# Do Non-Pharmacological Sleep Interventions Affect Anxiety Symptoms? A Meta-Analysis.

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## Abstract

Research indicates a bidirectional relationship between sleep and anxiety with findings suggesting anxiety can precede poor sleep and vice versa. Evidence suggests sleep-related thought processes associated with anxiety are involved in the maintenance of insomnia. Previous meta-analyses provide some evidence to suggest Cognitive Behavioural Therapy for Insomnia moderately improves anxiety, yet little research has investigated the effect of other sleep interventions on anxiety symptoms. The aim of this meta-analysis was to review whether non-pharmacological sleep interventions have an impact on anxiety symptoms immediately post-intervention. A systematic search of electronic databases was conducted to identify all Randomised Control Trials (RCTs) investigating non-pharmacological sleep interventions which included anxiety symptoms as an outcome. Forty-three RCTs (n = 5945) met full inclusion criteria and were included in a random-effects meta-analysis model. The combined effect size of non-pharmacological sleep interventions on anxiety symptoms was moderate (hedges $g$ = -0.38) indicating a reduction in symptoms. Subgroup analyses found a moderate effect for those with additional physical health difficulties ($g$ = -0.46), a moderate effect for those with additional mental health difficulties ($g$ = -0.47) and a moderate effect for those with elevated levels of anxiety at baseline ($g$ = -0.43). A secondary meta-analysis found a large effect of non-pharmacological sleep interventions on sleep-related thought processes ($g$ = -0.92). These findings indicate non-pharmacological sleep interventions are effective in reducing anxiety and sleep-related thought processes, and these effects may be larger in patients with anxiety. This has clinical implications for considering sleep interventions in the treatment of anxiety.


*Keywords.* Adults, Cognition, Mood, Mental Health, Treatment Effectiveness

## Introduction

Anxiety disorders are amongst the most common mental health problems with research from a large European population-based survey indicating a lifetime prevalence of 16.6% (Somers et al., 2006). In addition, findings from primary care in the United Kingdom (UK) have reported a point prevalence rate of 7.2%, with a higher prevalence found in females and young adults (aged 20-29 years; Martín-Merino et al., 2010). Sleeping difficulties are also a common problem with research indicating around one third of adults in Western countries experience sleep problems at least once a week, and between 6-10% fulfil the criteria for insomnia disorder (Morphy et al., 2007). Research has shown that the prevalence of insomnia is 1.5–2 times higher in females than males (Wilson et al., 2019) and is most common in older adults (Alberta Medical Association, 2015; McCall, 2004). What is more, research has found high rates of insomnia comorbid with anxiety disorders. For instance, in a large nationally representative cross-sectional survey study, it was found respondents with comorbid mood and anxiety disorders had significantly higher rates of severe insomnia complaints (42.1-62.8%; Soehner & Harvey, 2012). Moreover, severe insomnia complaints were significantly more prevalent in individuals with anxiety disorders (24.9-45.5%) relative to those with no disorder (12.4-24.3%; Soehner & Harvey). These findings demonstrate anxiety and insomnia often co-occur.

National Institute of Clinical Excellence (NICE) recommends evidence-based psychological interventions in the treatment of anxiety disorders, usually Cognitive Behavioural Therapy (CBT) as the first-line approach for both adults and children (NICE, 2014). Meta-analyses of CBT for anxiety have reported varying effect sizes. One review explored the efficacy of a CBT intervention for anxiety, on anxiety symptoms relative to treatment as usual (TAU) and found the pooled effect size was in the moderate to high range (Watts et al., 2015). Another review found CBT for anxiety had moderate placebo-

controlled effects on target disorder symptoms and small to moderate effects on other anxiety symptoms (Carpenter et al., 2018). However, previous meta-analyses have found high rates of non-respondence and non-adherence to CBT for anxiety disorders, with findings indicating around a fifth of patients drop out prematurely (Taylor et al., 2012). Therefore, through addressing symptoms of anxiety disorders that are not part of standard 'CBT for anxiety' packages, like insomnia, may address these non-response rates.

Current literature in both adult and child populations indicate a bidirectional relationship between sleep problems and emotional difficulties such as stress and anxiety. A longitudinal study investigating a large sample of 1057 children (aged 4.5-10.5 years) found preschool sleep problems directly predicted 'anxious-depressed' symptoms two years later, and indirect effects continued into preadolescence (Foley & Weinraub, 2017). Similarly, research in the adolescent population has found that sleep problems, particularly wakefulness in bed at night, *precedes* the development of anxiety and depression (Lovato & Gradisar, 2014; McMakin & Alfano, 2015). Longitudinal adult research has found anxiety symptomology can be both a predisposing and precipitating factor for the onset of insomnia (LeBlanc et al., 2009). Finally, research from a large population-based cohort study found evidence to suggest that chronic insomnia may be a trait marker for adults at risk of developing anxiety disorders (Neckelmann et al., 2007). This has important implications when considering treatment for individuals experiencing anxiety and sleep problems.

The mechanisms underlying the maintenance of insomnia have important relevance for the type of intervention offered within mental health services. The current first-line NICE-recommended non-pharmacological treatment for adults with chronic insomnia (>3 months) is Cognitive Behavioural Therapy for Insomnia (CBT-I; NICE, 2020). CBT-I typically includes behavioural components including stimulus control and sleep restriction, as well as cognitive components including cognitive restructuring with a focus on challenging dysfunctional beliefs about sleep and worries or preoccupation about sleep.

Advice on sleep hygiene is recommended for both chronic and mild insomnia, and the guidelines advise to treat comorbid mental health difficulties as required (NICE, 2020). NICE-recommended therapy for anxiety treatment tends not to incorporate strategies to improve sleep problems (e.g., CBT for Anxiety manuals; Lenz, 2018) despite research highlighting high rates of comorbidity. This poses potential intervention dilemmas for clinicians when patients present with anxiety and comorbid sleep disturbance.

Meta-analyses have provided preliminary evidence to suggest there may also be a bidirectional relationship in the treatment of insomnia and anxiety. One meta-analysis exploring the impact of CBT for anxiety disorders on comorbid sleep disturbance found a moderate effect (pooled effect size: 0.53; Belleville et al., 2010). Conversely, another previous meta-analysis has shown a moderate effect (pooled effect size: 0.41) of CBT-I (Cognitive Behavioural Therapy for Insomnia) on concomitant anxiety, arousal, worry, and stress (Belleville et al., 2011). Similarly, previous meta-analyses have found self-help CBT-I is superior to control conditions (including wait-list control, routine care or no treatment) in reducing anxiety symptoms, with small to moderate effect sizes found (van Straten & Cuijpers, 2009; Ho et al., 2015). Further, a systematic review and network meta-analysis exploring effects of CBT-I on anxiety/worry symptoms found small effects for CBT-I delivered individually face-to-face, in group and internet self-help settings, and individually administered CBT-I was not superior to the other settings (Benz et al., 2020). Further, Benz and colleagues found the largest effect for CBT (not CBT-I) for other conditions which included CBT for pain, depression, and Generalised Anxiety Disorder (Benz et al., 2020). Additionally, this meta-analysis comments that effects may be biased given many studies excluded participants with severe levels of anxiety. However, these previous meta-analyses did not consider additional non-pharmacological sleep interventions other than CBT-I, often included measures of both anxiety and co-related anxiety processes such as worry or stress, and effects were not investigated for those from a mental health population. This makes it difficult to draw firm conclusions about

mechanisms contributing to post-treatment change. Therefore, the extent to which anxiety symptoms indirectly improve after non-pharmacological (non-anxiety focused) sleep interventions warrant further investigation.

Previous meta-analyses have found strong evidence to suggest physical health difficulties such as cancer, diabetes, and multiple sclerosis are highly comorbid with anxiety symptoms (Nikbakhsh et al., 2014; Janzen Claude et al., 2014; Boeschoten et al., 2017). Moreover, research has found in newly diagnosed cancer patients, the estimated prevalence of insomnia was between 30-50% (Savard & Morin, 2001). Treating insomnia early in this population is important, to prevent this becoming a chronic problem given research has shown that several years after cancer treatment, 23-44% of cancer survivors still experience insomnia (Savard et al., 2001; Savard et al., 2005). Notably, these findings highlight the importance for research to provide evidence for appropriate treatments for sleep disturbance and anxiety for those with a range of physical health difficulties.

Emerging evidence suggests there may be an interaction between insomnia and anxiety in individuals experiencing physical health difficulties. A large population-based study exploring the prevalence and predictors of insomnia in women with ovarian cancer found 17% of women reported clinically significant insomnia and elevated anxiety was a key predictor (Price et al., 2009). There have been no meta-analyses investigating the effect of non-pharmacological sleep interventions on anxiety symptoms for those with additional physical health problems.

From a theoretical perspective, cognitive models of insomnia have proposed that sleep-related thought mechanisms associated with anxiety play a key role in the development and maintenance of sleep problems. Harvey's (2002) 'Cognitive Model of Insomnia' proposes that excessive worry and preoccupation about the impact sleep disturbance may have on health or daytime functioning triggers a physiological anxiety response. The model suggests the combination of an increased cognitive (e.g., attending to sleep-related threats, rumination, dysfunctional beliefs about sleep) and physiological (e.g.,

increased heart rate, sweating) anxiety response prevents the onset of sleep. This for some can then persist into a vicious cycle and can lead to chronic insomnia (Harvey, 2002; Harvey, 2005). Additionally, the Attention-Intention Effort model (Espie et al., 2006) suggests after a period of acute insomnia, unhelpful beliefs about sleep arise (e.g., "I can never sleep again"), leading to anxiety or preoccupation about sleep and its consequences, which leads to worry about going to sleep and direct attempts to control sleep.

Recent meta-analyses have investigated the impact of CBT-I on certain pre-sleep thoughts involved in the maintenance of insomnia. For instance, a meta-analysis by Thakral et al. (2020) found dysfunctional beliefs and attitudes about sleep improve after a period of CBT-I in adults, with a large effect reported. There have been no meta-analyses exploring the impact of other non-pharmacological sleep interventions on sleep-related thought processes including other processes such as sleep anticipatory anxiety, and sleep effort.

The present review aimed to investigate whether non-pharmacological sleep interventions change anxiety symptoms. Cognitive models of insomnia suggest there are certain sleep-related thought processes often associated with anxiety that can maintain insomnia. Research has not investigated the impact of non-pharmacological sleep interventions on these processes. The present review therefore also aimed to investigate whether non-pharmacological sleep interventions change sleep-related thought processes.

