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SPECIAL ARTICLE

Combination treatment for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline

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Abstract

Introduction This guideline establishes clinical practice recommendations for combination treatment of chronic insomnia disorder in adults, defined here as treatment with cognitive-behavioral therapy for insomnia (CBT-I) started concurrently with pharmacotherapy.

Methods The American Academy of Sleep Medicine (AASM) commissioned a task force of experts in sleep medicine to develop recommendations and assign strengths to those recommendations based on a systematic review of the literature and an assessment of the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) process. The task force provided a summary of the relevant literature, the certainty of evidence, the balance of benefits and harms, patient values and preferences, and resource use considerations that support the recommendations. The AASM Board of Directors approved the final recommendations.

Recommendations The following recommendations are intended as a guide for clinicians on the use of combination treatment for chronic insomnia disorder in adults. Each recommendation statement is assigned a strength ("Strong" or "Conditional"). A "Strong" recommendation (i.e., "We recommend…") is one that clinicians should follow under most circumstances. A "Conditional" recommendation (i.e., "We suggest…") is one that requires that the clinician use clinical knowledge and experience and strongly consider the patient's values and preferences to determine the best course of action. One recommendation includes a remark that provides additional context to guide clinicians with implementation of this recommendation.

Conditional recommendation for:

1. In adults with chronic insomnia disorder, the AASM suggests the use of combination treatment with CBT-I plus insomnia medication over insomnia medication alone. (Conditional recommendation, low certainty of evidence).

Conditional recommendation against:

2. In adults with chronic insomnia disorder, the AASM suggests against the use of combination treatment of CBT-I plus insomnia medication over CBT-I alone. (Conditional recommendation, low certainty of evidence).

Remark: Patients who place higher value on increasing total sleep time early in the course of treatment, and/or who place lower value on reducing daytime symptoms with treatment, may reasonably select combination treatment versus CBT-I alone.

Keywords Chronic insomnia disorder · Behavioral treatments · Psychological treatments · Pharmacologic treatments · Combination therapy · Clinical practice guideline

Introduction

This clinical practice guideline (CPG) provides an American Academy of Sleep Medicine (AASM) guideline on combination treatment of chronic insomnia in adults and reflects the current recommendations of the AASM. In 2017, the AASM issued a CPG on the pharmacological treatment of chronic insomnia in adults [1]. A separate CPG was released by the AASM in 2021 to inform practice related to the use of behavioral-psychological treatments for chronic insomnia

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in adults [2]. However, evidence-based guidance regarding the benefits and harms of combination treatment for chronic insomnia is lacking. Combination treatment is likely to be prevalent, although empirical data on the frequency of combination treatment in clinical practice are not available in the literature. This CPG was therefore developed to address this gap in knowledge in their comparative efficacy.

Chronic insomnia disorder occurs in roughly 10–15% of adults [3]. This disorder is characterized by difficulty falling asleep, staying asleep, waking too early, or a combination of these nighttime symptoms, which is associated with significant distress and functional impairment [4]. It is associated with reduced quality of life and increased risk of cardiovascular disease, hypertension, diabetes, mental health and substance use disorders [5–12]. Other sleep disorders (e.g., sleep apnea), medical conditions (e.g., chronic pain), and mental health disorders (e.g., depression) commonly co-occur with chronic insomnia disorder. Clinical diagnosis of chronic insomnia disorder should be based on a careful clinical history using accepted nosologies, such as the International Classification of Sleep Disorders (ICSD) [4] or the Diagnostic and Statistical Manual of Mental Disorders (DSM) [13]. No objective testing is required for diagnosis, but best practice recommends objective sleep testing in patients with high suspicion of another sleep disorder, such as a sleep-related breathing disorder.

The AASM issued a CPG on pharmacological treatment of chronic insomnia in 2017 [1] and provided *conditional* recommendations for medications to manage sleep onset insomnia (triazolam, ramelteon, zaleplon), sleep maintenance insomnia (doxepin, suvorexant), and combined sleep onset and maintenance insomnia (temazepam, zolpidem, eszopiclone). The task force (TF) emphasized that medications should be considered primarily in patients unable to participate in cognitive-behavioral therapy for insomnia (CBT-I), with residual symptoms following an adequate trial of CBT-I, or as a temporary adjunct to CBT-I in select cases. The TF also provided *conditional* recommendations against trazodone, tiagabine, diphenhydramine, melatonin, tryptophan, and valerian due to insufficient evidence of efficacy, absence of high-quality data, and/or other considerations such as potential risks and patient values and preferences. Notably, several insomnia medications (e.g., lemborexant, daridorexant) have been approved by the U.S. Food and Drug Administration (FDA) since the publication of the 2017 CPG.

