus control component aims to reassociate the bed or bedroom with sleep (Bootzin, 1972). This is achieved by minimising the amount of time awake in bed, by eliminating sleep-incompatible behaviours/activities, and by regulating the sleep-wake schedule. The rationale is that there is a negative or maladaptive conditioning between sleep-related behaviours and sleep-incompatible behaviours (Bootzin, 1972; Bootzin et al., 1981). Individuals are instructed to 1) Only go to bed when sleepy; 2) Get out of bed if not asleep within 20 minutes; and 3) Use the bed only for sleep (Morin et al., 2006). However, these instructions can be aversive for older adults who may experience mobility difficulties, and anxiety (and potential risk of) falls (Davies et al., 1986). This can lead to nonadherence and reduce the potential clinical benefits.

Currently it is unclear whether all the components of BBTI must be included for the technique to be effective. Lundh et al., (1991) found that individuals with insomnia were more likely to engage in behaviours such as overthinking and worrying in bed (e.g., sleep-incompatible behaviours). They found that activities (e.g., reading in bed) made the individual focus on something else, instead of entering the vicious cycle of worrying, and frustration about their lack of sleep. Consistent with previous research (e.g., Gross & Borkovec, 1982), it was hypothesised that the disruption of difficult thoughts and worries may be the effective component of stimulus control. If this is correct, the instruction of the individual having to leave the bed/bedroom would be unnecessary. Thus, removing the out of bed requirement might increase adherence and treatment effectiveness as well as be more feasible for older adults.

Countercontrol

A method called countercontrol was designed to replace the stimulus control instruction of having to leave the bed (Zwart & Lisman, 1979). Instead, individuals are instructed to sit up and read, or listen to music until they feel sleepy. Its effectiveness has been demonstrated since the learned association between the bed and/or bedroom with the arousal and frustration associated with insomnia is still disrupted (Zwart & Lisman, 1979). Thus, countercontrol may offer a more acceptable alternative for older adults who find the standard instructions of getting out of the bed difficult due to physical health conditions limiting their mobility or anxiety about (and potential risk of) falls. However, some

procedural requirements of countercontrol may still be aversive (e.g., turning on the lights in the middle of the night and engaging in an activity). Therefore, additional research is required to ascertain whether countercontrol enhances adherence without reducing its efficacy for older adults with insomnia.

The Present Thesis Portfolio

This thesis portfolio aims to contribute to the literature concerning psychological interventions for older adults with insomnia. Chapter two presents a systematic review on the effect of CBT-I on cognitive performance for older adults with insomnia. Chapter four follows on from this and presents an empirical study which investigates the feasibility and acceptability of BBTI with countercontrol in older adults with insomnia. Lastly, chapter five presents a critical evaluation of the principal findings, strengths and limitations of this thesis, and the theoretical and clinical implications of the systematic review and empirical study are discussed, alongside areas for future research.

Chapter Two:

Systematic Review

Evaluating the Effectiveness of Cognitive Behavioural Therapy for Insomnia (CBT-I) on Cognitive Performance in Older Adults with Insomnia: A Systematic Review

Prepared for the Journal of Clinical Sleep Medicine

(see Appendix A for author guidelines for manuscript preparation)

Evaluating the Effectiveness of Cognitive Behavioural Therapy for Insomnia (CBT-I) on Cognitive Performance in Older Adults with Insomnia: A Systematic Review

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Abstract

Objectives: The aim of this review was to synthesise evidence from studies that evaluated the effect of Cognitive Behavioural Therapy for Insomnia (CBT-I) on cognitive performance for older adults with insomnia.

Methods: Searches were conducted on four electronic databases and a total of 1084 references were retrieved. Seven studies were included in the review.

Results: There is a lack of studies exploring the effect of CBT-I on cognitive performance for older adults with insomnia. Preliminary evidence suggested CBT-I improved cognitive performance in the following domains: overall cognitive function, memory, executive function, and attention. No improvements were found in the domains of language.

Conclusions: CBT-I improves some domains of cognitive performance for older adults with insomnia. Current evidence is limited due to the small number of studies, methodological limitations, and heterogeneity. Further studies utilising a standardised battery of cognitive performance including a measurement of each cognitive domain is required for comparison and replication of results.

Keywords: CBT-I, Older adults, Insomnia, Cognitive performance, Cognitive measures

Introduction

Sleep allows the brain to reorganise, recharge, and remove toxic waste by-products to help maintain normal functioning. The consequences of insufficient sleep are concerning since insomnia is associated with an increased risk of cognitive decline and structural brain changes, including reduced bilateral hippocampal volume and atrophy in the hippocampus (Fortier-Brochu et al., 2012; Riemann et al., 2007). This impacts upon an individual's cognitive performance. Specifically, their long-term memory, working memory, attention, higher order executive function, and various decision-making processes (Alhola & Polo-Kantola, 2007).

Impairments in cognitive abilities are one of the most reported symptoms of insomnia among older adults (Fortier-Brochu et al., 2012). Older adults report deficits in attention, concentration and memory which impacts on their decision making, social functioning and daily activities (Carey et al., 2005). Difficulties in cognition negatively impacts older adults through decreasing their quality of life, increasing their costs of care, and putting them at an increased risk of accidents and mortality (Klepac et al., 2008). Further, older adults with insomnia are at an increased risk of developing Alzheimer's Disease (AD), and those with AD and insomnia, experience a faster cognitive decline than those without insomnia (Osorio et al., 2011). Thus, the association between sleep and cognitive function is likely to be bi-directional (Ju et al., 2014). This association is of particular importance, it is possible that interventions aimed at treating insomnia prior to the onset of cognitive changes may be a primary prevention strategy to delay the onset of cognitive decline and AD.

Cognitive Behavioural Therapy for Insomnia (CBT-I) is an effective and first line intervention for older adults with insomnia (Irwin et al., 2006). CBT-I is a multi-component treatment that consists of sleep education, sleep hygiene, stimulus control, sleep restriction, cognitive restructuring, and relaxation training (Morin et al., 2006). Robust evidence suggests CBT-I improves sleep for older adults (Trauer et al., 2015). However, despite cognitive difficulties featuring in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association [APA], 2013) and the International Classification of Sleep Disorders (ICSD-3; American Academy of Sleep Medicine, 2014), and causing significant difficulties to older adults, there has been little evaluation of the impact of CBT-I on

cognitive performance. This is important since interventions for insomnia should aim to improve not only sleep, but also the cognitive difficulties that contribute to the effect of the disorder (Wade, 2010). A review by Herbert et al. (2018) evaluated evidence regarding the impact of CBT-I on cognitive functioning in middle aged adults (mean age: 50.0). Results revealed small-to-moderate effects and noted studies with small sample sizes and many insignificant results.

There is therefore a gap in the research regarding the effect of CBT-I on cognitive performance in older adults. Findings would inform future CBT-I interventions and help to reduce the effect of poor cognitive performance on older adults' health, safety, and well-being. Thus, this systematic review aimed to add to existing knowledge by describing and synthesising studies that evaluated the effect of CBT-I on cognitive performance for older adults with insomnia.

Method

Protocol and Registration

The systematic review protocol was developed according to the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA; Moher et al., 2009) and it was registered with the International Prospective Register of Systematic Reviews (PROSPERO ID: CRD42022333349).

Search Strategy

A systematic search was conducted to identify all studies that evaluated the effectiveness of CBT-I on cognitive performance in older adults with insomnia. The CINAHL, EMBASE, PsycINFO, and MEDLINE databases were searched from inception to May 2022. The following search terms were used on the electronic databases: ((CBT-I OR ICBT OR BBTI) OR (("stimulus control" OR "sleep restriction" OR "paradoxical intention therap* OR cognitive behav* therap*" OR "behav* therap*" OR "brief behav* therap*" OR relaxation OR "self-help" OR "behav* modification" OR imagery OR psychotherapy) AND (sleeplessness OR insomnia* OR "sleep initiation" OR "sleep maintenance" OR "sleep disorder*" OR dysomnia* OR "poor sleep*" OR "sleep problem*" OR "sleep difficult*" OR

"sleep disturbance*"))) AND ("older adult*" OR "older people" OR elderly OR aging OR ageing OR geriatric*). All searches were limited to human studies that were peer reviewed and published in full in the English language.

Study Selection

Following the initial search, the primary author and a second reviewer independently screened all (n = 1024) of the retrieved titles and abstracts for eligibility. There was a 99.7% agreement on eligibility between raters. Inter-rater reliability on eligibility between raters was almost perfect, $\kappa = .99$. The full texts of eligible studies (n = 200) were then independently reviewed and rated by the first author and second reviewer. There was an 99.2% agreement on inclusion between raters. Inter-rater reliability on inclusion between raters was substantial, $\kappa = .69$. Disagreements regarding inclusion were discussed between the two reviewers were held until a consensus was reached.

Intervention studies were included in the review if they met the following criteria: 1) Older adult participants (≥60), 2) Diagnosed with insomnia disorder or presenting with insomnia symptoms that met diagnostic criteria of the Diagnostic and Statistical Manual, fifth edition (DSM-5), or the International Classification of Sleep Disorders-Third Edition (ICSD-3), 3) Interventions included CBT-I, BBTI or single components of CBT-I (e.g., relaxation training, stimulus control therapy, sleep restriction therapy), 4) Utilised a measure of sleep (objective and/or subjective) and a measure of cognitive performance, and 5) Experimental or non-experimental study designs.

Studies were excluded for the following reasons: 1) Qualitative studies or systematic reviews, 2) Conference abstracts, unpublished data, reports, commentaries without original results, or study protocol descriptions, and 3) Only utilised sleep psychoeducation or sleep hygiene interventions.

Data Extraction and Narrative Synthesis

Data extracted from studies meeting inclusion criteria included country, study design, information about the sample (n, sex, mean age), insomnia criteria, components of CBT-I and

procedures, comparison conditions, and outcome measures (sleep and cognitive). A narrative synthesis was completed using the Guidance on the Conduct of Narrative Synthesis in Systematic Reviews (Popay et al., 2006). This method of synthesis was used as included studies varied in methodological characteristics (e.g., sample population, CBT-I intervention) and quality. This involved developing preliminary synthesis by interpreting the main findings of each included study and exploring associations by evaluating and grouping the studies according to outcomes. In accordance with the guidance, quality assessment was conducted before the narrative synthesis.

Quality Assessment

The Downs and Black checklist (Downs & Black., 1998) was used to assess the methodological quality of included studies that were randomised and nonrandomised controlled trials. It consists of 27 items assessing study reporting, external validity, internal validity, and power. Items are rated either as yes (= 1) or no/unable to determine (= 0). It has been found to have adequate levels of internal consistency, good inter-rater reliability, and high test-retest reliability. Like a previous review (Herbert et al., 2018) Item 27, which relates to statistical power was excluded since cognitive functioning is often a secondary outcome within studies and therefore power calculations were not based on this variable. Score ranges were given corresponding quality levels as previously reported (Hooper et al., 2008): excellent (≥26); good (20-25); fair (15-19); and poor (≤14). All included studies were independently appraised by the primary author. To ensure process rigour, all the included studies were rated by a second reviewer. In the case of any inconsistencies in appraisal of quality, discussions between the two reviewers were held until a consensus was reached. Percentage agreement for the individual items in the scale was 91.9%. Inter-rater reliability for total quality score between raters was almost perfect, $\kappa = .82$.

Results

Search Outcomes

Database searches yielded 1084 references. After removing duplicates (n = 60), the titles and abstracts of 1024 references were screened. Following this process, 824 references were deemed irrelevant and were excluded from the retrieval and screening of full text articles. Two hundred full text papers were assessed for eligibility, and a total of seven published studies met the inclusion criteria for this systematic review (see Figure 1).

Study Characteristics

Table 1 shows the seven studies that were included in this review along with their characteristics. Studies were published between 2008 and 2018. Geographical locations included: USA, Netherlands, Norway, and China. Six studies adopted a RCT design, whilst one was an uncontrolled clinical trial.

The overall sample was comprised of 432 participants. Sample sizes varied between 25 (Altena et al., 2008) to 99 (Wilckens et al., 2017). Most participants were female. The mean age of the sample was 69.59 across the seven studies, ranging from 60.60 (Altena et al., 2008) to 89.36 (Cassidy-Eagle et al., 2018).

The criteria for insomnia disorder were ascertained via. diagnostic criteria (e.g., DSM-IV, ICSD) or a questionnaire (e.g., Pittsburgh Sleep Quality Index, PSQI) for all included studies.

Of the seven studies, six employed three components of CBT-I. One study (Sun et al., 2013) employed two (e.g., sleep hygiene and relaxation training). All studies employed sleep hygiene alongside other components of CBT-I. Four studies delivered both the cognitive and behavioural components of CBT-I alongside sleep hygiene (e.g., sleep restriction, stimulus control, cognitive restructuring/therapy, and relaxation). Whereas three studies employed only the behavioural components (e.g., Sleep restriction, stimulus control, relaxation),

alongside sleep hygiene. Two of these studies (Wilckens et al., 2016; McCrae et al., 2018) employed BBTI; an evidence-based adapted version of CBTI focused on the behavioural components of CBT-I, sleep hygiene, sleep restriction and stimulus control. Two studies (McCrae et al.,2018; Sun et al., 2013) also incorporated relaxation. CBT-I sessions were delivered individually or by group, over four to eight sessions by a range of individuals, including a psychologist, therapist, masters level health clinician, nurse practitioner, and a postgraduate student and two nursing lecturers.

It was common for the included studies to adapt the intervention to ensure adherence. This included extending either the wake time in bed (McCrae et al., 2018) or the intervention delivery period (Omvik et al., 2008). Another study decreased the amount of content covered in sessions and utilised repetition and memory aids (Cassidy-Eagle et al., 2017). Two studies (Cassidy-Eagle et al., 2017; Sun et al., 2013) included between session telephone calls to remind participants of the protocol and between session tasks (e.g., their sleep schedule). Other studies utilised adherence logs (McCrae et al., 2018) whilst another asked a therapist to rate participants level of compliance (Omvik et al., 2008). Only one study (McCrae et al., 2018) utilised objective methods to ensure treatment fidelity, whereby sessions were taped with 50% being scored by one of the authors. Participants were also provided with a quiz to ensure they had understood the intervention procedure.

The control groups were either passive or active control groups. Two studies (Sun et al., 2013; Wilckens et al., 2016) used self-help information as a comparator. One study (Omvik et al., 2008) compared CBT-I to zopiclone. Whilst another study used a self-monitoring control (McCrae et al., 2018) whereby participants participated in social conversations unrelated to sleep with a therapist for the same number of sessions and duration as the intervention condition. Similarly, Cassidy-Eagle et al., (2018) compared CBT-I to nutrition group, with identical in-person and phone contact hours to the intervention group. Two studies (Altena et al., 2008; Wilckens et al., 2017) compared CBT-I to a waitlist control with participants that did not meet criteria for insomnia.

All studies used a self-reported measure of sleep. This included a sleep diary, PSQI, Insomnia Severity Index, Epworth Sleepiness Scale. Sleep diary data was collected for seven or 14 consecutive nights, with scores averaged at each assessment timepoints. Studies which used sleep diaries (McCrae et al., 2018; Altena et al., 2008; Omvik et al., 2008) collected information on the following sleep parameters: SOL, WASO, TST and SE. Self-report

questionnaires focused on specific aspects of sleep: overall sleep quality (e.g., PSQI), insomnia severity (e.g., ISI), and daytime functioning (e.g., ESS). All questionnaires were administered at baseline, post-intervention, and follow-up timepoints of each study. Three studies employed objective measures of sleep: Polysomnography (PSG; Omvik et al., 2008) or actigraphy (Cassidy-Eagle et al., 2017; McCrae et al., 2018). These methods were used continuously throughout the study (McCrae et al., 2018) or at baseline, post treatment and follow up (Omvik et al., 2008; Cassidy-Eagle et al., 2017).

Outcome Measures of Cognitive Performance

All included studies employed an objective measure of cognitive performance. Overall cognitive performance was assessed through a range of cognitive domains, from overall cognitive functioning to executive functioning. A total of 18 measures were used, ranging from one to 13 in each study. Detailed descriptions of the measures of cognitive performance can be found in Table 3.