**Research questions**

1. Do non-pharmacological sleep interventions aimed at improving sleep change anxiety symptoms?
    a. Do non-pharmacological sleep interventions aimed at improving sleep change anxiety symptoms for individuals with additional physical health difficulties?
    b. Do non-pharmacological sleep interventions aimed at improving sleep change anxiety symptoms for individuals with additional mental health difficulties?

2. Do non-pharmacological sleep interventions aimed at improving sleep change sleep-related thought processes?

## Methods

### Search Strategy and Inclusion Process

This systematic review followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist and flow diagram for conducting and reporting systematic reviews (Moher et al., 2009). Details of the protocol for this systematic review were registered on PROSPERO and can be accessed at: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=205499

Five electronic databases were systematically searched from inception up to 21st January 2021: Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsychINFO, MEDLINE (plus PubMed), Cochrane Central Register of Controlled Trials (CENTRAL) and EMBASE. These databases were chosen as they were relevant to mental health, psychology, interventions, and sleep. Unpublished grey literature was also searched (opengrey.ac.uk and core.ac.uk). A sensitive search strategy for each individual database was developed, using keywords and MeSH terms with Boolean operators. The following search terms were used: (sleep* OR insomnia OR "sleep disorder*") AND (non-pharmacological OR intervention* OR treatment* OR "Cognitive Behavioural Therap*" OR CBT* OR Education OR hygiene) AND (anx* OR GAD OR GAD-7).

The inclusion criteria were: 1) Randomised Control Trials (including studies which used any control condition including any other treatment, no treatment, treatment as usual and waiting-list control that was not designed to improve sleep) 2) Anxiety symptoms or disorders (reported as a primary or secondary outcome) were measured using; a validated instrument; a diagnostic tool for DSM-5 or ICD-10 mental health disorder; a validated assessment measure, and obtained at immediate post-intervention 3) Human participants of

any age, including those in the general population, those receiving treatment for mental health care and those receiving treatment for physical health difficulties 4) The intervention must include a non-pharmacological intervention aimed at improving sleep 5) The intervention can be delivered in any form 6) The intervention can be delivered by any person 7) For Aim 2 ‘sleep related thought processes’ as measured by the following questionnaires which have been cited in a previous meta-analysis to capture ‘pre-sleep thoughts’ (Lemyre et al., 2020): Night-time Thoughts Questionnaire, Self-statement Test, Glasgow Content of Thoughts Inventory, Insomnia Worry Questionnaire, Bedtime Counterfactual Processing Questionnaire, Nocturnal Regret Questionnaire, Pre-Sleep Arousal Scale (cognitive subscale), Sleep Disturbance Questionnaire (three items), Thought Control Questionnaire (cognitive subscale), Sleep Associated Monitoring Index (pre-sleep questions). Questionnaires capturing other sleep-related thought processes will also be included: Dysfunctional Beliefs About Sleep Scale, Glasgow Sleep Effort Scale, Sleep Anticipatory Anxiety Questionnaire 8) The article was reported in the English language and in a peer-reviewed journal.

The exclusion criteria were: 1) The trial intervention included a pharmacological treatment (including herbal remedies) 2) The trial intervention was not directly aimed at improving sleep (e.g., CBT for anxiety/depression, acupuncture, yoga, stimulus control for worry) 3) The trial control condition was specifically designed to improve sleep (for instance a pharmacological sleep aid or sleep hygiene) 4) Any studies which used sleep devices such as Continuous Positive Airway Pressure (CPAP) 5) Non-experimental designs (e.g., pre-post within subjects designs / AB designs) 6) Studies which provided qualitative data only 7) RCT protocols 7) Non-pharmacological interventions for other sleep-related problems including chronic fatigue, night-eating syndrome, nightmare disorders, narcolepsy, sleep apnoea, ‘excessive daytime somnolence’ 8) The anxiety outcome measure did not explicitly measure anxiety symptoms (e.g. a measure of stress or worry). This was to limit the scope of the review to specifically focus on ‘anxiety

symptoms' as a construct, rather than additional separate components associated with anxiety such as stress or worry. Anxiety questionnaires measure both psychological and physiological components of anxiety whereas some scales pertaining to stress or worry primarily focus on the psychological/cognitive components (e.g., the Penn State Worry Questionnaire). This reflects other efficacy based meta-analyses involving anxiety symptoms (e.g., Carter et al., 2021) 9) Any study involving animal participants 10) The intervention was not a sleep-focused intervention in isolation (e.g., a combined CBT-I and anxiety intervention).

**Study Selection**

The process from study selection to extraction was followed in line with the PRISMA flowchart. Initial title and abstract screening were completed by one reviewer (AS) independently to establish eligibility for inclusion in this review. A random subset of abstracts (10%) retrieved were then screened by a second reviewer (JB) for concordance to be checked. If it was unclear from the title and abstract whether anxiety symptoms or sleep-related thought processes were measured as an outcome, the full text was searched. Duplicates were removed, then full texts were assessed for eligibility against the inclusion/exclusion criteria by two reviewers independently (AS and JB). Disagreements between reviewers were discussed and a consensus agreed, or if needed resolved by a third reviewer (LP). The reference lists of all identified eligible articles were searched for additional studies to ensure any relevant studies were not missed by the electronic search.

**Data Extraction and Quality Assessment**

Data from included studies were extracted by AS and cross-checked by JB. Authors were contacted if there was insufficient outcome data reported for conducting the meta-analysis. The methodological quality of studies included in this review were assessed by

AS using the most recent Cochrane Risk of Bias tool for randomized trials (RoB2; Sterne et al., 2019). This tool is suitable for individually randomized, parallel-group trials. A second reviewer (JB) assessed a subset (20%) of the included studies using this tool. A discrepancy check was also conducted. Where there were disagreements, these were discussed between the two reviewers, and if there were any further disagreements, this was discussed with a third reviewer, and a consensus agreed.

**Data Synthesis**

All eligible studies which included sufficient data on a validated anxiety outcome measure and numbers of participants in each condition were included in a random effects meta-analysis. A random effects model was selected for analyses as this does not assume that each study included in the meta-analysis is identical, meaning each study can introduce its own underlying variance. This model is predominantly used in trials of mental health or social science (Cuijpers, 2016). The random effects meta-analysis was used to compare the effect sizes of interventions relative to control conditions, using the online meta-analysis tool Meta-Analysis via Shiny Version 1.1.2 or 'MAVIS' (Hamilton et al., 2016). Studies were weighted to calculate a combined effect size (Hedge's g). Hedge's g is calculated by computing the difference between means (e.g. experimental sample and a control sample) using a pooled standard deviation. Hedge's g is generally interpreted where 0.2 indicates a small effect, 0.5 indicates a medium effect and 0.8 indicates a large effect (Hedges, 1981). MAVIS software allowed for the examination of possible sources of heterogeneity using the $I^2$ statistic (Higgins et al., 2003). In general, it is assumed that a percentage of 25% indicates low heterogeneity, 50% moderate and 75% high heterogeneity (Higgins et al., 2003). A sensitivity analysis was planned to be conducted a priori where studies rated as low quality were removed from the overall meta-analysis. Four meta-analyses were conducted in MAVIS to address the aims of the study. This included:

1. Overall meta-analysis of the effect of sleep interventions on anxiety symptoms

   a. Sub-group analysis of studies involving participants with additional physical health difficulties
   b. Two sub-group analyses of studies involving participants with additional mental health difficulties and clinically significant anxiety symptoms at baseline
2. Secondary meta-analysis of the effect of sleep interventions on sleep related thought processes

Additional subgroup analyses were planned to be conducted if there were enough studies. This included 1) sub-group analyses of studies which reported sleep medication as an inclusion criterion, compared to studies which excluded sleep medication use 2) subgroup analyses of CBT-I interventions compared to 'other' non-pharmacological sleep interventions.

Relevant data required for the meta-analysis was extracted from the results section of the included studies. This included the number of participants, means (M), standard deviations (SD), effect size (ES) and standard error. Cohen's d effect sizes were used for analyses rather than M/SD, given some studies only reported ES. When not reported, a Cohen's d effect size was computed for each included study for data input into the random effects model. The effect size was calculated based on reported data available (mean, standard error and/or confidence intervals).

For studies with two sleep intervention conditions compared to a control condition (e.g., Cognitive Therapy, Behavioural Therapy and Wait List Control; Sunnhed et al., 2020), a hierarchy was developed to decide which intervention was included in the meta-analysis. In line with other similar meta-analyses (e.g., Gee et al., 2019), the intervention opted for was the 'most intensive' or which had a more robust evidence base. For example, as some research has indicated behavioural components of CBT-I are more effective than

cognitive components (Blake et al., 2017), in a study which compared 'behavioural therapy', 'cognitive therapy' and 'Wait List Control', behavioural therapy was included in the meta-analysis. Similarly, face-to-face interventions were opted for over self-help interventions as they are more intensive and in meta-analyses have demonstrated higher efficacy (van Straten et al., 2018). For the planned subgroup analysis exploring CBT-I and 'other' non-pharmacological sleep interventions, there were only three included studies which were classified as 'other'. However, there were several studies which included behavioural interventions only. Therefore, subgroup analyses were conducted on studies which offered an entire CBT-I package and studies which offered behavioural interventions. This was categorised based on information available in the studies intervention description. 'CBT-I' included any study which included at least four components of CBT-I, including sleep restriction, stimulus control, cognitive restructuring, sleep hygiene education and relaxation. This categorisation was used in a previous meta-analysis exploring the effectiveness of internet CBT-I on insomnia (Ye et al., 2016). Behavioural interventions included studies which offered behavioural components of CBT-I only, without cognitive elements such as cognitive restructuring.