In 2021, the AASM developed a CPG focused on behavioral-psychological treatments for chronic insomnia [2]. In this CPG, the TF provided a *strong* recommendation for multicomponent CBT-I due to substantial evidence of its efficacy across multiple high-quality randomized controlled trials (RCTs). Conditional recommendations were provided for multicomponent brief therapies for insomnia and the single-component therapies stimulus control, sleep restriction therapy, and relaxation therapy, which showed variable evidence of efficacy, but few undesirable effects. Sleep hygiene therapy, although commonly used in clinical practice, received a conditional recommendation *against* its use as a single-component treatment for chronic insomnia. Additionally, the TF found evidence that patients prefer behavioral-psychological treatments for insomnia because these treatments are perceived to have better long-term efficacy, provide more benefits for daytime symptoms, and have fewer side effects compared to pharmacological treatment.

The existing AASM CPGs comprehensively addressed pharmacological and behavioral-psychological treatments used in isolation but left unaddressed critical clinical questions including whether, how, and when to combine these treatment modalities. In clinical practice, these treatments are combined for many different reasons including availability of behavioral-psychological treatments, patient and clinician preference, cost, and convenience. However, no evidence-based clinical guidelines exist to inform best clinical practices. With this guideline, we begin to fill this knowledge gap by providing recommendations following a systematic review of the benefits and harms of combination treatment for chronic insomnia in adults. We use the term "combination treatment" throughout this guideline and the accompanying systematic review to refer to the initiation of a behavioral-psychological treatment *concurrently* with a pharmacological treatment. Most of the available data evaluated efficacy and safety outcomes for concurrent initiation of combination treatment. However, we recognize that *sequential* treatment strategies (e.g., adding CBT-I to ongoing pharmacological treatment) may be more common in clinical practice. Unfortunately, clinical trials on sequential treatments are few in number and variable in design. Most recruit participants who have persistent symptoms of insomnia despite open clinical treatment with one modality (e.g., pharmacotherapy), but with no information on symptom severity prior to the first treatment or the magnitude of clinical response to the first treatment, and with no random assignment at either the first or second treatment stage. We utilized the existing CPGs to inform this guideline and, where appropriate, maintained consistency in our approach. For example, all the behavioral-psychological multicomponent and single-component therapies from the 2021 CPG were included in our evidence evaluation for this guideline. We also included all pharmacological treatments from the 2017 CPG but added prescription medications and other agents to treat insomnia that have more evidence or are more widely used than in 2017. Consistent with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) [14, 15] process, recommendations reflect an appraisal of the balance of benefits and harms in addition

to evaluations of the quality of the evidence, patient values and preferences, and resource use.

This guideline, in conjunction with the accompanying systematic review, [16] provides a comprehensive review of the available evidence and a synthesis of clinical practice recommendations for combination treatment of chronic insomnia in adults. It is intended to optimize patient-centered care by broadly informing clinicians who care for patients with chronic insomnia disorder.

Methods

The AASM commissioned a TF of sleep medicine clinicians with expertise in the treatment of adults with chronic insomnia disorder, along with guideline methodologists. 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 COI policy, TF members with a Level 1 conflict were not allowed to participate. TF members with a Level 2 conflict were required to recuse themselves from any related discussion or writing responsibilities. All relevant conflicts of interest are listed in the Declarations section.

The TF conducted a systematic review of the published scientific literature, focusing on patient-oriented, clinically relevant outcomes. Studies included in the analysis had to be original research on the treatment of chronic insomnia in adults and addressing an outcome of interest. The key terms, search limits, and inclusion/exclusion criteria specified by the TF are detailed in the supplemental material of the accompanying systematic review [16]. The purpose of the review was to compare the efficacy and harms of combination treatment (behavioral-psychological treatment used concurrently with pharmacological treatment) to either treatment modality alone in adults with chronic insomnia disorder. *Critical* outcomes prioritized for decision making included: (1) global insomnia severity assessed by patient-reported insomnia symptom or sleep quality measures; (2) sleep continuity outcomes including sleep efficiency (SE), sleep onset latency (SOL), and wake after sleep onset (WASO) assessed by sleep diary; and (3) daytime outcomes assessed by patient-reported fatigue, depression, anxiety, or quality of life measures. Other *important* outcomes used for clinical decision-making included diary total sleep time (TST) and treatment side effects (Table 1). The available data focused primarily on short-term outcomes measured soon after the end of acute treatment, which were therefore the focus of this guideline. Data regarding objective outcomes (e.g., polysomnography) are presented in supplemental material to the accompanying systematic review.