Two studies used the Mini-Mental Status Exam to assess for overall cognitive functioning. One of these studies (McCrae et al., 2018) also used the Vocabulary, Digit Symbol- Wechsler Adult Intelligence Scale-III to assess overall cognitive functioning. Four studies assessed attention, two studies used the Trail Making Test A to assess visual attention and processing speed, whilst two studies assessed sustained attention using a computerised vigilance test (Omvik et al., 2008) or a simple and complex vigilance task (Altena et al., 2008). The Controlled Oral Word Association (COWA)-Semantic Verbal Fluency and Boston Naming Test (BNT) – Second Edition were also used in one study (McCrae et al., 2018) to assess language. Memory was assessed in six studies through: California Verbal Learning Test (CVLT-II; McCrae et al., 2018), Hopkins Verbal Learning Test (HVLT-R; Cassidy-Eagle et al., 2017), Rey-Osterreith Complex figure test (Rey-O; Mccrae et al., 2018), Logical Memory from Wechsler Memory Scale 3 (LM-WMS-III; McCrae et al., 2018l; Wilkens et al., 2016), and the Wechsler Memory Scale-Chinese Revised (Sun et al., 2013). A number of measures were used to assess executive functioning: The Controlled Oral Word Association Test (COWA) – Phonemic Fluency (McCrae et al., 2018), Trail making B (McCrae et al., 2018, Cass eagle), task switching (Wilckens et al., 2017), letter-number sequencing (Wilckens et al., 2016), Test of Non-verbal Intelligence III (TONI; Wilckens et al., 2016), and the Delis Kaplan Executive Function System (D-KEFS; Cassidy-Eagle et al.,

2017) . All tests were administered at baseline and post-intervention, with some also including follow up.

Quality Assessment

Included studies were assessed using the Downs and Black checklist (Downs & Black., 1998). The quality of the studies varied, with scores ranging between 12 and 18 out of a possible 26 (M = 15). According to the Downs and Black score ranges (Hooper et al., 2008) four papers were rated as fair and three were rated as poor. Full quality ratings for each of the included studies are shown in Table 4.

All studies reported clear hypothesis/aims, outcomes, participants, interventions, and findings. Weaknesses in the RCT's were due to lack of blinding or insufficient evidence of the blinding process. A few studies attempted to minimise bias by incorporating an active control group. For example, one study with older adults from two residential care facilities (Cassidy-Eagle et al., 2018) employed a nutrition class with identical in-person and phone contact hours. However, it was noted that there was no way of knowing if participants discussed the contents of their sessions with other residents in the facility, potentially causing bias. Further weaknesses related to the analysis. Despite their RCT design five studies analysed the change from baseline to follow up but not the between group comparisons at follow up. Some studies reported differences between the two groups at baseline, however it was unclear if there was an adjustment for baseline differences at analysis. Additionally, six studies were unclear regarding the management of missing data. This led to unclear evidence of intent-to-treat analysis to limit bias from attrition.

Relationship Between CBT-I and Cognitive Performance

Four studies out of seven (57.14%) indicated that CBT-I had a positive effect on a domain of cognitive performance. This meant that the cognitive outcome measures improved over time. However, it is important to note that none of these studies had good quality ratings. Four out of the seven included studies reported null findings. These four studies yielded fair and poor-quality ratings.

Overall Cognitive Functioning

Two studies measured the effectiveness of CBT-I on overall cognitive functioning. Both studies measured overall cognitive functioning using the MMSE, with McCrae et al. (2018) also employing the Vocabulary, Digit Symbol- Wechsler Adult Intelligence Scale-III.

Results of the MMSE were conflicted. One poor quality study (Sun et al., 2013) reported significant improvements at post-intervention and follow up. In this study, participants were provided with sleep hygiene information and taught relaxation skills. MMSE results were compared to a group that received sleep hygiene information only. However, researchers administering the neuropsychological tests were not blind to group assignment. This may have caused an exaggeration of treatment effects through ascertainment bias.

In contrast a fair quality study (McCrae et al., 2018) reported insignificant results. Reasons for null findings may be due to the demographic of the participants. Most participants (60%) had 16 years of education, which may not be representative of the sample population. Further, participants may have already been performing at a high level, and there was little room for improvement.

Attention

Two studies of fair quality measured visual attention and processing speed using the TMT part A (Cassidy-Eagle et al., 2018; McCrae et al., 2018), although neither reported positive findings. In the study by Cassidy-Eagle et al. (2018), participants were older adults with Mild Cognitive Impairment (MCI) across two residential facilities. Participants were randomised to either a six-session adapted CBT-I intervention group or an active control nutrition class. However, reasons for the null findings may be due to the small sample size.

Two studies assessed sustained attention through tasks of vigilance. There is evidence of fair quality that CBT-I improves vigilance (Altena et al., 2008). In this study, the intervention consisted of sleep restriction, cognitive behavioural therapy, bright-light therapy, structured physical activity, and body temperature manipulations. The intervention restored normal performance, with participants with insomnia returning to the performance levels of participants in the control group at baseline. However, participants in the control group did

not have insomnia. Thus, it is difficult to generalise the findings. Further, it is difficult to conclude which of the intervention components was most effective in alleviating insomnia. Participants may have benefited from bright-light therapy which is not a component of CBT-I.

Contrastingly, a poor-quality study found performance on a vigilance task worsened following CBT-I (Omvik et al., 2008). However, the sample size was small which may have provided insufficient statistical power to detect small effects. Moreover, the authors did not account for participants who dropped out of the study and therefore attrition bias may also be a factor.

Language

Only one study of fair quality measured language and found no significant results on the COWA and BNT. In this study (McCrae et al., 2018) older adults underwent four sessions of BBTI. One possible reason for null findings is that cognitive performance was only evaluated at baseline and follow up. Therefore, participants may have been able to recruit the necessary cognitive resources to perform at a high level. Daily assessment of cognition may be more sensitive to insomnia related effects as participants may be less likely to be able to maintain on-going recruitment of the cognitive resources needed to perform at a high level.

Memory

Four studies measured memory, with only two poor-quality studies noting improvements in memory following CBT-I (Wilckens et al., 2016; Sun et al., 2013).

Three of the four studies utilised a version of the Wechsler Memory Scale: LM-WMS-III (McCrae et al., 2018; Wilkens et al., 2016) and WMS-CR (Sun et al., 2013). However only Sun et al. (2013) reported improvements in scores following the intervention. Large effects may be explained by non-specific effects of the intervention such as participant expectations of improvement and the increased social contact provided by group relaxation practice.

Conversely, Wilckens et al. (2016) assessed memory before and after BBTI treatment and found no significant differences. Null findings may be due to the short duration between baseline and post-intervention testing (i.e., four weeks). The BBTI group underwent sleep

restriction therapy which is associated with increases in daytime sleepiness and impairments in vigilance. Therefore, this may have hindered their performance on the cognitive tests. Further, the time of day at which the cognitive tests were administered was not controlled for, which may have also impacted the results.

Two fair quality studies found no significant improvements in memory following the intervention (McCrae et al., 2018; Cassidy-Eagle et al., 2018).

Executive Functioning

Four studies tested executive function (McCrae et al., 2018; Cassidy-Eagle et al., 2018; Wilckens et al., 2017; Wilkens et al., 2016). Tentative evidence from fair quality studies report improved executive functions following CBT-I (Wilckens et al., 2017; Cassidy-Eagle et al., 2018).

Positive findings were reported on task switching (Wilckens et al., 2017) and D-KEFS (Cassidy-Eagle et al., 2018) only. Wilckens et al. (2017) assessed executive functioning through a task switching paradigm. Task-repetition accuracy significantly improved following CBT-I. However, the control group did not complete follow-up cognitive assessments. It is possible participants improvements were due to practice or learning effects. Further, only a subset of participants with insomnia returned for follow-up assessments (i.e., 38 out of 48), thus there is a risk of bias and results should be interpreted with caution.

The D-KEFS Colour-Word Interference Test was administered to older adults with MCI following CBT-I (Cassidy-Eagle et al., 2018). Although participants in the treatment group experienced a change in D-KEFS, it is impossible to know absolutely whether it was the result of the intervention or the cognitive training that was the cause, since the active control group included neither.

Discussion

The aim of this review was to describe and synthesise evidence on the effects of CBT-I on cognitive performance in older adults with insomnia. From 1084 references, seven studies were eligible for review. The lack of research on the impact of CBT-I on cognitive performance in older adults is surprising, given that insomnia is related to cognitive impairments in memory, attention, and executive function (Bastien et al., 2003).

Results from the available evidence suggests CBT-I may improve some domains of cognitive performance. Significant improvements were found on tests of overall cognitive function, memory, attention, and executive functioning. Our findings review aligned with a previous meta-analysis (Fortier-Brochu et al., 2012), whereby insomnia was associated with deficits in some cognitive domains (e.g., overall cognitive function, memory, executive functioning, and attention), but not others (e.g., language/verbal fluency). Results from this review provides tentative evidence that CBT-I may lead to positive improvements in domains of cognitive performance in older adults with insomnia. However, findings should be viewed with caution since most of the supporting evidence was from studies with fair or poor-quality ratings.

Our ability to draw conclusions based on this synthesis is limited by methodological limitations and heterogeneity. Firstly, our review included studies with a younger cohort of older adults, aged ≥60 instead of using the conventional 'older adult' age criterion ≥65 (Orimo et al., 2006). Previous research highlighted inconsistencies in the definition of 'older adults', with studies often including an age criterion of ≥60 or ≥65 (Alterovitz & Mendelsohn, 2013). Our review used the ≥60 age criterion to ensure studies that defined 'older adults' as ≥60 was not excluded. Five of the seven studies included in our review used the ≥60 age criterion (e.g., Altena et al., 2008; Omvik et al., 2008; Sun et al., 2013; Wilkens et al., 2016; Wilkens et al., 2017). The mean age of the overall sample included in this review was 69.59, thus this was an older adult sample. However future studies should recruit participants ≥65 to aid generalisability of results.

Outcome measures of cognitive performance varied in the included studies, which ranged from the MMSE to vigilance testing. The MMSE provides a poor measure of executive function with no timed component and is often used to assess cognitive impairment

(Nasreddine et al., 2005). It may therefore not be sensitive enough to detect subtle, situational changes in cognitive performance and may be subject to ceiling effects. Future research should ascertain whether any domains of cognitive performance or measures are more sensitive to the effects of CBT-I.

Additionally, included studies reporting improvements in measures of cognition may have been due to practice or learning effects due to repeated exposure to test materials and procedures within a small re-test interval (Goldberg et al., 2015; Fawns-Richie & Deary, 2020). This is a major issue in clinical and research settings (Houx et al., 2002) since practice effects may mask cognitive decline and delay diagnosis and clinical care for patients with cognitive deficits. Future research should clearly state whether the re-test interval falls within guidance (e.g., between two to four weeks, Fawns-Richie & Deary, 2020) and whether alternate versions of the same task were administered (e.g., different words in a verbal memory test).

Further, individuals with insomnia may compensate for cognitive difficulties through increased cognitive effort and the recruitment of additional cerebral resources (Varkevisser et al., 2007). To minimise these effects, it would be beneficial to develop a standardised battery of cognitive performance that includes a measurement of each cognitive domain to create consistency in methods across studies measuring insomnia and cognitive performance. This would allow for further comparison and replication of results. To date, no such study involving the impact of CBT-I on cognition in older adults has been conducted.

Overall, the review of the literature revealed fair and poor-quality studies. Findings from the quality assessment identified most studies were weakened due to lack of blinding given participants and researchers were often not blind to group assignment. Although double-blinded placebo-controlled studies are difficult to implement when evaluating psychological interventions, the specific effects of CBT-I cannot be separated from non-specific effects. This includes effects such as therapist attention and participant expectations, which have been found to exert a strong influence on measures of cognitive performance (Oken et al., 2008).

Further, despite their RCT design many of the included studies compared the change from baseline to follow up but not the between group comparisons of follow up. Some studies either reported significant or non-significant differences between the two groups at baseline.

However, it was unclear whether adjustments were made to account for baseline differences in the analysis. Baseline values of the outcome variable can be seen as a confounder in the estimation of the treatment effect. This is important in RCT designs as the baseline value of the outcome is highly related to the follow-up measurements of the same variable. Thus, a small difference in baseline value of the outcome between two groups can have a confounding effect. Therefore, future RCT designs should adjust for the baseline value of the outcome variable irrespective whether the difference is significant or not. This can be done by normalising values measured at post-intervention to baseline values at an individual (e.g., post-intervention/baseline*100) level to compare individual changes across time on all outcomes.

Implications

Findings from this review contribute to the literature suggesting CBT-I improves older adults' cognitive performance in the following domains: overall cognitive function, memory, executive functioning, and attention. This has important clinical implications since 50% of older adults experience insomnia which is linked to an increased risk of cognitive decline and AD (Osorio et al., 2011). Given that research suggests 15% of AD may be prevented by sleep interventions (Bubu et al., 2017), CBT-I may be a treatment for cognitive decline as well as insomnia.

If CBT-I does improve cognitive performance, it will be important to understand the mechanism through which this occurs. Previous research identified several putative mechanisms which could underlie the link between insomnia and poor cognitive performance. This includes increased amyloid-β deposition, neuroinflammation and alterations in specific neurotransmitter systems (Ju et al., 2013). The underlying mechanisms may also be modified by such factors as sex, APOE ε4 status, depression, or medication use (Spira et al., 2013; Byers & Yaffe, 2011). Due to the preliminary nature of the literature and the large number of ways in which the included studies varied, it was not possible to identify specific mechanisms or moderators of improvements in cognitive performance. Future research should investigate the relationship between cognitive performance and insomnia using multivariable regression models to evaluate differences in cognitive performance between individuals with and without insomnia, as well as potential interactions between insomnia and sex, APOE ε4 status, depression, and/or medication use. Findings would

increase knowledge in the relationship between cognitive performance and insomnia and may identify ways to mitigate the risk of insomnia and poor cognitive performance.

Limitations and Future Directions

The inclusion criteria used in this study resulted in a limited number of low-quality studies that differed on a range of factors, including methodology, components of CBT-I and cognitive performance measures. The diversity between studies precluded the use of meta-analysis, and studies rarely found unequivocal significance across all outcomes. This made comparisons between studies difficult. The variability in the interventions and cognitive outcome measures used reflects this field of research, whereby there is a lack of consensus and standardised components of a CBT-I intervention and measures of cognitive performance. For example, some studies utilised just two components of CBT-I (e.g., relaxation and sleep hygiene), whereas other studies delivered all the components. The validity of this is questionable since standard CBT-I should at least include stimulus control and sleep restriction procedures. Future studies should aim to incorporate the standard CBT-I procedures (e.g., sleep restriction and stimulus control) to aid comparisons in this field of research. Further, to improve our understanding in the field of CBT-I and cognitive performance, further development of a more standardised, domain-based approach to neuropsychology testing (as per the dementia field, e.g., the CogState Brief Battery; Maruff et al. 2009). This would enable consistency in future research and aid comparisons and replication of results.

Conclusion

There is a distinct lack of research regarding CBT-I and cognitive performance in older adults. This is surprising given the high prevalence of insomnia in older adults and the relationship between insomnia and cognitive impairment. Whilst the research is limited, there is preliminary evidence to suggest CBT-I with older adults has a positive effect on the following domains of cognitive performance: overall cognitive function, memory, executive functioning, and attention. However, it is important to note the large amount of heterogeneity that exists in the relationship between CBT-I and cognitive performance due to the diversity of assessments used to quantify cognitive performance and the lack of high-quality studies.

Future research in this area calls for high-quality studies using standardised CBT-I procedures alongside a neuropsychology test battery, measuring all domains of cognition performance are required to improve rigor and provide future clinical recommendations.

