Behavioral and Psychological Treatments for Chronic Insomnia Disorder in Adults:

An American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment.

Introduction: The purpose of this systematic review is to provide supporting evidence for a clinical practice guideline on the use of behavioral and psychological treatments for chronic insomnia disorder in adult populations.
Methods: The American Academy of Sleep Medicine commissioned a task force of nine experts in sleep medicine. A systematic review was conducted to identify randomized controlled trials that addressed behavioral and psychological interventions for the treatment of chronic insomnia disorder in adults. Statistical analyses were performed to determine if the treatments produced clinically significant improvements in a range of critical and important outcomes. Finally, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process was used to evaluate the evidence for making specific treatment recommendations.
Results: The literature search identified 1171 studies; 121 studies met the inclusion criteria; 86 studies provided data suitable for statistical analyses. Evidence for the following interventions are presented in this review: Cognitive Behavioral Therapy for Insomnia (CBT-I), Brief Behavioral Therapies (BBTs), stimulus control, sleep restriction therapy, relaxation training, sleep hygiene, biofeedback, paradoxical intention, intensive sleep retraining and mindfulness. This review provides a detailed summary of the evidence along with the quality of evidence, the balance of benefits versus harms, patient values and preferences, and resource use considerations.

INTRODUCTION

This systematic review (SR) is intended to provide supporting evidence for a clinical practice guideline (CPG) [1] on behavioral and psychological treatments of chronic insomnia disorder in adults. This SR is an update of the evidence review conducted for the previously published American Academy of Sleep Medicine (AASM) guideline. [2] AASM published a separate CPG on the pharmacological treatment of chronic insomnia in 2017. [3]

BACKGROUND

Diagnosis, Prevalence, Course and Etiology

The International Classification of Sleep Disorders, 3rd edition (ICSD-3) [4] diagnostic manual describes chronic insomnia disorder as a report of difficulty initiating or maintaining sleep or waking up too early with associated daytime consequences, occurring despite adequate opportunity and circumstances for sleep. The sleep difficulties must occur at least three times per week for at least three months. Historically, insomnia disorders have been divided into primary and secondary (comorbid) subtypes, based on the clinician's diagnostic assessment of the role of medical and/or psychiatric comorbidities in the genesis and maintenance of the insomnia disorder. However, with the publication of ICSD-3, as well as the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) [5], this nosological dichotomy is no longer utilized. The decision to eliminate this distinction was based on the observation that it is often difficult to discern cause-effect relationships between insomnia and co-occurring disorders as well as the fact that insomnia often becomes an independent disorder even if it is initially caused by another medical or psychiatric condition. Of note, many studies included in this systematic review employed the historical distinction between primary and secondary (comorbid) subtypes in identifying patients for inclusion in treatment trials.

Insomnia symptoms occur in a high percentage of the adult population, with estimates ranging from 35-50%. [6-8] Chronic insomnia disorder, defined by specific diagnostic criteria, has an estimated prevalence of 5-15%. [4, 5, 8] Chronic insomnia disorder is more common among women, those with lower socio-economic status, and those with medical or psychiatric illness. [6-8] The course of chronic insomnia disorder is typically measured in years or even decades with spontaneous remission rates generally less than 50%. [9] Isolated sleep-onset difficulties are less common than sleep maintenance difficulties, although a substantial proportion of persons with insomnia report difficulties with both sleep onset and sleep maintenance. [10]

Chronic insomnia disorder is associated with daytime fatigue, depressed mood, increased incidence of non-remitting depression with increased suicide risk, impairment in social/vocational functioning and reduced quality of life.[11-14] Studies

have shown insomnia contributes to increased health care costs and utilization, [15-17] in addition to lower worker productivity. [18] In fact, more than 90% of insomnia-related costs are attributable to work absences and reduced productivity. [19]

The etiology of chronic insomnia disorder is multi-factorial. Emerging research indicates that some individuals may be genetically predisposed to insomnia as a result of clock gene polymorphisms or other genetic factors. [20] As noted above, numerous medical and psychiatric disorders are associated with high risk for insomnia. Some disorders, such as major depressive disorders, show rates of concurrent insomnia as high as 80-90%. [21] A variety of maladaptive cognitions and behaviors play a critical role in the development and maintenance of chronic insomnia. [22] These include performance anxiety and negative expectations regarding sleep, with associated worry about potential consequences of not sleeping as well as unhelpful beliefs and attitudes around sleep. In addition, unhelpful behaviors can have a direct impact on the physiological systems controlling sleep. For example, variability in the timing of sleep-wake behaviors can create circadian dysregulation; excessive time in bed can diffuse homeostatic drive for deep sleep and can also lead to conditioned arousal. Finally, psychophysiologic studies indicate increased 24-hour metabolic rate, elevated cortisol levels particularly in the pre-sleep and early sleep period, elevated fast (waking) EEG activity and heightened regional brain activity during sleep among individuals with insomnia. [6, 23] These findings collectively support the theory that *physiological hyperarousal* is an additional significant factor for many patients in the etiology of this sleep disorder.

Definition of behavioral and psychological treatments

Several options are available for treating insomnia, including a range of pharmacotherapies and non-pharmacological approaches. Various psychological and behavioral therapies have been specifically developed for insomnia treatment, and a number of complementary and alternative strategies (e.g., dietary supplements, acupuncture) have also been used. This review focuses on psychological and behavioral therapies for insomnia that are available to clinicians for treating patients with sleep disorders. The nature and focus of these treatments vary considerably, but they all are designed to reduce or eliminate one or more of the putative factors that perpetuate insomnia including sleep-disruptive arousal and/or habits and conditioning factors that sustain insomnia over time. Among these therapies are a range of single-component therapies, each of which targets a specific subset of insomnia perpetuating factors. Second generation therapies that evolved from the various single component therapies combine several such treatments to comprise a more comprehensive, multicomponent intervention approach. Table 1 provides a brief description of each of the therapies considered in this review.

TABLE 1—Summary of interventions

Intervention	Treatment Type	Description
Cognitive Behavioral Therapy for Insomnia (CBT-I)	Multi-component	CBT-I combines one or more of the cognitive therapy strategies with education about sleep regulation plus stimulus control instructions and sleep restriction therapy. CBT-I also often includes sleep hygiene education, relaxation training and other counter-arousal methods. Treatment progresses using information typically gathered with sleep diaries completed by the patient throughout the course of treatment (typically 4-8 sessions)..
Brief Behavioral Therapies for Insomnia (BBTs)	Multi-component	BBTs include abbreviated versions of CBT-I (typically 1-4 sessions). BBTs typically consist of education about sleep regulation, factors that influence sleep, and behaviors that promote or interfere with sleep, along with a tailored behavioral prescription based on stimulus control and sleep restriction therapy and on information typically derived from a pre-treatment sleep diary. Some therapies include brief relaxation or cognitive therapy elements.
Stimulus Control	Single-component	A set of instructions designed to (1) extinguish the association between the bed/bedroom and wakefulness to restore the association of bed/bedroom with sleep; and (2) establish a consistent sleep-wake schedule. Stimulus control instructions are: (a) go to bed only when sleepy; (b) get out of bed when unable to sleep; (c) use the bed/bedroom for sleep and sex only (no reading, watching TV, etc. in bed); (d) wake up the same time every morning; (e) refrain from daytime napping.

Sleep Restriction Therapy	Single-component	A method designed to enhance sleep drive and consolidate sleep by limiting time in bed equal to the patient's sleep duration, typically estimated from daily diaries. Time in bed is initially limited to the average sleep duration, and subsequently increased or decreased based on sleep efficiency thresholds, until sufficient sleep duration and overall sleep satisfaction is achieved.
Relaxation Therapy	Single-component	Structured exercises designed to reduce somatic tension (e.g., abdominal breathing, progressive muscle relaxation; autogenic training) and cognitive arousal (e.g., guided imagery training; meditation) that may perpetuate sleep problems.
Cognitive Therapy	Single-component	A set of strategies including structured psychoeducation, Socratic questioning, use of thought records, and behavioral experiments designed to identify and modify unhelpful beliefs about sleep that may support sleep-disruptive habits and/or raise performance anxiety about sleeping.
Sleep Hygiene	Single-component	A set of general recommendations about lifestyle (e.g., diet, exercise, substance use) and environmental factors (e.g., light, noise, temperature) that may promote or interfere with sleep. Sleep hygiene may include some education about what constitutes "normal" sleep and changes in sleep patterns with aging.
Biofeedback	Single-component	A variant of relaxation training that employs a device capable of monitoring and providing ongoing feedback on some aspect of the patient's physiology. This technique has most commonly employed continuous monitoring of frontalis electromyography (EMG) activity to assess the overall level of muscle tension. Typically, the biofeedback device produces an ongoing auditory tone to train the patient to relax by learning how to alter the auditory feedback tone in the desired direction (e.g., reduced muscle tone).
Paradoxical Intention	Single-component	Patients are instructed to remain awake as long as possible after getting into bed. The patient is instructed to purposefully engage in the feared activity (staying awake) in order to reduce performance anxiety and conscious intent to sleep that confound associated goal-directed behavior (falling asleep). This method alleviates both the patient's excessive focus on sleep and anxiety over not sleeping; as a result, sleep becomes less difficult to initiate.
Intensive Sleep Retraining	Single-component	This newly described treatment is designed to markedly enhance homeostatic sleep drive in order to reduce both sleep onset difficulties and sleep misperception. Following a night wherein the patient limits time in bed to no more than 5 hours, the treatment includes a 24-hour laboratory protocol in which the patient is given an opportunity to fall asleep every 30 minutes in sleep conducive conditions. If sleep occurs the patient is awakened after three minutes and remains awake until the subsequent 30-minute trial. For each sleep opportunity, the patient is given feedback as to whether or not sleep occurred.
Mindfulness	Single or multi-component	Mindfulness approaches are used as a form of meditation emphasizing nonjudgmental state of heightened or complete awareness of one's thoughts, emotions, or experiences on a moment-to-moment basis. Mindfulness therapies are typically administered in a group format. Structured exercises teach momentary awareness, self-acceptance, and muted reactivity. Home practice of mindfulness exercises is required. When applied to people with insomnia, standard mindfulness is often combined with other insomnia therapies such as stimulus control, sleep restriction therapy, and sleep hygiene (described above).

Many of the interventions described here can be delivered using a variety of methods. In describing delivery methods, we use the term "in-person, one-on-one," which involves a therapist providing a patient the treatment in individual, one-on-one therapy visits. However, "in-person group" format has also been used, in which such treatment is provided by a therapist to a group of patients. Self-help format can include self-help books or other written materials that provide treatment instruction, audio recordings or pre-recorded video treatment sessions. Internet-based delivery has also been used for one-on-one or group delivery as well as for self-help interventions. Telephone and telehealth delivery has also been used in the delivery

of insomnia treatments, either with the patient traveling to a clinic with telehealth services (with the provider in a different location) or with the patient at home engaging with the provider using a telephone or on-line service for real-time interactions. This review included all delivery modalities for each intervention.

Measurement of Insomnia Treatment Outcomes

A variety of approaches can be taken to measure the effects of behavioral and psychological treatments for insomnia, including questionnaires, daily sleep diaries, polysomnography (PSG), and wrist actigraphy. To address this variability in measurement approaches, standardized assessment instruments have been proposed for insomnia research. [24] Current definitions of insomnia disorder include reports of both nighttime symptoms (difficulties with sleep initiation, maintenance and/or duration) and daytime consequences attributed to insomnia (e.g., fatigue, depression, memory impairment). Thus, treatment measures assessing the impact of behavioral and psychological treatments on insomnia should capture both domains. [2] Global measures of sleep disturbances provide an index of the nature and severity of insomnia and can be administered longitudinally to measure treatment response. The Pittsburgh Sleep Quality Index (PSQI) [25] and Insomnia Severity Index [26] are the two most widely used tools to assess patient-reported sleep disturbances. The PSQI is a measure of global sleep quality and the ISI more specifically measure subjective insomnia symptom severity but both are categorical scales and provide total scores that can be evaluated across treatment as well as accepted scale-specific criteria for defining treatment response and remission. [25-27] These categorical measures, especially insomnia remission, are increasingly recognized as of primary importance for evaluating the benefits of treatment.

In the study of insomnia treatments, nighttime sleep and insomnia symptoms are most commonly measured with daily sleep diaries [28], which capture information about the timing of sleep (bedtime, rise time) in addition to individual sleep parameters, such as sleep latency (time to fall asleep initially), wake after sleep onset (duration of nighttime wakefulness), and early morning awakenings (waking in advance of desired rise time) that are commonly the primary symptoms targeted in insomnia treatments. Additional summary metrics commonly derived from daily sleep diaries include total sleep time and sleep efficiency (total sleep time/time in bed*100%). Daytime napping/sleeping behaviors are also commonly tracked on daily diaries when delivering treatments. The primary advantages of sleep diaries are that they allow for prospective collection of daily information on nighttime symptoms, making them less subject to recall bias. Treatment effects are most commonly assessed with aggregated mean-level changes in individual sleep diary parameters across time, generally every 1 or 2 weeks but increasingly, the variability of these parameters across days is being viewed as clinically important.

Objective evaluation of nighttime sleep and insomnia parameters with PSG and/or actigraphy provide complementary information to sleep diaries and allow for a multi-method comprehensive assessment although objective evidence of sleep disturbance is not required to establish a diagnosis of insomnia disorder. When objective information is deemed necessary wrist actigraphy is a suggested option for clinicians to consider.[29]

Daytime impairments associated with insomnia commonly include fatigue and/or sleepiness, mood disturbances, impaired cognitive abilities, and overall reduced quality of life. Although discrepancies may exist between the magnitude of self-reported and objectively measured daytime impairments [30], daytime impairment from insomnia is what often leads patients to seek treatment. Thus, perceptions about daytime functioning are important to target with behavioral and psychological treatments. These daytime correlates of insomnia can be measured by a variety of methods, but a limited number of valid and reliable self-report instruments have been recommended for insomnia research [24]. Since daytime fatigue is among the most common daytime symptoms of insomnia, various self-report questionnaires designed to assess daytime fatigue have been included in the studies included in this systematic review. Those measures are listed in the Table 3 caption below. Finally, the Dysfunctional Beliefs and Attitudes about Sleep scale [31] is a sleep-specific scale that is often included in clinical insomnia trials to determine changes in unhelpful sleep-related beliefs that can serve to perpetuate insomnia.

Statements and Recommendations Regarding Treatment of Insomnia Disorder

Assessment and treatment of chronic insomnia in adults has been addressed in numerous recent practice guidelines and clinical recommendation statements over the years.[3, 29, 32-35]Recent guidelines and statements that address comprehensive treatment for chronic insomnia uniformly support the use of cognitive-behavioral therapies as first-line treatment for the

disorder. [33, 34, 36, 37] A 2016 report from the American College of Physicians [33] recommended that: "all adult patients (should) receive cognitive behavioral therapy for insomnia (CBT-I) as the initial treatment for chronic insomnia disorder. (Grade: strong recommendation, moderate-quality evidence)." Likewise, in 2017 the Australian Sleep Association (ASA) developed recommendations for a limited set of psychological and behavioral treatments for insomnia disorder, noting that CBT-I should be considered first line treatment[38]. The ASA also noted emerging evidence for mindfulness-based treatments for insomnia. The British Association for Psychopharmacology's recent consensus statement also notes that CBT-I should be considered a first-line approach. [37]

The current guideline differs from previous guidelines in two significant ways. First, it is a comprehensive review of both single-component and multi-component psychological and behavioral interventions. Second, it is designed to complement the existing AASM guidelines specifically related to pharmacological treatments for insomnia disorder, which were published in 2017. [3]

Meta-analytic reviews

Individual, group, internet-based and self-help CBT-I have also been the subject of numerous meta-analyses. [39-51] A recent comprehensive meta-analysis of individual, group and self-help cognitive and behavioral therapies [48] demonstrated robust clinical improvements in numerous sleep-related outcomes including questionnaires (ISI and PSQI) and sleep diary metrics (e.g., sleep efficiency, wake after sleep onset and sleep onset latency). Comparable improvements have also been shown in a meta-analysis of insomnia comorbid with medical or psychiatric conditions, [49] although the magnitude of improvement was greater among psychiatric comorbidities. Several meta-analyses have also found clinically significant improvements with internet-based CBT-I. [39, 47, 50, 51] suggesting multiple delivery modalities can be used to provide treatment to patients with insomnia disorder.

Previous AASM Practice Guidelines for Psychological and Behavioral Treatments of Insomnia

The initial (1999) practice parameters [52] found the strongest evidence for stimulus control therapy (identified as a "Treatment Standard"), somewhat weaker evidence in support of relaxation therapy, paradoxical intention and biofeedback ("Guideline") and the weakest evidence for multicomponent CBT and sleep restriction therapy ("Option"), reflecting treatment trends and the existing literature of that time period. An update of those parameters was published in 2006. [53] Based on extensive review of the evidence since the previous publication, stimulus control, relaxation training and cognitive-behavioral therapy (CBT) (with or without relaxation) were recommended as demonstrating the strongest evidence for efficacy (Standard). Sleep restriction therapy, multicomponent behavioral therapy (without cognitive therapy), biofeedback and paradoxical intention were also found to be "individually effective therapies in the treatment of chronic insomnia (Guideline)." Sleep hygiene alone was not identified as an effective single component therapy in any of these reports. To date, there have been no specific guidelines that address superiority of one psychological or behavioral treatment over another based on direct comparisons, and this remains a limitation of the current guidelines.