The TF set a clinically meaningful threshold (CMT) for each outcome to determine whether the mean difference between the intervention and the comparator was clinically meaningful. The clinical practice recommendations were then developed according to the GRADE process [14, 15]. The TF assessed the following four components to determine the direction and strength of a recommendation: certainty of evidence; balance of desirable (beneficial) and undesirable (harmful) effects; patient values and preferences; and resource use. Details of these assessments can be found in the accompanying systematic review [16].

Recommendations

Taking these components into consideration, recommendation statements were assigned a strength ("Strong" or "Conditional"). The recommendations in this guideline define principles of practice that should meet the needs of most patients in most situations. A "Strong" recommendation is one that clinicians should follow for almost all patients (i.e., something that might qualify as a Quality Measure). A "Conditional" recommendation is one that requires that the clinician use clinical knowledge and experience and strongly consider the patient's values and preferences to determine

Table 1 Critical and important outcomes used for decision-making

Outcome category	Specific outcome	Measures
Critical outcomes		
Global insomnia severity measures	Insomnia symptoms, sleep quality	Insomnia Severity Index, Pittsburgh Sleep Quality Index
Sleep continuity	Sleep efficiency, sleep latency, wake after sleep onset	Sleep diary
Daytime outcomes	Depression, anxiety, fatigue, quality of life	Beck Anxiety Inventory, Beck Depression Inventory, Penn State Worry Questionnaire, Patient Health Questionnaire, Multidimensional Fatigue Inventory, 36-Item Short Form Survey
Important outcomes		
Total sleep time	Total sleep time	Sleep diary
Treatment side effects	Various outcomes reported	Adverse event questionnaire

Table 2 Implications of strong and conditional recommendations for users of AASM clinical practice guidelines

User	Strong Recommendations "We recommend…"	Conditional Recommendations "We suggest…"
Clinicians	Almost all patients should be offered the recommended course of action. Adherence to this recommendation could be used as a quality criterion or performance indicator.	Most patients should be offered the suggested course of action; however, different choices may be appropriate for different patients. The clinician must help each patient determine if the suggested course of action is clinically appropriate and consistent with their values and preferences.
Patients	Almost all patients should be offered the recommended course of action, although a small proportion of patients would not choose it.	Most patients should be offered the suggested course of action, though some may not choose it. Different choices may be appropriate for different patients. The patient should work with their clinician to determine if the suggested course of action is clinically appropriate and consistent with their values and preferences.
Policy makers	The recommended course of action should be adopted as policy for most situations. Adherence to the recommended course of action could be used as a quality criterion or performance indicator.	The ultimate judgment regarding the suitability of the suggested course of action must be made by the clinician and patient together, based on what is best for the patient. This decision-making flexibility should be accounted for when establishing policies.

the best course of action. The implications of the strength of recommendations for guideline users are summarized in Table 2. Additional information is provided in the form of "Remarks" immediately following the recommendation statements, when deemed necessary by the TF. Remarks are based on evidence evaluated during the systematic review and are intended to provide context for the recommendations and to guide clinicians in the implementation of the recommendations in daily practice. The ultimate judgment regarding any specific course of treatment must be made by the treating clinician and the patient, taking into consideration the individual circumstances of the patient, available treatment options, and resources.

This CPG reflects the evidence and state of knowledge at the time of the last literature search in June 2025. Scoping literature searches are performed every two years on all published AASM CPGs to review new evidence. Based on this review, updates may be made if there are significant changes in areas such as the available interventions, outcomes of interest (or values placed on outcomes), or evidence of the existing benefits and harms.

Recommendations for specific interventions for the treatment of adults with chronic insomnia disorder are below. A remark is provided to guide clinicians in the implementation of one of these recommendations. The strength of the recommendations reflects the extent to which the TF was confident that the desirable effects of an intervention outweighed the undesirable effects across the range of populations for whom the recommendations are intended. The smaller the net benefit or harm and the lower the certainty of evidence about the net effect, the more likely the TF is to conclude that a conditional recommendation for or against the intervention would be appropriate. The balance of effect (desirable and undesirable effect) was assessed together with the values of people affected and resource use.