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Figure 1

PRISMA flow diagram of studies

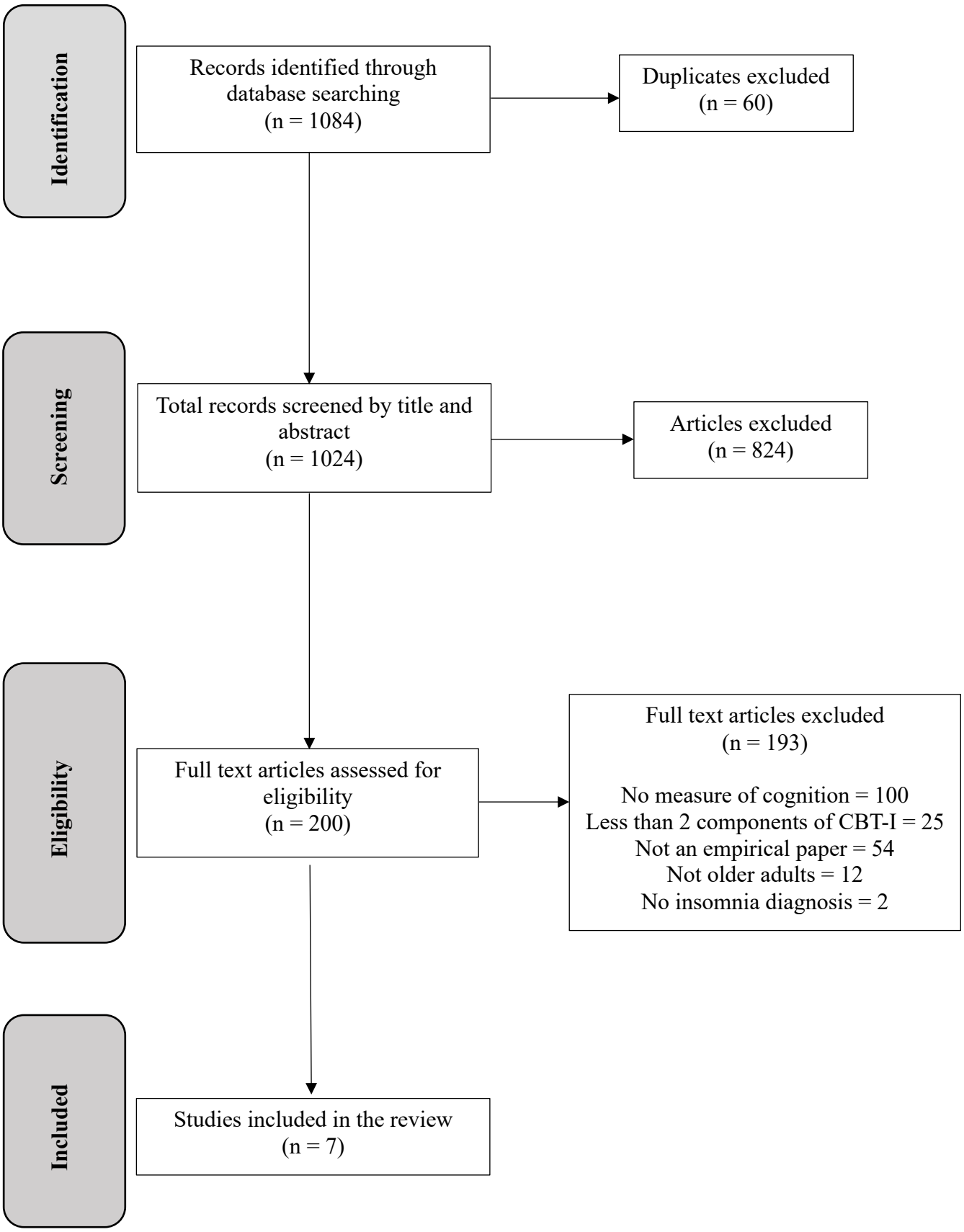

Table 1

Characteristics of included studies

Author (Date), Country	Design	Total *n*, Sex % F	Mean age (SD)	Insomnia criteria	Components of CBT-I, Procedure, *n*	Comparison condition, Procedure, *n*	Sleep measures	Cognitive measures
Altena et al. (2008) Netherlands	RCT	25 71.05%	60.6 (6.0)	Primary insomnia (DSM-IV) and SDQ ≥ 2.6, all other SDQ sub scores ≥ 3 and PSQI >6	SH, SR, CR Individual 6 weekly sessions with a therapist *n* = 12	WLC *n* = 13	Sleep diary	'simple' and 'complex' vigilance testing
Omvik et al. (2008) Norway	RCT	66 43.93%	60.84 (5.49)	Primary insomnia (DSM-IV) > 6 months	SH, SC, SR, CT Individual 6-8 weekly sessions with a Clinical Psychologist *n* = 23	Zopiclone 2 individual meetings with a Clinical psychologist to receive medication for 6 weeks and to check adherence *n* = 22	Sleep diary	Vigil, 5.0
Sun et al. (2013) China	RCT	75 74.7%	69.69 (7.98)	PSQI >5 points	SH, RL Group 4 weekly sessions with assisted follow up for 1 year with a Postgraduate student and two lecturers in Nursing. *n* = 37	SH Brochure Provided with written information on sleep hygiene *n* = 38	PSQI ESS	MMSE WMS-CR

Wilckens et al. (2016) USA	RCT	77 70%	71.67 (6.69)	Chronic insomnia (DSM-IV-TR) and Insomnia disorder (ICSD-2). DSM-IV exclusions for medical, sleep, and psychiatric disorders were not applied	SH, SC, SR Individual 4 weekly sessions with a mental health nurse practitioner *n* = NR	IC Provided with information about behavioural treatment for insomnia 2 weeks *n* = NR	PSQI PSG	Logical memory test TONI Letter-Number Sequencing
Wilckens et al., (2017) USA	Uncontrolled Clinical trial	99 62%	67.26 (NR)	General insomnia disorder (DSM-IV/ICSD-2), ISI ≥ 10, mean SOL + WASO > 40 minutes, and SE < 90%	SH, SR, SC, RL, CR Individual 8 weekly sessions with a masters-level health clinician *n* = 48	WLC *n* = 51	ISI PSG	Task switching

Cassidy-Eagle et al. (2018) USA	RCT	28 85%	89.36 (NR)	Insomnia (DSM-V)	SH, SC, SR, CT, RL Group and individual phone calls 6 weekly sessions with a Clinical Psychologist *n* = 14	Active control Nutrition group and individual phone calls 6 weekly sessions with a dietician *n* = 14	ISI Actigraphy	HVLT-R TMT A TMT B D-KEFS
McCrae et al. (2018) USA	RCT	62 67.74%	69.45 (7.71)	Chronic insomnia: insomnia complaints (SOL or WASO > 30 minutes) ≥ 3 nights per week > 6 months; daytime dysfunction; and no prescribed/ over- the-counter sleep medication for ≥ 1 month or stabilised on medication for ≥ 6 months	SH, SC, SR, RL Individual 4 one-hour sessions weekly with a therapist *n* = 32	SMC Individual 4 weekly sessions with a therapist participating in social conversations *n* = 30	Sleep diary Actigraphy	MMSE Vocabulary, Digit Symbol-Wechsler Adult Intelligence Scale-III TMT A COWA BNT CVLT-II Rey-O LM-WMS-III TMT B

Note. BNT = Boston Naming Test; CBT-I = Cognitive Behavioural Therapy for Insomnia; COWA = Controlled Oral Word Association; CVLT-II = California Verbal Learning Test); CT = cognitive therapy; D-KEFS = Delis Kaplan Executive Function System; DSM = Diagnostic and Statistical Manual of Mental Disorders; HVLT-R = Hopkins Verbal Learning Test-Revised; ICSD-2 = International Classification of Sleep Disorders; ISI = Insomnia Severity Index; MMSE = Mini Mental State Exam; n = sample size; NR = Not reported; LM-WMS-III = Logical Memory from Wechsler Memory Scale 3; PSG = Polysomnography; PSQI = Pittsburgh Sleep Quality Index; RCT = Randomised Controlled Trial; Rey-o = Rey-Osterreith Complex Figure Test; RL = Relaxation; SC = Stimulus Control; SD = Standard Deviation; SDQ = Sleep Disorders Questionnaire; SE = Sleep Efficiency; SH = Sleep Hygiene; SMC = Self-Monitoring Control; SOL = Sleep Onset Latency; SR = Sleep Restriction; TMT A = Trail Making A; TMT B = Trail Making B; TONI = Test of Non-verbal Intelligence III; WASO = Wake After Sleep Onset; WLC = Wait List Control; WMS-CR = Wechsler Memory Scale-Chinese Revised

Table 2
Summary of cognitive findings for the included studies

Reference	Cognitive outcome	Length of follow up	Summary of cognitive findings at follow up	QR score out of 26
Altena et al. (2008)	'simple' and 'complex' vigilance testing	Between 5 and 7 weeks (average 6 weeks) after baseline	Sleep therapy effectively restored normal performance: the CBT-I group were significantly slower on the 'simple' task and faster on the 'complex' task from baseline to follow up, returning to the performance levels of participants in the control group ($p < 0.05$).	15
Omvik et al. (2008)	Vigilance test	8-10 weeks and 6 months after baseline	Change in performance on this test was not significantly different between groups	14
Sun et al. (2013)	MMSE WMS-CR	12, 24 and 52 weeks after baseline	Scores on the MMSE and four subtests from the WMS-CR significantly increased in the experimental group whereas they decreased in the control group ($p < 0.01$)	14
Wilckens et al. (2016)	Logical memory test TONI Letter-Number Sequencing	4 weeks after baseline	There were no significant changes in cognitive performance from baseline to follow-up across treatment groups	12
Wilckens et al. (2017)	Task switching	8 weeks after baseline	The intervention group significantly improved on task-repetition accuracy. This improvement was associated with improvements in WASO. There were no group or treatment effects on response time or task alternation accuracy	17

Cassidy-Eagle et al. (2018)	HVLT-R TMT A TMT B D-KEFS	6 weeks and 4 months after baseline	The intervention group experienced significant improvements in Condition 3 of D-KEFS ($p < .05$), an improvement in Condition 4 of D-KEFS ($p < .10$), and no change in verbal memory (HVLT-R) compared with the active control group	17
McCrae et al. (2018)	MMSE Vocabulary, Digit Symbol-Wechsler Adult Intelligence Scale-III TMT A COWA - Semantic Verbal Fluency BNT CVLT-II Rey-O COWA - Phonemic Fluency LM-WMS-III; TMT B	4 weeks and 3 months after baseline	No significant changes between baseline and post-intervention or follow up (all ps > .003).	18

Note. BNT = Boston Naming Test; CBT-I = Cognitive Behavioural Therapy for Insomnia; COWA = Controlled Oral Word Association; CVLT-II = California Verbal Learning Test); D-KEFS = Delis Kaplan Executive Function System; HVLT-R = Hopkins Verbal Learning Test-Revised; MMSE = Mini Mental State Exam; WMS-CR = Wechsler Memory Scale-Chinese Revised

Table 3
Description of cognitive measures used in the included studies

Domain	Measure	Description	Used in
Overall cognitive functioning	Mini-Mental Status Exam (MMSE)	The MMSE is a measure of cognitive functioning. It assesses the following domains: orientation to time and place, memory, basic arithmetic, language use and comprehension, and basic motor skills. Scores range from 0-30 points with scores lower than 23 (9th grade education or higher) or lower than 18 (less than 9th grade education) indicating impairment. Test-retest reliabilities are acceptable, ranging from .48 - .65 (Tombaugh, 2005). The MMSE is a valid measure of a breadth of cognitive functioning (Folstein et al., 1975; Mitrushina & Satz, 1991).	McCrae et al. (2018) Sun et al. (2013)
	Vocabulary, Digit Symbol-Wechsler Adult Intelligence Scale-III	The Vocabulary subtest consists of a list of words measuring verbal expression and comprehension. Participants are shown the written form of the word as it is spoken aloud by the examiner. The participant then provides a definition of the word (Wechsler, 1997). The vocabulary subtest has shown good test-retest reliability (r = .94; Dikmen, et al., 1999). The Digit Symbol subtest consists of several symbols that are paired with numbers. The participant	McCrae et al. (2018)

		draws each symbol under its number. There is a 120-second time limit for the task and the number of symbols correctly drawn by the participant is scored. The Digit Symbol subtest has good reliability ranging from .84 to .93 (Wechsler, 1997).	
Attention, Processing Speed, Vigilance	Trail Making Test A	Trail Making Test A is a test containing numbered circles. Participants are asked to connect the circles in order (e.g., 1 to 2 to 3, etc.) as fast as they can. The primary score is the number of seconds needed to finish but the number of errors is also recorded (Reitan, 1992). A good test–retest reliability has been shown for TMT part A (Giovagnoli et al., 1996). TMT part A has been shown to be a good measure of attention and visuoperceptual ability (O'donnell et al., 1994; Sanchez et al., 2009)	McCrae et al. (2018) Cassidy-Eagle et al. (2018)
	'simple' and 'complex' vigilance testing	Altena et al. (2008) constructed two tasks for psychomotor vigilance. During the tasks, stimuli appeared in the middle of a computer screen. For the 'simple' vigilance task, 110 asterisks would sequentially appear on the screen on the same location but with time intervals of between 1 and 10 seconds. Participants were required to immediately click their mouse button whenever they saw the target. In the 'complex' task, either the target	Altena et al. (2008)

		letter ‘p’ or the distractor letter ‘d’ would appear in the middle of the screen.	
	Vigil, 5.0	Vigil is a 25-min computerised test which registers enduring attention in a situation with few stimuli. Participants are required to watch a brightly flashing dot and press a button when the dot takes a double jump. Mean reaction time’’ in seconds and ‘‘number of correct responses’’ makes up the two parameters of vigilance performance.	Omvik et al. (2008)
Language	Controlled Oral Word Association (COWA)-Semantic Verbal Fluency	COWA is a measure of an individual’s ability to make as many associations as possible to a specific category (e.g., animals, names etc) in one minute (Benton et al., 1989) The COWA has shown acceptable test-retest reliability (Dikmen et al., 1999).	McCrae et al. (2018)
	Boston Naming Test (BNT) – Second Edition	The BNT consists of 60 pictures ordered from easiest to most difficult. A picture is shown, and individuals have 20 seconds to answer. If an incorrect answer is provided, a phonemic cue is provided. A stimulus cue is also provided is the individual fails to recognise the picture. Total scores are the number of items correctly named (Kaplan et al., 1983). The BNT has acceptable test-retest reliability (Flanagan & Jackson,	McCrae et al. (2018)

		1997).	
Memory	California Verbal Learning Test (CVLT-II)	In the CVLT-II, individuals are presented with a list of 16 words (four words from each of four sementic categories). Participants must then recall the lists over five trials, recall an interference list of words, recall the original list of words, and deliver a category-cued recall of the first list of words. After a 20-minute delay, free recall, category-cued recall, and recognition of the first list are assessed (Delis et al., 1987). The CVLT has shown good construct validity and retest reliability (Delis et al., 1987; Jacobs & Donders., 2007).	McCrae et al. (2018)
	Hopkins Verbal Learning Test (HVLT-R)	Hopkins Verbal Learning Test (HVLT-R) is a measure of verbal learning and memory. Participants are asked to memorise a list of words to test the ability to recall immediately after memorisation and after 20 minutes (Benedict et al., 1998).	Cassidy-Eagle et al. (2018)
	Rey-Osterreith Complex Figure Test (Rey-O)	The Rey-O is used to assess individuals visuoconstructional ability and visual memory. Individuals are required to copy a figure, reproduce the Figure from memory, and reproduce the Figure again after a 30-minute delay (Osterrieth, 1944; Rey, 1941). The measure has been shown to be a valid with interrater reliability estimates report correlation	McCrae et al. (2018)

		coefficient of .98 (Elderkin-Thompson et al., 2004; Loring et al., 1990).	
	Logical Memory from Wechsler Memory Scale 3 (LM-WMS-III)	The Logical Memory subtest of the Wechsler Adult Intelligence Scale – III (Wechsler, 1997a) assesses memory. It requires immediate and delayed verbal recall of two orally presented story passages. Questions about both stories are also administered and require a yes or no response. This test has been shown to have a reliability estimate of approximately 0.72 (Theisen et al., 1998).	McCrae et al. (2018) Wilkens et al. (2016)
	Wechsler Memory Scale-Chinese Revised	The Wechsler Memory Scale-Chinese Revised (WMS-CR), tests memory. There are 10 subtests and an overall 'memory quotient'. The test–retest reliability is 082 (Gong, 1989).	Sun et al. (2013)
Executive functioning	The Controlled Oral Word Association Test (COWA) – Phonemic Fluency	The COWA – Phonemic Fluency asks individuals to quickly list as many words as they can that begin with a specific letter. The COWA has shown to be reliable and valid (Dikmen et al., 1999; Lezak et al., 2004).	McCrae et al. (2018)
	Trail Making Test B (TMT B)	TMT B is a test containing numbered circles and letters. Participants are asked to connect the circles in order	McCrae et al. (2018) Cassidy-Eagle et al. (2018)

	(e.g., 1 to A to 2 to B, etc.) as fast as they can. The primary score is the number of seconds needed to finish, but the number of errors was recorded. Performance time is unlimited (Reitan, 1959). A good test–retest reliability has been shown for TMT Part B (*Giovagnoli et al., 1996*). TMT B has been shown to be a valid measure of cognitive flexibility, an executive function (Kortte et al., 2002).	
Task switching	Task-switching performance was assessed with a paradigm that included a block of trials where participants are cued to perform one of two tasks with a varying cue- target interval (Wilckens., et al., 2014). For one task participants judge whether the number is greater or less than 5 (GL task). In the other task, participants judge whether the number is odd or even (OE task). A circle preceding or accompanying the target number cues participants to perform the GL task, and a square cues participant to perform the OE task. Participants first completed the practice block, comprised of 16 trials of each task, followed by two single-task blocks comprised of 32 trials each. The switching block contains 96 trials: 16 trials of GL and OE.	Wilckens et al. (2017)

	Successive trials within this block are classified as “task repetition” or “task alternation” depending on whether successive trials used the same task.	
Letter-Number Sequencing (Wechsler, 1997)	The letter number sequencing subtest measures an individual’s short term memory skills in being able to process and re-sequence information. Individuals are read a series of letters and numbers and asked to first recall the digits in numerical order and then the letters in alphabetical order (Wechsler, 1997).	Wilckens et al. (2016)
Test of Non-verbal Intelligence III (TONI)	The TONI requires no reading, writing, speaking, or listening for the participant. Participants are shown a set of 4 black and white abstract figures representing a pattern with one space missing. Participants must choose the symbol which completes the pattern (Brown et al., 1997). The TONI has been shown to have reliability estimates ranging from 0.71 to 0.92 (Goldberg et a., 1998; McGhee & Lieberman, 1991).	Wilckens et al. (2016)
The Delis Kaplan Executive Function System (D-KEFS)	The Delis Kaplan Executive Function System (D-KEFS) is a test of inhibition and switching (Delis et al., 2001). Participants are required to do the following: name colour patches, read colour-words printed in black ink, read colour words printed in	Cassidy-Eagle et al. (2018)

	dissonant colours, and switch back and forth between naming the dissonant ink colours and reading the words.