The present guidelines represent a further advancement in establishment of clinical practice guidelines in that the specific recommendations offered herein are based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) process (see below), which uses efficacy data as well as an assessment of the quality of the evidence, patient values and preferences, benefits versus harms and resource utilization to inform the final recommendation statements, with a goal of improving patient-centered care. We believe that these guidelines are based on the most comprehensive review of available evidence and analysis to date. All single-component therapies (e.g. stimulus control alone) and multicomponent therapies (i.e., CBT-I and BBTs) for which evidence was available were examined. In addition to analysis of efficacy data for pooled patient populations, we attempted to determine the efficacy of treatment for sub-groups of patients such as those with and without identified comorbidities which might affect sleep (i.e., medical or psychiatric conditions). We also attempted to examine if outcomes varied across delivery methods and which delivery method appeared most efficacious; however, limitations in the available evidence, including heterogeneity across study samples and methods, did not allow for comparative meta-analysis or specific recommendations; however, delivery methods were still considered in formulating the recommendations and are discussed in detail below.

METHODOLOGY

Expert Task Force

The AASM commissioned a task force (TF) of sleep medicine clinicians and researchers with expertise in psychological and behavioral treatments of chronic insomnia disorder. The TF was required to disclose all potential conflicts of interest (COI), per the AASM's COI policy, prior to being appointed to the TF and throughout the research and writing of these documents. In accordance with the AASM's conflicts of interest policy, individuals were not allowed to be appointed to the TF if they reported a professional or financial conflict that might diminish the integrity, credibility or ethical standards of the guideline. Individuals reporting professional or financial conflicts that represented potential bias but did not prohibit participation in the development of the guideline, agreed to recuse themselves from discussion or writing responsibilities related to the conflicts. All relevant conflicts of interest are listed in the Disclosures section.

PICO Questions and Clinical Significance Thresholds

PICO (Patient, Intervention, Comparison, and Outcomes) questions were developed by the TF to assess 1) the efficacy of interventions and 2) the efficacy of different delivery methods (see **Table 2**). The AASM Board of Directors approved the final list of questions prior to the literature searches.

Table 2—PICO Questions

1. In adults with chronic insomnia disorder[1], which behavioral and psychological treatments[2], compared to control condition[3], lead to clinically significant improvements in sleep quality, sleep latency, wake after sleep onset, remission rates and responder rates?
2. In adults with chronic insomnia disorder[1], how do different delivery methods[4] for behavioral and psychological insomnia treatments[3] compare for improving the above outcomes?

[1] When data were available, treatment efficacy was examined in the following subgroups: a) Insomnia without comorbidities; b) Insomnia with medical comorbidities c) insomnia with psychiatric comorbidities

[2] The efficacy of the following behavioral and psychological treatments was evaluated a) Biofeedback; b) Brief behavioral therapies c) Cognitive behavioral therapy-insomnia; d) Cognitive therapy e) Intensive sleep retraining; f) Mindfulness; g) Relaxation therapy; h) Paradoxical intention treatment; i) Sleep hygiene; j) Sleep restriction therapy; k) Stimulus control.

[3] Control conditions examined: a) sleep hygiene or sleep education; b) pharmacologic –placebo drug c) quasidesensitization d) usual care e) wait-list

[4] Delivery methods for behavioral and psychological treatments a) in-person one-on-one visit with a trained CBT-I specialist, b) group behavioral and psychological treatment, c) telephone delivery, d) self-help book, e) internet-delivery

Through consensus the TF then developed a list of patient-oriented, clinically relevant outcomes to determine the efficacy of the interventions and delivery methods. The outcomes and/or measurement tools that were employed in the research literature were rated by relative importance for clinical decision-making; outcomes deemed most important for decision-making were considered "critical", while the remaining outcomes were considered "important".

The TF set a threshold for each outcome/measurement tool to determine whether the mean treatment versus control differences in the outcomes assessed at post-treatment were clinically significant. The clinical significance threshold was defined as the minimum level of improvement in the outcome of interest that would be considered clinically important to clinicians and patients. For PICO 1, thresholds based on the mean difference between treatment and control at post-treatment were used for most outcomes; however, standardized mean differences (SMDs) were used when the TF concluded that interpretation of effect sizes would be more meaningful (see **Table 3**). For PICO 2 thresholds were set for different delivery methods. Clinical significance thresholds were determined based on a TF literature review of commonly used thresholds including past AASM guidelines[ref]. Where no clearly established threshold values could be determined, the TF used the literature review, clinical judgment, and experience to establish a clinical significance threshold based on consensus. A summary of the clinical significance thresholds for the outcome measures is presented in **Table 3.**

Table 3—Summary of outcomes and clinical significance thresholds

Outcome Tool	Critical Outcome	Clinical Significance Thresholds		
		Intervention vs Control (Differences)	Delivery Method vs Delivery Method (Differences)	Desired direction post- treatment difference
Sleep quality[1]				
Diary	✓	0.5 SMD	0.5 SMD	higher
PSQI		0.5 SMD	0.5 SMD	lower
Sleep latency				
Diary	✓	20 min	10 min	lower
PSG		20 min	10 min	lower
Wake after sleep onset				
Diary	✓	20 min	15 min	lower
Actigraphy		20 min	15 min	lower
PSG		20 min	15 min	lower
Remission rate				
Insomnia Severity Index (ISI)	✓	≥10% patients w/ < 8 points	≥10% patients w/ < 8 points	higher
Diary	✓	≥10% patients w/ <31 min sleep latency and/or WASO	10% patients w/ <31 min sleep latency and/or WASO	higher
PSQI	✓	≥10% patients w/ ≤ 5 points	≥10% patients w/ ≤ 5 points	higher
Responder rate				
Insomnia Severity Index (ISI)	✓	≥10% patient w/ ≥ 8-point drop	≥10% patient w/ ≥ 8-point drop	higher
Diary	✓	≥10% patients w/ ≥ 0.5 SD improvement over baseline sleep latency and/or WASO	≥10% patients w/ ≥ 0.5 SD improvement over baseline sleep latency and/or WASO	higher
Total wake time				
Diary		30 min	20 min	lower

Actigraphy		30 min	20 min	lower
PSG		30 min	20 min	lower
Nights with Hypnotic Use				
Diary		2 nights/week	2 nights/week	lower
Total sleep time				
Diary		15 min	15 min	Higher
Actigraphy		15 min	15 min	Higher
PSG		15 min	15 min	Higher
Number of nighttime awakenings				
Diary		0.5 awakenings/night	0.5 awakenings/night	Lower
Sleep efficiency				
Diary		10%	5%	Higher
Actigraphy		10%	5%	Higher
PSG		10%	5%	Higher
Beliefs and attitudes about sleep				
DBAS[2]		0.5 SMD	0.5 SMD	lower
Daytime fatigue domain				
All fatigue-specific tools[3]		0.5 SMD	0.5 SMD	lower
Insomnia severity				

Insomnia Severity Index (ISI)		0.5 SMD	0.5 SMD	lower
Insomnia Severity Questionnaire (ISQ)		0.5 SMD	0.5 SMD	lower

[1]Tools to assess sleep quality: Daily sleep diary (Higher scores indicate higher sleep quality); Pittsburgh Sleep Quality Index (PSQI; higher score indicates worse sleep quality)
[2]DBAS: Dysfunctional beliefs about sleep (DBAS: Higher scores reflect greater dysfunctional beliefs about sleep)
[3]Daytime fatigue tools (all grouped together): Fatigue severity scale (FSS); Multidimensional Fatigue Inventory (MFI); Profile of Mood States Fatigue subscale (POMS-F); Fatigue symptom index (FSI); Flinders Fatigue Scale (FSS). For all scales, higher scores indicating greater fatigue; *For standardized mean-difference (SMD), an effect size of 0.5 is considered clinically significant (based on Hedge's G)

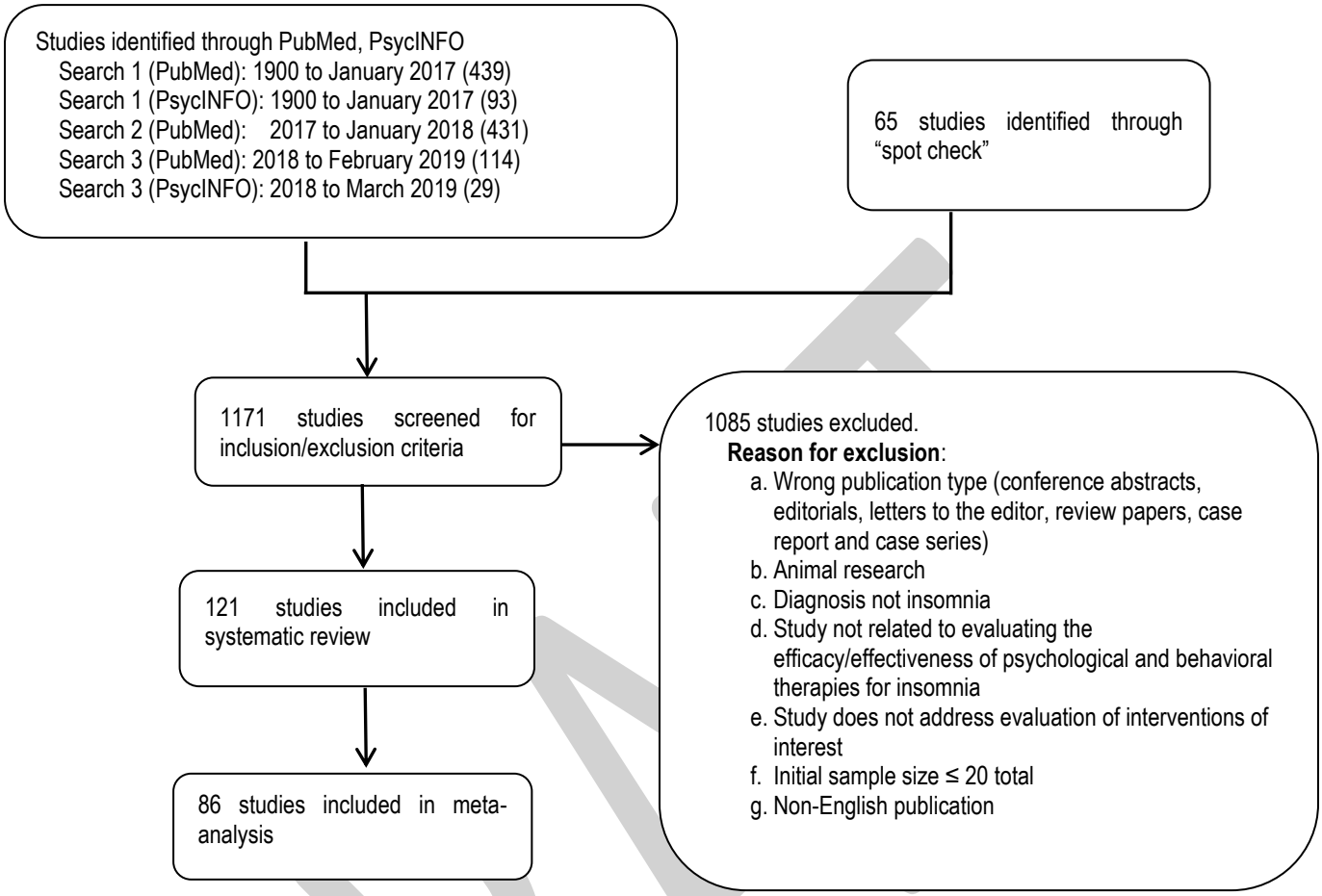
Literature Searches, Evidence Review and Data Extraction

Literature searches were performed using the PubMed and PsycINFO databases for each PICO question (see Appendix for search strings). The initial search was performed January 2017 with no date limits, resulting in 532 unique hits. The publications cited in the 2006 review were also included if they met the inclusion criteria for this systematic review. An updated literature search was performed in January 2018, resulting in 431 additional unique hits. In February 2019 a subsequent literature search was conducted to identify recently published literature, dated from December 2016 to January 2019 resulting in 114 unique hits. The final PsycINFO search that considered the time period between 2018 and March 2019 identified an additional 29 publications. Lastly, the TF reviewed previously published guidelines, systematic reviews, and meta-analyses to identify references that may have been missed during the prior searches. The TF identified 65 additional articles through this spot check process for a total of 1142 articles that were screened for inclusion/exclusion in the systematic review.

Initial screening by title and abstract was performed by pairs of TF members. Discrepancies were resolved by a third reviewer. Articles were included for further review if they focused on the efficacy of psychological or behavioral treatments for chronic insomnia in adults; addressed at least one of the PICO questions; and included at least one of the outcomes of interest. Full publications were reviewed by pairs of TF members and were excluded if they did not provide evidence for any PICO questions. The full inclusion/exclusion criteria are listed in the supplemental materials.

A total of 121 articles from the literature searches were accepted and considered for meta-analysis and evidence grading. Specific data elements of all accepted studies were extracted into evidence tables (not published) to address each PICO question. Upon review of these articles, 86 studies were determined to be suitable for meta-analysis and/or the Grading of Recommendations Assessment, Development and Evaluation (GRADE) process. An evidence base flow diagram is presented in **Figure 1**.

Figure 1—Evidence base flow diagram



Statistical methods, Meta-analysis and Interpretation of Clinical Significance

Meta-analyses were performed on outcomes of interest for each PICO question (Table 2), using Review Manager 5.3 software (The Cochrane Collaboration, London, United Kingdom) when at least 3 studies with the relevant outcome of interest were available for pooling of data. Depending on the number of studies, data analysis proceeded in one of two ways:

- If 3 or more studies were available, a meta-analysis was conducted. The meta-analysis results were then sub-grouped by delivery methods (Table 4) and pooled results are reported for each outcome in the results section.
- When fewer than 3 studies were available, studies are described individually and were not subjected to meta-analysis

Results were also sub-grouped by patient populations which included patients with insomnia with and without comorbidities (Table 5). Data were excluded from the sub-group analyses if studies included a mixed population where the data could not be categorized in any one of the subgroups. For delivery method comparisons the TF chose to compare all alternative delivery methods to in-person one-on-one delivery which, historically has been the most common and standard delivery method employed. As above, when fewer than 3 studies were available for any delivery method, studies are described individually and were not subjected to meta-analysis.

For each outcome unadjusted posttreatment data were used for all statistical analyses; Mean differences were calculated for all outcomes with the exception of sleep quality, ISI, daytime fatigue and DBAS, for which SMDs were calculated. Some studies had data presented as standard error (SE) and in these cases, the data was converted into standard deviation (SD) so the study could be included. There were also some studies which reported data in the form of median and interquartile range (IQR). These, too, were converted into data expressed as means and SD. [54, 55] The pooled results for each continuous outcome

measure are expressed as the mean difference or SMD between the intervention and comparator groups. The pooled results for dichotomous outcome measures are expressed as the risk difference between the intervention and comparator. All analyses were performed using a random effects model with results displayed as a forest plot. If outcome data were not presented in the format necessary for statistical analysis (i.e., mean, SD, and sample size), or data was presented only in graphical formats, the authors were contacted to obtain the necessary data.

Interpretation of clinical significance for the outcomes of interest was conducted by comparing the mean difference in effect size, or risk difference for dichotomous outcomes, of each treatment approach to the clinical significance threshold.

Table 4- Definitions of delivery methods

Delivery method	Definition
In-person, one-on-one delivery	Treatment is provided individually to the patient in a clinical setting by a trained healthcare provider
In-person, group delivery	Treatment is provided to a group of participants in the clinical setting by a trained healthcare provider
Internet delivery	Treatment is provided via the internet using email interaction, audio-video recordings, and/or visual graphics and animations used by patients in their homes. No clinical support or healthcare provider interaction is necessary.
Self-help delivery	Treatment is provided by reading materials and/or audio recordings used by patients in their homes. No clinical support or healthcare provider interaction is necessary.
Telephone delivery	Treatment is provided via live telephone interaction with a trained healthcare provider.
Video delivery	Treatment is delivered via a recorded video, often including self-help booklets as part of the treatment package used by patients in their homes. No clinical support or healthcare provider interaction is necessary.
Telehealth delivery	Treatment is provided real time by a trained healthcare provider using interactive audio-video telecommunications system.