## Results

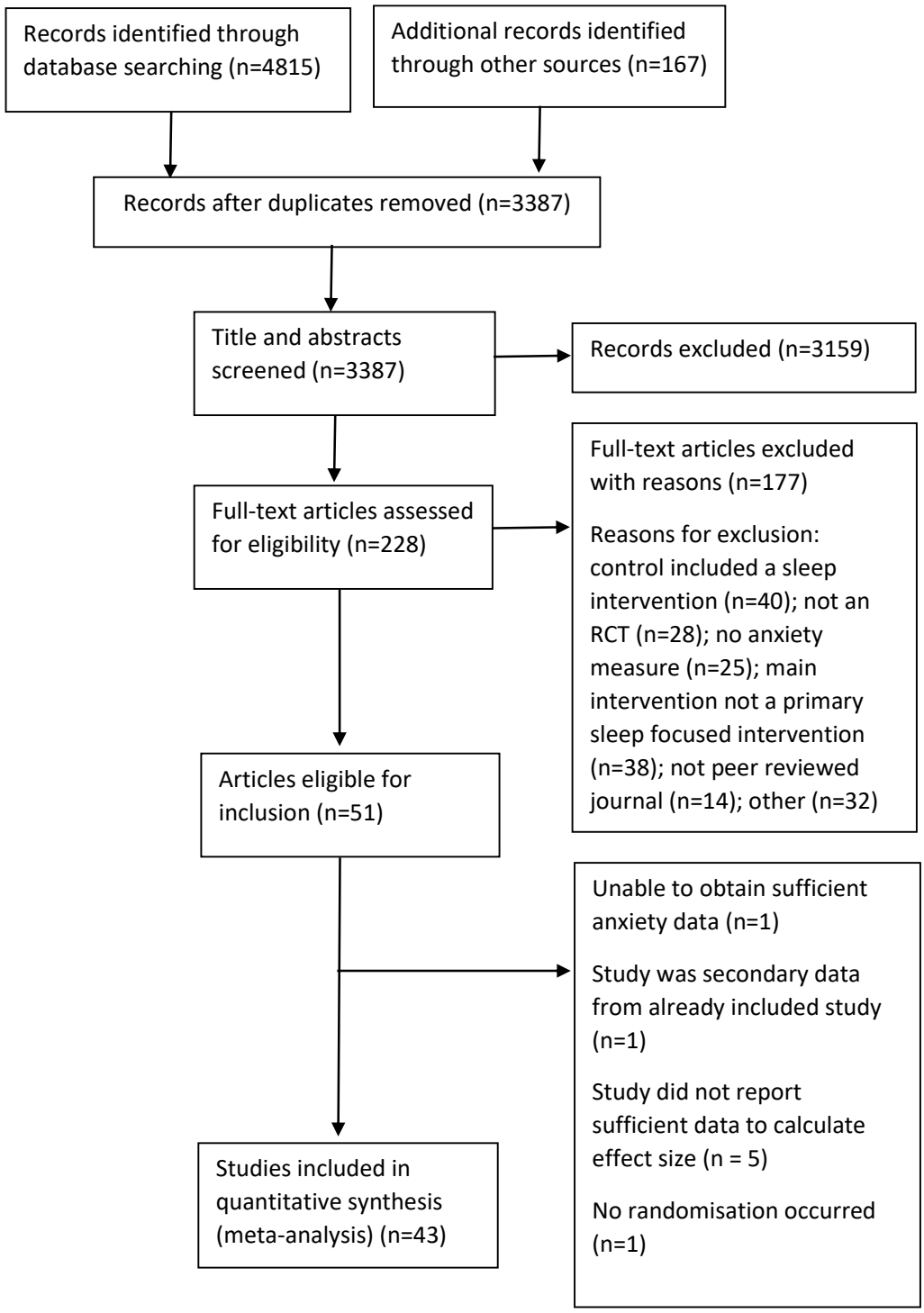
### Study Selection

A PRISMA flow-diagram shows the selection of papers for inclusion and exclusion (Figure 1). A total of 4982 articles were retrieved, of which 1595 were duplicates. There were 3017 articles excluded following title and abstract screening and 177 were excluded following the full text screen. During quality checking and data extraction, eight studies were excluded which meant 43 studies were included in the meta-analysis. Of the 43 included studies, eight had more than one intervention arm compared to a control. One study (Thorndike et al., 2013) included two participant groups; those in a 'low' depression

group and those in a ‘high’ depression group as identified by the Beck Depression Inventory. The low depression group was included in the meta-analysis as most participants included in this review either had no reported mental health difficulties, had been excluded due to screening high for depression, or had subthreshold mental health difficulties.

**Figure 1**

*PRISMA flow diagram of study selection process*




*Note*. The full description of reasons for exclusion can be found in the appendices. 'Additional records identified through other sources' includes grey literature and searches of references of retrieved studies.

## Characteristics of Included Studies

Table 1 outlines the characteristics of included studies. In total, there were data on 5945 participants included in the meta-analysis, with data on 2741 for those receiving a non-pharmacological sleep intervention. Data from 37 of the included studies indicated the overall mean age of the intervention group was 43.33 and the control was 46.46. The additional six studies either reported median values, or a mean of the overall sample. Data from 40 of the included studies indicated 72% (n = 5580) were female and 28% (n = 2167) were male. The additional three studies reported median values only or did not include descriptive gender data. Forty-two of the studies were psychological-based sleep interventions and one study used artificial bright light exposure as the sleep intervention (Huang et al., 2013). Most studies included (n=34) were described by the authors as primarily 'CBT-I'. Two of these studies were combined CBT-I interventions with additional 'third-wave' approaches incorporated which specifically focused on sleep (CBT-I + Mindfulness and CBT-I + Acceptance and Commitment Therapy). 'Third-wave' approaches tend to focus on an individual's relationship with their thoughts and emotions, rather than the content (Hayes & Hoffman, 2017). Therefore, third-wave approaches incorporate concepts such as mindfulness, acceptance and values (Hayes & Hoffman, 2017). Three of the studies were purely behavioural interventions, three were combined sleep hygiene and behavioural interventions, one study was a combined imagery, behavioural and sleep hygiene intervention and one study focused on cognitive strategies to manage pre-sleep worries. Of the psychological-based studies (n = 42), 18 were delivered either via self-help (guided or self-directed) including use of an app or an online intervention. Twenty-four were delivered face-to-face either on a one-to-one basis with a trained professional or in a group format. One study's intervention was delivered by video conference. The control conditions included both active interventions (such as acupuncture or completing puzzles) and passive controls (such as waitlist control or treatment as usual conditions), all not specifically designed to improve sleep.

Most studies included adult participants, with only two studies focusing on young people under 18 years old (Blake et al., 2016; de Bruin et al., 2018) and three studies specifically focused on interventions with older adults (>65) (Black et al., 2015; McCrae et al., 2018; Rybarczyk et al., 2005). Most studies focused on individuals who were experiencing insomnia or sleep disturbance as identified by a validated screening tool or by assessment against classification systems for insomnia disorder. Baseline anxiety scores from questionnaires indicated twelve studies included participants with clinically significant anxiety, ten included participants with mild to moderate anxiety symptoms, and fifteen included participants with no clinically significant anxiety symptoms. Six studies used anxiety questionnaires which did not provide a cut off score for interpretation. Eleven studies had participants who were experiencing sleep disturbance comorbid with additional physical health difficulties (4 = cancer, 1 = traumatic brain injury, 1 = chronic migraine, 1 = fibromyalgia, 1 = hearing difficulties, 1 = multiple sclerosis, 1 = heart failure, 1 = high blood pressure). Subjective sleep quality using a validated questionnaire, or a sleep diary was measured in 40 studies. Some studies (n=6) included inclusion criteria specifically focusing on mental health difficulties, including depression, substance misuse disorder and stress. Most studies (n = 8) included in the sleep-related thought process secondary meta-analysis used the Dysfunctional Beliefs and Attitudes About Sleep (DBAS) scale. Where multiple measures regarding the same construct were reported, the most used measure across studies were selected.