Table 4
Quality assessment - Downs and Black Checklist

Criteria	McCrae et al. (2018)	Cassidy-Eagle et al. (2017)	Altena et al. (2008)	Wilkens et al. (2017)	Omvik et al. (2008)	Sun et al. (2013)	Wilkens et al. (2016)
1. Is the hypothesis/aim/objective of the study clearly described?	1	1	1	1	0	1	1
2. Are the main outcomes to be measured clearly described in the Introduction or Methods section?	1	1	1	1	1	1	1
3. Are the characteristics of the patients included in the study clearly described?	1	1	1	1	1	1	1
4. Are the interventions of interest clearly described?	1	1	1	1	1	1	0
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?	1	1	1	1	1	1	0
6. Are the main findings of the study clearly described?	1	1	1	1	1	1	1
7. Does the study provide estimates of the random	1	1	1	1	1	1	1

variability in the data for the main outcome?							
8. Have all important adverse events that may be a consequence of the intervention been reported?	0	0	0	0	0	0	0
9. Have the characteristics of patients lost to follow-up been described?	1	1	1	1	0	0	0
10. Have actual probability values been reported (e.g., 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	1	1	0	1	1	1	1
11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	0	0	0	0	0	0	0
12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	0	0	0	0	0	0	0
13. Were the staff, places, and facilities where the patients were treated, representative	0	0	0	1	0	0	0

of the treatment the majority of patients receive?							
14. Was an attempt made to blind study subjects to the intervention they have received?	0	0	0	0	0	0	0
15. Was an attempt made to blind those measuring the main outcomes of the intervention?	0	0	0	0	0	0	0
16. If any of the results of the study were based on “data dredging”, was this made clear?	1	1	1	1	1	1	0
17. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?	1	1	1	1	1	1	1
18. Were the statistical tests used to assess the main outcome appropriate?	1	1	1	1	1	1	1
19. Was compliance with the intervention/s reliable?	1	1	1	1	1	0	1

20. Were the main outcome measures used accurate (valid and reliable)?	1	1	1	1	1	1	1
21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	1	1	1	1	1	1	1
22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?	0	1	0	0	0	0	0
23. Were study subjects randomized to intervention group?	1	1	1	0	1	1	1
24. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	0	0	0	0	0	0	0
25. Was there adequate adjustment for confounding in the analyses from which	1	0	0	1	0	0	0

the main findings were drawn?							
26. Were losses of patient to follow-up taken into account?	1	0	0	0	0	0	0
Total Score	18	17	15	17	14	14	12

Chapter Three:

Bridging Chapter

Bridging Chapter

This chapter aims to summarise the findings of the systematic review and provide a background and rationale to the empirical paper.

The systematic review in chapter two synthesised evidence from studies that evaluated the effect of Cognitive Behavioural Therapy for Insomnia (CBT-I) on cognitive performance for older adults with insomnia. Specifically, the review summarised and evaluated studies that included a component of CBT-I, an older adult sample (≥60years), and an outcome measure of sleep and cognitive performance. Previous research had linked insomnia to an increased risk of cognitive decline and Alzheimer's Disease (AD, Osorio et al., 2011). It is hoped that interventions aimed at treating insomnia prior to the onset of cognitive changes may delay the onset of cognitive decline and AD. Results from the review suggests CBT-I may improve some domains of cognitive performance but not others. Significant improvements were found on tests of overall cognitive function, memory, attention, and executive functioning, whereas no improvements were found in the domains of language. Results provide tentative evidence that CBT-I may lead to positive improvements in some domains of cognitive performance in older adults with insomnia. However, the review highlighted a distinct lack of research in this field. Further research studies utilising components of CBT-I, and measures of cognitive performance are required to improve our understanding of the effectiveness of CBT-I on cognitive performance for older adults with insomnia.

Most of the included studies within the review utilised the behavioural components of CBT-I (e.g., sleep education, sleep restriction and stimulus control), which together form what is known as Brief Behavioural Treatment for Insomnia (BBTI; Buysse et al., 2011). Previous research has evidenced its effectiveness in treating older adults with insomnia. However, older adults can experience difficulties with adherence to the stimulus control component. One way to increase adherence is to utilise a modified method called countercontrol (Zwart & Lisman, 1979). However, it is unknown whether the countercontrol method improves adherence, whilst being acceptable to older adults.

Therefore, the following chapter presents an empirical study that explores the feasibility and acceptability of BBTI with countercontrol in older adults with insomnia.

Chapter Four:

Empirical Research Paper

The Feasibility and Acceptability of a Brief Behavioural Treatment for Insomnia (BBTI) with Countercontrol in Older Adults with Insomnia

Prepared for the Journal of Clinical Sleep Medicine

(see Appendix A for author guidelines for manuscript preparation)

The Feasibility and Acceptability of a Brief Behavioural Treatment for Insomnia (BBTI) with Countercontrol in Older Adults with Insomnia

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Abstract

Objectives: To explore the feasibility and acceptability of a Brief Behavioural Treatment for Insomnia (BBTI) with countercontrol in older adults with insomnia.

Methods: Twenty-four older adults (mean age: 70.83 years, SD: 4.75, 15 Females) with insomnia according to ICSD-3 (American Academy of Sleep Medicine, 2014) were randomly allocated to receive BBTI with countercontrol or sleep hygiene information. Participants completed seven days of sleep diaries and actigraphy at baseline and post-intervention after four weeks. Participants also completed measures of sleep quality, wellbeing, and cognition at the two time points. Participants completed a questionnaire at the end of the study assessing acceptability of the intervention.

Results: All participants were retained and adhered to the BBTI with countercontrol intervention. Participants reported positive experiences and notable improvements in sleep following the intervention. Countercontrol was cited as one of the most useful elements of the intervention. Results also revealed that BBTI with countercontrol significantly improved self-reported measures of sleep, wellbeing, and cognition. Clear discrepancies were observed between objective (actigraphy) and self-reported (sleep diary) measures of sleep.

Conclusions: BBTI with countercontrol is a feasible and acceptable intervention for older adults with insomnia. Future research should further explore the impact BBTI with countercontrol has on older adult's sleep, wellbeing, and cognition.

Keywords: feasibility; acceptability; insomnia; older adults; brief behavioural intervention; countercontrol; wellbeing; cognition.

Brief Summary

Current Knowledge/Study Rationale: Brief Behavioural Treatment for Insomnia (BBTI) is an evidence-based treatment for insomnia; however, studies have indicated difficulties with older adults' adherence to the stimulus control component. One way to increase adherence is to utilise a modified method called countercontrol. Therefore, the purpose of the current study was to explore the feasibility and acceptability of BBTI with countercontrol in older adults with insomnia.

Study Impact: Preliminary findings indicate that BBTI with countercontrol is a feasible and acceptable intervention for older adults with insomnia. Future research should further explore the impact BBTI with countercontrol has on older adult's sleep, wellbeing, and cognition.

Introduction

Cognitive Behavioural Therapy for Insomnia (CBT-I) is an effective and first-line treatment option for older adults with insomnia (Morin et al., 2006). Several meta-analyses have reported that CBT-I is effective in improving older adults sleep (Irwin et al., 2006; Van Straten et al., 2018). CBT-I is a multi-component treatment that consists of sleep education, sleep hygiene, stimulus control, sleep restriction, cognitive restructuring, and relaxation training (Morin et al., 2006). Whilst studies have demonstrated the efficacy of CBT-I as a multicomponent treatment package, research has not yet determined the most effective components (Vitiello et al., 2002; Schwartz & Carney, 2012). This would provide useful insights given the evidence which suggests shorter versions of CBT-I may be as efficacious among older adults (Irwin et al., 2006; Pallesen, 2003).

Brief Behavioural Treatment for Insomnia (BBTI) is an evidence-based adapted version of CBTI which offers a briefer intervention of four sessions. Studies utilising BBTI have shown moderate to large effect sizes compared to control groups given brochures on sleep hygiene to read (Buysse et al., 2011; Edinger et al., 2007). BBTI focuses on the behavioural components of CBT-I, sleep education, sleep restriction and stimulus control (Troxel et al., 2012). The stimulus control component aims to reassociate the bed or bedroom with sleep (Bootzin, 1972). It assumes that insomnia is the result of maladaptive conditioning between environmental (e.g., bed) and temporal (bedtime) stimuli and sleep-incompatible behaviours (e.g., worrying; Bootzin, 1972; Bootzin et al., 1981). Stimulus control instructions include: 1) To only go to bed when sleepy tired; 2) To get out of bed if not asleep within 20 minutes; and 3) To use the bed only for sleep (Morin et al., 2006).

Implementation of stimulus control procedures warrants special attention when working with older adults, to ensure adherence and safety. For example, the requirement to leave the bed or bedroom should be adapted for those with mobility difficulties or anxiety about (and potential risk of) falls (Gross & Borkovec, 1982). One way to increase adherence to the stimulus control procedure is to utilise a modified method called countercontrol (Zwart & Lisman, 1979). Instead of getting out of bed, individuals are instructed to sit up and read, or listen to music until they feel sleepy tired. There is some evidence to suggest that countercontrol is as effective as stimulus control (Zwart & Lisman, 1979). However, other studies suggest the magnitude of the effect observed with countercontrol was lower than with the traditional stimulus control instructions (Davies et al., 1986). Additional research is

required to ascertain whether countercontrol enhances adherence without reducing its efficacy.

The present study explored the feasibility and acceptability of BBTI with countercontrol for older adults with insomnia to inform a future RCT. This study was designed as a feasibility and acceptability RCT and followed the Medical Research Council (MRC; Craig et al., 2013) guidance. Feasibility data were gathered through recruitment, adherence and retention rates, and acceptability of the intervention was assessed through a questionnaire focused on participants experiences of BBTI with countercontrol. The secondary aims of the study explored whether BBTI with countercontrol lead to measurable changes in self-reported (diary) and objective (actigraphy) sleep quality as well as cognition and mental wellbeing in older people with insomnia. Finally, this study explored how the objective and self-reported measures of sleep quality compare to each other.

Method

Ethics

This study was granted ethical approval by the University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee (ID: ETH2122-0490; see Appendix B).

Design

A mixed method design was used to establish feasibility and acceptability (Craig et al., 2013; Thabane et al., 2010). The quantitative element included feasibility data, closed questions from the acceptability questionnaire, and the secondary outcome measures related to sleep, wellbeing, and cognition. The open-ended questions from the acceptability questionnaire provided the qualitative element of the study.

Participants

Participants (n = 24) were recruited between May-August 2022 through multiple channels including: an existing database held within the Sleep and Brain Research Unit (SBRU) at the University of East Anglia (UEA), online advertisements, and community groups. The current study employed a feasibility and acceptability design; therefore, no power calculations were

conducted since sample size is not based upon estimation of efficacy (National Institute for Health Research; Craig et al., 2013). The sample size (n = 24) was in keeping with published recommendations for feasibility studies (Julious, 2005). Individuals who expressed interest in participating were screened according to the inclusion and exclusion criteria.

Inclusion

- ≥55 years
- Clinically significant sleep problems cf. ICSD-3 (American Academy of Sleep Medicine, 2014) = 1. a report of sleep initiation or maintenance problems at least three times per week for at least three months, and 2. adequate opportunity, and circumstances to sleep, and 3. reported daytime consequences (e.g., fatigue, decreased mood or irritability, or cognitive impairment)
- Willing to undergo randomisation
- Able to read and understand English

Exclusion

- Sleep disorder diagnosis other than insomnia (e.g., sleep apnoea)
- Psychiatric disorders, or chronic neurological conditions (e.g., dementia)
- Severe depressive symptomatology (e.g., scoring two or above on Question 9 of the PHQ-9 indicating suicidal ideation)
- Sensory impairments (e.g., deafness)
- Receiving any ongoing psychological treatment for insomnia or any other mental health disorders
- Participants scoring <5 on the Pittsburgh Sleep Quality Index indicating absence of clinically significant sleep problems.

Outcome Measures

Primary Outcomes

Feasibility

Feasibility outcomes were assessed by the study's recruitment rate, retention rate, and participants adherence to the intervention and study.

Acceptability

Acceptability Questionnaire (Appendix H) was developed to gather feedback on participants experiences of the BBTI with countercontrol intervention. The questionnaire contains 14 questions, consisting of seven closed and seven open-ended questions.

Demographics

General Demographic and Health Questionnaire (Appendix E) is a 19-item questionnaire developed to gather information on participants demographics and to address inclusion/exclusion criteria. The questionnaire is made up of two sections: demographics and general health.

Sleep Quality

The Consensus Sleep Diary (CSD; Carney et al., 2012) is a prospective measure that involves daily completion within an hour of getting out of bed. The CSD contains nine items used to derive estimates of sleep parameters. The diary provides the following outcomes: Sleep Onset Latency (SOL), Wake After Sleep Onset (WASO), Total Sleep Time (TST), and Sleep Efficiency (SE; TST/ time in bed*100). These outcomes are useful for the assessment of insomnia symptoms and for the implementation of CBT-I (Carney et al., 2012).

Pittsburgh Sleep Quality Index (PSQI; Buysse et al., 1989) is a 19-item questionnaire that assesses self-reported sleep quality. Each item is rated 0 (no difficulty) to 3 (severe difficulty). A global PSQI score of 0-21 can be calculated by combining the

subscales. A global score of over five is indicative of poor sleep quality. Research suggests the PSQI to a reliable and valid assessment of sleep problems (Grander et al., 2006).

Wrist Actigraphy (Motionwatch 8, CamNTech Ltd) is a device worn on the wrist to record movements that can be used to determine objective sleep-wake patterns. Data is analysed with Actiware software using sleep diary data to identify bedtime and wake time. Outcomes include SOL, WASO, TST, and SE (e.g., TST/ time in bed*100). Previous research has found actigraphy to be a valid method of measuring activity and sleep (Ancoli-Israel et al., 2003).

Wellbeing

Patient Health Questionnaire 9 (PHQ9; Kroenke et al., 2001) is a nine-item self-report measure used to measure depression. Questions are based on diagnostic criteria of depression from DSM-IV. Total scores range between 0 and 27 (0 – 4 = minimal or none, 5 – 9 = mild, 10 – 14 = moderate, 15 – 19 = moderately severe, 20–27 = severe). The PHQ-9 has demonstrated good reliability and construct validity (Kroenke et al., 2001).

Generalized Anxiety Disorder 7 (GAD7; Spitzer et al., 2006) is a seven-item self-report anxiety questionnaire. Total scores suggest the following levels of anxiety: normal (0–4), mild (5–9), moderate (10–14), and severe (15–21). Research has shown the GAD-7 has adequate internal consistency reliability and validity for assessing anxiety (Löwe et al., 2008).

Cognition

The Addenbrooke's Cognitive Examination (ACE-III; Hsieh et al, 2013) is a screening test composed of tests of attention, orientation, memory, language, visual perceptual and visuospatial skills. It is scored out of 100, with a higher score denoting better cognitive function. The ACE-III has been validated against standard neuropsychological tests and has been shown to be a valid cognitive screening tool (Hsieh et al., 2013).

Cognitive Change Index (CCI; Rattanabannakit et al, 2016) is a tool used to assess the perception of cognitive decline in memory, executive function, and language domains from both self and informant perspectives. It contains 20 items and asks participants

to rate their cognitive status relative to the previous five years. Each item is rated on a Likert scale out of five possible points (1 = no change or better, 2 = minimal change or slight/occasional problem, 3 = some change or mild problem, 4 = clearly noticeable change or moderate problem, 5 = much worse or severe problem).

Digit Span Task (Wechsler, 1997) is a valid measure of speed of mental processing and working memory (Joy et al., 2004). Participants are presented with a random series of digits and are asked to repeat them in the order presented (forward span) and in reverse order (backwards span). Research has shown it has good test-retest reliability (Dikmen et al., 1999).

Trail Making Test A (TMT A; Reitan, 1992) has been shown to be a valid and reliable measure of attention and visuoperceptual ability (O'Donnell et al., 1994). Participants are instructed to connect numbered circles in order as fast as they can. The primary score is the number of seconds needed to finish but the number of errors is also recorded. TMT A has good test–retest reliability (Giovagnoli et al., 1996).