Table 5- Descriptions of patient populations for sub-group analyses

Patient Population[1]	Description
Patients with insomnia and no comorbidities	Patients diagnosed with chronic insomnia disorder and no concurrent comorbidities
Patients with insomnia and psychiatric comorbidities	Patients diagnosed with chronic insomnia disorder and diagnosed concurrent psychiatric comorbidities e.g. depression, post-traumatic stress disorder (PTSD), anxiety, alcohol and substance use
Patients with insomnia and medical comorbidities	Patients diagnosed with chronic insomnia disorder and have concurrent medical comorbidities e.g. cancer, fibromyalgia, osteoarthritis

[1] Study populations that do not meet the above descriptions, or were the combination of the patient populations were not included in the sub-group analyses

GRADE Assessment for Developing Recommendations

The assessment of evidence quality was performed according to the GRADE process for the purposes of making clinical practice recommendations. [56, 57] GRADE assessment was only performed for PICO 1; the TF determined there was insufficient evidence for PICO 2 delivery method comparisons to warrant recommendations, therefore the GRADE process was not followed for these comparisons. Quality of evidence was assessed only for the studies reporting data that could be

included in the meta-analysis. The TF assessed the following four components to determine the direction and strength of a recommendation:

1. **Quality of evidence:** based on an assessment of the overall risk of bias (blinding, allocation concealment, selective reporting), imprecision (95% confidence interval relative to the clinical significance threshold, total sample size of <200), inconsistency (I^2 cutoff of 50%), indirectness (study population), and risk of publication bias (funding sources), the TF determined their overall confidence that the estimated effect found in the body of evidence was representative of the true treatment effect that typical adult patients with insomnia would experience. The overall quality of the evidence was based on outcomes that the TF deemed critical for decision making.
2. **Benefits versus harms:** based on any harms/side effects reported within the accepted literature, and the clinical experience and expertise of the TF, the TF determined if the beneficial outcomes of using each intervention outweighed any harms.
3. **Patient values and preferences:** based on the clinical experience and expertise of the TF members and any data published on the topic relevant to patient preferences for psychological and behavioral interventions for insomnia, the TF determined if patient values and preferences would be consistent across the majority of patients, and if patients would use the interventions based on the body of evidence.
4. **Resource use:** based on the clinical experience and expertise of the TF members, the TF determined if accessibility and costs associated with each treatment approach compared favorably to alternative treatments. Information on both costs to patients and to the health care system were considered.

A summary of each GRADE domain is provided after the detailed evidence review for each intervention.

Public Comment and Final Approval

Drafts of the systematic review with supplemental materials and accompanying clinical practice guideline[ref] were made available for public comment for a two-week period on the AASM website. AASM members, the general public and other relevant stakeholders were invited to provide feedback on the drafts. The TF took into consideration all the comments received and made decisions about whether to revise the draft based on the scope and feasibility of comments. The public comments and revised documents were submitted to the AASM Board of Directors who subsequently approved the final documents for publication.

The AASM expects this systematic review to have an impact on professional behavior, patient outcomes, and, possibly, health care costs. This review reflects the state of knowledge at the time of publication and will be reviewed and updated as new information becomes available.

RESULTS

The aims of the current systematic reviews and data analyses were to inform PICO questions assessing the efficacy of Psychological and Behavioral treatments for chronic insomnia and treatment efficacy across delivery methods. We found evidence for the following interventions: Cognitive Behavioral Therapy (CBT-I), Brief Behavioral Therapies (BBTs), Stimulus Control, Sleep Restriction Therapy, Relaxation Training, Sleep Hygiene, Biofeedback, Paradoxical Intention, Intensive Sleep Retraining (ISR) and Mindfulness. No studies meeting our inclusion criteria were found for Cognitive therapy as a single-component treatment.

Below are detailed summaries of the evidence identified in the literature searches and the statistical analyses performed by the task force to inform recommendations within the clinical practice guideline[ref]. All figures can be found in the supplemental materials. All values of the critical outcomes results are reported in the text below. For important outcomes results, values are only reported if the results met the clinical significance threshold. Each evidence summary is accompanied by a discussion of the quality of evidence, balance of benefits and harms, patient values and preferences, and resource use considerations that contributed to the development of the clinical practice recommendations, which are provided in the accompanying CPG.

Cognitive behavioral therapy for Insomnia (CBT-I)

Our review of the literature identified 64 randomized controlled trials (RCTs) [58-121] included in the meta-analyses examining the effect of CBT-I versus control in adult patients with chronic insomnia. Forty-nine studies [58-60, 62-74, 76-106, 117, 118] reported at least one of the critical outcomes (see Table 3). In addition, 17 RCTs [122-138] provided data not suitable for meta-analyses but were included as supporting evidence. The delivery formats of CBT-I in these studies included in-person one-on-one, in-person group, internet-based delivery, self-help and video delivery. The control groups included treatment as usual, wait list control, minimal intervention (e.g., sleep hygiene education), placebo behavioral treatment (e.g., quasi-desensitization), and placebo drug.

The figures and tables are provided in supplemental material, Figures **[S1-S70]** and Tables **[S1-S34].** Summary of the meta-analyses conducted are provided in the supplemental material, Tables **[S35-38]**. A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** are provided below.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section for sleep quality, sleep latency and WASO.

SLEEP QUALITY: Meta-analysis of 18 studies [59, 60, 62, 68, 70, 73, 74, 78, 79, 81, 83, 85, 93, 97, 99, 100, 102, 104] reporting post-treatment comparisons of diary-determined sleep quality between CBT-I and control showed an effect size of 0.46 (95% CI: 0.29 to 0.63 higher) favoring CBT-I compared to control; these results did not reach the threshold for clinical significance established by the TF **(Figure S1)**.

In sub-group analyses of patient populations, diary-determined sleep quality was reported in two studies of patients with insomnia in the absence of comorbidities [97, 100]. One study [100] showed a clinically significant post-treatment difference with an effect size of 1.48 (95% CI: 0.64 to 2.32 higher) favoring CBT-I compared to control **(Table S1)**. The other study [97] did not show a clinically significant post-treatment difference between CBT-I and control with an effect size of 0.16 (95% CI: 0.29 lower to 0.61 higher) **(Table S1)**. There was one study in patients with insomnia and comorbid psychiatric conditions, [60] which showed a clinically significant post-treatment difference with an effect size of 0.85 (95% CI: 0.23 to 1.46 higher) favoring CBT-I over control **(Table S2)**. There were two studies in patients with insomnia and comorbid medical conditions, [68, 78] one[78] of which reported a clinically significant post-treatment difference with an effect size of 0.91 (95% CI: 0.15 to 1.67 higher) favoring CBT-I over control and the other[68] of which showed a clinically significant post-treatment difference between treatment and control with an effect size of 0.54 (95% CI: 0.07 to 1.01 lower) favoring control **(Table S3)**.

Meta-analysis of 21 studies [58-60, 63, 71-74, 85, 90-92, 100, 103, 105, 108, 111-114, 118] reporting PSQI-determined sleep quality (i.e., PSQI total score) showed an effect size of 0.66 (95% CI: 0.54 to 0.78 lower) favoring CBT-I over control **(Figure S2)**; this effect was above the clinical significance threshold established by the TF.

Two studies[63, 100] reporting PSQI-determined sleep quality for patients with insomnia and no comorbidities showed a clinically significant post-treatment differences with effect sizes of 0.55 (95% CI: 1.24 lower to 0.14 higher) and 1.67 (95% CI: 0.80 to 2.53 lower) favoring CBT-I over control **(Table S4)**. Similarly, meta-analysis of four studies[60, 72, 92, 105] in patients with insomnia and comorbid psychiatric conditions showed a clinically significant post-treatment differences with an effect size of 0.80 (95% CI: 0.53 to 1.06 lower) favoring CBT-I over control **(Figure S3)**. Meta-analysis of five studies[75, 90, 113, 114, 118] including patients with insomnia and comorbid medical conditions showed an effect size of 0.86 (95% CI: 0.60 to 1.13 lower) which met the clinical significance threshold favoring CBT-I over control **(Figure S4)**.

The quality of evidence for sleep quality ranged from low to moderate due to imprecision and risk of bias.

Seven studies[66, 88, 103, 125, 130, 132, 136] reporting diary-determined and five studies[91, 98, 124, 127, 135] reporting PSQI determined sleep quality compared to control were not included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

For direct comparisons of delivery methods, five studies[60, 83, 99, 139, 140] reporting diary-determined sleep quality were included in the meta-analysis of in-person one-on-one delivery compared to another delivery modality **(Figure S5)**. One study[139] comparing in-person one-on-one delivery to group delivery showed an effect size of 0.46 favoring in-person one-on-one delivery over group delivery (95% CI: 0.25 lower to 1.18 higher). Three studies[83, 99, 140] comparing in-person to internet delivery reported an effect size of 0.06 favoring in-person one-on-one delivery compared to internet delivery (95% CI: 0.99 lower to 1.12 higher) **(Figure S5)**. Out of two studies[139, 140] comparing in-person to telephone delivery, one study [139] reported an effect size of 0.57 favoring in-person one-on-one delivery over telephone delivery (95% CI: 0.18 lower to 1.31 higher) which met the clinical significance threshold **(Figure S5)**. The other study [140] had an effect size of 0.27 (95% CI: 0.75 lower to 0.21 higher) favoring telephone delivery and did not meet the clinical significance threshold when compared to in-person one-on-one delivery. One study[60] comparing in-person one on one to self-help delivery met the clinical significance threshold with an effect size of 0.65 (95% CI: 0.33 lower to 1.64 higher) favoring in-person one-on-one delivery of CBT-I over self-help **(Figure S5)**.

Two studies[58, 141] comparing in-person, one-on-one delivery to in-person group delivery reported clinically significant mean effect sizes of 0.66 (95% CI: 0.27 to 1.05 lower) and 1.79 (95% CI: 1.09 to 2.50 lower) for PSQI-determined sleep quality favoring in-person one-on-one delivery over group delivery **(Figure S6)**. One study[60] comparing in-person, one-on-one to self- help delivery also met the clinical significance threshold with an effect size of 0.61 (95% CI: 1.34 lower to 0.11 higher) favoring in-person, one-on-one delivery over self-help delivery **(Figure S6)**.

SLEEP LATENCY: Meta-analysis of 45[58-60, 62-65, 67-74, 76, 77, 79-85, 87-104, 106, 117, 118] studies reporting diary-determined sleep latency showed a mean difference of 12.33 minutes lower (95% CI: 10.12 to 14.54 minutes lower) for CBT-I as compared to control which did not meet the clinical significance threshold **(Figure S7)**.

In sub-group analyses of patient populations, diary-determined sleep latency was reported in nine studies[63, 65, 77, 84, 87, 89, 97, 100, 106] of patients with insomnia and no comorbidities with a mean difference of 10.64 minutes lower (95% CI: 5.99 to 15.28 minutes lower) for CBT-I compared to control **(Figure S8)**; this difference did not meet the clinical significance threshold. Five studies [60, 72, 80, 98, 101]of patients with insomnia and comorbid psychiatric conditions showed a mean difference of 30.60 minutes lower (95% CI: 20.37 to 40.83 minutes lower) for CBT-I compared to control **(Figure S9)**. Ten studies[64, 68, 88, 90-92, 94-96, 118] in patients with insomnia and comorbid medical conditions reported a mean difference of 10.30 minutes lower (95% CI: 5.22 to 15.38 minutes lower) compared to control **(Figure S10)**. Only the studies[ref] reporting insomnia in individuals with comorbid psychiatric conditions met the clinical significance threshold.

Meta-analysis of five studies[76, 87, 95, 96, 106] reporting PSG-determined sleep latency also did not meet the clinical significance threshold **(Figure S11)**.

One[106] out of two[87, 106] studies reporting PSG-determined sleep latency in patients with insomnia and no comorbidities showed a clinically significant post-treatment difference of 31.50 minutes lower (95% CI: 15.52 to 47.48 minutes lower) for CBT-I compared to control **(Table S5)**. The other study[87] did not show a clinically significant post-treatment difference favoring CBT-I. Two studies[95, 96] reporting PSG-determined sleep latency in patients with insomnia and comorbid medical conditions did not meet the clinical significance threshold **(Table S6)**.

The quality of evidence for sleep latency ranged from low to moderate due to imprecision and risk of bias.

Eight studies[91, 123, 125, 126, 130, 132, 133, 136] reporting diary determined sleep latency, and one study[131] reporting PSG-determined sleep latency were not included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

For direct comparisons of delivery methods, four studies [58, 139, 141, 142] reporting on diary determined sleep latency, were included in a meta-analysis comparing in-person, one-on-one to in-person group delivery showed a mean post-treatment difference of 5.94 minutes lower (95% CI: 1.01 to 10.87 minutes lower) for the one-on one delivery method **(Figure S12)**. Three studies [83, 99, 140]comparing in-person, one-on-one to internet delivery reported a mean difference of 3.79 minutes lower

(95% CI: 14.31 minutes lower to 6.72 minutes higher) **(Figure S12)** for the in-person one-on-one delivery method. Two studies [139, 140] comparing in-person one-on-one to telephone delivery reported a mean difference of 11.68 minutes lower (95% CI: 0.28 minutes to 23.08 minutes lower) and 7.49 minutes higher (95% CI: 7.28 minutes lower to 22.26 minutes lower) for the one-on-one delivery method **(Figure S12)**. One study [60] comparing in-person one-on-one to self-help delivery and one [94] comparing in-person one-on-one to video delivery reported mean differences of 2.70 minutes lower (95% CI: 13.25 minutes lower to 7.85 minutes higher) and 4.61 minutes lower (95% CI: 0.21 minutes to 9.01 minutes lower) in the in-person one-on-one delivery arm respectively **(Figure S12)**. None of the comparisons reported results that met the clinical significance threshold for in-person delivery compared to the other delivery methods.

WAKE AFTER SLEEP ONSET (WASO): Meta-analysis of 42 studies [58-60, 62-65, 67-74, 76, 79-101, 104, 117, 118] reporting diary determined WASO showed a post-treatment mean difference of 19.13 minutes lower (95% CI: 15.40 to 22.86 minutes lower) favoring CBT-I over control, a result which did not meet the clinical significance threshold **(Figure S13)**.

In sub-group analyses of patient populations, eight studies [63, 65, 84, 86, 87, 89, 97, 100] reporting diary determined WASO reported a clinically significant post-treatment difference of 24.10 minutes (95% CI: 9.30 minutes to 38.90 minutes lower) favoring CBT-I over control in patients with insomnia and no comorbidities **(Figure S14)**. In contrast, five studies [60, 72, 80, 98, 101]of patients with insomnia and comorbid psychiatric conditions reported a mean post-treatment non-clinically significance difference of 14.55 minutes lower (95% CI: 2.05 to 26.84 minutes lower) **(Figure 15)** for the CBT-I group versus control. Ten [64, 68, 88, 90-92, 94-96, 118] studies with insomnia and comorbid medical conditions showed a mean difference of 20.36 minutes lower (95% CI: 11.50 minutes to 29.21 minutes lower) for CBT-I compared to control **(Figure 16)**, a difference which met the clinical significance threshold favoring the CBT-I treatment group.

Ten studies [63, 64, 68, 69, 71, 84, 96, 98-100] reporting actigraphy estimated WASO did not meet the clinical significance threshold for favoring CBT-I over control **(Figures S17)**.
Three studies [63, 84, 100]in patients with insomnia and no comorbidities, one study [98] in patients with insomnia and comorbid psychiatric conditions and three studies [64, 68, 96] with insomnia and comorbid medical conditions assessed WASO by actigraphy: none of these comparisons met the clinical significance threshold that would favor CBT-I over control **(Figures S18-19, Table S7)**.
Meta-analysis of six studies [76, 86, 87, 95, 96, 98] reporting PSG-determined WASO did not meet the clinical significance threshold for favoring CBT-I over control **(Figures S20)**
Two studies [86, 87] assessed WASO by PSG in patients with insomnia and no comorbidities out of which only one [86] reported a clinically significant post-treatment difference of 27.94 minutes lower (95% CI: 6.63 to 49.25 minutes lower) favoring CBT-I over control **(Table S8)**. One study [98]did not report a clinically significant post-treatment difference in PSG WASO between CBT-I and control among patients with insomnia and comorbid psychiatric conditions **(Table S9)**. Of the two studies [95, 96] reporting PSG in patients with insomnia and comorbid medical conditions, one [96] reported a clinically significant post-treatment difference of 37.17 minutes lower (95% CI: 14.08 to 60.26 minutes lower) favoring CBT-I **(Table S10)**.

The quality of evidence for WASO ranged from low to moderate due to imprecision and risk of bias.

Eleven studies [66, 91, 123, 125, 126, 128, 130, 132, 133, 136, 137] were not included in the meta-analyses as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings. These studies showed post-treatment intervention improvements in WASO.

For direct comparisons of delivery methods, three studies [58, 139, 142] reporting diary-determined WASO were included in a meta-analysis comparing in-person one-on-one delivery to in-person group **(Figure S21)**. A post-treatment WASO difference of 8.62 minutes lower (95% CI: 9.75 minutes lower to 26.99 minutes higher) was found favoring the group delivery method, a difference that did not meet the clinical significance threshold. Meta-analysis of three studies [83, 99, 140] comparing in-person one-on-one to internet delivery showed a post-treatment difference in WASO of 10.11 minutes lower (95% CI: 2.00 minutes to 18.23 minutes lower) favoring the in-person one on one method; these results also did not meet the clinical significance threshold **(Figure S21)**. Two studies [139, 140] comparing in-person, one-on-one to telephone delivery reported a mean difference in WASO of 19.23 minutes higher (95% CI: 4.82 minutes lower to 43.28 minutes higher) and 8.01 minutes higher (95% CI: 10.18 minutes lower to 26.20 minutes higher) for the in-person one-on-one method at post-

treatment **(Figure S21)**. These results did not meet the clinical significance threshold. One study [60] comparing in-person one-on-one to self-help delivery reported a mean difference of 4.00 minutes lower (95% CI: 26.54 minutes lower to 18.54 minutes higher) for the in-person one-on-one method **(Figure S21)**. One study comparing in-person [94] one-on-one to video delivery showed a mean difference of 3.16 minutes lower (95% CI: 8.37minutes lower to 2.05 minutes higher) for the in-person one-on-one method **(Figure S21)**. Neither of the results met the clinical significance thresholds.