**Table 1**

*Characteristics of studies included in the meta-analysis (n=43)*

| Study | Country | Participants | Intervention | Age (M/SD) | Control | Age (M/SD) | Sleep Medication Status | Gender | Anxiety Measure | Baseline Anxiety | Sleep Measure |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Barati & Amini, 2020 | Iran | Adults with substance addiction admitted to treatment camps and those on methadone maintenance therapy | 4 session sleep hygiene training (including sleep restriction) | 34.14 (8.01) | Passive control | 38.24 (8.69) | Not reported | Not reported | DASS Anxiety Subscale | 'Severe' | PSQI |
| Batterham et al., 2017 | Australia | Adults (18-64) with depression & insomnia | Online CBT-I ('Shut-I') | *43 (12)* | Healthwatch | *43 (12)* | Not reported | 430 F 151 M | GAD-7 | 'Mild' | ISI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| Bergdahl et al., 2016 | Sweden | Adults (18-75) meeting DSM-V criteria for insomnia disorder | CBT-I in a group format delivered by psychologists | 60.5 (11.2) | Auricular acupuncture | 60.8 (7.1) | Excluded | Not reported | HADS-A | No clinical anxiety (Cut off = >8) | ISI |
| Black et al., 2015 | USA | Older adults (>55) with active sleep disturbance | Group sleep hygiene education | 66.1 (8.5) | Mindfulness meditation | 66.5 (6.3) | Not reported | 33 F 16 M | BAI | 'Mild' | PSQI |
| Blake et al., 2016 | USA | Secondary school students with insomnia symptoms | CBT-I + mindfulness sleep intervention (7 sessions) | *14.4 (1.13)* | No treatment control | *14.4 (1.13)* | Excluded | 71 F 52 M | SCAS | Not available | PSQI |
| Carney & Waters, 2006 | USA | Undergraduate students with sleep onset difficulty | Constructive worry (focus is on pre- | *20.97 (3.0)* | Worry procedure (no | *20.97 (3.0)* | Excluded | 26 F 7 M | STAI-S | 'Moderate' | Sleep log (total |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | sleep worries) | | interventi on) | | | | | | sleep time) |
| Casualt et al., 2015 | Canada | Adults with a diagnosis of non-metastatic cancer & acute insomnia symptoms | Self-help CBT-I with 3 brief phone consultations | 56.9 (10.8) | WLC | 57.0 (9.4) | Excluded | 35 F 3 M | HADS-A | No clinical anxiety (Cut off = >8) | ISI |
| Chapoutot et al., 2020 | France | Adults with ICD-10 chronic insomnia and DSM-V sedative, hypnotic or anxiolytic use disorder | CBT/ACT sleep intervention (4 videoconfere nce sessions delivered by psychologist s) | *48 (10)* | WLC | *48 (10)* | Not reported | 24 F 6 M | QoL (anxiety) | Not available | ISI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| De Bruin et al., 2018 | The Netherlands | Adolescents (12-19) meeting DSM-5 criteria for insomnia | Group CBT-I | 15.6 (1.7) | WLC | 15.9 (1.6) | Excluded | 54 F<br>22 M | YSR | Not available | HSDQ – insomnia symptoms |
| Denis et al., 2020 | UK | Females enrolled on a psychology degree with sub-threshold insomnia | Online CBT-I (‘Sleepio’) | 19.73 (2.94) | Puzzle completion | 20.22 (5.69) | Included | 145 F | STAI | ‘Severe’ | PSQI |
| Espie et al., 2008 | UK | Adults (>18) with breast, prostate, bowel or gynaecological cancer & chronic insomnia | CBT-I (based on Espie & Morin, 2003) delivered face-to-face by nurses (5 sessions) | 60.5 (median) | TAU | 58 (median) | Included | *Median*<br>CBT: 69 F<br>31 M<br>Control:<br>34 F<br>16 M | HADS-A | Clinically significant anxiety (Cut off = >8) | Sleep diary |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| Espie et al., 2014 | UK | Adults meeting DSM-V criteria for insomnia disorder | CBT-I online intervention with virtual therapist (6 weekly sessions) | *49* | TAU | *49* | Included | 78 F<br>31 M | DASS-Anxiety subscale | No clinical anxiety (>8 = 'Mild') | None |
| Freeman et al., 2017 | UK | Adults (>18) attending university with positive screen for insomnia | Online CBT-I ('Sleepio') | 24.8 (7.7) | TAU | 24.6 (7.6) | Included | 2676 F<br>1043 M | GAD-7 | 'Mild' | SCI-8 |
| Friedrich et al., 2018 | Germany | Adults with insomnia disorder, nightmare disorder or irregular sleep-wake type (as per DSM-V) | Group manualised CBT-I and HT-I (6 sessions) | 25.13 (3.82) | WLC | 27.73 (7.26) | Not reported | 34 F<br>18 M | German version of (PHQ-D) - anxiety (6 items) | Not available | None |
| Gieselmann & | Germany | Adults (>18) with insomnia disorder | Face-to-face psychotherap | 39.30 (14.47) | WLC | 42.74 (11.73) | Included | 25 F<br>24 M | STAI-T | No clinical anxiety | PSQI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| Pietrowsky, 2019 | | | y for insomnia (4 weeks) | | | | | | | | |
| Harris, Schiele & Emery, 2019 | USA | Symptomatic heart failure patients (>18) with comorbid insomnia | BBT-I delivered over 4 weeks by graduate psychology students | 55.7 (12.2) | Sleep monitoring | 55.6 (10.8) | Not reported (use of CPAP included) | 16 F 7 M | HADS-A | Cut off met for intervention, not control (Cut off = >8) | ISI |
| Ho et al., 2014 | China | Adults (>18) with self-reported sleep difficulties | Self-help internet CBT-I based on Espie & Morin (2003) | 38.6 (11.8) | WLC | 39.9 (12.7) | Included | 149 F 60 M | HADS-A | Clinically significant anxiety (Cut off = >8) | ISI |
| Horsch et al., 2017 | The Netherlands | Adults (>18) with insomnia disorder (DSM-V) | Mobile phone | 39 (13) | WLC | 41 (13.9) | Excluded | 94 F 57 M | HADS-A | No clinical anxiety (Cut off = >8) | ISI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | delivered CBT-I | | | | | | | | |
| Huang et al., 2013 | China | Female hospital nurses on rotating shifts with ISI score >14 | Exposed to artificial bright light for 10 days over a period of 2 weeks | 30.2 (4.5) | No light exposure | 30.3 (4.7) | Included | 92 F 0 M | HADS-A | Cut off met for intervention, not control (Cut off = >8) | ISI |
| Jansson-Fröjmark et al., 2012 | Sweden | Adults with hearing difficulties and insomnia complaints | CBT-I delivered by trained psychologists (7 sessions) | 57.8 (6.6) | WLC | 53.6 (10.4) | Included | 20 F 12 M | HADS-A | No clinical anxiety (Cut off = >8) | ISI |
| Kyle et al., 2020 | UK | Adults (>25) with DSM-5 insomnia disorder & difficulties | Online CBT-I (‘Sleepio’) | 52.5 (11.2) | WLC | 52.4 (11.7) | Excluded | 355 F 55 M | GAD-2 | No clinical anxiety (Cut off = >3) | ISI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | with concentration or memory | | | | | | | | | |
| Lancee et al., 2012 | Germany | Adults (>18) with insomnia disorder (DSM-IV) | Electronic self-help CBT-I based on Espie & Morin (2003) | 52.2 (11.4) | WLC | 51.9 (12.2) | Included | 283 F 131 M | HADS-A | No clinical anxiety (Cut off = >8) | Insomnia SLEEP-50 |
| Lancee et al., 2015 | The Netherlands | Adults (>18) with insomnia according to DSM-V criteria | Online CBT-I based on Espie & Morin (2003) | 47.47 (14.37) | WLC | 49.98 (13.71) | Included | 50 F 13 M | HADS-A | No clinical anxiety (Cut off = >8) | ISI |
| Lancee et al., 2016 | The Netherlands | Adults (>18) meeting DSM-V criteria for insomnia disorder | Face-to-face CBT-I | 38.5 (13.1) | WLC | 45.1 (13.7) | Included | 47 F 13 M | HADS-A | No clinical anxiety (Cut off = >8) | ISI |
| Lorenz et al., 2019 | Germany | Adults (>18) with a minimum of 8 on the ISI | Online web-based unguided | 41.72 (17.31) | WLC | 44.04 (20.05) | Included | 39 F 17 M | BSI (Anxiety subscale) | Not available | ISI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CBT-I with automated feedback | | | | | | | | |
| Matthews et al., 2014 | USA | Women with breast cancer and chronic insomnia | CBT-I delivered by an advanced practice nurse | 52.17 (6.86) | BPT | 52.85 (7.75) | Included | 56 F 0 M | HADS-A | No clinical anxiety (Cut off = >8) | ISI |
| McCrae et al., 2018 | USA | Older adults (>65) with chronic insomnia | Manualised (4 week) BBT-I delivered by predoctoral psychology students | 67.97 (5.97) | Self-monitoring control | 71.03 (9.06) | Included | 42 F 20 M | STAI-Y | 'Severe' | Sleep diary |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| McCrae et al., 2019 | Columbia | Adults (18+) with fibromyalgia and chronic insomnia | Manualised (8 session) CBT-I delivered by predoctoral ClinPsy students | 54.13 (11.03) | WLC | 52.27 (11.19) | Excluded | 76 F 0 M | STAI-Y | 'Severe' | Sleep diary |
| McGrath et al., 2017 | UK | Adults (>18) with mean blood pressure readings of 130–160 & mild sleep impairment | Online CBT-I ('Sleepio') with digital therapist (6-8 sessions) | 59.7 (9.9) | No interventi on | 58.3 (11.9) | Included | 82 F 52 M | BAI | No clinical anxiety (>8 = mild) | ISI |
| Mimeault & Morin., 1999 | France | Adults (>18) with sleep-onset insomnia | Bibliotherap y with professional guidance | 49.83 (13.26) | WLC | 56.94 (13.43) | Included | 21 F 15 M | BAI | 'Mild' = intervention group, 'no anxiety' = control group | PSQI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| Morris et al., 2016 | UK | Undergraduate students experiencing stress | Unguided internet delivered "insomnia relief" | 20.69 (2.61) | No intervention | 20.27 (1.56) | Not reported | 62 F 33 M | STAI-S | 'Severe' | PSQI |
| Nguyen et al., 2017 | Australia | Adults with history of TBI and clinically significant sleep and/or fatigue complaints | CBT-I adapted for TBI delivered by neuropsychologists | 45.53 (13.87) | TAU | 41.90 (12.95) | Included | 8 F 16 M | HADS-A | No clinical anxiety (Cut off = >8) | PSQI |
| Ritterband et al., 2012 | USA | Adults (>21) in remission from cancer and DSM-IV insomnia | CBT-I ('Shut-I') internet intervention | 53.7 (10.8) | WLC | 59.6 (12.3) | Not reported | 24 F 4 M | HADS-A | Clinical cut off met for intervention, not for control | Sleep diary |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| Rybarczyk et al., 2005 | USA | Adults with insomnia and geriatric depression symptoms | 8 classroom sessions of CBT-I | 66.5 (8.9) | WLC | 71.4 (8.8) | Included | 12 F 12 M | BAI | 'Mild' | PSQI |
| Siengsukon et al., 2020 | USA | Adults (18-64) with multiple sclerosis, and insomnia symptoms | CBT-I (6 week) delivered by clinical psychologist | 51.1 (7.9) | Active control | 50.4 (12.4) | Included | 17 F 3 M | GAD-7 | No clinical anxiety (>5 = 'Mild') | ISI |
| Smitherman et al., 2016 | USA | Adults with chronic migraine and comorbid insomnia | CBT-I delivered by graduate-level therapists | 29.6 (13.4) | 'Sham Control' | 32.1 (12.8) | Not reported | 16 F 13 M | GAD-7 | 'Moderate' = intervention, 'Mild' = control | PSQI |
| Sunnhed et al., 2020 | Sweden | Adults with insomnia symptoms | Internet delivered BT (10 weeks) | 51.8 (14.5) | WLC | 54.2 (14.6) | Included | 105 F 42 M | HADS-A | Cut off met for intervention | ISI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | group, not for control | |
| Taylor et al., 2018 | USA | Active-duty US army soldiers with persistent insomnia disorder | Face-to-face CBT-I (6 weeks) delivered by 'mental health professionals'* | 32.21 (7.18) | Brief check in every other week | 32.67 (7.97) | Included | 2 F 124 M | BAI | 'Mild' | ISI |
| Thorndike et al., 2013 | USA | Adults (18-65) with low depression and insomnia | CBT-I ('Shut-I') online intervention (6 intervention cores) | 44.68 (10.61) | WLC | 45.05 (11.67) | Included | 34 F 10 M | STPI-Trait Anxiety | Not available | None |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| van der Zweerde et al., 2017 | The Netherlands | Adults (>18) with DSM-5 insomnia and depression symptoms | CBT-I ('i-Sleep') online intervention (5 sessions) based on Espie & Morin, 2003 | 44.64 (1.82) | No intervention | 46.29 (2.09) | Included | 85 F 19 M | HADS-A | No clinical anxiety (Cut off = >8) | ISI |
| van der Zweerde et al., 2020 | The Netherlands | Patients recruited from GP practices (≥18 years old) with clinical insomnia symptoms | Nurse-guided I-CBT-I ('i-Sleep') | 51.7 (15.77) | Care as usual | 49.4 (16.01) | Included | 87 F 47 M | HADS-A | 'Subclinical anxiety' | ISI |
| Xing et al., 2020 | China | Adults meeting DSM-V criteria for insomnia | Group CBT-I | 49.41 (14) | Electro-acupuncture | 56.32 (9.01) | Excluded | 51 F 12 M | HAM-A | 'Mild' | PSQI |