Trail Making Test B (TMT B; Reitan, 1992) is a test containing numbered circles and letters. Participants are asked to connect the circles alternating between numbers and letters in consecutive in order (e.g., 1 to A to 2 to B, etc.) as fast as they can. The primary score is the number of seconds needed to finish, but the number of errors is recorded. TMT B has been shown to be a valid measure of cognitive flexibility (a component of executive function) with good test–retest reliability (Kortte et al., 2002).

Procedure

Screening

Those who expressed an interest to take part in the study were given a participant information sheet (Appendix D) and asked to complete a consent form (Appendix C). Participants were then invited to attend a meeting at UEA to complete questionnaires and tests. Participants that could not attend the meeting due to travel arrangements were offered telephone or videoconference meetings with the first author via Microsoft Teams.

At the initial meeting, the General Demographic and Health Questionnaire was completed to address inclusion/exclusion criteria and establish probable insomnia diagnosis. In line with guidance, participants were not screened for cognitive impairment prior to their participation (Canadian Task Force on Preventive Health Care; Pottie et al., 2016). Participants were assigned with an alphanumeric code and given questionnaires to self-report sleep quality (PSQI), wellbeing (PHQ-9, GAD-7) and cognition (CCI). The tests assessing cognition (ACE-III, Digit span task, TMTA, TMTB) were then administered by the first author. To complete the baseline assessment, participants were provided with a sleep diary (CSD) and actiwatch for seven consecutive nights.

A follow-up appointment was booked in with the first author and each participant for seven days' time. These appointments were conducted over the telephone or via videoconferencing on Microsoft Teams due to travel commitments.

Randomisation

Participants were randomly assigned to the intervention groups by computer-generated block randomisation (https://www.sealedenvelope.com/). Participants had provided consent and completed all baseline assessments before being informed of their assignment by the first author. Given the nature of the intervention, it was not possible for participants and the first author who delivered the intervention to remain blind.

BBTI with Countercontrol Intervention

Participants received four individual sessions of BBTI across four consecutive weeks. BBTI was delivered based on the protocol and workbook developed by Buysse et al. (2011). The stimulus control element was adapted in this study to utilise the countercontrol method developed by Zwart & Lisman (1979). Participants were provided with countercontrol instructions, whereby they were instructed to remain in bed, sit up, and engage in some activity (e.g., reading) if they could not fall asleep (Appendix F). In this study, all sessions were conducted over the telephone and/or Microsoft Teams.

Sleep Hygiene Control

Participants in the control condition received one session of sleep hygiene, lasting one hour. Sleep hygiene was chosen as the active control condition since sleep hygiene

instructions are often used in clinical settings for individuals with insomnia (Irish et al., 2015). The session was delivered based on the work of Hauri (1993), whereby environment and behavioural recommendations were suggested to help improve sleep quality. All participants in the control condition completed the same assessments (e.g., sleep diary, actigraphy) as the BBTI group and the session entailed a similar delivery format and level of engagement as the BBTI group. At the end of the session, participants received the sleep hygiene information sheet (Appendix G; Hauri et al., 1993; Irish et al., 2015).

Therapist

All sessions were delivered by the first author (VS) who received regular supervision from the third author (NB).

Post-Intervention

All participants met with the first author via. telephone or Microsoft Teams and completed outcome measures to self-report sleep quality (PSQI), wellbeing (PHQ-9, GAD-7) and cognition (CCI). The tests assessing cognition (ACE-III, Digit span task, TMTA, TMTB) were then administered by the first author. Participants were sent the acceptability questionnaire and asked to complete this and return to the first author in a pre-paid envelope. An optional follow-up appointment was offered to all participants for the following week.

Follow up

Participants who opted for the follow up appointment met with the first author where there was an opportunity to ask any questions about the study or intervention.

Analysis

Primary analysis

Feasibility

The recruitment rate was calculated by averaging the number of participants that contacted the first author by the number of days recruitment was open (21st May – 31st August 2022). Descriptive statistics was used to report the demographic data of the sample.

The retention rate was calculated by averaging the number of participants who completed the study by the number of participants that were recruited. Adherence was calculated by averaging the total number of sessions participants attended. The number of participants that completed the intervention and completed all data collection methods was each summed and reported using percentages.

Acceptability

The number of participants that reported: any changes in their sleep since using the intervention; any changes in their life since the intervention; any difficulties using the intervention; if they will continue using the intervention, and if they would recommend the intervention to someone with insomnia were summed and reported using percentages.

The qualitative data were content analysed. Following guidance, the data were condensed into information units (Erlingsson & Brysiewics, 2017). Information units were segments of text that contained one idea or piece of information (Schilling, 2006). Information units were categorised according to the features of what participants experience was of the intervention, what element was most useful, and any difficulties experienced, the information units in each category were counted for frequency.

Secondary Analysis

Microsoft Excel and IBM SPSS Statistics were used to analyse whether BBTI with countercontrol leads to measurable changes in self-reported and objective sleep quality as well as cognition and mental wellbeing in older people with insomnia.

First, non-normalised outcome data from the sleep diary and actigraphy (e.g., SOL, WASO, TST, and SE) were derived as median of the seven consecutive days. All data was checked for normality using the Kolmogorov-Smirnov test to determine whether independent samples t-tests or Mann Whitney U tests were used to explore group differences on all outcomes.

Next, two additional analyses using the normalisation to individual baseline methodology were performed in line with previous research to ascertain that effects were detected given the smaller same size used for randomisation (Vickers & Altman., 2001). First, values measured at post-intervention phase were normalised to baseline values at an

individual (e.g., post-intervention/baseline*100) level to compare individual changes across time on all outcomes. T-tests or Mann-Whitney U tests were then conducted to analyse between group differences.

Second, a generalised linear model was used to evaluate the main effects and interaction effects across time, for all outcomes. Residuals were inspected for normality, and effect sizes for each variable were computed.

Finally, spearman correlation was used to investigate how the objective (actigraphy) and self-reported (sleep diary) measures (e.g., SOL, WASO, TST, and SE) compared to each other.

Given the pilot nature of the analyses related to the secondary outcome measures no correction for multiplicity was performed. Effect sizes were reported across the multiple statistical approaches and conclusions are based on the consistent results with the strongest effect sizes.

Results

Description of the Sample

Table 1 shows the characteristics of the overall sample (n = 24) and the intervention conditions. The mean age of participants was 70.83 years, with participants ranging from 62 to 80 years old. Participants in the BBTI group scored significantly higher on the PSQI, PHQ-9, and GAD-7 compared to those in the control group at baseline. There were no significant differences between the intervention and control groups at baseline for age, sex, educational level, or use of medication.

Feasibility of BBTI with Countercontrol

Recruitment, Adherence, and Retention Rate

A total of 40 participants contacted the first author between 21st May - 31st August 2022 to express their interest in taking part in the study, an average recruitment rate of 0.56 participants per day. Of the 40 participants, nine were from a pre-existing database held at

UEA, 19 were from social groups aimed at those over 55 years old, and 12 were from local church groups. Of the 40 participants referred, 13 (32.5%) did not meet inclusion criteria, were uncontactable, or did not respond. Twenty-four participants were recruited and provided their consent to take part in the study. Figure 1 outlines the participant flow chart throughout the study.

There was a 100% adherence and retention rate, with participants (n = 24) attending all sessions and completing the study. The completion rate for participants outcomes measures was excellent; 100% at baseline and 95% (n = 23) post-intervention. One participant's outcome actigraphy and acceptability questionnaire was lost in the post, and therefore, was not included in the analysis.

Acceptability of BBTI with Countercontrol

Eleven (95%), participants from the BBTI group completed the questionnaire regarding the acceptability of the intervention. All responses were typically two sentence answers, and the data was condensed into information units. Information units were categorised according to the features of what participants experience was of the intervention, difficulties experienced, and what they found most useful. The information units in each category were counted for frequency.

Thirteen out of the 14 information units generated from the question regarding participants experience of the intervention, imply that the intervention was well-received (Table 1a). Participants also reported which elements of the intervention were most useful. A total of 19 information units were identified. Six out of the 17 information units identified countercontrol as the most useful element (Table 1b).

Table 1
Participants experiences of the intervention.

Acceptability Questions	Categories	Supporting Quotes	Information units
a) What has been your experience of the intervention?	Positive	*"I am very thankful to have had the opportunity to take part in this research study. My experience has been positive, and my sleep has improved!"*	8
	Improvements in sleep and lifestyle	*"My sleep pattern has improved, the quality is better, and I sleep longer."*	5
	Difficult	*"The study took place for me over a difficult time."*	1
b) What was the most useful part?	Awareness of sleep pattern	*"The realisation that I have been spending too many hours in bed trying to sleep. The intervention seemed to rectify this."*	7
	Countercontrol	*"Sitting up in the middle of night if I woke in the night instead of tossing and turning or alike previous therapy – being told to get out of bed!"*	6
	Specific BBTI skills	*"Learning the skills to improve my sleep which I can continue with as/when I need in the future."*	6

Note. BBTI = Brief Behavioural Therapy for Insomnia

Participants reported whether they experienced any difficulties taking part in the intervention. A total of 9 (82%) answered no whilst 2 (18%) answered yes. The two participants that answered yes provided further details, generating five information units. Of

the 5 information units, 4 related to difficulties associated with the sleep diary and sleep restriction element of BBTI (Table 2).

Table 2
Difficulties participants experienced completing the intervention

Acceptability Questions	Categories	Supporting Quotes	Information units
Were there any difficulties taking part in the intervention?	Sleep diary	*"Finding it hard to answer precise timing questions on the sleep diary."*	2
	Sleep restriction	*"Unable to stay up as late as requested."*	2
	External factors	*"The heat."*	1

Eleven participants responded yes to the question asking if they will continue using the intervention. Of the 11 responses, 10 answered yes whilst one answered no.

Secondary Results

We aimed to explore whether BBTI with countercontrol leads to measurable changes in self-reported and objective sleep quality as well as cognition and mental wellbeing in order adults with insomnia. Findings using the normalisation to individual baseline methodology (Vickers & Altman, 2001) to compare between group differences, and main effects and interaction effects across time, for all outcome measures are presented below. Next, findings from the spearman correlation are presented, which investigated how the objective and self-reported sleep measures compared to each other. Findings of all non-normalised comparisons can be found in Appendix J.

Self-Reported Sleep Quality

Significant group differences with a large effect size were found also supporting a greater decrease of the PSQI score in the intervention group compared to the

control group (Table 5). Large effect sizes were also observed on sleep diary TST and SE (Table 4).

A significant group x time interaction was observed for the PSQI with a large effect size (Table 6) and with the BBTI group showing a decrease in the PSQI score over time. Significant group x time interactions were also observed for TST, and SE. Main effects of group were observed for WASO, and SE. A main effect of time was also observed for WASO, TST, and SE (Table 5).

Objective Sleep Quality

Significant group differences with a medium effect size were observed supporting a greater decrease in SOL in the BBTI group compared to the control group (Table 4).

There were no significant group x time interactions for SOL, WASO, TST, or SE (Table 5). A main effect of time for SOL and WASO was observed.

Mental Wellbeing

Significant improvements were found in PHQ-9 and GAD-7 scores for the BBTI group, yielding large (PHQ-9) and medium (GAD-7) effect sizes (Table 4), thus supporting a greater decrease in scores compared to the control group.

There was a significant group x time interaction for the PHQ-9 and GAD-7. Main effects of time were found for the PHQ-9 and GAD-7. A main effect of group was also found for the GAD-7 (Table 5).

Cognition

Significant group differences were found, with the BBTI group showing better performance for CCI, ACE–III, Digit Span, Trail making A, and Trail making B with medium to large effect sizes (Table 4).

Significant group x time interactions were observed for CCI, ACE–III, Digit Span, Trail Making A, and Trail Making B, showing an improvement over time in the BBTI group (Table 6).

Comparisons Between the Objective and Self-Reported Measures of Sleep Quality

Spearman correlation revealed few associations between sleep diary and actigraphy measures. In the control group, a significant positive correlation was observed for the objective and self-reported TST at baseline (Table 6). All other sleep measures showed no significant correlations between sleep diary and actigraphy.

Discussion

This study explored the feasibility and acceptability of BBTI with counter control for older adults with insomnia. Research in this area is lacking despite the high prevalence and negative consequences associated with insomnia (e.g., cognitive decline) in older adults. Although BBTI improves insomnia in older adults, adherence to the stimulus control element is challenging. One way to increase adherence is to utilise a method called countercontrol. However, it is unknown whether BBTI with countercontrol is acceptable to older adults with insomnia.

Our findings suggest BBTI with countercontrol is feasible given there was a 100% adherence and retention rate throughout the intervention and study period. Findings from the acceptability questionnaire revealed most participants had a positive experience of BBTI. Interestingly, one of the most useful elements of our intervention reported by participants was countercontrol. Our findings support the notion that countercontrol may be as effective as stimulus control procedures (Zwart & Lisman, 1979). However, future research comparing these two methods is needed.

A secondary aim was to explore whether BBTI with countercontrol leads to measurable changes in self-reported and objective sleep quality. Findings demonstrated measurable changes in self-reported sleep quality. A significant reduction in PSQI scores among the BBTI group was observed compared to the control group. Similar trends were observed in the sleep diary data, whereby BBTI improved participants SOL, WASO, TST,

and SE. Our results agree with previous studies noting improvement in older adult's self-reported sleep measures following BBTI (Buysse et al., 2011; Lovato et al., 2014).

There were no significant improvements in objective SOL, WASO and SE for the BBTI group. Our findings contrast a previous study (Buysse et al., 2011) that found improvements in actigraphy outcomes following BBTI in older adults. This discrepancy may be due to differences in sample size. Buysse and colleagues had a sample of 82 older adults, which may have enabled the detection of treatment effects, whereas our study was designed as a feasibility study and thus had a smaller sample of 24 (Julious, 2005). Further, actigraphy in our study relied on self-reported data (i.e., sleep diaries) to identify bed and rise times. Given that discrepancies in actigraphy and sleep diary assessments have been observed in older adults with insomnia (van den Berg et al., 2008), it is possible that this may have cause inaccuracies in the objective measure of sleep.

The study also explored whether BBTI with countercontrol leads to measurable changes in wellbeing. Significant group differences were found, showing improvement in symptoms of anxiety and depression following BBTI. Our findings support the notion that insomnia plays a role in the onset and maintenance of depression and anxiety, thus treating insomnia with BBTI may serve to improve older adults sleep, anxiety, and depression (Buysse et al., 2011).

This study also found significant improvements in all measures of cognition following BBTI. Our findings contradict previous research noting no improvement in older adults' cognition following CBT-I or BBTI (Fortier-Brochu et al., 2012; Riedel & Lichstein, 2000). This may be due to differences in the measures of cognition or participant age. Given our study adopted an older adult sample (mean age 70.83), our results may be more representative of the effectiveness of BBTI on cognition in older adults.

Lastly, this study also explored how the objective (actigraphy) and self-reported (sleep diary) measures of sleep quality compared to each other. Clear discrepancies were observed across both groups. Self-reported SOL was overestimated, with WASO and TST being underestimated. Findings are in line with previous research documenting discrepancies between objective and self-reported measures of sleep in older adults (DiNapoli et al., 2017; Kay et al., 2015).

Limitations and Future Research

A primary limitation of this study is the small sample size which decreases statistical power and can lead to overestimates of effect size and low reproducibility of results. The current study was designed as a feasibility and acceptability study, and the sample size (n = 24) fell within the recommended range for feasibility studies (Julious, 2005). However, a future RCT with a large sample size is warranted to improve generalisability of results. Further, participants were retired, community volunteers with more free time and thus were more able to complete all parts of our study.

Secondly, given our study was designed as a feasibility study and recruited 24 asymptomatic older adults we did not utilise a cognitive screening measure prior to participation selection. However, it would be helpful for a future RCT with a larger sample size to incorporate a cognitive screen to ensure participants meet inclusion criteria (i.e., no signs of cognitive impairment) and improve generalisability of results.

Thirdly, there was an imbalance between the two groups, with the BBTI group having higher levels of depression, anxiety, and self-reported sleep quality (see Table 3), at baseline. This is important given the impact this can have on insomnia (Chen et al., 2015). However, when scores were normalised to account for individual baseline differences, findings showed a reduction in PHQ-9, GAD-7 and PSQI scores with medium to large effect sizes.

It is possible that participants improvements in measures of cognition may have been due to practice or learning effects due to repeated exposure to test materials and procedures within a small re-test interval (Goldberg et al., 2015). Although our test re-test gap of four weeks was in line with previous research (e.g., two to four weeks between test-retest intervals; Fawns-Richie & Deary, 2020), participants completed the same tests at baseline and post-intervention. This is a major issue in clinical and research settings (Houx et al., 2002) since practice effects may mask cognitive decline and delay diagnosis and clinical care for patients with cognitive deficits. Future research should address this through administering alternate versions of the same task (e.g., different words in a verbal memory test) within the recommended time frame of two to four weeks.