For comparisons of delivery methods two studies [99, 141] reported actigraphy-assessed WASO. One study [141] comparing in-person, one-on-one to group delivery showed a mean difference of 3.30 minutes lower for the group delivery (95% CI: 3.10 minutes lower to 9.70 minutes higher) **(Table S11)**. Another study [99] comparing in-person one-on-one to internet delivery reported a mean post-treatment difference of 4.80 minutes lower (95% CI: 16.27 minutes lower to 6.67 minutes higher) for the in-person one-on-one delivery method (**Table S12).** Results did not show clinically significance differences between delivery methods.

REMISSION RATE: A meta-analysis of 25 studies [59, 60, 62, 63, 71, 72, 74, 76-79, 84, 86, 88, 89, 93-96, 98-100, 105, 106, 118] reported a clinically significant 33% higher (95% CI: 28% to 39% higher) remission rate for CBT-I compared to control **(Figure S22)**.

In sub-group analyses of patient populations, meta-analysis of seven studies [63, 77, 84, 86, 89, 98, 106] consisting of patients with insomnia and no comorbidities showed a clinically significant 46% higher (95% CI: 33% to 58% higher) remission rate in the CBT-I group than in the control group **(Figure S23)**. Similarly clinically significant remission rate differences were noted in the CBT-I group in the four studies [60, 72, 98, 105] which included patients with insomnia and comorbid psychiatric conditions and eight studies [78, 88, 91, 92, 94-96, 118] which included patients with insomnia and comorbid medical conditions; the remission rate differences of 31% higher (95% CI: 13% to 48% higher) and 35% higher (95% CI: 27% to 42% higher) favoring CBT-I were found in these comparisons **(Figures S24-25)** respectively.

The quality of evidence for remission rate ranged from low to moderate due to imprecision and risk of bias.

Fourteen studies [67, 80-83, 87, 101, 103, 104, 115, 117, 125, 128, 130] comparing CBT-I to control could not be included in the meta-analysis as the definition of remission rate used in the studies was not consistent with the TF definition of remission rate or post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Direct comparisons of delivery methods included three studies [60, 94, 142] that met the TF's definition of remission rate (Table 3). One study [142] compared in-person, one-on-one to in-person group delivery and reported a clinically significant 18% higher remission rate (95% CI: 6% lower to 43% higher) for the group method **(Figure S26)**. Similarly, one study [60] compared in-person one-on-one to self-help delivery and one study [94] to video delivery. Results of both studies met the clinical significance threshold with the in-person one-on-one method showing 17% (95% CI: 14% lower to 49% higher) and 10% (95% CI: 5% lower to 26% higher) higher remissions rates than did the self -help and video delivery respectively **(Figure S26)**.

RESPONDER RATE: A meta-analysis of 15 studies [59, 64, 65, 70, 72, 74, 78, 79, 81, 83, 90-93, 117] showed a clinically significant 45% greater responder rate (95% CI: 39% to 51% higher) for CBT-I versus control **(Figure S27)**.

In sub-group analyses of patient populations, all subgroups met the clinical significance thresholds favoring the CBT-I group over control. One study [65] included patients with insomnia and no comorbidities and reported a clinically significant 36% (95% CI: 15% to 56% higher) higher responder rate for CBT-I **(Table S13)**. Three studies [72, 91, 92] included patients with insomnia and comorbid psychiatric conditions with a clinically significant result of a 49% higher responder rate in the CBT-I group (95% CI: 36% to 63% higher) **(Figure S28)**. Similarly, clinically significant differences were noted from meta-analysis of three studies [64, 78, 90] in patients with insomnia and comorbid medical conditions with a 58% (95% CI: 42% to 73% higher) higher responder rate for CBT-I group **(Figure S29)**.

The quality of evidence for responder rate ranged from low to moderate due to imprecision and risk of bias.

Fourteen studies [63, 66, 80, 82, 84, 88, 91, 95, 103, 104, 117, 125, 130, 132] comparing CBT-I to control could not be included in the meta-analysis as the responder rate definitions in the studies were not consistent with the Task Force's definition of responder rate, or post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

For the direct comparisons of delivery methods, only one study [83] reported a responder rate that met the definition set by the TF. The study[83] showed a 33% higher (95% CI: 8% lower to 57% higher) responder rate favoring in-person one-on-one delivery over internet delivery **(Table S14).**

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention: beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time.

BELIEFS AND ATTITUDES ABOUT SLEEP: Fourteen studies[59, 74, 79, 90-92, 94, 97, 99, 100, 102, 104, 108, 112] reported data acquired from the Dysfunctional Beliefs and Attitudes Scale (DBAS) for CBT-I versus control. Studies used different versions of DBAS, including the 30, 28, 20, 16 and 10 item versions. Results met the clinical significance threshold with an effect size of 0.78 (95% CI: 0.31 to 1.26 lower) favoring CBT-I compared to control **(Figure S30)**.

In sub-group analyses of patient populations, DBAS results were reported in two studies[97, 100]in patients with insomnia and no comorbidities. Both showed clinically significant improvements in the treatment group with effect sizes of 2.06 (95% CI: 1.13 to 2.99 lower) and 0.75 (95% 0.28 to 1.22 lower) favoring CBT-I over control **(Table S15)**. Meta-analysis of four studies[90-92, 94] included patients with insomnia and comorbid medical conditions showed an effect size of 1.28 favoring the CBT-I group (95% CI: 0.72 to 1.83 lower) over control for lowering DBAS scores **(Figure S31)**. These results met the clinical significance threshold favoring CBT-I when compared to control.

The quality of evidence for beliefs and attitudes about sleep ranged from very low to low due to imprecision, inconsistency and risk of bias.

Four studies[91, 106, 132, 133] were not included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

For the direct comparisons of delivery methods, of the three studies[94, 99, 142] comparing delivery methods that reported post-treatment DBAS comparisons, only one[94] met the clinical significance threshold favoring in-person one-on-one delivery over video delivery with an effect size of 0.85 (95% CI: 0.53 to 1.17 lower) **(Figure S32)**. The other two studies[99, 142], which compared in-person one-on-one to group and internet delivery, did not meet the clinical significance threshold **(Figure S32)**.

DAYTIME FATIGUE: Ten studies[59, 61, 84, 89, 100, 104, 110, 113, 119, 121] reported data on daytime fatigue. Results of various tools such as the Fatigue severity scale (FSS), Multidimensional Fatigue Inventory (MFI), Profile of Mood States Fatigue subscale (POMS-F), Fatigue Symptom Index (FSI), and Flinders Fatigue Scale (FFS) were pooled. Meta-analysis of ten studies[59, 61, 84, 89, 100, 104, 110, 113, 119, 121] demonstrated an effect size of 0.56 (95% CI: 0.25 to 0.87 lower) favoring CBT-I over control and falling above the clinical significance threshold **(Figure S33)**.

In sub-group analyses of patient populations, findings for all three patient subgroups met the clinical significance threshold for daytime fatigue improvements favoring the CBT-I treatment. Two studies[84, 100] that included patients with insomnia and no comorbidities showed an effect size of 0.96 (95% CI: 0.18 to 1.74 lower) and 0.62 (95% CI: 0.19 to 1.06 lower) favoring CBT-I over control **(Table S16)**. Only one study[121] reported on patients with insomnia and comorbid psychiatric conditions with an effect size of 0.81 (95% CI: 0.19 to 1.42 lower) favoring CBT-I over control **(Table S17)**. Meta-analysis of four studies[61, 88, 113, 119] that included patients with insomnia and comorbid medical conditions showed a mean effect size of 0.53 (95% CI: 0.22 to 0.84 lower) favoring CBT-I over control **(Figure S34)**.

The quality of evidence for daytime fatigue ranged from moderate to low due to imprecision and risk of bias.

Nine studies[76, 79, 94, 117, 124, 128, 133, 135, 137] could not be included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Only one study[140] directly compared in-person one-on-one delivery of CBT-I to internet and telehealth methods with no clinically significant differences observed among the delivery methods for reducing daytime fatigue **(Table S18).**

INSOMNIA SEVERITY: Meta-analysis of 29 studies[58, 59, 61, 62, 72-74, 78-80, 83-85, 89, 93-96, 98-101, 104, 107, 109, 116, 117, 119, 120] reporting insomnia severity measured by the Insomnia Severity Index (ISI) showed a clinically significant result with an effect size of 0.94 favoring the CBT-I intervention (95% CI:0.76 to 1.12 lower) over control **(Figure S35)**.

In sub-group analyses of patient populations of ISI determined insomnia severity, five studies[84, 89, 100, 109, 116] reporting on patients with insomnia and no comorbidities, four studies[72, 80, 98, 101] reporting on patients with insomnia and comorbid psychiatric conditions and six studies[61, 78, 94, 96, 107, 119] reporting on patients with insomnia and comorbid medical conditions resulted in ISI scores differences that met the clinical significance threshold favoring CBT-I over control in all three groups with effect sizes of 1.24 (95% CI:0.86 to 1.61 lower), 1.61 (95% CI:1.16 to 2.05 lower) and 0.67 (95% CI: 0.30 to 1.04 lower) respectively **(Figures S36-38).**

Three studies[63-65]reported insomnia severity measured by Insomnia Symptom Questionnaire (ISQ). No clinically significant differences between CBT-I and control were noted using this questionnaire **(Figure S39)**.

In sub-group analyses of patient populations for ISQ determined insomnia severity, there were two [63, 65]studies that included patients with insomnia and no comorbidities. Of those, one study[65] met the clinical significance threshold with an effect size of 0.86 (95% CI: 0.15 to 1.57 lower) **(Table S19)** favoring CBT-I over the control. One study[64] reported on patients with insomnia and comorbid medical conditions. This study[64] did not show clinically significant differences between the CBT-I and control at post-treatment **(Table S20)**.

The quality of evidence for insomnia severity ranged from low to moderate due to imprecision, inconsistency and risk of bias.

Eight studies[67, 92, 122, 126, 129, 130, 134, 138] reporting insomnia severity measured by ISI and one study[66] measured by ISQ could not be included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

In studies including direct comparisons of delivery methods using ISI to measure insomnia severity, meta-analysis of three studies[83, 99, 140] comparing in-person one-on-one to internet showed a clinically significant effect size of 0.61 (95% CI: 0.10 to 1.11 lower) favoring the in-person one-on-one delivery method over the internet method **(Figure S40)**. One study[139] comparing in-person one-on-one to telephone delivery and another[94] comparing in-person one-on-one to video delivered CBT-I both met the clinical significance threshold with effect sizes of 0.67 (95% CI: 1.42 lower to 0.09 higher) and 0.57 (95% CI: 0.21 to 0.93 lower) respectively favoring the in-person one-on-one delivery method **(Figure S40)**. Clinical significance thresholds were not met in two studies[58, 139] that compared in-person one-on-one to group delivery and one study[140] comparing in-person one-on-one to telehealth delivery **(Figure S40)**.

NIGHTS WITH HYPNOTIC USE: Our literature search identified five studies[82, 90, 91, 102, 108] reporting diary-determined nights per week of hypnotic use; results of the meta-analysis did not meet the clinical significance thresholds for CBT-I versus control comparisons **(Figure S41)**.

In sub-group analyses of patient populations, one study[87]that included insomnia patients and no comorbidities and a second[91] that included patients with insomnia and comorbid psychiatric conditions did not meet the clinical significance threshold that would favor CBT-I over control for reducing hypnotic use **(Tables S21-22)**.

The quality of evidence for nights with hypnotic use ranged from low to moderate due to imprecision, inconsistency and risk of bias.

Data from seven studies[71, 83, 91, 97, 113, 135] reporting hypnotic use could not be included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

No studies were present for direct comparisons of in-person one-on-one delivery to other delivery methods.

NUMBER OF NIGHTTIME AWAKENINGS: A total of 19 studies[59, 60, 62, 67, 74, 80-84, 88, 89, 93, 97, 99, 100, 103, 104, 118] that reported diary-determined data for number of nighttime awakenings were included in a meta-analysis. Results did not meet the clinical significance threshold **(Figure S42)** for comparisons of CBT-I and control.

In sub-group analyses of patient populations, four studies[84, 89, 97, 100] that included patients with insomnia and no comorbidities reported no clinically significant differences in the treatment group when compared to control **(Figure S43)**. Two studies[60, 80] included patients with insomnia and comorbid psychiatric conditions of which one[60] was clinically significant with 0.86 fewer awakenings favoring CBT-I (95% CI: 1.73 lower to 0.01higher) when compared to control **(Table S23)**. Two studies[88, 118] reported patients with insomnia and comorbid medical conditions of which one[118] study met the clinical significance threshold of 0.70 fewer awakenings favoring CBT-I group (95% CI:1.86 lower to 0.46 higher) when compared to control **(Table S24)**.

The quality of evidence for nighttime awakenings ranged from low to moderate due to imprecision and risk of bias.

Data from four studies[117, 133, 136, 137] reporting diary determined number of nighttime awakenings could not be included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

In direct comparisons of delivery methods using diary-determined data for number of nighttime awakenings, meta-analysis of three studies[83, 99, 140] comparing in-person one-on-one to internet, one study[142] comparing in-person one-on-one to in-person group and one study[140] comparing in-person one-on-one to telehealth delivery methods did not meet the clinical significance threshold for treatment group differences **(Figure S44)**. One study[60] comparing in-person one-on-one to self-help delivery showed a clinically significant result of 0.70 fewer awakenings (95% CI: 0.06 to 1.34 lower) favoring the in-person one-on-one delivery method **(Figure S44)**.

SLEEP EFFICIENCY: Our literature search identified 48 studies [58-60, 62-65, 67-74, 76, 77, 79-104, 106, 115, 118-120] reporting diary determined sleep efficiency which were included in the meta-analyses. Results did not meet the clinical significance threshold when comparing CBT-I to control **(Figure S45)**.

Similarly, in sub-group analyses of patient populations, no clinically significant CBT-I versus control differences were seen in a meta-analysis of ten studies[63, 65, 77, 84, 86, 87, 89, 97, 100, 106] reporting diary-determined efficiency in patients with insomnia and no comorbidities **(Figures S46).** No clinically significant differences between CBT-I and control were observed in a meta-analysis of five studies[60, 72, 80, 98, 101] reporting diary-determined in patients with insomnia and comorbid psychiatric conditions **(Figure S47).** Also, a meta-analysis of eleven studies[64, 68, 88, 90-92, 94-96, 118, 119] reporting diary-determined sleep efficiency in patients with insomnia and comorbid medical conditions did not meet the clinical significance threshold when comparing CBT-I to control **(Figures S48).**

Ten studies[58, 63-65, 68, 69, 71, 90, 96, 99] reporting sleep efficiency measured by actigraphy did not meet the clinical significance threshold **(Figures S49)** in the CBT-I versus control comparisons.

Similarly, in sub-group analyses of patient populations, no clinically significant differences were seen in two studies[63, 65] reporting actigraphy-determined sleep efficiency in patients with insomnia and no comorbidities, one study[90] reporting actigraphy-determined sleep efficiency in patients with insomnia and comorbid psychiatric conditions and three studies[64, 68, 96] reporting actigraphy determined sleep efficiency among patients with insomnia and comorbid medical conditions when comparing CBT-I to control (**Tables S25-S26, Figure S50).**

Seven studies[76, 86, 87, 95, 96, 106, 115] employing PSG also did not meet the clinical significance threshold **(Figures S51)** in the CBT-I versus control comparisons.

In sub-group analyses no clinically significant differences between CBT-I and control were observed in a meta-analysis of three studies[86, 87, 106] reporting PSG-determined sleep efficiency in patients with insomnia and no comorbidities **(Figure S52)**. Also, two studies[95, 96] measuring sleep efficiency by PSG among patients with insomnia and comorbid medical conditions did not meet the clinical significance threshold when comparing CBT-I to control **(Table S27).**

The quality of evidence for sleep efficiency ranged from low to moderate due to imprecision and risk of bias.

Data from nine studies[66, 91, 117, 123, 125, 132, 133, 136, 138] measuring sleep efficiency by diary, two studies[134, 138] by actigraphy and one study[66] by PSG could not be included in the meta-analysis as post-treatment mean differences could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Direct comparisons of delivery methods included a meta-analysis of three studies[58, 139, 142] reporting diary-determined sleep efficiency that compared in-person one-on-one to group delivery and another three studies[83, 99, 140] that compared in-person one-on-one to internet delivery. None of these studies met the clinical significance threshold for differences among the delivery methods **(Figure S53)**. Similarly, one study[60] comparing in-person one-on-one to self-help, another[139] comparing in-person one-on-one to telephone delivery and one study[94] comparing in-person one-on-one to video delivery did not meet the clinical significance threshold **(Figure S53)** for differences among the delivery methods. Two studies[58, 141] compared in-person one-on-one to group delivery and one study[99] compared in-person one-on-one to internet delivery measuring sleep efficiency by actigraphy **(Figure S54)**. None of these studies met the clinical significance threshold for comparisons among delivery methods **(Figure S54)**.