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|---|---|---|---|---|---|---|---|---|---|---|---|
| Yeung et al., 2018 | China | Adults (18-65) fulfilling DSM-5 criteria for insomnia | Group sleep hygiene education based on Harsora & Kessmann, 2009 & Espie & Morin, 2003 | 55.8 (6) | Self-administered acupressure | 50.4 (11) | Excluded | 24 F 7 M | HADS-A | Clinically significant anxiety (Cut off = >8) | ISI |

*Note.* For the domain 'Sleep Medication Status', 'Excluded' means sleep medication was an exclusion criterion within that study, and 'Included' means sleep medication was permitted within that study. For the domain 'Age', figures which are in italics represent studies which provided the overall mean age of both the control and intervention. Abbreviations: CBT-I = Cognitive Behavioural Therapy for Insomnia; Shut-I = an automated, interactive, internet based intervention based on CBT-I components; GAD-7 = Generalised Anxiety Disorder scale-7/2; ISI = Insomnia Severity Index; DSM = Diagnostic and Statistical Manual of Mental Disorders; HADS-A = Hospital Anxiety and Depression Scale-Anxiety subscale; BAI = Beck Anxiety Inventory; PSQI = Pittsburgh Sleep Quality Index; SCAS = Spence Children's Anxiety Scale; STAI, STAI-S, STAI-T = State-Trait Anxiety Inventory, S= State subscale, T= Trait subscale; ICD = International Statistical Classification of Diseases and Related Health Problems; ACT = Acceptance and Commitment Therapy; HSDQ = Holland Sleep Disorders Questionnaire; HT-I = Hypnotherapy for Insomnia; WLC = Waiting List Control; QoL = Quality of Life scale; YSR = Youth

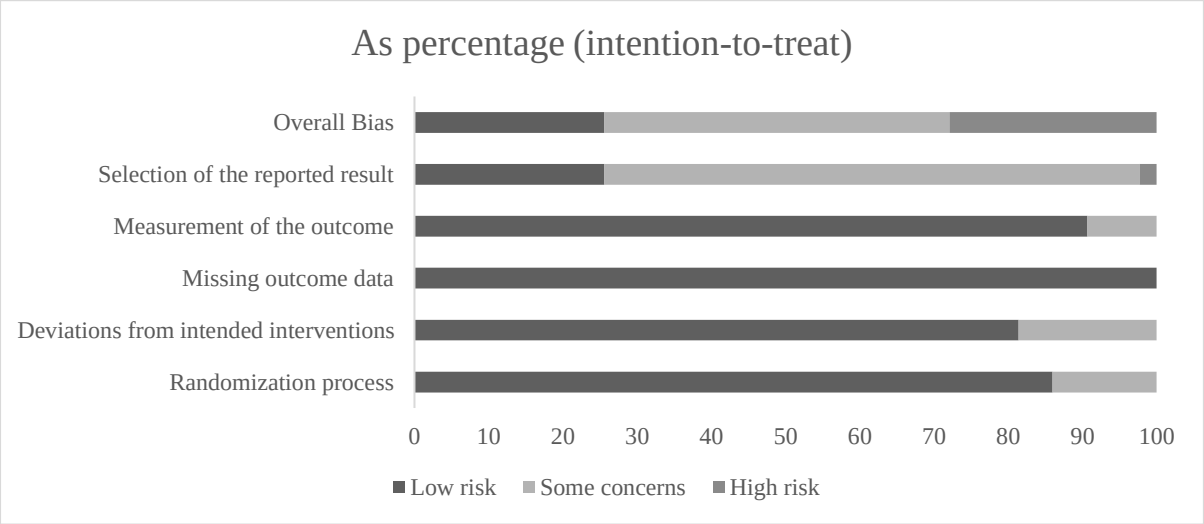
Self-Report (based on DSM subscales for anxiety; Sleepio = a digital sleep improvement program based on CBT-I techniques (developed by Colin Espie and Peter Hames); TAU = Treatment As Usual; DASS = Depression Anxiety Stress Scale; SCI-8 = Sleep Condition Indicator; PHQ-D = Patient Health Questionnaire; BBT-I = Brief Behavioural Therapy for Insomnia; BSI = Brief Symptom Inventory; ClinPsy = Clinical Psychology; PSWQ = Penn State Worry Questionnaire; STPI = Spielberger's State-Trait Personality Inventory; i-sleep = guided, online CBT-I intervention; HAM-A = Hamilton Anxiety Rating Scale. Other terminology: 'Healthwatch' is an online, interactive lifestyle website with no specific mental health or sleep-related content (Griffiths et al., 2010); *'Mental health professionals' included a clinical psychologist, clinical psychology postdoctoral fellows and a licensed clinical social worker; 'BPT' or behavioural placebo therapy is based on the concept of desensitization (Steinmark & Borkovec, 1974) and has been used as a placebo treatment in previous insomnia trials (Arnedt et al., 2011; Edinger et al., 2001); 'Sham Control' or 'Lifestyle Modification'. Sham control instructions were identical to those used by Calhoun and Ford (2007). Participants received no sleep intervention; 'Insomnia relief' is a commercially available program retailed by Ultrasis UK Limited and is based on CBT-I

## Risk of Bias

The quality of articles included in the meta-analysis were reviewed against the Cochrane Risk of Bias tool- Version 2 (Sterne et al., 2019). The risk of bias summary graph is presented (Figure 1). In most domains assessed, the quality of the studies was judged to be of high quality, though there were often a lack of reported information in study protocols, which impacted the quality of the reporting bias domain ('selection of the reported result'). Given the nature of the intervention studies included in this review, particularly those that were delivered face-to-face, it was difficult to blind participants and individuals providing interventions to conditions. However, several studies were able to blind the outcome assessors who obtained and analysed pre-post data. The measures of anxiety used in the studies were generally appropriate to the aims of the studies and had robust psychometric properties.

**Figure 2**

*Risk of bias graph (n = 43)*



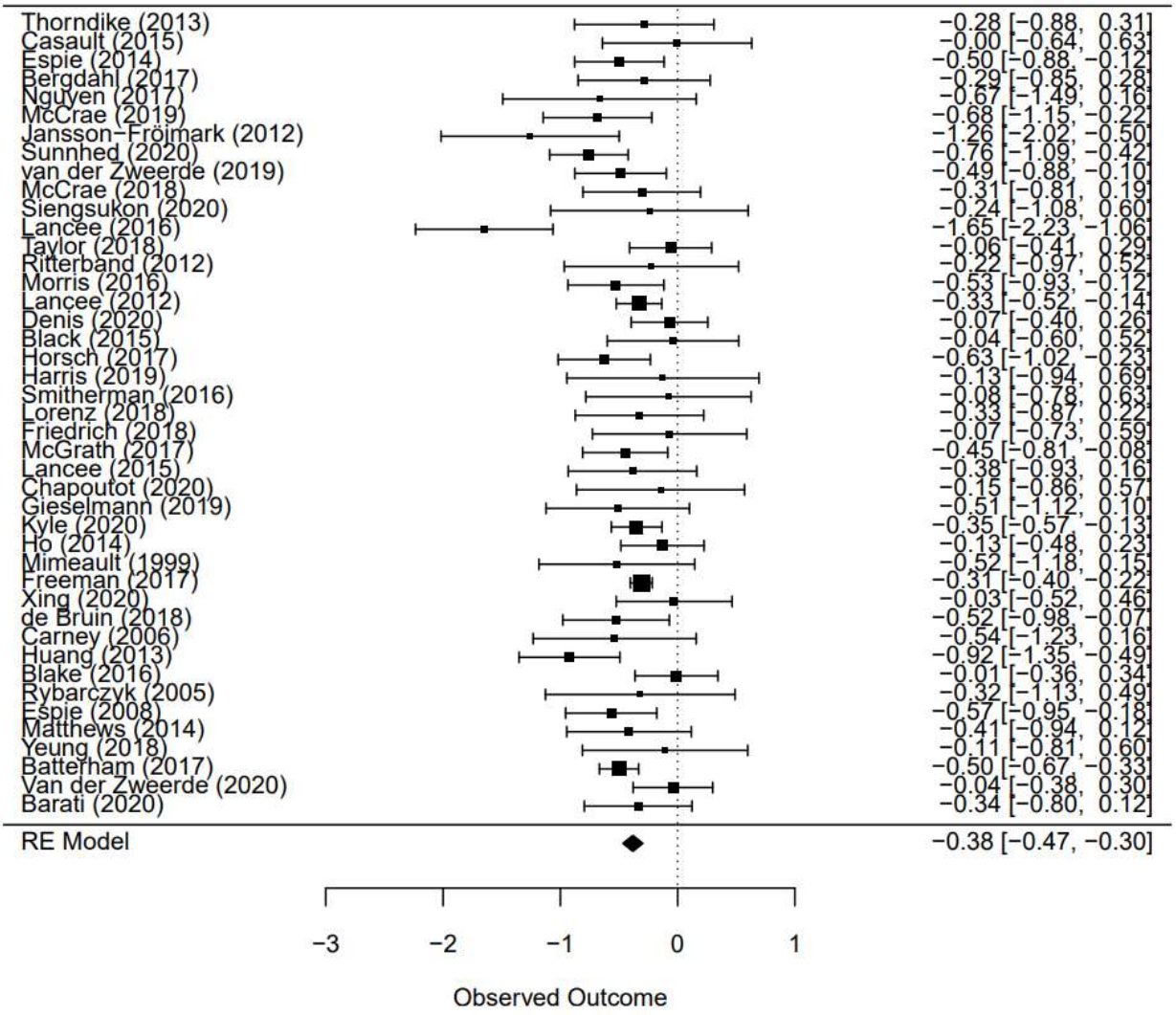

## Sleep Interventions and Anxiety Effect Size Summary Data

***RQ1. Do non-pharmacological sleep interventions aimed at improving sleep change anxiety symptoms?***

All individual effect sizes were negative, indicating that sleep interventions led to a reduction in anxiety symptoms. The results of the overall random effects meta-analysis exploring the effect of sleep interventions on anxiety symptoms at post-treatment are displayed in Figure 3. Across studies, the effect size varied considerably from a large negative effect (-1.65) to a small negative effect (-0.01). Overall, there was a significant, small to moderate effect of non-pharmacological sleep interventions in reducing anxiety symptoms in comparison to control conditions which were not aimed at improving sleep (hedges $g$ = -0.38, 95% CI -0.30 to -0.47, p <.0001, K = 43). The statistical heterogeneity in the effect sizes among studies was moderate ($I^2$ = 44.86%, Q = 69.83, df = 42, p < 0.005).