Another limitation was the study's inclusion criteria. Participants met criteria for 'older adult' if they were ≥ 55 years. Although there are inconsistencies in research with ways to classify this population, most studies define older adults as ≥65 (Alterovitz & Mendelsohn, 2013). Given the mean age of our participants was 70.83, with the youngest participant being 62, it can be noted that this was an older adult sample. Future studies should recruit a larger sample size with all participants ≥65 to aid generalisability of results.

Further limitations include the use of an active sleep hygiene control group that was not matched for therapist time, and the use of a single researcher/therapist. However, all participants in the control group completed the same assessments as the BBTI group and the session had a similar delivery format as the BBTI group (e.g., level of engagement).

Further, all phases of this study were conducted by the primary author. Thus, double blinding was not achieved. Instead, alphanumeric codes were assigned to all participants and used throughout the study and the primary author received regular supervision from the second and third authors to minimise bias. Future research should include an active control condition matched for therapist time, and a researcher team to achieve double blinding to minimise bias and maximise validity of the results.

Implications

Our findings support the use of BBTI to improve older adults' sleep, wellbeing, and cognition. Thus, given the potential acute and adverse effects of pharmacological treatment for insomnia, sleep interventions should be considered a primary treatment option for older adults with insomnia (Bertisch et al., 2014).

The acceptability of the countercontrol element adds to the limited evidence that it may be a preferable alternative than standard stimulus control methods. Our findings support previous research (Gross & Borkovec, 1982; Lundh et al., 1991), that disrupting cognitive arousal (e.g., thoughts/worries associated with sleeplessness) with activity allows the bed/bedroom to be reconditioned with sleep. Thus, the standard stimulus control instruction of having to leave the bed/bedroom is unnecessary. Instead, countercontrol offers an acceptable alternative (e.g., reading in bed) whilst still disrupting the learned association between the bed bedroom with arousal and frustration. These findings may also be generalisable to other populations with a high prevalence of insomnia (e.g., stroke survivors,

people with Parkinson's disease, brain injury and/or those with physical disabilities) who may encounter difficulties with adherence to the out-of-bed requirement. However further research is required.

Finally, the discrepancies in the objective (actigraphy) and self-report (sleep diary) measures of sleep adds to the evidence that there may be discrepancies between objective and self-reported sleep data in older adults with insomnia (van den Berg et al., 2008). Clinical practice should not rely on a single sleep measurement tool since results could be inaccurate and lead to invalid assessments, misdiagnosis, and incorrect treatment.

Conclusions

Findings of this study suggest that BBTI with countercontrol is feasible and acceptable to older adults with insomnia. The study also suggests that BBTI with countercontrol leads to measurable changes in sleep, cognition, and mental wellbeing for older adults with insomnia. A future RCT is warranted to confirm our findings and improve generalisability of the results.

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Figure 1

Participant flowchart

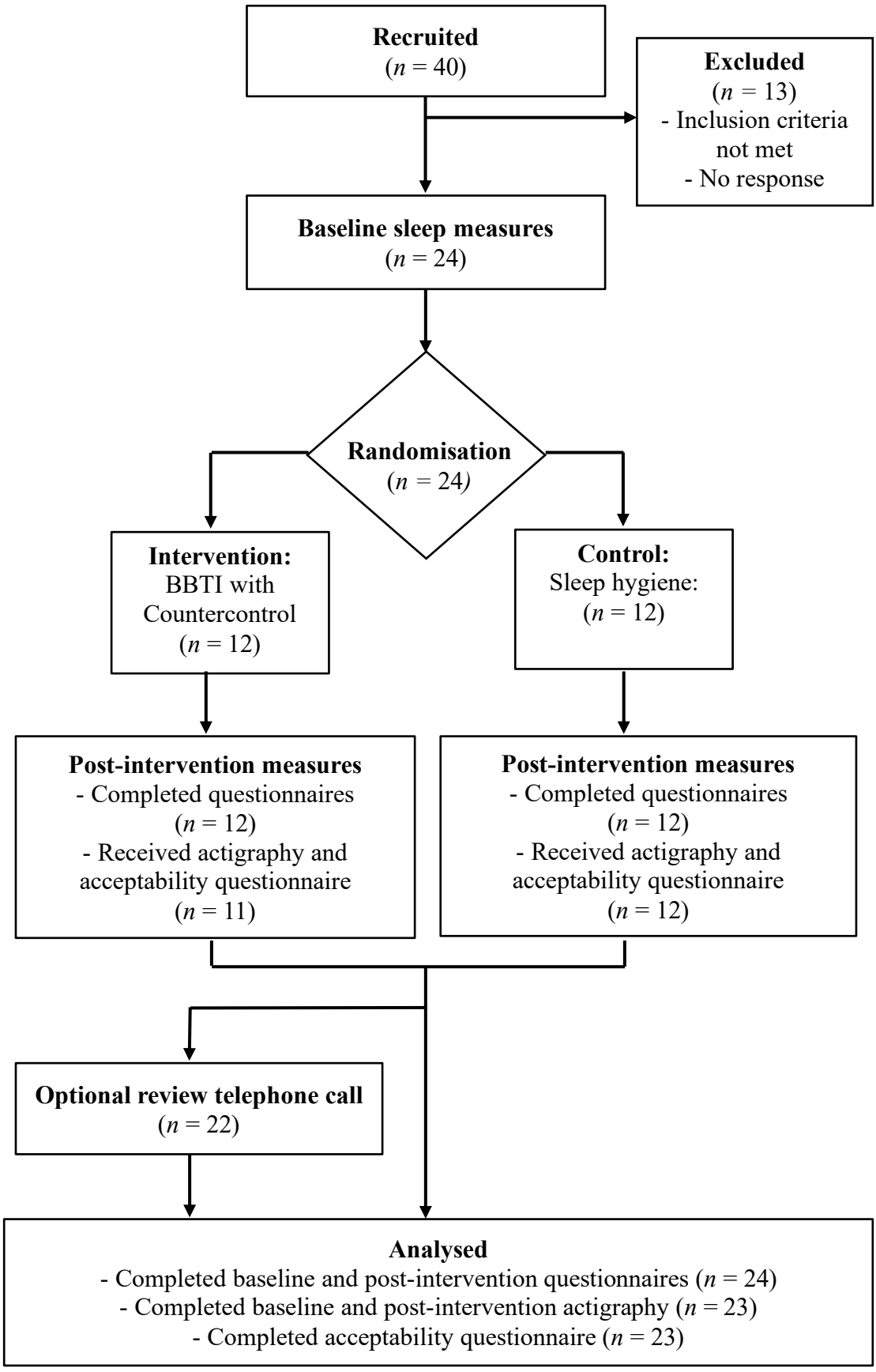

Table 3

Participant demographics

Demographics	**All** (*n* = 24)	**BBTI** (*n* = 12)	**SH Control** (*n* = 12)	**Statistics** (*p* Value)
Age, *M (SD)*	70.83 (4.75)	71.08 (4.99)	70.58 (4.69)	0.88
Range	62-80	65-80	62-77	
Gender, *n* (%)				0.35
Male	9 (37.5%)	2 (8.3%)	7 (29.2%)	
Female	15 (62.5)	10 (41.6%)	5 (20.8%)	
Years spent in Education, *M (SD)*	14.16 (4.53)	14.66 (5.68)	13.66 (3.17)	0.88
Taking sleep medication, *n* (%)	4 (16.6%)	2 (8.3%)	2 (8.3%)	1.00
PSQI Baseline, *M (SD)*	11.75 (2.31)	13.36 (1.85)	10.33(1.83)	<.001

Note. BBTI = Brief Behavioural Treatment of Insomnia; SH = Sleep Hygiene; *n* = number of participants; *M* = Mean; *SD* = Standard Deviation; PSQI = Pittsburgh Sleep Quality Index

Table 4
Normalised comparisons, between group differences (%)

Measures	**Between group differences**		
	M (SD) difference between the two group means	*ES (d)*	*P value*
Actigraphy			
SOL	92.95 (110.56)	-0.64	0.003
WASO	86.67 (31.43)	-0.22	0.3
TST	100.36 (14.61)	-0.24	0.28
SE	138.02 (169.36)	-0.04	0.88
Sleep Diary			
SOL	124.88	-0.40	0.52
WASO	80.45 (73.45)	-0.43	0.03
TST	114.65 (20.49)	1.33	0.002
SE	122.58 (22.61)	1.93	<.001
Sleep			
PSQI	69.77 (56.15)	-0.86	<.001
Wellbeing			
PHQ-9	58.44 (40.5)	-0.82	<.001
GAD-7	69.1 (38.65)	-0.62	0.003
Cognition			
CCI – 20 – S	95.51 (14.80)	-0.55	0.007
ACE – III	102.54 (5.12)	-0.66	<.001
Digit Span	106.73 (16.89)	-0.77	<.001
Trail Making A	91.51 (9.45)	-0.73	<.001
Trail Making B	83.22 (16.36)	-1.91	<.001

Note. BBTI = Brief Behaviour Therapy for Insomnia, *M* = Mean; *SD* = Standard Deviation; ES = Effect size; SOL = Sleep Onset Latency; WASO = Wake After Sleep Onset; TST = Total Sleep Time; SE = Sleep Efficiency; PSQI = Pittsburgh Sleep Quality Index; PHQ-9; Patient Health Questionnaire; GAD-7 = Generalised Anxiety Disorder Assessment; CCI-20-S = Cognitive Change Index; ACE – III =Addenbrooke's Cognitive Examination

Table 5

Normalised Comparisons, main effects, and interactions for all outcome measures

Measures	Main effect of group		Main effect of time		Group x time interaction	
	P value	ES (η^2)	P value	ES (η^2)	P value	ES (η^2)
Actigraphy						
SOL	0.83	0.02	0.03	0.22	0.18	0.09
WASO	0.52	0.02	0.03	0.22	0.91	0.00
TST	0.58	0.02	0.81	0.00	0.51	0.02
SE	0.40	0.04	0.36	0.04	0.23	0.07
Sleep Diary						
SOL	0.28	0.05	0.08	0.14	0.07	0.14
WASO	0.00	0.32	0.01	0.024	0.44	0.03
TST	0.11	0.11	<.001	0.40	0.01	0.31
SE	0.01	0.28	<.001	0.71	<.001	0.57
Sleep						
PSQI	<.001	0.74	<.001	0.87	<.001	0.89
Wellbeing						
PHQ-9	0.09	0.22	<.001	0.70	<.001	0.66
GAD-7	<.001	0.47	<.001	0.49	<.001	0.44
Cognition						
CCI – 20 – S	0.26	0.06	0.04	0.18	0.00	0.32

ACE – III	0.64	0.01	0.01	0.29	<.001	
Digit Span	0.88	0.00	0.03	0.19	<.001	0.46
Trail Making A	0.62	0.01	<.001	0.44	0.01	0.2
Trail Making B	0.50	0.02	<.001	0.50	0.00	0.35

Note. BBTI = Brief Behaviour Therapy for Insomnia, *M* = Mean; *SD* = Standard Deviation; SOL = Sleep Onset Latency; WASO = Wake After Sleep Onset; TST = Total Sleep Time; SE = Sleep Efficiency; PSQI = Pittsburgh Sleep Quality Index; PHQ-9; Patient Health Questionnaire; GAD-7 = Generalised Anxiety Disorder Assessment; CCI-20-S = Cognitive Change Index; ACE – III =Addenbrooke's Cognitive Examination

Table 6

Comparisons between objective and self-reported measures of sleep

Measure	**BBTI**				**Control**			
	Baseline		Post-intervention		Baseline		Post-intervention	
	Correlation	P Value	Correlation	P Value	Correlation	P Value	Correlation	P Value
SOL	0.01	0.98	0.59	0.06	0.28	0.38	0.30	0.35
WASO	-0.07	0.84	0.40	0.22	0.23	0.47	-0.17	0.61
TST	0.14	0.66	0.37	0.26	0.68	0.02	0.37	0.24
SE	0.24	0.45	-0.03	0.94	0.20	0.53	-0.37	0.24

Note. BBTI = Brief Behaviour Therapy for Insomnia; SOL = Sleep Onset Latency; WASO = Wake After Sleep Onset; TST = Total Sleep Time; SE = Sleep Efficiency

Chapter Five:

Discussion and Critical Evaluation

Discussion and Critical Evaluation

The aim of this thesis portfolio was to contribute to the sleep literature concerning psychological interventions for older adults with insomnia. Research in this area is lacking despite the high prevalence and negative consequences associated with insomnia (e.g., cognitive decline) in older adults (Bastien et al., 2003). All of which can have a profound impact on the individual's quality of life and put strain on caregivers and healthcare services (Goldstein et al., 2004; Simon & VonKorff, 1997). Previous research has evidenced Brief Behavioural Intervention for Insomnia (BBTI) as an effective intervention for treating older adults with insomnia (Buysse et al., 2011). However, despite cognitive difficulties featuring in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association [APA], 2013) and the International Classification of Sleep Disorders (ICSD-3; American Academy of Sleep Medicine, 2014), and causing significant difficulties to older adults, there has been little evaluation of the impact of sleep interventions on cognitive performance. This is important since interventions for insomnia should aim to improve not only sleep, but also the cognitive difficulties that contribute to the effect of the disorder (Wade, 2010).

Further, adherence to the stimulus control element included in BBTI is reportedly challenging for older adults due to mobility difficulties and anxiety about (and potential risk of) falls. Utilising a modified method called countercontrol is one way to increase adherence to stimulus control procedures (Zwart & Lisman, 1979). However, studies utilising countercontrol are limited and it is unknown whether it is acceptable to older adults with insomnia. Therefore, this thesis portfolio aimed to contribute to the field with a systematic review of the literature to evaluate the effectiveness of Cognitive Behavioural Therapy for Insomnia (CBT-I) on cognitive performance for older adults with insomnia and an empirical research study to explore the feasibility and acceptability of a BBTI with countercontrol in older adults with insomnia.

This chapter presents a critical evaluation of the principal findings, strengths and limitations of this thesis, and the theoretical and clinical implications of the systematic review and empirical study are discussed, alongside areas for future research.

Principal Findings

The systematic review summarised the literature and evaluated the evidence for the effects of CBT-I on cognitive performance for older adults with insomnia. A total of 7 studies met inclusion criteria and were included for review. These studies all utilised a component of CBT-I, an older adult sample, and an outcome measure of sleep and cognitive performance. Most studies found CBT-I improved performance in one or more domains of cognition. Significant improvements were reported in the following domains: overall cognitive function, memory, executive function, and attention. No improvements were found in the domains of language.

The empirical study followed from the systematic review and explored the feasibility and acceptability of BBTI with countercontrol in older adults with insomnia. Participants were randomised to receive either BBTI or sleep hygiene (control). The feasibility of BBTI was assessed based on the recruitment, adherence, and retention rates of participants throughout the study. Acceptability of the intervention was assessed through a questionnaire focused on participants experiences of BBTI with countercontrol. Secondary aims of the study explored whether BBTI with countercontrol lead to measurable changes in self-reported (sleep diary, questionnaire) and objective (actigraphy) sleep quality, cognition, and mental wellbeing in older adults with insomnia, and explored how the objective and self-reported measures of sleep compared to each other. Findings indicated that BBTI with countercontrol was feasible and acceptable to older adults with insomnia. All participants were retained and adhered to the intervention. Participants in the BBTI group reported positive experiences, and countercontrol was cited as one of the most useful elements of the intervention. Results also revealed that BBTI with countercontrol significantly improved self-reported measures of sleep, wellbeing, and cognition. Clear discrepancies were observed between the objectively measured actigraphy and self-reported measured sleep diary data, across both groups.

Strengths and Limitations

Systematic Review

Strengths

The systematic review provided a comprehensive narrative synthesis of existing research. It explored the effectiveness of CBT-I on cognitive performance for older adults with insomnia. Given that insomnia in older adults is related to cognitive impairments (Bastien et al., 2004; Hauri, 1997), a better understanding of the effect of CBT-I on cognitive performance may inform future CBT-I interventions and help to reduce the effect of poor cognitive performance on older adults' health, safety, and well-being.

A particular strength of the review relates to the methodology. The review followed guidance on conducting a narrative synthesis (Popay et al., 2006) and studies of all methodological quality were eligible for review to increase reliability (Higgins et al., 2011). However, synthesis was stratified by methodological rigour of included studies to reduce possible source of bias in results and subsequent conclusions (Popay et al., 2006; Higgins et al., 2011). Methodological quality of the included studies was assessed using the Downs and Black checklist (Downs & Black., 1998), which has been found to have adequate levels of internal consistency, good inter-rater reliability, and high test-retest reliability. In addition, to further ensure process rigour, all the included studies were co-rated by a second reviewer. In the case of any inconsistencies in appraisal of quality, discussions between the two reviewers were held until a consensus was reached.