TOTAL WAKE TIME: A meta-analysis of 15 studies[58, 64, 65, 70, 72, 78, 83, 85, 87, 94, 95, 97, 100, 115, 119] reported a clinically significant 39.60 minutes (95% CI: 26.07 to 53.12 minutes lower) lower post-treatment values of diary-determined total wake time for CBT-I compared to control **(Figure S55)**.

In subgroup analysis in patients with insomnia and no comorbidities, meta-analysis of four studies[65, 87, 97, 100] reporting total wake time measured by diary did not meet the clinical significance threshold **(Figure S56)** for CBT-I versus control comparisons. Similarly, one study[72] reporting total wake time measured by diary in patients with insomnia and comorbid psychiatric conditions did not meet the clinically significance threshold for group differences **(Table S28)**. Meta-analysis of five studies[64, 78, 94, 95, 119] reporting diary-determined total wake time in patients with insomnia and comorbid medical conditions showed a clinically significant 39.51 minutes lower (95% CI: 20.18 to 58.84 minutes lower) post-treatment total wake time for the CBT-I group **(Figure S57).**

Meta-analysis of three studies[64, 65, 100] measuring total wake time by actigraphy did not meet the clinical significance threshold for CBT-I versus control comparisons **(Figure S58)**.

In subgroup analysis in patients with insomnia and no comorbidities two studies[65, 100] measured by actigraphy did not meet the clinical significance threshold for CBT-I versus control comparisons **(Table S29).** One study[64] reporting total wake time measured by actigraphy in patients with insomnia and comorbid medical conditions also did not meet the clinical significance threshold for group differences **(Table S30)**.

Three studies[87, 95, 115] reporting total wake time measured by PSG showed a clinically significant 36.98 minute (95% CI: 79.33 lower to 5.37 higher) lower amount of total wake time for CBT-I when compared to control **(Figure S59)**.

In subgroup analysis in patients with insomnia and no comorbidities, one study[87] measured by PSG showed a clinically significant 37.92 minute lower (95% CI: 6.57 to 69.27 minutes lower) total wake time in the CBT-I group (95% CI: 6.57 to 69.27 minutes lower) when compared to control **(Table S31).**

The quality of evidence for total wake time was low due to imprecision, inconsistency and risk of bias.

In comparisons of delivery methods, two studies[58, 139] compared diary-determined total wake time of in-person one-on-one and group delivery methods, one study[139] compared in-person one-on-one to telephone delivery, and one study[94] compared in-person one-on-one to video delivery; none of these comparisons met the clinical significance threshold. **(Figure S60)** for group differences. One study[83] comparing in-person one-on-one to internet delivery showed a clinically significant greater post-treatment difference in total wake time of 29.90 minutes (95% CI: 7.28 to 52.52 minutes lower) favoring the in-person one-on-one delivery method **(Figure S60)**.

TOTAL SLEEP TIME: A meta-analysis of 47 studies [59, 60, 62-65, 67-74, 76-104, 106, 115, 118, 119] comparing CBT-I to control for diary-determined total sleep time did not meet the clinical significance threshold at post-treatment for CBT-I as compared to control **(Figures S61).**

In sub-group analyses of patient populations, a meta-analysis of 10 studies[63, 65, 77, 84, 86, 87, 89, 97, 100, 106] that included patients with insomnia and no comorbidities reported total sleep time measured by diary, showed results that did not meet the clinical significance threshold for CBT-I versus control comparisons **(Figure S62)**. A meta-analysis of five studies[60, 72, 80, 98, 101] that considered diary based total sleep time among patients with insomnia and comorbid psychiatric conditions showed a

clinically 40.12 minutes higher (95% CI: 19.05 minutes to 61.19 minutes higher) total sleep time in the CBT-I group **(Figure S63).** A meta-analysis of 12 studies[64, 68, 78, 88, 90-92, 94-96, 118, 119] reported diary-determined determined total sleep time in patients with insomnia and comorbid medical conditions; the results did not meet the clinical significance threshold **(Figures S64).**

Meta-analysis of 11 studies[63-65, 69, 71, 84, 90, 96, 98-100] reporting total sleep time measured by actigraphy also did not meet the clinical significance threshold at the post-treatment time for CBT-I as compared to control **(Figure S65)**.

In sub-group analyses of patient populations meta-analysis of four studies[63, 65, 84, 100] that used actigraphy in patients with insomnia and no comorbidities found a clinically significant 23 minute (95% CI: 51.11 minutes lower to 5.11 minutes higher) lower total sleep time in the CBT-I group **(Figure S66).** One study[98] estimated total sleep time using actigraphy did not reach the clinically significance in the CBT-I group at the post-treatment comparison **(Table S32)**. A meta-analysis of four studies[64, 68, 90, 96] reported actigraphy-determined total sleep time in patients with insomnia and comorbid medical conditions; the results also did not meet the clinical significance threshold **(Figures S67)** for group differences.

Eight studies[76, 86, 87, 95, 96, 98, 106, 115] measured by PSG did not meet the clinical significance threshold at post-treatment for CBT-I as compared to control **(Figures S68)**.

In sub-group analyses of patient populations meta-analysis of three studies[86, 87, 106] reporting total sleep time measured by PSG among patients with insomnia and no comorbidities showed a clinically significant mean difference of 23.38 minutes higher (95% CI: 20.18 minutes lower to 66.93 higher) total sleep time favoring the CBT-I group over control **(Figure S69).** One study[98] reporting total sleep time measured by PSG in patients with insomnia and comorbid psychiatric conditions reported a clinically significant 33.60-minutes higher (95% CI: 17.27 minutes lower to 84.47 minutes higher) total sleep time in the CBT-I group at post-treatment compared to control **(Table S33).** In patients with insomnia and comorbid medical conditions, out of two studies[95, 96] reporting PSG-determined total sleep time, one study[96] showed a clinically significant difference favoring control by a 31.20 minutes (68.88 minutes lower to 6.48 minutes higher) lower total sleep time for the CBT-I group; the other study[95] did not meet the clinical significance threshold **(Table S34)**.

The quality of evidence for total sleep time ranged from very low to moderate due to imprecision, inconsistency, and risk of bias.

Data from nine studies[66, 91, 117, 125, 126, 132, 133, 136, 137] measuring total sleep time by diary, one study[125] by actigraphy and one study[66] by PSG could not be included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Direct comparisons of in-person one-on-one delivery methods to self-help, group, internet, video, telephone delivery and telehealth delivery of CBT-I measuring diary-determined total sleep time consisted of a total of 9 studies[60, 83, 94, 99, 139-142]**(Figure S70)**. Out of these, one study[139] showed a clinically significant 18.69 minutes (95% CI: 22.33 minutes lower to 59.71 minutes higher) higher total sleep time for in-person one-on-one delivery when compared to telephone delivery of CBT-I **(Figure S70)**. The rest of the results, which consisted of one study[60] comparing in-person one-on-one to self-help delivery, three studies[139, 141, 142] comparing in-person one-on-one to group delivery, and one study[94] comparing in-person one-on-one to video delivery did not meet the clinical significance threshold for treatment group differences **(Figure S70)**. A meta-analysis of three studies[83, 99, 140] comparing in-person one-on-one to internet delivery showed clinically greater total sleep time at post-treatment favoring internet delivery by 18.28 minutes (95% CI: 66.17 minutes lower to 29.61 minutes higher) **(Figure S70)**.

Overall quality of evidence

The quality of evidence for the use of CBT-I in patients with chronic insomnia ranged from low to moderate for critical outcomes due to imprecision and risk of bias. Therefore, the overall quality of evidence was rated as low **(Table S35)**.

Benefits versus harms

The overall benefits of CBT-I for the treatment of insomnia were determined to be moderate based on improvements in WASO, remission rates and responder rates that met the clinical significance thresholds established by the TF. Improvements in these critical patient outcomes were evident for insomnia patients without comorbidities in addition to patients with comorbid medical and psychiatric disorders, which represent the majority of patients seen for treatment. In

addition, substantial evidence exists that treatment gains are durable over the long-term without additional intervention. These benefits, however, need to be considered in the context of potential harms.

Based on available evidence and the TF's experience, the principal harms associated with CBT-I may include symptoms of daytime fatigue and sleepiness, mood impairment (e.g., irritability), and cognitive difficulties (e.g., attention problems), primarily restricted to the early stages of treatment when behavioral therapies are introduced. Studies [143] have specifically shown that daytime sleepiness is increased, and psychomotor performance is impaired during the initial phase of sleep restriction therapy. Thus, patients should be routinely warned about the possible dangers associated with daytime sleepiness, such as drowsy driving, when undergoing treatment. There's also the potential risk of nighttime falls when patients are out of bed at night in some patient populations such as older adults, those using sleep medications, or patients with physical disabilities who are following stimulus control instructions. However, the TF assessed that these harms are generally temporary, resolve as treatment continues, are small in magnitude, and tolerable to most patients. The TF noted that most RCTs of CBT-I did not include assessments of side effects associated with treatment, so adequate data on the direct harms associated with CBT-I are lacking. Based on the available literature and their clinical experience, the TF determined that the overall benefits of CBT-I strongly outweighed the harms for adults with chronic insomnia.

Resource use

Cost effectiveness was considered to favor CBT-I based on ad hoc analysis which suggests significant cost advantage with CBT-I versus estimated costs of untreated chronic insomnia [144]. Multiple formats are available for delivering CBT-I, with resource requirements ranging from moderate (e.g. in person one-on-one treatment) to minimal intervention (e.g., internet-delivered). In-person one-on-one or group CBT-I carries substantial costs, owing to the resources needed to train therapists to deliver the treatment and space required for patients to be seen, but the emergence of other formats for delivering CBT-I, such as via the internet, represents a significant cost savings in terms of resource use. Two cost analysis studies [145, 146] showed that internet-delivered CBT-I has a high probability of being more cost effective than both treatment as usual alone and in-person group therapy Cost-benefit estimates projected a net benefit to the employer of $512 per internet-delivered CBT-I participant and a return on investment of 208%, stemming mostly from the effects on presenteeism [146]. Available data are limited by small sample sizes and therefore more systematic work is needed in this area.

Patients' values and preferences

Based on their clinical experience, the TF determined that the majority of patients with chronic insomnia would choose CBT-I given its demonstrated efficacy and safety. The limited available data indicate that CBT-I is preferred to medications because it is perceived to have better long-term efficacy [147], to benefit daytime symptoms more, and to have fewer side effects [147, 148]. Furthermore, patients may prefer CBT-I over other single-component therapy options [149], however the relative preference for CBT-I compared to other available treatments may differ by insomnia subgroup [125, 150].

Brief Behavioral Therapies for Insomnia (BBTs)

Our review of the literature identified eight RCTs [151-158] that examined the effect of BBTs versus control treatment on adult patients with chronic insomnia that were included in the meta-analyses. In addition, three RCTs [159-161] were identified that could not be pooled with other studies but were reviewed as supporting evidence. The delivery formats of BBTs in the studies included only in-person one-on-one, in-person delivery. One study was conducted in the general adult population [158]; three studies [151, 152, 156] were conducted in older adults; two studies[153, 154] were conducted in military veterans; one study[153] was conducted in patients with insomnia not related to comorbid conditions. One study[152] delivered BBTs over the course of 2 sessions. Four studies[151, 154, 156, 158] delivered BBTs over the course of 4 sessions. One study[153] also incorporated imagery rehearsal therapy for nightmares into the BBT program and the combined program was delivered over the course of 8 sessions.

The figures and tables are provided in the supplemental material, **Figures [S71-S78]** and **Tables [S39-S48]**. Summary of findings tables are provided in the supplemental material, **Tables [S49].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below. There was insufficient data present for sub-group analyses and delivery method analysis.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section.

SLEEP QUALITY: Meta-analysis of three studies[151, 155, 158] reporting diary-determined sleep quality showed a clinically significant effect size of 1.73 (95% CI: 0.16 lower to 3.62 points higher) favoring BBT when compared to control **(Figure S71)**. Meta-analysis of four studies[151-154] reporting PSQI-determined sleep quality also showed a clinically significant treatment group difference with an effect size of 2.10 (95% CI: 4.24 lower to 0.04 higher) favoring BBT over control (**Figure S72)**.

The quality of the evidence for sleep quality was low due to imprecision, inconsistency and risk of bias.

Data from two studies[159, 161] measuring sleep quality by diary and one study[161] measuring sleep quality PSQI were not included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

SLEEP LATENCY: Meta-analysis of seven studies[151-158]reporting diary-determined sleep latency showed a reduction of 10.54 minutes (95% CI: 9.25 to 11.83 minutes lower); these results did not meet the clinical significance threshold for the treatment versus control comparisons (**Figure S73)**. Two studies[151, 153] reported PSG-determined sleep latency. Neither of them met the clinical significance threshold **(Table S39)** for group differences.

The quality of the evidence for sleep latency was moderate due to imprecision.

Data from three studies[159-161] measuring sleep latency by diary and two studies[160, 161] of sleep latency measured by PSG could not be included as post-treatment mean differences could not be calculated. Therefore, the TF could not evaluate the clinical significance of these findings.

WAKE AFTER SLEEP ONSET: Meta-analysis of seven studies[151-153, 155-158] reporting diary-determined WASO showed a 16.16 minutes (95% CI: 8.83 to 23.48 minutes lower) lower mean value of WASO in the BBT group at post-treatment compared to control; these results did not meet the clinically significant threshold (**Figure S74)**. Two studies[153] assessing WASO by actigraphy and two studies[151, 153] employing PSG comparing BBT versus control did not meet the clinical significance threshold for treatment versus control comparisons **(Tables S40-41).**

The quality of the evidence for WASO was low due to imprecision and inconsistency.

Three studies[159-161] measuring WASO by diary and two studies[160, 161] measured by actigraphy and PSG were not included in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

REMISSION RATE: Meta-analysis of five studies[151, 152, 154-156] reported a clinically significant 34% (95% CI: 22% to 45% higher) higher remission rate in the BBT group versus the control group **(Figure S75)**.

The quality of the evidence for remission rate was moderate due to imprecision.

Data from two studies[159, 160] measuring remission rate were not included in the analysis as the remission rate definition in the studies did not meet the TF definition of remission rate or the post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

RESPONDER RATE: Results of two studies[154, 157] reporting responder rates, met the clinical significance threshold of responder rate for BBTs when compared to control. Results were 26% higher (95% CI: 5% lower to 58% higher) and 21% higher (95% CI: 14% lower to 56% higher) for BBT **(Table S42)**.

The quality of the evidence for responder rate was moderate due to imprecision.

Data from three studies[152, 159, 160] measuring responder rate were not included in the analysis as the definition in the studies did not meet the TF definition of responder rate or post-treatment mean difference could to be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention: beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for daytime fatigue, nights with hypnotic use and total wake time.

BELIEFS AND ATTITUDES ABOUT SLEEP: Results of one study[158] reporting beliefs and attitudes about sleep on the DBAS scale did not show any clinically significant BBT versus control differences **(Table S43)**.

The quality of the evidence for beliefs and attitudes about sleep was low due to imprecision and risk of bias.

INSOMNIA SEVERITY: Meta-analysis of four studies[153, 154, 157, 158] reporting insomnia severity on the ISI scale showed a clinically significant result with an effect size 0.81 (95% CI:0.18 to 1.43 lower) favoring BBT when compared to control **(Figure S76)**.

The quality of the evidence for insomnia severity was low due to imprecision and risk of bias.

Data from one study[159] were not included in the analysis as post mean difference was unable to be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

NUMBER OF NIGHTTIME AWAKENINGS: Two studies[156, 157] reporting diary-determined number of nighttime awakenings, among which only one study[157] met the clinical significance threshold of 0.50 fewer number of nighttime awakenings (95% CI: 1.33 lower to 0.33 higher) for the BBT group as compared to control **(Table S44)**. The other study[156] did not meet the clinical significance threshold.

The quality of the evidence for number of nighttime awakenings was moderate due to imprecision.

SLEEP EFFICIENCY: Meta-analysis of seven studies[151, 152, 155-159] reporting diary-determined sleep efficiency showed no clinically significant group differences **(Figure S77)**. Results of two studies[151, 155] reporting actigraphy-determined sleep efficiency and two studies[151, 153] reporting PSG-determined sleep efficiency also did not meet the clinical significance threshold when BBT was compared to control **(Tables S45-46)**.

The quality of the evidence for sleep efficiency was moderate due to imprecision and risk of bias.

Data from two studies[159, 161] were not included in the analysis as post mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

TOTAL SLEEP TIME: Meta-analysis of six studies[151, 152, 155-158]reporting diary-determined total sleep time comparing BBT to control reported clinically significant results favoring control over BBT with a 23.89 minutes (95% CI:9.89 to 37.88 minutes lower) lower total sleep time in the BBT group at post-treatment **(Figure S78)**. Two studies[151, 155] reporting actigraphy assessed total sleep time, out of which one study[151] reported a clinically significant 32.28 minutes (95% CI:28.72 to 35.84 minutes lower) lower total sleep time at post-treatment for the BBT group (95% CI:28.72 to 35.84 minutes lower) **(Table S47**) compared to control. Out of the two studies[151, 153] reporting PSG-determined total sleep time, one[153] showed clinically significant difference favoring control over BBT with a 34.10 minute lower total sleep time (95% CI:77.23 minutes lower to 9.03 minutes higher) at post-treatment **(Table S48)**.