**Figure 3**

*Forest plot of the meta-analysis for investigating the effect of non-pharmacological sleep interventions on anxiety symptoms*




## Subgroup Analyses

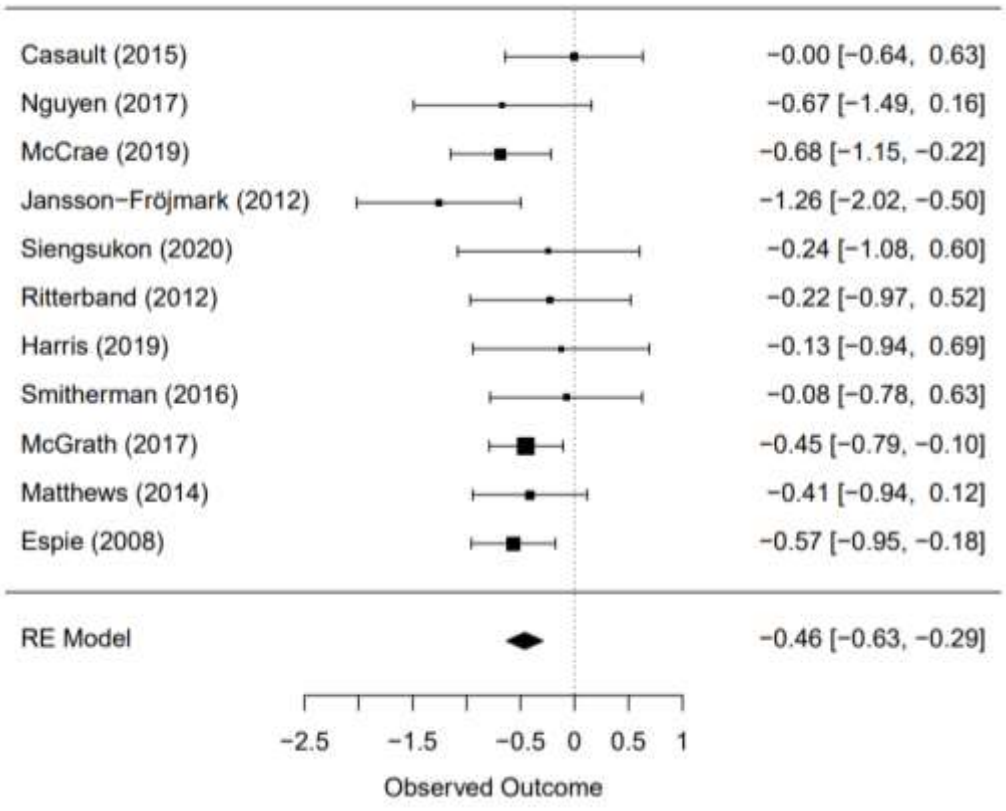
### *Sub-group analysis of studies involving participants with additional physical health difficulties*

The results of the subgroup analysis exploring the effect of sleep interventions on anxiety symptoms for participants who had comorbid physical health difficulties are displayed in Figure 4. For the 11 studies including participants with physical health conditions, there was a significant, moderate effect of non-pharmacological sleep interventions in reducing anxiety symptoms in comparison to control conditions which were

not aimed at improving sleep (hedges *g* = -0.46, 95% CI -0.29 to -0.63, p < .0001, K = 11). The statistical heterogeneity in the effect sizes among these studies was low ($I^2$ = 0.01%, Q = 10.07, df = 10, p = 0.43). A subgroup analysis was also conducted on the studies which did not report physical health difficulties. For these 32 studies, there was a significant, moderate effect of non-pharmacological sleep interventions in reducing anxiety symptoms in comparison to control conditions which were not aimed at improving sleep (hedges *g* = -0.38, 95% CI -0.27 to -0.48, p < .0001, K = 32). The statistical heterogeneity in the effect sizes among these studies was moderate ($I^2$ = 56.16%, Q = 60.22, df = 31, p = 0.013).

**Figure 4**

*Forest plot for the subgroup analysis for investigating the effect of non-pharmacological sleep interventions on anxiety symptoms in participants with additional physical health difficulties*



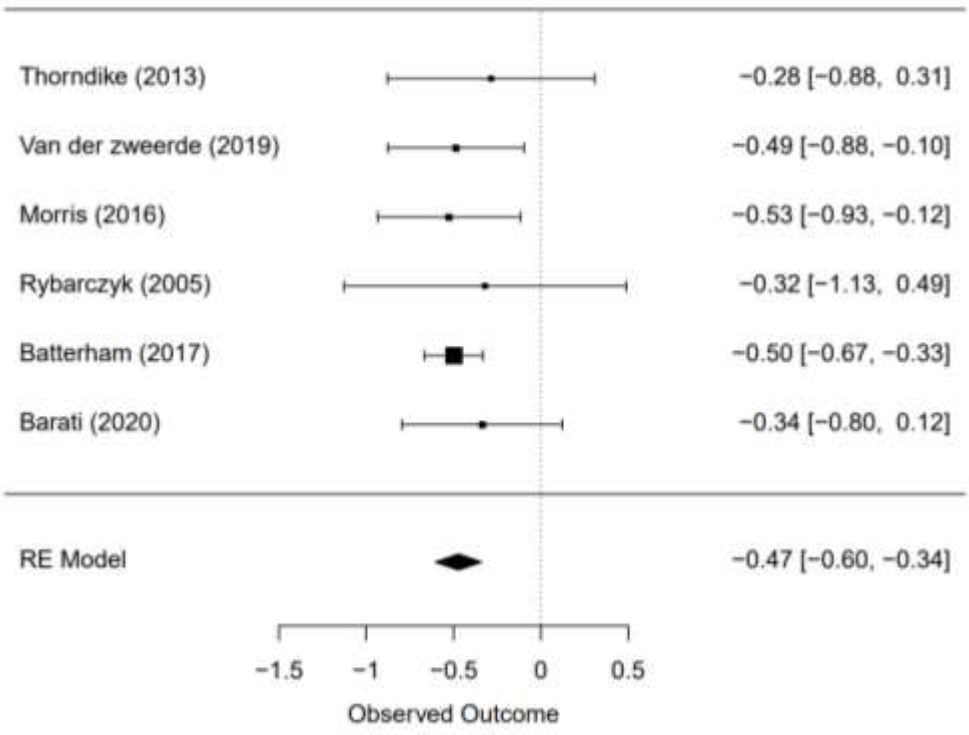
### *Sub-group analysis of studies involving participants with additional mental health difficulties*

A subgroup analysis was conducted on six studies which specifically investigated non-pharmacological sleep interventions efficacy on individuals with comorbid mental health difficulties such as depression, stress, substance misuse disorder and worry, as evaluated by a validated questionnaire tool or diagnostic instrument (Figure 5). For this subgroup, there was a significant moderate effect of non-pharmacological sleep interventions in improving anxiety symptoms relative to control conditions which were not aimed at improving sleep (hedges $g$ = -0.47, 95% CI -0.34 to -0.60, p <.0001, K = 6). The statistical heterogeneity among these studies was low ($I^2$ = 0.00%, Q = 1.03, df = 5, p = 0.96). A subgroup analysis was also conducted on the studies which did not report mental health difficulties. For these 37 studies, there was a significant, moderate effect of non-pharmacological sleep interventions in reducing anxiety symptoms in comparison to control conditions which were not aimed at improving sleep (hedges $g$ = -0.37, 95% CI -0.27 to -0.47, p < .0001, K = 37). The statistical heterogeneity in the effect sizes among these studies was moderate ($I^2$ = 53.16%, Q = 65.68, df = 36, p = 0.0018).

A subgroup analysis was also conducted on studies with participants who had clinically significant or ‘severe’ levels of anxiety symptoms at baseline. For these 12 studies, there was a significant, moderate effect of non-pharmacological sleep interventions in reducing anxiety symptoms in comparison to control conditions which were not aimed at improving sleep (hedges $g$ = -0.43, 95% CI -0.25 to -0.61, p < .0001, K = 12). The statistical heterogeneity in the effect sizes among these studies was moderate ($I^2$ = 46.18%, Q = 20, df = 11, p = 0.0455).

**Figure 5**

*Forest plot for the subgroup analysis for investigating the effect of non-pharmacological sleep interventions on participants with elevated mental health difficulties*




***Subgroup Analysis: CBT-I and Behavioural Interventions***

Two further subgroup analyses were conducted on studies which offered CBT-I interventions, and studies which offered behavioural interventions. Results from studies which offered CBT-I interventions found a significant, moderate effect in improving anxiety symptoms, compared to control conditions not aimed at improving sleep (hedges g = -0.36, 95% CI -0.27 to -0.45, p<.0001, K = 34). The statistical heterogeneity in the effect sizes among these studies was moderate ($I^2$ = 40.39%, Q = 55.09, df = 33, p = 0.0093). A subgroup analysis was conducted on studies which offered behavioural interventions only. For these studies, a significant moderate effect was found (hedges g = -0.41, 95% CI -0.16 to -0.66,

p<.005, K = 6). The statistical heterogeneity in the effect sizes among these studies was low ($I^2$ = 31.38%, Q = 6.47, df = 5, p = 0.2631).