Limitations

Although, the overall methodological rigour of the narrative review was strong, one notable limitation to the analytical approach was the lack of meta-analysis due to the lack of studies meeting inclusion criteria and the heterogeneity in measures of cognitive performance. This made it difficult to synthesis findings and draw conclusions. For example, results within the cognitive domain of attention were conflicted due to a lack of apparent consensus regarding the conceptualisation of attention as a multi-component cognitive domain (Posner & Petersen, 1990). Four studies assessed attention, with two that assessed visual attention and processing speed, and two that assessed sustained attention using

computerised vigilance tests. Although only one study reported significant improvements following CBT-I.

Similarly, another limitation of the systematic review was that the included studies lacked good methodological quality. All included studies were rated with poor or fair methodological quality. Most studies were weakened due to a lack of blinding given participants and researchers were often not blind to group assignment. Although double-blinded placebo-controlled studies are difficult to implement when evaluating psychological interventions, the specific effects of CBT-I cannot be separated from non-specific effects (e.g., therapist attention and participant expectations; Oken et al., 2008). This limited the ability for firm conclusions to be drawn and generalised from the findings.

Empirical Paper

Strengths

The empirical study was, to the author's knowledge, the first of its kind to explore the feasibility and acceptability of BBTI with countercontrol for older adults with insomnia. The study highlights the importance of insomnia in this population due to the detrimental effects this can have on sleep quality, cognition, and mental wellbeing.

The planning, design and delivery of this study was in line with guidance and previous research. The study followed the Medical Research Council (MRC; Craig et al., 2013) guidance for feasibility and acceptability RCT studies. A mixed method design was used to gather information on recruitment, retention, adherence, and completion rates, whilst also providing an understanding of participants experiences of the intervention. The BBTI intervention was delivered based on the protocol and workbook developed by Buysse et al. (2011), with the stimulus control element being adapted to utilise the countercontrol method developed by Zwart & Lisman (1979). Sleep hygiene was chosen as the active control condition since sleep hygiene instructions are often used in clinical settings for individuals with insomnia (Irish et al., 2015). The sleep hygiene session was delivered based on the work of Hauri (1993), whereby environment and behavioural recommendations were suggested to help improve sleep quality. Given that discrepancies between objective and self-reported measures of sleep quality have been noted in previous research with older adults, this study

utilised objective (actigraphy) and self-reported methods of sleep quality (sleep diary, questionnaire) across multiple days (van den Berg et al., 2008),

Due to the feasibility design of the study, the analyses of the secondary outcome measures (e.g., sleep quality, wellbeing, and cognition) were carefully planned because of the small sample size. First, values measured at post-intervention were normalised to baseline values at an individual (e.g., post-intervention/baseline*100) level to compare individual changes across time on all outcomes. T-tests or Mann-Whitney U tests were conducted to analyse between group differences. Second, a multivariate approach was used implemented in a general linear model to evaluate the main effects of Group allocation and test sessions as well the interactions, for all outcomes. Residuals were inspected for normality, and effect sizes for each variable were computed.

The results of this study found BBTI with countercontrol to be a feasible and acceptable intervention for older adults with insomnia. Findings warrant a future Randomised Control Trial (RCT) to confirm and improve generalisability of findings.

Limitations

The empirical study had several limitations. Firstly, the sample was limited in size (*n* = 24) and heterogeneity. Given the study was designed as a feasibility study, the sample was however limited to 24 participants (Julious, 2005). Participants were community volunteers so their sleep may have been less severe than that of patients seeking insomnia treatment in a clinical setting. Further, most of the participants were female, not regularly taking medication for sleep, and had no other sleep disorders. Taken together, our sample may not have been representative of the older adult population. Therefore, generalisability of the findings is limited.

Secondly, there was an apparent imbalance between the intervention and control groups in terms of levels of depression, anxiety, and self-reported sleep quality. The BBTI group had significantly higher levels of depression, anxiety and lower levels of sleep quality compared to the control group at baseline. This is important to note given the impact depression, anxiety and sleep quality can have on insomnia (Chen et al., 2015). However, when scores were normalised to account for individual baseline differences, findings showed

a reduction in scores on depression, anxiety, and sleep quality with medium to large effect sizes.

The study may also be subject to bias given that the intervention and analysis was conducted by the first author. This also meant that double blinding was not achieved. However regular supervision with the second and third authors, and use of alphanumerical codes were used to minimise bias.

Implications and Future Research

Systematic Review

The systematic review revealed a large amount of heterogeneity in the relationship between insomnia and cognitive performance. Most studies included a range of outcomes to represent cognitive performance, although they did not find unequivocal significance.

The inconsistent results across cognitive performance domains in the review could be driven by various factors. Firstly, it is possible that discrepancies in findings are due to how insomnia was defined across studies. Prevalence rates of insomnia can vary from 6% to 33% dependent upon which diagnostic criteria is used. Most studies in our systematic review utilised either the DSM-5 or the International Classification of Sleep Disorders, Third Edition (ICSD-3) as inclusion criteria for their participants. However, research suggests a large percentage of people experiencing insomnia symptoms do not meet DSM-5 criteria for insomnia disorder. Thus, insomnia may be better assessed on a continuous dimension of symptoms with multiple phenotypes as opposed to a categorical diagnosis. Further research is required to distinguish between complaints/symptoms of insomnia and insomnia diagnoses (Ohayon & Reynolds, 2009).

Further, measures of cognitive performance varied throughout the studies. Measures ranged from the Mini-Mental State Examination (MMSE) to Trail Making Test B. This is important to consider when interpreting findings since measures like the MMSE are typically used to assess cognitive impairments such as dementia or Parkinson's disease (Nasreddine et al., 2005; Mamikonyan et al., 2009). Therefore, it may not be sensitive enough to measure small changes in cognitive performance, since they may be subject to ceiling effects. Future research should utilise more sensitive measures of cognitive performance. Moreover, it would

be beneficial to develop a more standardised, domain-based approach to neuropsychology testing in studies of insomnia and cognition (as per the dementia field, e.g., the CogState Brief Battery; Maruff et al. 2009). This would enable consistency in future research and aid comparisons and replication of results.

Other factors that may have contributed to the inconsistent results include the time of cognitive testing and participant's previous night's sleep. Research suggests time of testing may impact on cognitive performance due to circadian rhythmicity of alertness and fatigue, aging effects (e.g., cognitive decline), and a participants' chronotype (e.g., preferred sleep/wake schedule) (Newson & Kemps, 2006). Further, research has evidenced that older adults with insomnia experience both good and bad nights of sleep (Buysse et al., 2010). This suggests that cognitive performance may only be affected after a bad night's sleep, and not after a good night of sleep. Future studies should consider participants previous night's sleep when assessing the impact of CBT-I on cognitive performance.

Findings of the review also have important implications for clinical practice. Overall, CBT-I was found to improve older adults' cognitive performance in the following domains: overall cognitive function, memory, executive functioning, and attention. This suggests the possible effectiveness of treating insomnia to improve cognitive performance. This is critical to older adults since studies have found associations between sleep and the risk of cognitive decline and Alzheimer's Disease (AD). Thus, improvement in sleep through CBT-I might be an intervention for cognitive decline and/or AD prevention and treatment (Bubu et al., 2017). Given that dementia is known to cause irreversible effects on quality of life and a strain on global health, it is imperative to educate clinicians about this and the importance of safely promoting healthy sleep as having a potentially useful role in dementia prevention (Lim & Saper, 2011).

Empirical Paper

The empirical study suggests BBTI with counter control is feasible and acceptable to older adults with insomnia. Findings of this study revealed participants in the BBTI group experienced significantly improved self-reported measures of sleep. There were significant differences between the BBTI with countercontrol and control groups in the improvement on sleep parameters and sleep quality indicating that participants in the BBTI with countercontrol group experienced better sleep at night. Findings lend support to the original

approach (Buysse et al., 2011) and demonstrate the success of BBTI with older adults with insomnia. These findings have important implications for clinical practice given that CBT-I is often limited in clinical settings due to a lack of resources, trained clinicians (e.g., Clinical Psychologists) as well as the duration and intensity of the intervention (Morin, 2010). Therefore, the brevity of BBTI is an effective and efficient way to increase clinical throughput in busy clinical settings with limited resources (Buysse et al., 2011). Further, given the potential acute and adverse effects of medication for older adults with insomnia our findings support the notion that BBTI should be considered as a primary treatment option for older adults with insomnia (Omvik et al., 2006; Bertisch et al., 2014).

Further, the success of countercontrol supports the hypothesis that the key element in the stimulus control treatment could be the provision of activities that can disrupt cognitive arousal. Both countercontrol and stimulus control require the individual to interrupt their period of sleeplessness with some activity, either in bed (countercontrol) or out of the bedroom (stimulus control). This interruption, which is filled with an activity (e.g., reading), prevents the individual engaging in thoughts and worries about their lack of sleep. Our findings provide preliminary support that removing the out-of-bed requirement might increase adherence and treatment effectiveness. These findings may also be applicable to other populations that may experience difficulties with adherence to the out-of-bed requirement (e.g., those with Parkinson's disease, stroke, brain injury) due to safety concerns. Although our findings support the notion that countercontrol may be as effective as stimulus control procedures, further research is also required to compare these two methods directly. Findings would provide useful insights as to whether countercontrol should be offered to all individuals with insomnia or just patients who may have difficulties with standard stimulus control procedures.

No significant improvements were reported for objective sleep measures (e.g., actigraphy) following BBTI. Our findings contribute to evidence highlighting a discrepancy between self-reported and objective measures of sleep among older adults (Rosa & Bonnet, 2000). Previous research with adolescents highlighted the role self-reported sleep has in mediating the relationship between objective measures of sleep and low mood (Bei et al., 2015). Given that significant improvements in self-reported sleep, depression and anxiety were observed following BBTI, our findings further support the notion that low mood and anxiety are interlinked with self-reported sleep. This is an important finding since the

prevalence of depression and anxiety increases with age, as does insomnia (Solhaug et al., 2012). Therefore, interventions that aim to improve self-reported experiences of sleep, may also serve to improve, and prevent low mood.

Similarly, there was a positive effect on cognitive performance following BBTI, with significantly increased scores on the ACE-III, Digit Span and reduced times on the Trail Making Test A and B tasks, indicating those that received BBTI experienced improvements in their cognitive performance. The present results lend support to previous findings supporting the relationship between sleep and cognitive functioning (Fortier-Brochu & Morin, 2014), whilst having important implications. Given that insomnia is associated with an increased risk of cognitive decline and structural brain changes (e.g., reduced bilateral hippocampal volume and atrophy in the hippocampus), our findings tentatively suggest that BBTI may be a treatment for cognitive decline as well as insomnia (Bubu et al., 2017). Clearly, there is a need for future research to explore the potential effects of sleep interventions on cognitive performance, given the association with insomnia and cognitive decline.

Overall Conclusion

Insomnia is a highly prevalent condition amongst older adults, and it is linked to a range of negative physical and mental health outcomes including depression, anxiety, hypertension, diabetes mellitus, cognitive decline, cardiovascular diseases, and an increased risk of falls (Stoller, 1994). This can have a profound impact on the individual's quality of life and increases the strain on caregivers and healthcare services (Goldstein et al., 2004; Simon & VonKorff, 1997). Medication is often used to treat insomnia but for older adults this has detrimental side effects, including stroke, impaired cognition and coordination which increases risk of falls and death (Glass et al., 2005). This thesis portfolio focused on improving sleep for older adults using psychological interventions (e.g., CBT-I and BBT-I) and explored the effect this had on older adults sleep quality, wellbeing, and cognition. The systematic review found CBT-I improves some domains of cognitive performance for older adults with insomnia, although findings highlighted a small number of studies with methodological limitations, and heterogeneity in this field of research. The empirical study found BBTI with countercontrol is a feasible and acceptable intervention for older adults with insomnia, and leads to improved sleep, wellbeing, and cognition. Overall, further research in

this field is required to contribute to the knowledge and clinical practice of older adults with insomnia.

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Appendix A

Author Guidelines for the Journal of Clinical Sleep Medicine

JCSM | Journal of Clinical Sleep Medicine

Manuscript Submission Guidelines

Quick Links

About *Journal of Clinical Sleep Medicine*

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

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

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

Increase exposure to your research by publishing in JCSM:

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

Journal stats:

- 2021 Impact Factor: 4.324
- 5-year Impact Factor: 5.593
- Google Scholar h-5 index of 51 and an h-5 median of 86
- Visitors: More than 20,000 monthly, including 62,500 page views.

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Manuscript Submission Instructions

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

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 the email address used when you log in to your membership account and your telephone number. Optionally, you may also include your membership number.

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Categories of Manuscripts

The following types of manuscripts are accepted:

Original Articles

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

1. Typically, original articles will contain new data derived from a series of patients or 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 jcsmeditor@aasm.org 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 (https://www.prisma-statement.org/). 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 supplemental material.
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 assessment or 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 affective disorders; Transcranial stimulation devices to treat insomnia (electrical and magnetic); and software and hardware to modify the light spectrum of computer displays to prevent disruption of circadian rhythm. Below are some guidelines:

1. In general, manuscripts should be 1,500 to 2,000 words in length.
2. References should be limited to no more than 25 citations.
3. The references are not included in the 2,000-word limit.
4. Tables and figures are encouraged; the latter in particular might be of great utility in presenting new technologies that involve equipment.
5. If FDA approval (when/if appropriate) has not yet been received, a suitable disclaimer should accompany the article.

Global Practice of Sleep Medicine

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

1. 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 jcsmeditor@aasm.org to discuss their concepts for these manuscripts before submitting.

Solicited Articles

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

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Essential Elements of Manuscript Submissions

Each submitted manuscript must address the following elements:

Clinical Trial Registration

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

- Australian New Zealand Clinical Trials Registry (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
- German Clinical Trials Register (DRKS): http://www.germanctr.de
- ISRCTN Register: http://isrctn.org
- Nederlands Trial Register (NTR): http://www.trialregister.nl
- UMIN Clinical Trials Registry: http://www.umin.ac.jp/ctr

Ethics of Investigation

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

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

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

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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.

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

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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 Table Guidelines.

Supplemental Material

See Supplemental Material Guidelines.

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Details of Style

References and Citation Formatting

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

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

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

Sample Citations within the Body of a Paper

- According to our previous work,[1,3-8,19]
- The patients were studied as follows[3,4]:

Sample References

Journal article:

1. Rainier S, Thomas D, Tokarz D, et al. Myofibrillogenesis regulator 1 gene mutations cause paroxysmal dystonic 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 **AASM Style Guide for Sleep Medicine Terminology**. Authors should use respiratory event index (REI) instead of using apnea-hypopnea index (AHI) when using home sleep apnea testing (HSAT) to diagnose obstructive sleep apnea (OSA). The abbreviations are acceptable on second use within a document, after the abbreviation has been previously defined.

Drug Names

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

People-Centered Language

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

Avoid	Use Instead
OSA patients	patients with OSA

narcoleptics	people with narcolepsy
suffers from	experiences
burden	effect
subjective data	self-reported data
subjects	participants
compliance	adherence

For more guidance, read People-Centered Language Recommendations for Sleep Research Communication by Rebecca E. Fuoco, MPH.

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Figure Guidelines

All figure files must follow the JCSM digital art guidelines. Include the total number of figures on the title page of the manuscript submission.

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.

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Table Guidelines

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

1. Tables must not duplicate data reported in the manuscript text or figures.
2. All tables must be created using the table function in Microsoft Word. Tables created in PowerPoint are not acceptable. Tables submitted as images are not acceptable.
3. Tables must be numbered consecutively in the order in which they are cited in the manuscript.
4. Each table must have a corresponding short title above the table and caption below.
5. Authors are responsible for obtaining full permission to publish tables that have been previously published. Proof of this permission is required prior to publication. See Third-Party Copyright.
6. Tables can be no more than 10 columns wide. Lengthy column headings may require that the number of columns be reduced.
7. Tables can be no more than 45 rows tall. Lengthy captions may require that the number of rows be reduced.

8. Each table should fit on one, letter-sized page in portrait orientation. If necessary, large datasets can be submitted as supplemental material.
9. Each table must be self-contained and comprehensible without referring to the manuscript. This includes the following requirements:
    a. All symbols used in a table must be defined for that table (eg, *, †). If a symbol is used in multiple tables, the definition of the symbol must also be repeated for every table in which it appears. Symbols should be defined in the table caption.
    b. All abbreviations used in a table (including those used in the table title and caption) must be defined in the table's caption. This includes abbreviations defined in the manuscript. If the same abbreviation is repeated in multiple tables, the definition of that abbreviation must be repeated for every table in which it appears. Only the most widely recognized abbreviations are the exception to this rule.
10. Footnotes are acceptable in tables. Footnotes should clearly be marked with superscript lowercase letters or symbols in the table. Do not use numbers (Arabic or Roman numeral) to indicate a footnote. All footnotes should be fully expanded in the table caption.

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Supplemental Material Guidelines

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

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

General Formatting Guidelines

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 issue a correction or retract the paper, whichever is deemed appropriate. The journal reserves the right to inform authors' institutions about plagiarism detected either before or after publication.