The quality of the evidence for total sleep time was moderate due to imprecision.

Overall quality of evidence

The overall quality of evidence ranged from low to moderate. Of the evidence for the "critical" outcomes, three out of five outcomes had moderate quality evidence, while two had low quality evidence. It is noteworthy that the quality of evidence

for 14 of the 18 outcomes was downgraded due to an insufficient number of participants (<200), indicating that this is an area of research that would benefit from further work. The overall quality of evidence was determined to be moderate **(Table S49)**.

Benefits versus harms

Based on clinically significant differences in sleep quality and insomnia remission rates compared to control, the TF determined that the efficacy is moderate. In addition, BBT also improves sleep latency and wake after sleep onset when compared to control, though not at a level which exceeds clinical significance thresholds. Studies [143] have specifically shown that daytime sleepiness is increased, and psychomotor performance is impaired during the initial phase of sleep restriction therapy. Thus, patients should be routinely warned about the possible dangers associated with daytime sleepiness, such as drowsy driving, when undergoing treatment. There's also the potential risk of nighttime falls in specific populations such as older adults, those using sleep medications, or patients with disabilities (e.g. frail older adults) following stimulus control instructions. Based on their clinical experience the TF determined that the undesirable effects are trivial and that the balance of benefits versus harms strongly favors the use of BBT.

Resource use

No prior analysis has examined resource use of BBT. It would stand to reason that BBT requires fewer resources than CBT-I and greater resources than single-component therapies such as sleep restriction therapy or stimulus control.

Patients' values and preferences

Based on their clinical experience, the TF determined that most patients would choose BBT treatment given the benefits of treatment, and the amount of time this treatment requires (e.g. attending fewer treatment sessions).

Stimulus Control

Our review identified seven RCTs [125, 162-167] that compared stimulus control to a control condition among adult patients with chronic insomnia. Three studies [162, 165, 166] focused on sleep onset insomnia and two studies enrolled only older adults [125, 167]. Four studies delivered stimulus control in a group format [125, 165-167], and two studies [162, 163] delivered stimulus control in person, using a one-on-one format.

The figures and tables are provided in the supplemental material, **Figure [S79]** and **Tables [S50-S57]**. Summary of findings tables are provided in the supplemental material, **Tables [S58].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below.

There were insufficient data to evaluate efficacy of this treatment among patients with psychiatric or medical comorbidities or to determine the relative efficacy of different delivery methods for this therapy.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section. None of the studies identified in our literature review reported data for responder rate.

SLEEP QUALITY: One study[163] reported sleep quality measured by PSQI. The results reported an effect size of 0.86 favoring stimulus control when compared to control (95% CI: 0.17 to 1.54 lower) **(Table S50)**. These results met the clinical significance threshold.

The quality of evidence for sleep quality was low due to imprecision and risk of bias

Data of three studies[125, 162, 164] reporting diary determined sleep quality were not included in the analysis as post mean differences could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings. The studies reported post-intervention differences in sleep quality.

SLEEP LATENCY: Meta-analysis of three studies reporting sleep latency measured by diary [163, 165, 167] comparing stimulus control to control showed a post-treatment difference of 14.40 minutes (95% CI: 35.22 minutes lower to 6.41 minutes higher) between treatment conditions. Results did not meet the clinical significance threshold **(Figure S79).**

The quality of evidence for sleep latency was low due to imprecision and risk of bias

Data from three studies [125, 162, 166] reporting diary-determined sleep latency were not included in the analysis as post mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings. All three[125, 162, 166] reported improvements in sleep latency with stimulus control compared to control. One of these studies[166] also reported greater improvement in sleep latency compared to a sleep education comparator. However, one study[162] found no difference between stimulus control and an imagery relief placebo for improving sleep latency.

WAKE AFTER SLEEP ONSET: Two studies[163, 167] reported WASO measured by diary, and both studies reported clinically significant 37.65 minutes (95% CI: 6.28 to 69.02 minutes lower) and 28.52 minutes lower (95% CI: 67.28 minutes lower to 10.24 minutes higher) WASO values respectively in the stimulus control treatment when compared to control **(Table S51)**. One study[163] also reported WASO measured by actigraphy, and results did not meet the clinical significance threshold for post-treatment comparisons **(Table S52)**.

The quality of evidence for WASO was low due to imprecision and risk of bias.

Data could not be included for one study[125] reporting WASO measured by diary and actigraphy as post mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

REMISSION RATE: One study[125] reported data on remission rate favoring stimulus control, however a post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and quality of evidence was not assessed.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention: beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for beliefs and attitude about sleep, daytime fatigue, nights with hypnotic use and total wake time.

INSOMNIA SEVERITY: Data from one study[125] reporting insomnia severity measured by ISI were not included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and quality of evidence was not assessed.

NUMBER OF NIGHTTIME AWAKENINGS: One study[167] assessed number of nighttime awakenings and reported a clinically significant difference between treatment and control of 0.69 fewer awakenings (95% CI:1.72 lower to 0.34 higher) favoring stimulus control **(Table S53)**.

The quality of evidence for number of nighttime awakenings was low due to imprecision and risk of bias.

SLEEP EFFICIENCY: One study[163] measuring sleep efficiency using diary, reported a clinically significant 13.33% (95% CI: 6.08 to 20.58% higher) higher sleep efficiency in the stimulus control group when compared to control **(Table S54)**. The same study [163] reported sleep efficiency measured by actigraphy and results did not meet the clinical significance threshold **(Table S55)**.

The quality of evidence for sleep efficiency was low due to imprecision and risk of bias.

Data from one study[125] could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

TOTAL SLEEP TIME: Two studies [163, 167] examined the efficacy of stimulus control on total sleep time measured by diary. Out of the two studies[163, 167] only one[163] reported clinically a significant 37.69 minutes (95% CI:6.30 minutes lower to 81.68 minutes higher) higher total sleep time with stimulus control of 37.69 minutes (95% CI:6.30 minutes lower to 81.68 minutes higher) **(Table S56)**. One study[163] also measured total sleep time by actigraphy; results did not meet the clinical significance threshold **(Table S57).**

The quality of evidence for total sleep time was low due to imprecision and risk of bias.

Data from two studies[125, 162] reporting total sleep time could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Overall quality of evidence
The overall quality of evidence was low for due to imprecision and risk of bias **(Table S58)**.

Benefits versus harms
The benefit of stimulus control is that it may produce clinically significant improvements in some of the critical and important sleep outcomes vs. control conditions. Although the data are limited by small sample sizes and few studies, at least one study[125]suggested stimulus control produced a higher insomnia remission rate compared to control, though it should be noted that only 44 participants were randomized to stimulus control in this study. In regard to harms, studies did not report adverse events. Potential risks include nighttime falls in specific populations such as older adults, those using sleep medications, or patients with disabilities. Based on their clinical experience the TF determined that the undesirable effects are trivial and that the balance of benefits versus harms strongly favors the use of stimulus control.

Resource use
Formal cost effectiveness studies have not been conducted with stimulus control. However, the literature review and TF expertise suggest that the resource use and costs of stimulus control relative to other psychological and behavioral therapies vary but appear in line with other single component therapies.

Patient Values and preferences
Based on their clinical experience, the TF determined that most patients would use stimulus control due to the sleep improvements it produces relative to minimal harms because it requires few resources.

Sleep Restriction Therapy
Our review of the literature identified three[62, 168, 169]randomized controlled trials (RCTs) that examined the effect of sleep restriction therapy versus control treatment on adult patients with chronic insomnia. Two additional RCTs[125, 170] were identified that could not be pooled with other studies but were included as supporting evidence. The control treatments included wait list control and minimal intervention (i.e. sleep hygiene). One of these studies[170] enrolled a general adult sample of insomnia patients, whereas three of these studies[125, 168, 169] included samples of older adults with insomnia. The remaining study[62] exclusively enrolled women with menopause-associated insomnia. Four studies[125, 168-170] included participants with insomnia without comorbid conditions. There were insufficient data to evaluate efficacy of this treatment among patients with psychiatric or medical comorbidities or to determine the relative efficacy of different delivery methods for this therapy.

The figures and tables are provided in the supplemental material, **Figures [S80-S83]** and **Tables [S59-S68]**. Summary of findings tables are provided in the supplemental material, **Tables [S69].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below.

Critical outcomes
The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section. None of the studies identified in our literature review reported data for responder rate.

SLEEP QUALITY: Two studies[62, 169] reporting sleep quality measured by diary-reported clinically significant post-treatment differences, with an effect size of 0.64 (95% CI: 0.24 to 1.04 higher) and 0.80 (95% CI: 0.31 to 1.30 higher) favoring sleep restriction therapy over control **(Table S59)**.

The quality of evidence for sleep quality was low due to imprecision and risk of bias.

Data from two studies[125, 170] measuring sleep quality by diary could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

SLEEP LATENCY: Three studies[62, 168, 169] included in a meta-analysis reported sleep latency measured by diary and one study [168]reported sleep latency measured by PSG. Results did not meet the clinical significance threshold when sleep restriction therapy was compared to control **(Figure S80, Table S60).**

The quality of evidence for sleep latency was low due to imprecision and risk of bias.

Data from one study[125] measuring sleep latency by diary could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

WAKE AFTER SLEEP ONSET: Three studies[62, 168, 169] included in a meta-analysis reported WASO measured by diary and one study[168] measured both by actigraphy and PSG did not meet the clinical significance threshold when sleep restriction therapy was compared to control conditions **(Figure S81, Tables S61-2)**.

The quality of evidence for WASO was low due to imprecision and risk of bias

Data from one study[125] measuring WASO by diary and one study[125] measured by actigraphy could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

REMISSION RATE: One study[62] reporting remission rate measured by diary showed sleep restriction showed a clinically significant 24% (95% CI: 5% to 43% higher) higher remission rate than did the control condition **(Table S63)**.

The quality of evidence for remission rate low due to imprecision and risk of bias.

Data from one study[125] measuring remission rate was not included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention: beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for beliefs and attitude about sleep, daytime fatigue, nights with hypnotic use, number of nighttime awakenings and total wake time.

INSOMNIA SEVERITY: One study [62] reported a clinically significant lower post-treatment difference in insomnia severity measured by ISI, with an effect size of 1.28 (95% CI: 0.85 to 1.71 lower) favoring sleep restriction therapy over control **(Table S64)**.

The quality of evidence for insomnia severity was low due to imprecision and risk of bias.

Data from one study [125] reporting insomnia severity measured by ISI could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

SLEEP EFFICIENCY: Meta-analysis of three studies[62, 168, 169] reporting sleep efficiency measured by diary and one study[168] measured by actigraphy and PSG did not meet the clinical significance threshold when sleep restriction therapy was compared to control **(Figure S82, Tables S65-66)**.

The quality of evidence for sleep efficiency was low due to imprecision and risk of bias.

Data from one study[125] reporting sleep efficiency measured by diary and actigraphy were not included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

TOTAL SLEEP TIME: Meta-analysis of three studies [62, 168, 169] comparing diary determined total sleep time reported a clinically significant post-treatment difference favoring control with a 16.96 minutes (95% CI: 35.31 minutes lower to 1.39 minutes higher) lower total sleep time in the sleep restriction treatment **(Figure S83).** One study[168] reporting total sleep time measured by actigraphy and PSG also reported clinically significant group differences favoring control with the sleep restriction group showing 40.26 minutes (95% CI: 4.36 to 76.16 minutes lower) and 43.91 minutes lower (95% CI: 90.52 minutes lower to 2.70 minutes higher) values of total sleep time in these comparisons **(Tables S67-68).**

The quality of evidence for total sleep time was low due to imprecision and risk of bias.

Data from one study[125] reporting total sleep time measured by diary and actigraphy could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Overall quality of evidence

The overall quality of evidence was determined to be low due to imprecision and risk of bias **(Table S69)**.

Benefits versus harms

The benefits of sleep restriction therapy are that of producing clinically significant improvements in several of the critical and important sleep outcomes compared to control conditions. Regarding harms, one study [143] found sleep restriction therapy produced an increase in daytime sleepiness and cognitive impairment as compared to a control condition. Such daytime effects could translate into increased risk for drowsy driving and impairment at work as a result of this treatment. In the experience of TF members these effects are usually transient and dissipate as treatment progresses and time in bed restriction is increased as sleep improves. Hence the potential harms may occur in the early phases of treatment but decline as treatment progresses. Based on their clinical experience the TF determined that the undesirable effects are trivial and that the balance of benefits versus harms strongly favors the use of sleep restriction therapy.

Resource use

Formal cost effectiveness studies have not been conducted with sleep restriction therapy. However, the literature review and TF expertise suggest that the resource use and costs of sleep restriction therapy relative to other psychological and behavioral therapies varies but falls in line with other single component therapies. Use of sleep restriction therapy may result in moderate cost and resource use savings compared to multi-component therapies such as CBTI, but such savings would be negligible compared to other single component therapies.

Patient values and preferences

Based on their clinical experience, the TF determined that most patients would use sleep restriction therapy as a treatment for insomnia. However, because restricting time in bed may lead to an average reduction in total sleep time and an increase in daytime sleepiness and reduction in alertness, many patients find it challenging to adhere to initial sleep restriction therapy schedules and are not inclined to choose this treatment [148]. Those who tolerate the initial increase in daytime sleepiness and reduced alertness and who can increase their time in bed and gradually increase their sleep time over the treatment period are likely to find this treatment acceptable and be willing to engage in it.

Relaxation Therapy

Our review of the literature identified 12 RCTs[66, 90, 162, 164, 165, 167, 171-176] that examined the efficacy of relaxation therapy versus control (waitlist, quasi-desensitization, or behavioral placebo) on adult patients with chronic insomnia. Of these studies, seven[66, 162, 164, 172-175] utilized a one-on-one in-person delivery format of the relaxation therapy, three[165, 167, 176] utilized group therapy (Morin 1988 and Lacks 1983), and two utilized[90, 171] audio delivery.

The figures and tables are provided in the supplemental material, **Figures [S84-S88]** and **Tables [S70-S77]**. Summary of findings tables are provided in the supplemental material, **Tables [S78].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below.

There were insufficient data to evaluate the efficacy of this treatment among pre-specified patient subgroups or to determine the relative efficacy of differing delivery methods.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section. None of the studies identified in our literature review reported data for remission rate.

SLEEP QUALITY: Two studies[171, 173] reported sleep quality measured by diary, of which one[173] showed a clinically significant post-treatment differences with an effect size of 0.99 (95% CI: 0.43 to 1.54 higher) favoring relaxation therapy compared to control **(Table S70)**. One study[90] reporting sleep quality measured by PSQI also reported clinically significant results with an effect size of 0.96 (95% CI: 0.15 to 1.76 lower) favoring relaxation therapy compared to control **(Table S71)**.

The quality of evidence for sleep quality ranged from low to very low due to imprecision, inconsistency and risk of bias.

Four studies[162, 164, 172, 174] reported sleep quality, measured by diary reported data that could not be added in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

SLEEP LATENCY: Meta-analysis of six studies[90, 165, 167, 171, 173, 175] reporting diary-determined sleep latency compared to control, showed a post-treatment difference of 7.21 minutes (95% CI: 0.60 to 13.83 minutes lower). These results did not meet the clinical significance threshold **(Figure S84)**.

The quality of evidence for sleep latency was low due to imprecision and risk of bias.

Three studies [162, 174, 176] also examined the effects of relaxation therapy compared to control on sleep latency but could not be added in the meta-analysis as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

WAKE AFTER SLEEP ONSET: Meta-analysis of four studies [90, 167, 171, 173] reporting diary determined WASO showed a post-treatment difference of 15.67 minutes (39.15 minutes lower to 7.81 minutes higher) between relaxation therapy and control. These results did not meet the clinical significance threshold for post-treatment comparisons **(Figure S85)**. One study[90] reporting WASO assessed by actigraphy showed clinically significant post-treatment difference of 25.00 minutes (95% CI: 62.89 minutes lower to 12.89 minutes higher) favoring relaxation therapy over the control **(Table S72)**.

The quality of evidence for WASO was low due to imprecision and risk of bias

One study[66] reporting WASO assessed by diary and PSG reported data that could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

RESPONDER RATE: Meta-analysis of three studies [66, 90, 162] reported clinically significant 16% higher responder rates (95% CI: 11% lower to 43% higher) favoring relaxation therapy compared to control **(Figure S86)**.

The quality of evidence for responder rate was very low due to imprecision, inconsistency and risk of bias.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention: beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for daytime fatigue and total wake time.

BELIEFS AND ATTITUDES ABOUT SLEEP: Two studies[90, 173] reported DBAS results in older adults and college students, respectively. Out of these two, only one study met the clinical significance threshold in DBAS scores with an effect size of 1.01 (95% CI: 0.20 to 1.82 lower) favoring the relaxation group as compared to control group **(Table S73)**.

The quality of evidence for beliefs and attitudes about sleep was low due to imprecision and risk of bias.

INSOMNIA SEVERITY: One study [66] examined insomnia severity measured by ISQ in response to relaxation therapy versus control. The data were not included as a post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and quality of evidence was not assessed.

NIGHTS WITH HYPNOTIC USE: One study[90] examined the effect of relaxation therapy versus control on hypnotic medication use; results did not meet the clinical significance threshold **(Table S74)**.