Conditional recommendation for: Combination treatment over pharmacotherapy alone

Recommendation 1: In adults with chronic insomnia disorder, the AASM suggests the use of combination treatment with CBT-I plus insomnia medication over insomnia medication alone. (Conditional recommendation, low certainty of evidence)

The TF identified six RCTs published in seven articles that reported one or more critical outcomes with data suitable for meta-analysis. Five trials delivered in-person CBT-I and the sixth trial used self-administered CBT-I. Insomnia medications in the trials included lormetazepam, temazepam, zolpidem, and zopiclone. The evidence showed clinically meaningful improvements in two critical outcomes—global insomnia severity measures and sleep continuity—for combination treatment compared to pharmacological treatment alone. Daytime outcomes were more favorable in the combination group compared to the pharmacological treatment alone group, but this difference was not clinically meaningful. The desirable effects of combination treatment were judged to have small effect sizes. TST did not show a clinically meaningful improvement for combination treatment when compared to pharmacological treatment alone and the point estimate favored medication alone. Treatment side effects (specifically, morning sleepiness) were reported using an outcome measure without a prespecified CMT. The combination group reported more morning sleepiness than the pharmacological alone group. The undesirable effects were deemed to have a minimal effect size. The TF judged that the potential benefits of combination treatment outweigh the potential harms.

The overall certainty of evidence was low due to risk of bias and imprecision. The cost associated with combined CBT-I and pharmacological treatment, compared to pharmacological treatment alone, was considered moderate. There was no direct evidence that combination treatment would impact health equity. However, in practice settings where CBT-I is unavailable or unaffordable, the recommendation for combination treatment could adversely impact health equity. Combination treatment was judged to probably be an acceptable intervention to key interest holders (e.g., patients, clinicians) and feasible to implement.

Conditional recommendation against: Combination treatment over CBT-I alone

Recommendation 2: In adults with chronic insomnia disorder, the AASM suggests against the use of combination treatment of CBT-I plus insomnia medication over CBT-I alone. (Conditional recommendation, low certainty of evidence)

Remark *Patients who place higher value on increasing total sleep time early in the course of treatment, and/or who place lower value on reducing daytime symptoms with treatment, may reasonably select combination treatment versus CBT-I alone.*

The TF identified six RCTs published in seven articles that reported one or more critical outcomes with data suitable for meta-analysis. All studies delivered in-person CBT-I to participants. Insomnia medications in the trials included temazepam, trazodone, zolpidem, and zopiclone. The evidence showed no clinically meaningful improvement in the critical outcomes of global insomnia severity, sleep continuity, and daytime outcomes for combination treatment compared to CBT-I alone. Although no clinically meaningful difference was found for daytime outcomes, the point estimate in this analysis could not exclude greater undesirable daytime effects with combination treatment. Moreover, there was a clinically meaningful improvement in TST with combination therapy compared to CBT-I alone although the confidence interval included zero. No treatment side effects were reported. Desirable and undesirable effects of combination treatment versus CBT-I alone were both deemed to have a minimal effect size. The TF judged that the potential benefits of combination treatment do not outweigh the potential harms.

The overall certainty of evidence was low due to risk of bias and imprecision. The cost associated with combined CBT-I and pharmacological treatment, compared to CBT-I alone, was considered negligible based on the medications in the included studies. There was no direct evidence that combination treatment would impact health equity. Combination treatment is probably an acceptable intervention to key interest holders and feasible to implement.

Discussion

The current recommendations were developed to guide clinicians on the use of combination therapy for chronic insomnia in adults, a common approach to managing insomnia in clinical practice. We conducted a systematic review and meta-analysis of studies comparing combination therapy for insomnia – defined as the concurrent initiation of behavioral-psychological treatment and pharmacological treatment – with behavioral-psychological treatment alone and pharmacological treatment alone. Our recommendations are derived from the current state of the literature following the GRADE process for rating the evidence quality, which considers the certainty of the evidence, balance of benefits and harms, patient values and preferences, and resource use. These recommendations are intended to provide a framework to allow for patient-centered clinical care.

Existing CPGs, including those of AASM and other professional associations, currently strongly recommend CBT-I alone for the treatment of chronic insomnia in adults. Some of these guidelines also recommend shared decision-making with the patient to consider adding pharmacotherapy when CBT-I alone has been unsuccessful [1, 2, 17]. The overall recommendations of this CPG suggest CBT-I alone over the combination of CBT-I with pharmacotherapy, but also suggests the use of combination treatment over pharmacotherapy alone. Thus, our overall recommendations place CBT-I above combination, and combination above pharmacotherapy alone. Based on the reviewed evidence, the TF also noted that patients and/or clinicians who place a higher value on increasing TST with treatment, and/or a lower value on reducing daytime symptoms, may reasonably select combination treatment over CBT-I alone. With regard to TST, this recommendation relies on the observation that TST increased to a greater degree with combination treatment versus CBT-I alone. With regard to daytime symptoms, this recommendation relies on the observation that, improvement in daytime symptoms with combination treatment was smaller than with CBT-I.