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After Acceptance

Author Agreement 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 (publications@aasm.org) of any changes in contact information after a paper has been accepted.

Accepted Papers Repository

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

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 12/21/2022

Appendix B

Ethical Approval Letter for the Empirical Research Paper

University of East Anglia

Study title: Improving sleep for older adults: A feasibility study

Application ID: ETH2122-0490

Dear Victoria,

Your application was considered on 7th February 2022 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 **28th February 2023**.

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.

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 (fmh.ethics@uea.ac.uk).

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 ETH2122-0490: Miss Victoria Silk

Appendix C

Participant Consent Form

Participant Consent Form

Study Title: Improving sleep for older adults: A feasibility study

Name of Researchers: Victoria Silk, Dr. Alpar Lazar and Prof. Niall Broomfield

Please read the following statements carefully:

1) I am over the age of 55 years and have been experiencing problems with my sleep.

2) I have read the participant information sheet for this study.

3) I have been provided with the opportunity to ask questions.

4) I understand that my data will be stored securely by the research team for a minimum of 10 years and may be accessed by other researchers in the future.

5) I agree to my GP/Medical practice being informed of my participation in this study and of any unexpected findings, such as identification of a sleep disorder that may require treatment. I have provided their contact details below.

6) I understand that my participation is voluntary, and I can withdraw from the study at any point, without reason, prior to publication. However, I understand that any data provided up until the point of withdrawal may be used.

I agree to take part in this study.

By signing below, you are confirming that you agree with all the above statements.

Participant's
Signature.....Date.....

Participant's
Name.....

Name and address of GP/ medical practice:

....

....

....

Appendix D

Participant Information Sheet

Participant Information Sheet

Study Title: Improving sleep for older adults: A feasibility study

My name is Victoria Silk, I am a Trainee Clinical Psychologist conducting this study as part of my Doctorate in Clinical Psychology at the University of East Anglia (UEA) with Dr. Alpar Lazar and Professor Niall Broomfield.

I would like to invite you to take part in a study that aims to improve sleep quality for older adults. You do not have to make any immediate decisions about taking part in this study. Please take your time to read the information below.

What is the purpose of this study?

This study aims to investigate the feasibility and acceptability of running a Randomised Control Trial (RCT) and whether an intervention (Brief Behavioural Therapy for insomnia with countercontrol) shows premise for older adults with insomnia.

Can I take part?

We are inviting people over the age of 55 years who have been experiencing problems with their sleep for at least one month.

People with a diagnosis of dementia, sleep disorder, and those who find it difficult to understand written English would not be suitable for the current study.

Do I have to take part?

No, it is your choice whether you take part or not. If you decide to do so, please sign the attached consent form. Please keep in mind that your participation in this study is voluntary so you can withdraw from the study at any point, without reason, prior to publication. However, any data provided up until the point of withdrawal may be used.

What do I have to do?

Please read this information carefully. By signing the attached consent form, you are agreeing to take part in the study.

After you have provided your consent to participate, you will be given some questionnaires to complete. Please read the instructions at the beginning of each questionnaire carefully before completing them. You will then take part in some tests that the researcher will guide you through. This process should take approximately 20 minutes to complete and enables the researcher to find out if your sleep problems are what we are investigating in this study.

If your sleep difficulties are of the types studied in this research and you want to participate in the study, the researcher will then provide you with a sleep diary and a wristwatch device to measure your sleep. The sleep diary should take approximately five minutes to complete every morning and you will be asked to complete this for the duration of the study. You will be asked to wear the wristwatch for the next seven nights to measure your sleep.

During the second meeting, the researcher will explain to you the intervention you will be receiving. If you are allocated to the BBTI with countercontrol group, the researcher will start the intervention with you and arrange three further sessions (one meeting and two telephone calls) with you. If you are allocated to the sleep hygiene, the researcher will provide you with an information pack on sleep.

After two weeks, you will be asked to wear the wristwatch device again for the last seven nights to measure your sleep.

Following this, the researcher will meet with you to complete the questionnaires you completed at the start, and an additional questionnaire about your experience of taking part in the study.

A follow up telephone call will also be provided one week after the end of the study.

What are the benefits of taking part?

Participating in this study will help you to understand your sleep pattern better. In addition, it is hoped that the sleep intervention will help you to improve your sleep, although this cannot be guaranteed. Finally, the information gathered with this research will help guide future research in the treatment for insomnia.

What are the possible disadvantages or risks of taking part?

We do not expect that the study will cause you any harm or risk by taking part. It may be possible that the study causes you to experience a temporary increase in daytime sleepiness. If this does happen, the main researcher will discuss the effect this is having on you and monitor closely during weekly treatment sessions. A follow up telephone call will also be provided one week after the study to discuss any questions you may have.

The research team are not trained to give medical advice or provide a clinical diagnosis. Your results from the questionnaires and tests will not be feedback to you. However, it is possible that your test results may require further medical attention. Therefore, confidentiality will be breached if you show any signs or symptoms of:

1) Sleep disorder
2) Significant low mood
3) Cognitive impairment
4) Risk of harm to yourself or others

In this case, a letter will be sent to your GP and the emergency services will be contacted if appropriate.

What will happen to my information?

All personally identifiable data will be held by the research team at the University of East Anglia and may be shared securely with other researchers. In accordance with good research practice, we will hold all data for a minimum of 10 years.

Please keep in mind that your participation in this study is voluntary so you can withdraw from the study at any point, without reason, prior to publication.

What will happen to the results of this study?

We may present the results of this study at conferences and in a peer-reviewed journal. No participants will be identifiable in any of these cases. If you would like to receive a copy of the final findings, please contact V.Silk@uea.ac.uk with your request.

Who is organising the research?

This study is being organised by Victoria Silk, Dr. Alpar Lazar and Prof. Niall Broomfield at UEA.

Who has reviewed this study?

This study has been reviewed independently by colleagues and granted ethical approval by FMH Ethics committee at the University of East Anglia.

How can I find out more?

You can contact the research team:

Victoria Silk	Dr Alpar Lazar	Prof. Niall Broomfield
V.Silk@uea.ac.uk	A.Lazar@uea.ac.uk	N.Broomfield@uea.ac.uk
(01603) 597539	(01603) 597539	(01603) 591217

If you have any concerns or complaints, please contact:

Professor Charles ffrench-Constant
(Pro-Vice-Chancellor, Norwich Medical School)
cffc@uea.ac.uk

Thank you for taking the time to read this information.

Appendix E
General Demographic and Health Questionnaire

General Demographic and Health Questionnaire
Study Title: Improving sleep for older adults: A feasibility study

It is very important that you provide full and accurate answers to the questions detailed below. If you have any concerns or questions when completing this information, please speak to the researcher. If you experience any changes to your health or wellbeing during the study, please inform the researcher as soon as possible.

Demographics

1) Age:

2) Gender:

   Woman

   Man

   Transgender

   non-binary/non-conforming

   Prefer not to respond

3) How many years have you spent in education?

General health

1) How long have you been experiencing difficulties with your sleep?

2) How many nights per week do you experience difficulties with your sleep?

3) Do you experience any of the following problems due to your sleep difficulties? *Please circle all that apply*

Fatigue	Attention, concentration, or memory impairment	Mood disturbance/irritability

Impaired social, family, occupational or academic performance	Daytime sleepiness	Behavioural problems (e.g., hyperactivity, impulsivity, aggression)
Reduced motivation/energy	Proneness for errors/accidents	Concerns about or dissatisfaction with sleep

4) Do you suffer from any sleep disorders/ sleep problems?

   YES / NO

   If YES, please provide details:

5) Have you received a diagnosis of sleep apnoea or any other sleep related disorder?

   YES/NO

   If YES, please provide details:

6) Have you been diagnosed or are you currently being investigated for a dementia related disorder (this includes mild cognitive impairment)?

   YES/NO

   If YES, please provide details:

7) Have you ever been diagnosed with a neurological, psychiatric/ mental health condition (e.g., depression, anxiety, brain injury, panic disorders, schizophrenia, multiple sclerosis, motor neurone disease etc.)?

   YES/NO

   If YES, please provide details:

8) Are you undergoing treatment or are you currently taking any medication for your sleep?

   YES / NO

   If YES, please provide details:

9) Do you have any disabilities of any kind?

YES / NO

If YES, please provide details:

10) Do you have dyslexia, other specific learning difficulty or other learning difficulty?

YES / NO

If YES, please provide details:

11) Do you currently have/ have had any alcohol/ substance abuse related disorders?

YES/ NO

If YES, please provide details:

12) What is your average weekly intake of alcohol?
(One unit is half a pint beer / one glass of wine / one measure of spirits)

..... units per week.

13) Has there been a time when you regularly consumed more than 14 units of alcohol per week?

YES / NO

If YES, please provide details:

14) What is your average daily intake of caffeinated beverages?
(e.g., coffee/tea/coke/ caffeinated energy drinks)

.....cups per day

15) Have you got any dependents or other responsibilities that could be affected by your participation in the study?

YES / NO

If YES, please provide details:

16) Have you ever suffered any complications from previous research, clinical trials, or treatment?

YES / NO

If YES, please provide details:

Participant's Name:

Date:

Personal Identifier:

Appendix F

Countercontrol Instructions

Countercontrol instructions
(Zwart & Lisman, 1979)

1. Stay in bed during the appropriated time whether you can fall asleep or not.

   From _____ to _____

2. If unable to fall asleep within 10 minutes remain in bed, sit up, and engage in some activity (read, eat, watch television, etc.).

3. Repeat as often as necessary.

Appendix G

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. Maintain a regular sleep timing.
    - Only sleep as much as you need to feel refreshed the next day. Excessively long periods in bed can result in fragmented sleep.
    - Have a regular wake time in the morning, no matter how little you slept the night before, seven days a week. This helps you have a regular sleep timing at night.

8. Avoid daytime naps.
    - Sleeping a lot during the day will affect your ability to fall asleep at night. If you do need a nap, try to limit it to 15 minutes. This should prevent you from going into deep sleep which would usually make it more difficult for you to wake up.

For the next few weeks, 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 influence your sleep. Continue to have patience and perseverance as you follow the instructions (as relevant to you).

Appendix H

Acceptability Questionnaire

Acceptability Questionnaire

Study Title: Improving sleep for older adults: A feasibility study

1. What has been your experience of the intervention?

2. What was the most useful part?

3. What was the least useful part?

4. Has there been any changes in your sleep?

   YES / NO

   Please provide details:

5. Have you noticed any changes in your life since you started the intervention?

   YES / NO

   Please provide details:

6. Were there any difficulties taking part in the intervention?

   YES / NO

   Please provide details:

7. What do you think could be improved about the intervention?

8. How successful do you believe the intervention has been for changing your sleep long-term?

9. Will you continue using the intervention?

   YES / NO

   Please provide details:

10. Would you recommend the intervention to someone with insomnia?

    YES / NO

    Please provide details:

11. What has been your experience of completing the sleep diaries?

12. Were there any difficulties completing the sleep diaries?

    YES / NO

    Please provide details:

13. What has been your experience of the using the actiwatch?

14. Were there any difficulties using the actiwatch?

    YES / NO

    Please provide details:

Appendix I

Aftercare Sheet

Aftercare Sheet

Study Title: Improving sleep for older adults: A feasibility study

Thank you for participating in this research.

The aim of this study is to investigate the feasibility and acceptability of running a Randomised Control Trial (RCT) and whether an intervention (Brief behavioural therapy for insomnia with countercontrol) is effective for older adults with insomnia. The results of this study will not include any information that is identifiable to you.

If you have any questions or would like a summary of the results of this study, please contact Victoria Silk (v.silk@uea.ac.uk).
It is possible that the study has impacted on your sleep. If you are concerned about your sleep and/or wellbeing, please contact your GP in the first instance.

Support services

Please find below a list of support services and organisations that may be of interest.

- **Free listening service**
  The Samaritans is a registered charity that offer confidential support from trained volunteers. You can talk about anything that is troubling you.
  Telephone: 116 123
  Email: jo@samaritans.org
  Website: https://www.samaritans.org/

- **NHS therapy and counselling services**
  Improving Access to Psychological Therapies (IAPT) is an NHS service that offers talking therapies for common mental health problems, like anxiety and depression, such as cognitive behavioural therapy (CBT), counselling, other therapies, and guided self-help. You can talk to your GP about IAPT services or get in touch with them directly.

  Cambridgeshire and Peterborough
  Psychological Wellbeing Service (PWS)
  Telephone: 0300 300 0055 (9am-4pm, Monday to Friday)
  Email: selfreferiapt@cpft.nhs.uk
  Website: https://www.cpft.nhs.uk/psychological-wellbeing-service

  Wellbeing Norfolk & Waveney
  Telephone: 0300 123 1503
  Website: https://www.wellbeingnands.co.uk/
  Email: admin@wellbeingnandw.co.uk

Appendix J

Supplementary Results – Non-normalised Comparisons

Self-Reported Sleep Quality

The BBTI group reported significant improvements in PSQI scores at post-intervention, compared to the control group (Table 1). Sleep diary data also showed some significant improvements in the BBTI group. Significant group differences in SOL, WASO and SE were found at post-intervention (Table 1).

Objective Sleep Quality

No significant effects of the intervention were found on objective actigraphy data on most analyses. The BBTI group had reduced SOL compared to the control group, but the difference was not significant (Table 1).

Mental Wellbeing

The BBTI group reported significant improvements in PHQ-9 and GAD-7 scores at post-intervention, compared to the control group (Table 1).

Cognition

No significant group differences were found at post-intervention (Table 1).

Table 1

Non-normalised comparisons for all outcome measures at baseline and post-intervention

Measures	Baseline			Post-intervention		
	BBTI, *M* (*SD*)	Control, *M* (*SD*)	P value	BBTI, *M* (*SD*)	Control, *M* (*SD*)	P value
Actigraphy						
SOL (hh:mm)	00:20 (00:20)	00:12 (00:13)	0.22	00:05 (00:09)	00:12 (00:10)	0.37
WASO (hh:mm)	01:40 (00:41)	01:51 (00:47)	0.22	01:21 (00:40)	01:30 (00:35)	0.37
TST (hh:mm)	06:23 (00:55)	06:05 (00:49)	0.29	06:12 (00:59)	06:10 (00:44)	0.46
SE (%)	53.05 (20.66)	69.63 (7.56)	0.41	77.99 (8.47)	67.98 (21.54)	0.13
Sleep Diary						
SOL (hh:mm)	00:37 (00:36)	00:30 (00:21)	0.81	00:10 (00:08)	00:30 (00:18)	<.001
WASO (hh:mm)	01:10 (00:53)	01:47 (01:13)	0.8	00:21 (00:20)	01:23 (00:37)	<.001
TST (hh:mm)	05:09 (00:39)	05:21 (00:47)	0.71	06:33 (01:07)	05:29 (00:53)	0.1
SE (%)	58.46 (9.06)	69.65 (8.56)	0.84	81.48 (11.31)	62.51 (7.26)	<.001
Sleep						
PSQI	13.36 (1.8)	10.33 (1.82)	<.001	2.63 (1.43)	11.91 (1.67)	<.001
Wellbeing						
PHQ-9	6.9 (2.54)	3 (2.9)	<.001	1.54 (1.86)	2.75 (2.37)	0.22
GAD-7	4.63 (2.24)	1.08 (0.9)	<.001	1.36 (1.28)	0.66 (0.88)	0.18
Cognition						
CCI – 20 – S	29.27 (10.45)	23.91 (4.27)	0.178	25.72 (9.36)	24.75 (4.45)	0.51

ACE – III	90.81 (6.24)	95.16 (3.97)	0.06	96.18 (3.89)	94.58 (3.62)	0.20
Digit Span (s)	18.63 (3.85)	21.08 (4.1)	0.15	22.09 (4.36)	20.08 (4.14)	0.10
Trail-making A (mm:ss.ss)	00:35.7 (00:10.3)	00:31.3 (00:07.1)	0.45	00:29.8 (00:07)	00:30.5 (00:07)	0.63
Trail-making B (mm:ss.ss)	01:19.9 (00:34.2)	01:03.2 (00:08.1)	0.06	00:54.2 (00:21.5)	00:59.3 (00:08.1)	0.24

Note. BBTI = Brief Behaviour Therapy for Insomnia, *M* = Mean; *SD* = Standard Deviation; SOL = Sleep Onset Latency; WASO = Wake After Sleep Onset; TST = Total Sleep Time; SE = Sleep Efficiency; PSQI = Pittsburgh Sleep Quality Index; PHQ-9; Patient Health Questionnaire; GAD-7 = Generalised Anxiety Disorder Assessment; CCI-20-S = Cognitive Change Index; ACE – III =Addenbrooke's Cognitive Examination; hh:mm = hours and minutes; s = seconds; mm:ss.ss = minutes, seconds and milliseconds