### *Subgroup Analysis: Medication Status*

Two subgroup analyses were conducted exploring medication status of the sample. One subgroup explored studies which excluded sleep medication use from the sample, and the second explored studies which included sleep medication use in the sample. Results from studies which excluded sleep medication found a significant, moderate effect in improving anxiety symptoms, compared to control conditions not aimed at improving sleep (hedges g = -0.33, 95% CI -0.17 to -0.49, p<.0001, K = 10). The statistical heterogeneity among the effect sizes was low ($I^2$ = 25.87%, Q = 11.46, df = 9, p = 0.2455). Results from studies which included sleep medication found a significant, moderate effect in improving anxiety symptoms, compared to control conditions not aimed at improving sleep (hedges g = -0.44, 95% CI -0.30 to -0.57, p<.0001, K = 24). The statistical heterogeneity among the effect sizes was high ($I^2$ = 64.13%, Q = 51.48, df = 23, p = 0.0006).

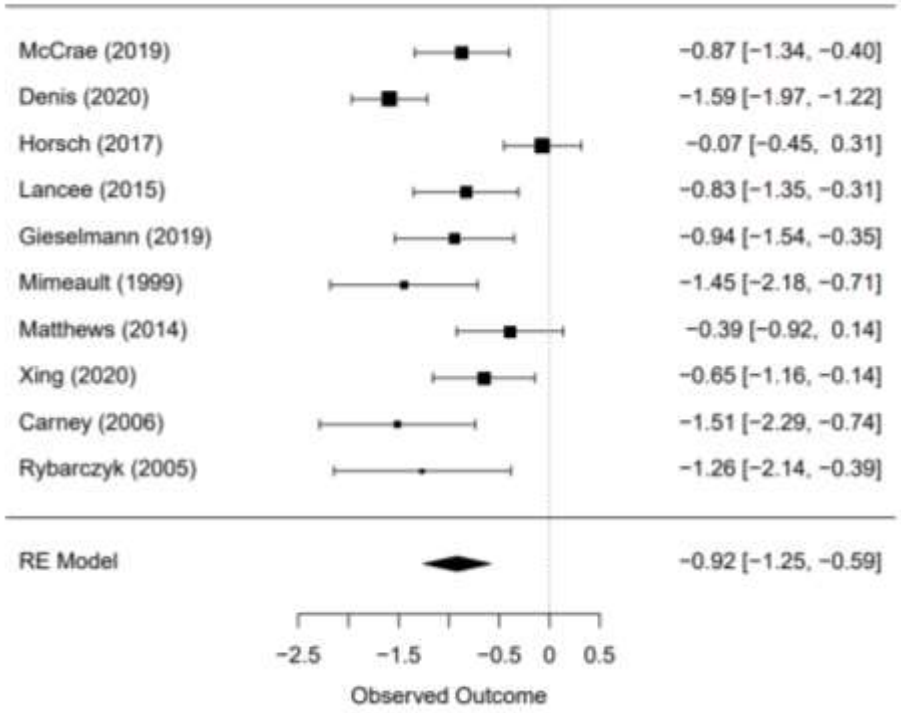
## Sleep Interventions and Thought Processes Effect Size Summary Data

### *RQ2. Do non-pharmacological sleep interventions aimed at improving sleep change sleep-related thought processes?*

A secondary meta-analysis was conducted on 10 studies which reported a measure of sleep-related thought processes and where an effect size was able to be computed from data available (Figure 6). For this subgroup, there was a significant, large effect of non-pharmacological sleep interventions in improving sleep-related thought processes in comparison to control conditions which were not aimed at improving sleep (hedges *g* = -0.92, 95% CI -0.59 to -1.25, p <.0001, K = 10). The statistical heterogeneity in the effect sizes among these studies was large ($I^2$ = 73.6%, Q = 40.65, df = 9, p < .0001).

**Figure 6**

*Forest plot for the meta-analysis for investigating the effect of non-pharmacological sleep interventions on sleep-related thought processes*




## Sensitivity Analysis

Two sensitivity analyses were performed. Firstly, a sensitivity analysis was conducted by removing 11 studies which were rated poor quality. The effect size was comparable to the overall meta-analysis conducted (hedges *g* = -0.37, 95% CI -0.28 to -0.46, p <.0001, K = 32). The statistical heterogeneity in the effect sizes among these studies was moderate ($I^2$ = 42.92%, Q = 49.01, df = 31, p = 0.0210). Secondly, a subgroup analysis was conducted with two notable outliers removed (Lancee et al., 2016; Casault et al., 2015). The effect size was comparable to the overall meta-analysis conducted (hedges *g* = -0.36, 95% CI -0.29 to -0.44,

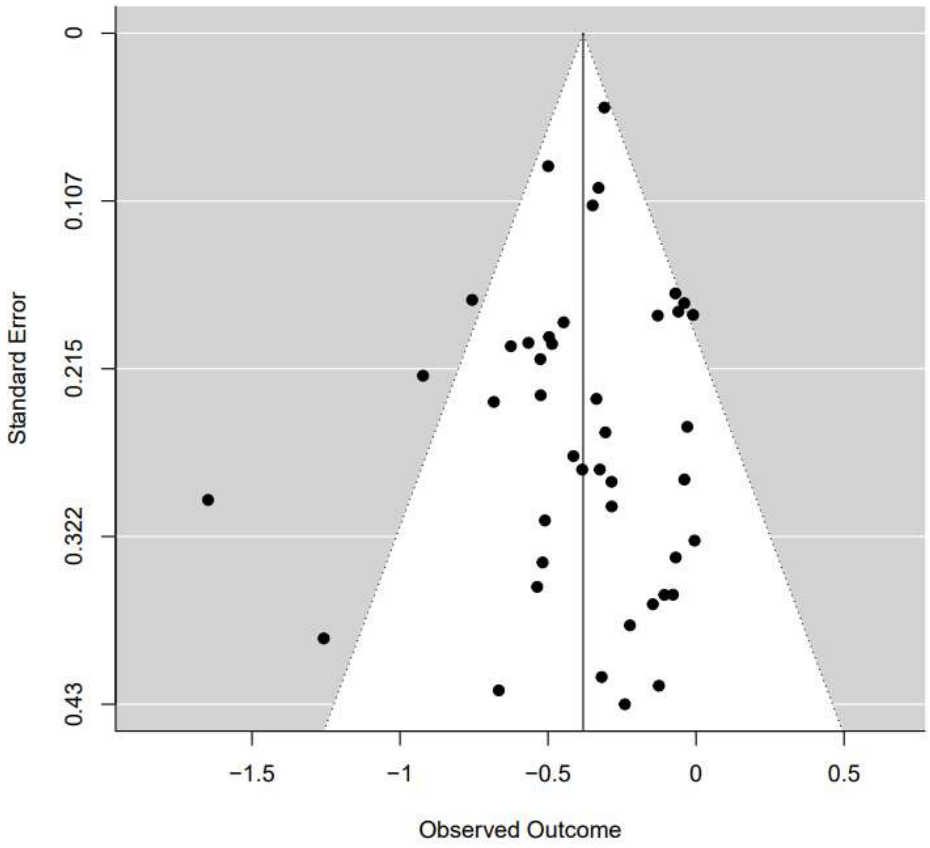
$p < .0001$, $K = 41$). The statistical heterogeneity in the effect sizes among these studies was low ($I^2 = 26.82\%$, $Q = 50.02$, $df = 40$, $p = 0.13$).

## Publication Bias

On inspection of the funnel plot (Figure 7), this highlights an almost symmetrical distribution around the mean effect size, implying a limited effect of publication bias on the results. However, there is one notable outlier and some additional inflated effect sizes for some studies, which could relate to these studies having fewer participants, as interpreted from the larger standard errors. To investigate this further, a statistical analysis was computed to assess publication bias of the included studies (Egger et al., 1997). The result was not significant suggesting there is no significant publication bias within the review ($t = -0.72$ $df = 41$, $p = 0.47$). Results from the funnel plot inspection together with the statistical analysis, suggests the findings in the review are reliable and are not affected by publication bias.

**Figure 7**

*Publication bias funnel plot*




## Discussion

This meta-analysis investigated whether non-pharmacological interventions aimed at improving sleep change anxiety symptoms, and sleep-related thought processes. An overall meta-analysis reviewed the evidence of the impact of non-pharmacological sleep interventions on anxiety symptoms taken at immediate post-intervention (k = 43), comparative to a control. Two subgroup analyses were conducted to explore the impact of non-pharmacological sleep interventions on anxiety symptoms in participants with physical health comorbidities (k = 11) and those without (k = 32). Two subgroup analyses were conducted to explore the impact of non-pharmacological sleep interventions on anxiety symptoms in participants with mental health comorbidities (k = 6) and those without (k = 37).

Another subgroup analysis was conducted to explore the impact of non-pharmacological sleep interventions on anxiety symptoms in participants with clinically significant or 'severe' levels of anxiety at baseline (k = 12). Two subgroup analyses were conducted on studies which offered CBT-I interventions (k = 34), and studies which offered behavioural interventions (k = 6). Two final subgroup analyses were conducted exploring medication status of the sample; one subgroup explored studies which excluded sleep medication use from the sample (k =10), and the second explored studies which included sleep medication use in the sample (k = 24). Finally, a secondary meta-analysis was conducted to review the impact of non-pharmacological sleep interventions on sleep-related thought processes taken at immediate post-intervention (k = 10), comparative to a control.

The overall meta-analysis (k = 43) indicated that non-pharmacological sleep interventions reduce the severity of anxiety symptoms, and this finding was not impacted by publication bias. The pooled effect on anxiety symptoms was in the small to moderate range (g = -0.38). The results suggest that despite not targeting anxiety directly, a non-pharmacological sleep intervention can improve anxiety symptoms. This supports previous research indicating a bidirectional relationship exists between anxiety and insomnia (Alvaro et al., 2013). These findings also reflect previous meta-analyses which found small to moderate effect sizes on (1) the impact of CBT-I on anxiety, stress, and worry (Belleville et al., 2011), (2) the impact of CBT-I delivered in a self-help format on anxiety symptoms (van Straten & Cuijpers, 2009; Ho et al., 2015; Benz et al., 2020) and (3) the impact of non-pharmacological sleep interventions on depression (Gee et al., 2019). Often these previous meta-analyses included studies which excluded participants with severe levels of anxiety. Similarly, given most studies included in our overall meta-analysis included participants with either no anxiety symptoms or mild to moderate symptoms at baseline, this may have biased the overall meta-analysis, and may explain the small to moderate effect found. Additionally,

previous meta-analyses which have investigated the impact of a CBT intervention for anxiety, on anxiety symptoms, have found effect sizes ranging from small to large (Watts et al., 2015; Goncalves & Byrne, 2012; Carpenter et al., 2018). The differences in these findings could be attributed to a variety of factors including the type of anxiety disorder, participant population, and measures used. This meta-analysis attempted to account for some of these possible factors through subgroup analyses, and by limiting the type of measure to those measuring anxiety symptomology only.