The quality of evidence for nights with hypnotic use was low due to imprecision and risk of bias.

NUMBER OF NIGHTTIME AWAKENINGS: One study [167] examined the effect of relaxation therapy versus control on number of nighttime awakenings. Results did not meet the clinical significance threshold **(Table S75)**.

The quality of evidence for number of nighttime awakenings was low due to imprecision and risk of bias.

SLEEP EFFICIENCY: Meta-analysis of three studies[90, 171, 173] of diary determined sleep efficiency **(Figure S87)** and one study [90]reporting actigraphy determined sleep efficiency did not meet the clinical significance threshold between relaxation therapy and control conditions (**Table S76)**.

The quality of evidence for sleep efficiency was low due to imprecision and risk of bias.

One study[66] reporting sleep efficiency measured by diary reported data that could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

TOTAL SLEEP TIME: Meta-analysis of three studies[90, 167, 171] met the clinical significance threshold for total sleep time at post treatment when compared to control (**Figure S88)**. One study[90] reporting total sleep time assessed by actigraphy reported a clinically significant result favoring control with the relaxation condition showing a 27.50 minutes lower (95% CI: 95.27 minutes lower to 40.27 minutes higher) total sleep time at post-treatment (**Table S77)**.

The quality of evidence for total sleep time was low due to imprecision and risk of bias.

Two studies [66, 162] reporting total sleep time measured by diary and one study [66] measured by PSG reported data that could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Overall quality of evidence
The overall quality of the evidence was very low due to imprecision, inconsistency and risk of bias.

Benefits versus harms
The TF concluded that for adult patients with insomnia the modest benefits of relaxation compared to no therapy likely outweigh the potential minimal harms and burdens. This was based on expert consensus. There were no data available on harm, but the potential harms were considered minimal. Furthermore, the potential benefits of relaxation therapy that go beyond sleep improvement, such as pain reduction or stress management, were also considered and deemed to add further evidence that the benefits outweigh the potential minimal harms or burden.

Resource use
There were no studies on cost-effectiveness identified. However, relaxation therapy can be delivered at relatively low cost and with few resources, particularly given that many therapists and clinical providers have training in relaxation therapy.

Patient values and preferences
A study of 18 combat veterans with traumatic brain injury and their care providers [125] found that relaxation therapy was the most acceptable form of behavioral intervention, perhaps underscoring the need to recognize that treatment preference may vary according to specific patient characteristics.

Based on their clinical experience the TF determined that the undesirable effects are trivial and that the balance of benefits versus harms strongly favors the use of relaxation therapy.

Sleep Hygiene
Our review of the literature identified three randomized controlled trials (RCTs) [64, 177, 178] that examined the effect of sleep hygiene (SH) versus control on adult patients with chronic insomnia. Delivery of sleep hygiene varied widely and included general education by a therapist in-person supplemented with audiocassette and pamphlet educational materials [64], individual therapist weekly educational sessions [177] and six sessions of therapist provided sleep hygiene advice with or without supportive therapy [178]. One study included patients with insomnia and comorbid medical condition [64] and another included older adults [177].

The tables are provided in the supplemental material, **Tables [S79-S88]**. Summary of findings table is provided in the supplemental material, **Table [S89].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below.

There were insufficient data to evaluate the efficacy of this treatment among varying patient types or the relative efficacy of differing delivery methods.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section. None of the studies identified in our literature review reported data for remission rate.

SLEEP QUALITY: One study compared sleep hygiene to control for diary-determined sleep quality [178] reported data that could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and quality of evidence was not assessed.

SLEEP LATENCY: One study [64] reported sleep latency measured by diary with a mean difference of 0.80 minutes lower (95% CI: 12.98 minutes lower to 11.38 minutes higher) in the sleep hygiene group; these results did not meet the clinical significance threshold **(Table S79)**.

The quality of evidence for sleep latency was low due to imprecision and risk of bias.

Two studies [177, 178] reported data on diary determined sleep latency that could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

WAKEFULNESS AFTER SLEEP ONSET: One study [64] comparing sleep hygiene compared to wait list control measuring WASO by diary showed a 15.20 minutes lower sleep WASO in the sleep hygiene group (95% CI: 39.65 minutes lower to 9.25 minutes higher). Results did not meet the clinical significance threshold **(Table S80)**. The same study measured WASO by actigraphy and also did not meet the clinical significance threshold **(Table S81)**.

The quality of evidence for WASO was low due to imprecision and risk of bias.

One study [178] reported data that could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

RESPONDER RATE: One study[64]comparing sleep hygiene to control reported a clinically significant 40% (95% CI: 7% to 74% higher) higher responder rates (95% CI: 7% to 74% higher) favoring sleep hygiene when compared to control (**Table S82)**.

The quality of evidence for responder rate was low due to imprecision and risk of bias.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention: beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for beliefs and attitude about sleep, daytime fatigue, insomnia severity and nights with hypnotic use.

NUMBER OF NIGHTTIME AWAKENINGS: Two studies [177, 178] comparing sleep hygiene to control reported number of nighttime awakenings measured by diary and one study [178] reported such comparisons measured by actigraphy. Both studies [177, 178] provided data that could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings quality of evidence was not assessed for these studies.

SLEEP EFFICIENCY: One study [64] compared sleep hygiene to control measured by diary and actigraphy, but post-treatment comparisons did not meet the clinical significance threshold **(Tables S83-84).**

The quality of evidence for sleep efficiency was low due to imprecision and risk of bias.

One study [178] reported data that could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

TOTAL WAKE TIME: One study[64] comparing sleep hygiene to control reported total wake time measured by diary and actigraphy and also did not show clinically significant results **(Tables S85-86).**

The quality of evidence for total wake time was low due to imprecision and risk of bias.

TOTAL SLEEP TIME: One study [64] comparing sleep hygiene to control reported total sleep time measured by diary and actigraphy and also did not show clinically significant differences between treatment conditions **(Tables S87-88)**.

The quality of evidence for total sleep time was low due to imprecision and risk of bias.

Two studies [177, 178]reported data that could not be included as post-treatment mean differences could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Overall quality of evidence

The overall quality of the evidence for sleep hygiene as a treatment for chronic insomnia was judged to be low for all critical outcomes. The quality of evidence was low due to risk of bias and imprecision **(Table S89)**.

Benefits versus harms

Based on the meta-analyses and other available evidence, the potential benefits of sleep hygiene were considered by the TF to be trivial compared to control. The one study that showed improvement in the sleep hygiene group also made additional behavioral changes such as standardizing their sleep schedules without being told to do so. The same study also showed CBT-I to be superior to sleep hygiene alone. The potential harms of utilizing a sleep hygiene intervention as a stand-alone therapy for insomnia disorder may include delayed implementation of effective therapies with continued or worsening insomnia symptoms. Patients with chronic insomnia could potentially elect not to undergo other treatments based on their experience using an ineffective intervention. As such, the TF did not favor the use of sleep hygiene as a stand-alone therapy for chronic insomnia.

Resource use

Cost analyses of sleep hygiene have not been systematically conducted. A systematic review of six electronic databases found no data regarding the cost-effectiveness of sleep hygiene interventions [179]. Sleep hygiene education is generally considered inexpensive, however, the TF judged that any resources utilized for an ineffective intervention may be considered excessive.

Patients' values and preferences

While previous studies report that patients prefer sleep hygiene to other elements of CBT-I [148], our analysis demonstrates that it does not produce clinically significant improvements in insomnia symptoms when used as a single component therapy. Therefore, based on their clinical experience the TF determined that the majority of informed adults with chronic insomnia would not choose sleep hygiene as stand-alone therapy given its lack of efficacy.

Biofeedback

Our review of the literature identified four RCTs [164, 175, 180, 181]. Only one of these studies [175] provided sufficient data to calculate mean difference at post-treatment.

The tables are provided in the supplemental material, **Table [S90]**. Summary of findings table is provided in the supplemental material, **Table [S91].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below.

There was insufficient data to evaluate the efficacy of this treatment among varying patient types or the relative efficacy of differing delivery methods.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were

considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section. None of the studies identified in our literature review reported data for sleep quality, responder rate, remission rate.

SLEEP LATENCY: One study [175]reporting diary-determined sleep latency showed a clinically significant post-treatment difference of 52.58 minutes (95% CI: 22.42 to 82.74 minutes lower) favoring biofeedback compared to control **(Table S90)**.

The quality of evidence for sleep latency was low due to imprecision and risk of bias.

Three studies [164, 180, 181]reporting sleep latency measured by diary were not suitable for meta-analysis as post-treatment mean differences could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

WAKE AFTER SLEEP ONSET: One study[181]reporting WASO, measured by diary, could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and the quality of evidence was not assessed.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention: beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use and total wake time.

NUMBER OF NIGHTTIME AWAKENINGS: One study[180] reporting number of nighttime awakenings, measured by diary, could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and the quality of evidence was not assessed.

SLEEP EFFICIENCY: One study [180]reporting sleep efficiency, measured by diary, could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and the quality of evidence was not assessed.

TOTAL SLEEP TIME: Two studies reporting total sleep time[180, 181] measured by diary, could not be included as post-treatment mean differences could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and the quality of evidence was not assessed.

Overall quality of evidence

Overall quality of evidence for the critical outcomes was low due to imprecision and risk of bias **(Table S91)**.

Benefits vs harms

There were no harms evaluated or reported in the included studies. Based on their clinical experience the TF determined that the balance between desirable and undesirable effects probably favors the use of biofeedback.

Resource Use

Biofeedback treatment requires expensive psychophysiological monitoring equipment and advanced training, therefore the costs of prescribing/providing this service would be considered moderate to high and may render this option less appealing or accessible than the other therapies. There were no studies that evaluated the cost effectiveness of this intervention.

Patients' values and preferences

Biofeedback does not require behavior change, which may make it more appealing to some patients. However, the expensive nature of biofeedback and the need to use monitoring equipment may factor negatively in the decision to use it. Because biofeedback is not widely available, and the TF could not identify any published evaluations of patient preferences, the TF determined that patients' values and preferences for this intervention were uncertain.

Paradoxical Intention

Our review of the literature identified 5 RCTs [165, 166, 182-184]which examined the effect of paradoxical intention versus control for adult patients with chronic insomnia. Determination of clinical significance was possible for only two of these studies.

All were conducted in the adult population. Three studies [165, 183, 184] excluded patients with medical comorbidities and one of these [165] also excluded patients with psychiatric comorbidities. One study delivered paradoxical intention over the course of 2 sessions [184], three studies [165, 166, 182] delivered treatment over 4 sessions and the final study [183] delivered therapy over the course of 8 sessions. Four studies [166, 182-184]conducted their last follow-up at post-intervention, and the remaining study [165] conducted the last assessment at 12 weeks post treatment.

The tables are provided in the supplemental material, **Tables [S92-S93]**. Summary of findings table is provided in the supplemental material, **Table [S94].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below.

There was insufficient data to evaluate the efficacy of this treatment among varying patient types or the relative efficacy of differing delivery methods.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section. None of the studies identified in our literature review reported data wake after sleep onset, remission rate, responder rate.

SLEEP QUALITY: Two studies [183, 184]reporting diary-determined sleep quality could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and the quality of evidence was not assessed.

SLEEP LATENCY: Two studies [165, 182]compared paradoxical intention to placebo control using diary measured sleep latency among adult patients with insomnia disorder. Results of one study[182] showed a clinically significant 28.25 minutes (95% CI: 8.37 to 48.13 minutes) lower post-treatment sleep latency for paradoxical intention (95% CI: 8.37 to 48.13 minutes) compared to control **(Table S92)**. The other study[165] reported a post-treatment difference of 1.38 minutes (95% CI: 19.50 minutes lower to 16.74 minutes higher), between paradoxical intention and control which did not meet the clinical significance threshold **(Table S92).**

The quality of evidence for sleep latency was very low due to imprecision, inconsistency and risk of bias.

Two studies[166, 183] reporting diary determined sleep latency could not be included as post-treatment mean differences could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention: beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, sleep efficiency, total wake time and total sleep time.

NUMBER OF NIGHTTIME AWAKENINGS: One study [182] compared paradoxical intention to placebo control for reducing the number of nighttime awakenings reported on sleep diaries. Results of that study showed a clinically significant difference of 0.75 fewer awakenings (95% CI: 0.15 to 1.35 fewer awakenings) for those receiving paradoxical intention compared to control **(Table S93)**.

The quality of evidence for number of nighttime awakenings was low due to imprecision and risk of bias.

TOTAL SLEEP TIME: One study [183]reporting diary-determined total sleep time could not be included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and the quality of evidence was not rated assessed.

Overall quality of evidence

The overall quality of evidence was determined to be very low for insomnia patients in general due to imprecision, inconsistency and risk of bias **(Table S94)**.

Benefits versus harms

The potential benefits of paradoxical intention could include a modest reduction in sleep latency. The results suggest that this treatment did produce a clinically significant reduction in the number of awakenings during the night, an outcome designated as important, but not critical, by the TF. The harms of this treatment, for the most part, remain unstudied. However, one report showed that paradoxical intention combined with feedback about a patient's accuracy in subjective sleep latency estimate can lead to an increase rather than a decrease in subjective sleep latency. Given the nature of paradoxical intention wherein patients are given the instruction to try to stay awake in bed, this intervention could increase anxiety about sleep in some patients.

Resource use

Formal cost effectiveness studies have not been conducted with paradoxical intention. However, the literature review and TF expertise suggest that there would be negligible costs or savings inherent in this treatment compared to other behavioral and psychological insomnia therapies.

Patient values and preferences

This approach may raise anxiety levels of some patients and may make sleep more difficult. Since our meta-analyses did not show benefit of this treatment vs. control for reducing sleep latency, it may not be viewed as a desirable treatment choice for insomnia patients. Based on their clinical experience, the TF determined that some patients would choose paradoxical intention, however it may be less appealing to patients who already have difficulty falling asleep.

Intensive Sleep Retraining (ISR)

One study [163]reported intensive sleep retraining using a one-on-one, in-person delivery compared to sleep hygiene. Participants consisted of patients with insomnia without comorbidities.

The tables are provided in the supplemental material, **Tables [S95-S101]**. Summary of findings table is provided in the supplemental material, **Table [S104].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below.

There were insufficient data to evaluate the efficacy for reducing sleep latency with this treatment among varying patient types or the relative efficacy of differing delivery methods.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section. None of the studies identified in our literature review reported data for remission rate, responder rate.

SLEEP QUALITY: One study [163] reporting PSQI-determined sleep quality compared ISR to sleep hygiene control and reported an effect size of 0.76 points (95% CI: 0.07 to 1.45 points lower), results that met the clinical significance threshold favoring ISR **(Table S95)**.

The quality of evidence for sleep quality was low due to imprecision and risk of bias.

SLEEP LATENCY: The same study[163] also reported diary-determined sleep latency and reported a clinically significant post-treatment difference of 30.24 minutes (95% CI: 11.51 to 48.97 minutes lower) favoring ISR when compared to control **(Table S96)**.

The quality of evidence for sleep latency was low due to imprecision and risk of bias.

WAKEFULNESS AFTER SLEEP ONSET: One study [163]comparing ISR to control measured WASO by diary; results showed a post-treatment difference of 19.60 minutes (95% CI: 58.35 minutes lower to 19.15 minutes higher) **(Table S97**) favoring ISR, which did not meet the clinical significance threshold.

The quality of evidence for WASO was low due to imprecision and risk of bias.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention; beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for beliefs and attitude about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings and total wake time.

SLEEP EFFICIENCY: One study[163] reported a clinically significant post-treatment difference of 11.61% (95% CI: 3.77 to 19.45 percent) for diary-determined sleep efficiency when compared to control **(Table S98)**. The same study[163] also reported sleep efficiency measured by actigraphy and the results did not meet the clinical significance threshold **(Table S99)**.

The quality of evidence for sleep efficiency was low due to imprecision and risk of bias.

TOTAL SLEEP TIME: One study[163] reported clinically significant post-treatment differences for total sleep time measured by diary of 52.97 minutes higher, (95% CI: 8.32 to 97.62 minutes higher) and actigraphy of 23.78 minutes higher, (95% CI: 21.70 minutes lower to 69.26 minutes higher) favoring the intensive sleep retraining intervention **(Tables S100-101).**

The quality of evidence for total sleep time was low due to imprecision and risk of bias.

Overall quality of evidence

The overall quality of the evidence was determined to be low for all critical outcomes due to imprecision and risk of bias.

Benefits versus harms

The potential benefits of intensive sleep retraining were based on one study that revealed clinically significant improvement in critical outcomes, including subjective sleep latency, sleep quality, and clinical response rate. These desirable effects were judged by the TF to be moderate. ISR was delivered in a brief 25-h sleep deprivation period and therefore treatment resulted in rapid sleep improvements [163]. These potential benefits need to be considered in relation to possible harms, which may include cognitive impairment, fatigue and increased sleepiness resulting from the procedure. The TF assessed these undesirable effects as minor. Based on their clinical experience the TF determined that the undesirable effects are trivial and that the balance of benefits versus harms favors the use of ISR.