Importantly to note, our findings found moderate heterogeneity in the main meta-analysis and large heterogeneity in the sleep-related thought process secondary meta-analysis. Many factors are likely to have contributed to increased heterogeneity including differing methodological procedures employed, different modalities in which the therapy was delivered (face-to-face versus online/app), differing number of participants in intervention versus control conditions, age ranges, intervention types, and different assessment methods used. This meta-analysis explored possible sources of heterogeneity by conducting subgroup analyses on studies involving participants with physical and mental health difficulties. When these analyses were conducted, heterogeneity reduced. This could suggest individual differences may contribute to the moderate heterogeneity found in the overall meta-analysis.

For participants with additional physical health difficulties, sleep interventions had a moderate effect on anxiety symptoms ($g = -0.46$) and there was low heterogeneity within this analysis. Some of the included studies in this review focused on participants with cancer ($n = 4$). This has clinical importance for physical health settings given insomnia and anxiety are common in cancer patients (Nikbakhsh et al., 2014; Savard & Morin, 2001). Our findings differ from recent meta-analyses investigating the efficacy of anxiety-based psychological interventions on anxiety in patients with cancer, which found an overall pooled effect size in

the small range (Sanjida et al., 2018). This could suggest sleep interventions may be more beneficial for individuals struggling with anxiety in this population.

For participants with additional mental health difficulties, sleep interventions had a moderate effect on anxiety symptoms (g = -0.47) and there was low heterogeneity within this analysis. For participants with elevated anxiety levels at baseline, sleep interventions had a moderate effect on anxiety symptoms (g = -0.43) and there was moderate heterogeneity in this analysis. Given there was slightly larger effect sizes found in those with additional mental health difficulties and clinically significant anxiety symptoms, this indicates sleep interventions may be more beneficial for individuals from a mental health population. This is in line with previous research which investigated the impact of non-pharmacological sleep interventions on depression, which also found elevated effect sizes in clinical populations (Gee et al., 2019). This further highlights the importance of treating sleep disturbance in the treatment of anxiety. However, only six studies were included in the mental health subgroup analysis, and all participants were adults. Therefore, further research is warranted investigating the impact of sleep interventions on those with mental health difficulties, particularly in the child and adolescent population.

A secondary meta-analysis indicated non-pharmacological sleep interventions led to reductions in sleep-related thought processes, particularly dysfunctional beliefs, and attitudes about sleep, with an overall pooled effect size in the large range (g = -0.92). This reflects a similar meta-analysis investigating the effects of CBT-I on dysfunctional beliefs and attitudes about sleep, where a large effect was found (Thakral et al., 2020). From a theoretical perspective, this supports cognitive models of insomnia which highlight factors involved in the development and maintenance of insomnia, including dysfunctional beliefs and attitudes about sleep (Harvey, 2002; Espie et al., 2006). Importantly to consider, the study by Horsch

et al. (2017) which was included in this secondary meta-analysis found a notably small effect size compared to the other studies included. Interestingly, this intervention was an app-based insomnia treatment which did not include cognitive components of CBT-I (Horsch et al., 2017). Therefore, this could suggest cognitive components of CBT-I are important for treating unhelpful sleep-related thought processes. However, no studies in this secondary meta-analysis included child or adolescent participants, suggesting more research is needed in understanding the mechanisms underlying insomnia in this population.

Given our study was not limited to exploring effects of CBT-I, a subgroup analysis was conducted exploring any differences in effects between CBT-I and other non-pharmacological sleep interventions. However, only three studies were not a CBT-I or a behavioural sleep intervention. Therefore, subgroup analyses were conducted comparing CBT-I and behavioural interventions. Interestingly, a slightly increased benefit was found for the behavioural intervention analysis. This may suggest behavioural sleep interventions could be offered to individuals with anxiety and may have slightly more benefit than sleep interventions which incorporate the entire CBT-I package. What is more, a slightly elevated effect was found for studies which included sleep medication alongside a non-pharmacological sleep intervention, compared to studies which excluded sleep medication. This may suggest combined sleep medication and non-pharmacological sleep interventions have more benefit for individuals with anxiety, than non-pharmacological sleep interventions in isolation. However, sleep medications notably have a range of adverse side effects, which should be considered when considering treatment.

**Clinical Implications**

Overall, these findings suggest non-pharmacological sleep interventions, particularly CBT-I, could be beneficial for individuals with anxiety symptoms. This has clinical

implications where services may consider screening individuals for insomnia and other sleep problems, as well as common mental health difficulties. Additionally, sleep disturbance is one of the criteria for generalised anxiety disorder (GAD), which further highlights the importance of screening for and treating sleep disturbance in anxiety disorders. Notably, given the common prevalence of both anxiety and insomnia in individuals with physical health difficulties, and given the moderate effect found in this subgroup, it may be particularly important to screen for both anxiety and sleep disturbance in this population.

Results from the secondary meta-analysis suggests non-pharmacological sleep interventions can reduce unhelpful sleep-related thought processes. This is clinically important given research has found a greater improvement in dysfunctional beliefs about sleep (after CBT-I) was associated with greater improvement in insomnia symptoms (Eidelman et al., 2016), sleep efficiency (Morin et al., 2002) and depression symptoms (Sunnhed & Jansson-Frojmark, 2014). This demonstrates the importance of screening for anxiety and sleep-related thought processes both clinically and in intervention research. Moreover, although our results may help us to understand the mechanisms by which treatment for sleep can in turn improve anxiety, more understanding of the interactions between these variables is needed. Notably, only eleven studies included in this meta-analysis used a sleep-related thought measure, none of which were conducted with children or adolescents and eight of which was the Dysfunctional Beliefs and Attitudes About Sleep scale. Therefore, conclusions cannot be drawn about other maintenance factors such as sleep effort. Understanding further the interactions between sleep-related thought processes and anxiety can only be achieved if measures are administered. This highlights the importance for future anxiety and sleep intervention research to consider measures of sleep-related thought processes, especially in the child and adolescent population.

Importantly for clinical practice, the findings from this meta-analysis suggest non-pharmacological sleep interventions could be offered to individuals with anxiety difficulties. Additionally, this review did not examine specific anxiety disorders or disorder-specific questionnaires, therefore our results may have clinical implications for treating other disorders where anxiety may be high. Some studies included in this review found treatment effectiveness with widely accessible treatment interventions such as app-based CBT-I and brief behavioural interventions. Therefore, these findings suggest sleep interventions may be offered in accessible, cost-effective modalities. Clinically, this could improve access and waiting times in psychological services.

**Strengths and Limitations**

This review provides a novel contribution to the literature, accounting for various subgroups within the overall analysis, and has several strengths. Notably, this was the first review to explore the effect of sleep interventions on anxiety symptoms in individuals with comorbid physical health difficulties. The meta-analysis included RCTs only, which are considered the 'gold standard' for effectiveness research (Hariton & Locascio, 2018), thus improving the validity of this study. Most of the anxiety measures included within the review had good psychometric properties. There was a robust and strict approach adopted to ensure control conditions did not include any components of a sleep intervention, which strengthens the findings of this meta-analysis. Moreover, the two sensitivity analyses conducted did not result in any significant changes in the overall effect size. This demonstrates our review can be regarded with a higher degree of certainty (Bown & Sutton, 2010).

There are some limitations of this current review which are important to discuss. Within some of the subgroup analyses conducted, there was a small number of studies included, such as the mental health subgroup ($k = 6$). Therefore, this should be considered

when interpreting the results. Only two RCTs included in this review focused on adolescents, thus the results cannot be generalised to this population. However, this further highlights the importance for future research in the field of insomnia and concomitant mental health difficulties to be focused on the adolescent population. The meta-analysis did not differentiate between different anxiety disorders, such as social phobia, thus conclusions cannot be drawn about specific anxiety disorders.

While current sleep medication was an exclusion criterion, it was not always possible to establish this from study reporting, therefore it is possible that some studies included participants who were taking medication to improve sleep. Additionally, it was not possible to establish whether participants included in the review had received any support for anxiety either before or after engagement in the study, as this was not reported in any of the studies included in the review. As this review focused only on immediate post-intervention effects, conclusions cannot be drawn about the long-term effects of sleep interventions on anxiety symptoms. However, most studies did not report long-term follow up data. Therefore, future research could include long-term follow up data to enable further meta-analyses to explore the long-term effects of non-pharmacological sleep interventions on anxiety symptoms.

Despite these limitations, the findings from this meta-analysis provide an important contribution to the literature. The findings suggest despite not targeting anxiety directly, anxiety symptoms can improve after a sleep-focused intervention. The findings provide important clinical implications including the importance of screening both anxiety and sleep disturbance, as well as providing evidence to suggest a non-pharmacological sleep intervention may be considered in the treatment of anxiety.

**Future Research**

As highlighted from our findings, more understanding is needed to explore whether sleep-related thought processes explain the pathway of change for anxiety improving after a sleep intervention. Therefore, future research could explore this pathway to investigate whether sleep interventions change sleep-related thoughts, which then leads to a change in anxiety. Future research would also benefit from exploring the effectiveness of combined anxiety-sleep interventions, comparative to sleep-targeted interventions in isolation. This would determine any advantage of directly targeting anxiety. Additional research is needed to (1) understand the long-term effects of non-pharmacological sleep interventions on anxiety symptoms, (2) to understand the effectiveness of non-pharmacological sleep interventions on adolescent sleep, and comorbid mental health problems, and (3) to understand any gender differences in the treatment of insomnia, especially given research indicates higher rates of insomnia in females.

## Conclusions

The results from this review provide evidence to suggest non-pharmacological interventions aimed at improving sleep; (1) improve anxiety symptoms, with a pooled effect size in the small to moderate range, (1a) improve anxiety symptoms for participants with physical health difficulties with a pooled effect size in the moderate range, (1b) improve anxiety symptoms for participants with mental health difficulties and clinically significant anxiety symptoms at baseline with a pooled effect size in the moderate range, (2) improve sleep-related thought processes, with a pooled effect size in the large range. Since almost all studies included in this meta-analysis investigated CBT-I, this may suggest CBT-I is a particularly useful approach when treating individuals with anxiety symptoms.

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