Resource use

The TF did not identify cost analysis for ISR treatment. This intervention as conducted by Harris and colleagues[163] would require a polysomnographic laboratory with intensive monitoring by a trained technologist throughout the treatment and would be conducted during periods that may not be typically staffed by laboratory personnel. The resource use and costs related to ISR would likely surpass other forms of chronic insomnia treatments. Future research investigating the utilization of a self-administered version of ISR at home could potentially result in substantial resource reductions for ISR treatment.

Patients' values and preferences

Based on their clinical experience, the TF determined that some adults with chronic insomnia would choose ISR therapy. The short-term nature of this intervention could be appealing to some adults with chronic insomnia. However, some patients may not want to engage in ISR treatment due to its demanding procedure.

Mindfulness

Our review of the literature identified three RCTs[185-187] that examined the effect of mindfulness versus control on adult patients with chronic insomnia. All three studies [163]utilized group therapy. One study [187]focused on older adults.

The tables are provided in the supplemental material, **Tables [S95-S101]**. Summary of findings table is provided in the supplemental material, **Table [S102].** A summary of the evidence, the results of the statistical analysis and whether the results met the clinical significance thresholds for each outcome **(Table 3)** is provided below.

There was insufficient data to evaluate the efficacy of this treatment among varying patient types or the relative efficacy of differing delivery methods.

Critical outcomes

The following outcomes were determined by the TF to be critical for decision-making when recommending the use of this intervention: sleep quality, sleep latency, WASO, remission rate and responder rate; of these outcomes, remission rate and responder rate were considered the most important. The TF also determined that only diary-reported outcomes were considered critical, but data reported using other tools (PSQI, actigraphy, PSG) are also reported in this section.

SLEEP QUALITY: Only one study [187]reported sleep quality measured by PSQI with a clinically significant effect size of 1.04 (95% CI: 0.50 to 1.50 points lower) at post-treatment favoring mindfulness over control **(Table S103)**.

The quality of evidence for sleep quality was low due to low sample size and risk of bias.

SLEEP LATENCY: One study [186] reporting sleep latency measured by sleep diary showed a post-treatment difference of 3.80 minutes (95% CI: 15.52 minutes lower to 7.92 minutes higher), between treatment and control, results that were not clinically significant **(Table S104)**.

The quality of evidence for sleep latency was low due to imprecision and risk of bias.

WAKE AFTER SLEEP ONSET: Similarly, one study [186] reporting WASO measured by sleep diary showed a post-treatment difference of 10.00 minutes (95% CI: 26.35 minutes lower to 6.35 minutes higher) between treatment and control, which did not meet the clinical significance threshold established by the TF **(Table S105)**.

The quality of evidence for WASO was low due to imprecision and risk of bias.

REMISSION RATE: One study reported remission rate based on the ISI [185]. Remission rate differences were clinically significant with the mindfulness group at having a 36% higher (95% CI: 11% to 61% higher) higher rate compared to placebo **(Table S106)**.

The quality of evidence for remission rate was low due to small sample size and risk of bias.

Data from one study[186] reporting remission rate measured by ISI was not included as post-treatment mean difference could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings.

RESPONDER RATE: Two studies [185, 186]reporting responder rate measured by ISI were not included as post-treatment mean differences could not be calculated. Therefore, the TF could not evaluate the clinical significance of the findings and the quality of evidence was not assessed.

Important outcomes

The following outcomes were determined by the TF to be important outcomes but not critical for decision-making when recommending the use of this intervention; beliefs and attitudes about sleep, daytime fatigue, insomnia severity, nights with hypnotic use, number of nighttime awakenings, sleep efficiency, total wake time and total sleep time. None of the studies identified in our literature review reported data for beliefs and attitudes on sleep, daytime fatigue, nights with hypnotic use and number of nighttime awakenings.

INSOMNIA SEVERITY: Two studies[185, 186] reported insomnia severity measured by ISI. Only one study[185] met the clinical significance threshold with an effect size of 1.01 (95% CI: 0.30 to 1.72 higher) favoring the mindfulness treatment **(Table S107)**.

The quality of evidence for insomnia severity was low due to imprecision and risk of bias.

SLEEP EFFICIENCY: Two studies[185, 186] reported sleep efficiency measured by sleep diary. The results did not meet the clinical significance threshold **(Table S108)**. One study [185] also reported PSG and actigraphy data, and in both cases, results did not meet the clinical significance threshold **(Tables S109-110)**.

The quality of evidence for sleep efficiency was low due to low sample size, imprecision and risk of bias.

TOTAL WAKE TIME: One study[185] reported total wake time reported by sleep diary, actigraphy and PSG. None of the measures met the clinical significance thresholds established by the TF **(Tables S111-113)**.

The quality of evidence for total wake time was low due to imprecision and risk of bias.

TOTAL SLEEP TIME: Two studies reported total sleep time measured by diary and actigraphy [185, 186]. Neither of them reported clinically significant results **(Table S114-115)**. [185] also reported PSG data, which showed a clinically significant post-treatment difference favoring control with the mindfulness treatment having 22.82 minutes (95% CI: 53.40 minutes lower to 7.76 minutes higher) lower total sleep time at post-treatment **(Table S116).**

The quality of evidence for total sleep time was very low due to low sample size, serious imprecision, and risk of bias.

Overall quality of evidence

The overall quality of the evidence was determined to be low for all critical outcomes due to imprecision and risk of bias.

Benefits versus harms

TF determined undesirable effects are no different from control. On balance, the benefits of mindfulness probably favor treatment over control.

Resource use

Resource use does not favor mindfulness or control but consideration should be given to the considerable time investment needed to become an accomplished mindfulness provider, the greater length of treatment sessions and home practice compared to typical CBT-I, and the absence of data indicating mindfulness is amenable to cost-efficient delivery formats.

Patients' values and preferences

Based on their clinical experience, the TF determined that the majority of patients with chronic insomnia would favor mindfulness given the benefits. However, the time investment required for mindfulness therapy may reduce patient adherence to this treatment. The limited data and the one study favoring control suggest that patient's preferences for this treatment are unclear.

DISCUSSION & FUTURE DIRECTIONS

Chronic insomnia disorder is a common sleep disorder among adults. It is known to cause and exacerbate physical and psychological morbidity for patients and is associated with significant financial costs at the societal level. There have been decades of research studying behavioral and psychological treatments for insomnia disorder in adults, and several recent international guidelines have recommended CBT-I as first-line therapy for insomnia patients[33, 35, 37]. The evaluation of behavioral and psychological treatments for insomnia in adults is the most comprehensive summary of the evidence to date and is intended to provide clinicians and researchers with a resource to guide their treatment of insomnia as well as to guide future research. It is noted that the conclusions drawn by this review are limited to the published data emerging from research on this subject and is inherently limited by issues with the study design of trials reported within those publications. Limitations observed across the body of available literature are outlined below, noting that individual studies may have had other limitations as well.

Limitations

There were several issues noted that spanned multiple studies reviewed by the TF, across treatment modalities, that limited the TF's ability to draw definitive conclusions about subgroups of patients, various methods of treatment delivery or the relative strengths and weaknesses of different behavioral and psychological treatments. They include:

1. *Variability in the control conditions*. There were numerous different control conditions used across studies, including waitlist or no treatment, minimal interventions, and sham interventions. Sleep hygiene was used as the control condition in a number of trials, especially in studies testing CBT-I; however, there was a limited discussion of the actual content of the SH condition and how it was delivered to participants making it difficult to understand the potential potency of the different control conditions used. This limited the ability of the TF to interpret variability across studies in terms of the benefits of some treatments for some outcomes.
2. *Variability of the intervention content and intervention delivery method across studies.* While studies generally described the components of treatment, there was not a sufficient number of studies to compare outcomes based on variations in content. For example, studies of CBT-I varied as some included relaxation therapy as a component of the treatment package and some did not. Also, the cognitive therapy strategies used across studies varied. Likewise, multiple biofeedback methods were used across studies, but there was not a sufficient number of studies to evaluate each specific biofeedback method relative to control. The TF therefore could not make specific recommendations about intervention content. Variability in delivery method was considered by the TF, and generally, it appears that behavioral and psychological treatments are effective across delivery methods; however, there was not a sufficient number of comparative effectiveness trials to make statements about the relative benefits across delivery methods. The TF considered conducting a network meta-analysis to compare the various delivery methods, but due to the heterogeneity of samples included in the various studies considered, the TF decided against conducting such an analysis.
3. *Small number of studies evaluating single component therapies, with key missing data in some published trials*. Many of the single component therapy studies were conducted more than 10 years ago, and there was not always sufficient information about the study methods or outcomes of interest. For example, in the scant literature on paradoxical intention (PI), most studies only reported changes in sleep onset latency; however, the TF was interested in other critical outcomes. In addition, there were few studies of relaxation therapy (RT) to conduct meta-analyses for most outcomes, limiting the TFs ability to evaluate some potential benefits.
4. *Small sample sizes in studies of some single component therapies (stimulus control, sleep restriction therapy, biofeedback, PI, and RT)*. The quality of evidence for a number of studies was downgraded due to small sample size. As noted above, this primarily was a concern for studies that were conducted more than 10 years ago.
5. *Drop-out rates not considered.* The analyses conducted did not consider treatment drop-out rates and whether these rates differed between treatment and control conditions.
6. *Lack of data concerning adverse effects/side effects of treatments:* In general, adverse events or side effects of the treatments were not assessed or reported in the majority of studies included in this systematic review. Thus, such effects of these treatments remain in question.

Some of the limitations of the available literature can be explained by when certain treatment approaches were developed and when the treatment was of interest to researchers. For example, the first ISR trial [188] was published in 2007, the first BBT trial was published in 2011 [151], and the first Mindfulness trial was published in 2014 [185]. Due to the relatively recent development of these treatments, there are few studies of their efficacy and much of the research has been conducted by a small number of research groups. Thus, even with promising data, more studies conducted by different centers/researchers are needed to ensure replicability and generalizability. In contrast to these emerging treatments, some treatments (e.g., Biofeedback, RT) emerged decades ago and thus reflect clinical conventions of those times, such as a focus on sleep onset insomnia and conceptualization of most insomnia as a symptom of another disorder, and therefore do not reflect current diagnostic or assessment standards. Thus, the data informing the efficacy of treatment modalities would benefit from evaluation in the context of current diagnostic criteria, as well as current measurement, reporting and statistical approaches. To date, there are no formal evaluations of cost effectiveness to compare different behavioral and psychological treatments for insomnia in adults. Some of the modalities vary greatly in the resources they require.

Generalizability of findings

Across the treatment modalities, study samples tended to be relatively homogenous demographically, and delivery of most interventions was conducted in-person, with one trained sleep interventionist treating one participant at a time. We know

less about the efficacy of the behavioral and psychological treatments for insomnia among key patient subgroups, such as ethnic/racial minorities, those living in rural areas, and older adults. Little is also know about the relative efficacy of treatments delivered via various modalities (e.g., in person vs. use of technology - internet), across various settings (e.g., in clinic vs. the community), and across different types of interventionists (e.g., CBT-I specialists vs. non-sleep specialist). Recently, there has been a focus on insomnia "phenotypes," such as insomnia with and without short objective sleep duration. These different types of insomnia have not been systematically evaluated in intervention trials.

Future research directions

There are several key areas in which additional research would inform the field of behavioral and psychological treatments for insomnia in adults, including:

1. Across behavioral and psychological treatments, there is a need for comparative effectiveness studies evaluating patient outcomes across different delivery methods and settings, and to examine outcomes when clinicians of varying training backgrounds provide care.
2. More studies that include objective, habitual sleep patterns are needed. While objective monitoring is not required for the diagnosis of insomnia disorder, with increasing technological advancements, this is an area that will likely see increased research attention, with a need to ensure the accuracy of monitoring habitual sleep patterns and elucidate the utility of objective outcomes for the potential to inform care for patients with insomnia.
3. Future trials of CBT-I should more consistently incorporate assessment of daytime symptoms associated with insomnia as well as quality of life and other important sleep-related outcomes (e.g., hypnotic use).
4. Studies to better understand the risks of behavioral and psychological interventions, including daytime sleepiness, which has been reported in observation studies, are needed. Methods to mitigate potential risks associated with treatment also need to be systematically evaluated, such as using alternatives to sleep restriction therapy or using other methods to attenuate sleepiness.
5. Studies of the relative efficacy of treatments in patient subgroups, including among insomnia phenotypes, racial/ethnic minority groups, and patients with low health literacy or cognitive impairment, as well as the impact among different cultural groups, are needed.
6. Studies are also needed to improve our understanding of moderators of treatment response and methods to target CBT-I components based on patient presentation and insomnia characteristics.
7. BBTs represent a potential method to increase access to care, and studies that directly compare BBTs to CBT-I, particularly among patients with complex comorbid conditions, are needed.
8. SH is one of the oldest treatment approaches for insomnia in adults; however, recent evidence demonstrates that it is no longer supported as a single component therapy. Given that SH is commonly delivered as single component therapy in current practice, often without systematic follow-up, studies to develop and evaluate dissemination strategies for educating patients and providers about more effective approaches are needed. It is also important to study whether the use of SH delays initiation of other evidence-based insomnia treatments and/or whether SH decreases a patient's willingness to engage in other behavioral or psychological treatments in the future.
9. ISR may represent an alternative to longer-term treatments and could be appealing to some patients (e.g., those who require quick treatment and/or cannot tolerate the temporary increase in sleepiness that can occur during CBT-I. More research is needed to determine optimal patient selection for ISR compared to other insomnia therapies (e.g., CBT-I) and to balance cost/resource utilization for this approach. Future studies should also test whether alternative forms of ISR implementation (e.g., utilizing self-monitoring devices at home) or variations of the therapy are efficacious.
10. Mindfulness-based approaches represent a recent addition to the insomnia treatment literature. Future studies should incorporate standard measures used to evaluate insomnia treatments, such as sleep diaries, actigraphy and/or PSG. Additionally, studies should explore if briefer mindfulness-based approaches preserve therapeutic benefits, and whether mindfulness-based concepts can be incorporated with other approaches (e.g., sleep restriction therapy and stimulus control) to enhance treatment benefits.
11. Cognitive therapy approaches (without behavioral treatment) could not be evaluated due to insufficient evidence; however, studies of the potential benefits of cognitive therapy alone may be beneficial. Understanding which patient groups are most likely to benefit from cognitive approaches is also worthy of future consideration.

12. It would also be useful to solicit patient engagement in the design of intervention trials so as to determine patient uptake and preferences for the available treatments.
13. To date, there have been no specific guidelines that address superiority of one psychological or behavioral treatment over another based on direct comparisons, and this remains a limitation of the current guidelines as well because there are few comparative effectiveness studies upon which to base such recommendations.
14. The TF noted that most randomized clinical trials do not include assessments of side effects associated with the psychological/behavioral therapies, so adequate data on the direct harms associated with them are lacking.

Other considerations

When considering the various psychological and behavioral treatments evaluated herein, it is important to consider a number of factors that may represent barriers or facilitators to their ongoing use in clinical venues. One of those is patient acceptance of these therapies. The limited available evidence does suggest that patients' acceptance of psychological and behavioral therapies is greater than pharmacological therapies;[147, 189] however, not all patients will be interested in these approaches. Among the available psychological treatments themselves, it appears that patients may initially believe sleep restriction therapy to be undesirable; however, those who improve with this treatment rate it positively [148, 190]. There remains a problem with the accessibility/scalability of these treatments. In fact, data would suggest that patients may have limited access to CBT-I, which has a strong evidence base of support. This limited access may be due to patient's lack of knowledge of this treatment, providers' perceptions that such treatment is not acceptable or accessible for their patients, and issues related to stigma of using mental health treatments overall [191, 192]. Since the psychological and behavioral treatments for insomnia have proven to be cost effective relative to care as usual (i.e., treatment in primary care mainly with medications) in terms of improving quality of life and presenteeism at worksites [193], improving communication between patients and providers about CBT-I and other behavioral and psychological treatments is an important priority. Whereas, effective internet-based interventions designed to disseminate CBT-I more broadly to patients who may not have access to a trained provider are available, it does not seem that these interventions have achieved their broadest use at this juncture, and it is not yet clear which patients can benefit from these self-directed approaches and which patients require the support of a skilled provider.

When considering the findings of this systematic review, there are a number of limitations that should be noted. The TF accepted a larger number of studies in the systematic review than were eventually included in our meta-analyses. This was largely due to how data were reported (i.e., investigators not reporting means and standard deviations, or reporting "adjusted" means and standard deviations or standard errors at post-treatment time points). It also should be noted that the GRADE process we used to evaluate available evidence required the TF to establish a threshold for "clinical significance," representing a meaningful difference between active treatment and control conditions for the critical and important outcomes. These thresholds were established by consensus of the TF based on their expertise and experience as there are no commonly accepted or empirically-based thresholds of this nature in the literature. In consensus the TF defined thresholds that were considered reasonable, given what is known about insomnia treatment at this time as well as their clinical expertise. We recognize that these thresholds may evolve with information from future research on patient-centered outcomes of insomnia treatment.

Summary

In summary, there is a large evidence base to support the use of behavioral and psychological treatments, particularly CBT-I for patients with insomnia disorder. While there are challenges to delivery of these interventions and a need for additional research to understand the optimal delivery modalities and benefits achieved by patient subgroups, clinicians should provide a recommended treatment to patients with chronic insomnia disorder, and programs to train providers in the delivery of these approaches should be continued and expanded.

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