Together with prior findings, [18–20] the recommendations of the present CPG have important implications for clinical practice: They support initiating CBT-I alone under most circumstances, reserving combination treatment with pharmacotherapy for specific clinical presentations. For example, combination treatment may be selected when increasing TST is considered a higher priority than improving sleep continuity early in treatment, either as valued by

the patient or as indicated by the clinician [16]. Patients presenting for treatment with chief concerns specifically related to lack of sleep or working in settings where obtaining adequate sleep is a high priority (e.g., safety-sensitive occupations) may appropriately choose combination treatment. This consideration may also be particularly relevant when increased TST is desired in the short-term, since CBT-I alone is associated with longer-term increases in TST [21]. Combination treatment may also be used when rapid symptom relief is a priority or when CBT-I is acceptable but not immediately available.

In light of the finding that combination treatment showed marginally smaller improvements in daytime symptoms compared to CBT-I alone, patients with mild daytime symptoms might reasonably select combination treatment. Our CPG did not specifically address sequential treatment with pharmacotherapy followed by initiation of CBT-I, which may be the most common clinical scenario. Nevertheless, our findings may be extrapolated to infer that adding CBT-I to existing pharmacotherapy would be beneficial in such cases. Patients' values and preferences may also lead to implementing pharmacotherapy alone in other instances–for example, patients who place higher value on the lower cost of and commitment required by pharmacotherapy alone versus CBT-I. Pharmacotherapy alone may also be warranted for patients with cognitive impairments, who lack the ability to make behavioral changes or use cognitive strategies or in other clinical scenarios, such as long wait times for CBT-I.

Another key driver of treatment choice for chronic insomnia disorder is acceptance of CBT-I, pharmacotherapy, or their combination [2]. Some evidence suggests that patients prefer CBT-I over pharmacotherapy, [2] but these studies are small and may not represent the broader population. Not all patients accept or engage in CBT-I, either alone or when combined with pharmacotherapy for several reasons, including the lack of access, increased time commitment, and greater costs, which will also influence specific treatment selection. Given that the evidence in the accompanying systematic review did not support combination treatment over CBT-I alone—but did suggest the use of combination treatment over pharmacotherapy alone—increasing access to CBT-I is critical to the optimal implementation of these recommendations.

However, existing evidence indicates that access to CBT-I remains a problem in the general population [20] and is an even greater challenge in underserved or rural areas [22, 23]. Digital CBT-I (dCBT-I) has shown promise for improving accessibility, but engagement and dropout rates remain challenges [24, 25] and it is not covered by all health insurance carriers. A large number of dCBT-I products are publicly available, but currently only two (Somryst, SleepioRx) are FDA-cleared and categorized as evidence-based, reimbursable digital mental health treatments by the Centers for Medicare and Medicaid Services (CMS). Other strategies may also help to extend the reach of CBT-I, including expanded telemedicine services (as offered by Veterans Administration Health) and PSYPACT, an interstate compact to facilitate access to psychological treatment across state boundaries. Brief behavioral and cognitive-behavioral treatments for insomnia, which incorporate key components of CBT-I, may also expand accessibility [26, 27]. Nevertheless, pharmacotherapy alone is likely to continue to be used as first-line treatment for many clinicians and patients, unless the upstream determinants of limited CBT-I access are resolved: availability of properly trained professionals, patients' lack of knowledge regarding CBT-I, providers' perceptions that CBT-I is not acceptable for their patients, and/or social stigma regarding the use of behavioral-psychological treatments.

The CPG recommendations refer specifically to combination treatment that includes CBT-I because the evidence base did not include studies of combination treatment with other multicomponent or single-component behavioral-psychological therapies. However, the AASM CPG on behavioral-psychological treatments for insomnia provided conditional recommendations for multicomponent brief treatment for insomnia and single component stimulus control, sleep restriction therapy, and relaxation therapy. It therefore seems reasonable that, in situations where CBT-I is not available, clinicians might choose to implement another recommended behavioral-psychological therapy along with pharmacotherapy over pharmacotherapy alone. In the absence of data, these decisions should be made collaboratively with patients and considering relevant individual factors such as patient values and preferences and available resources. The TF discourages clinicians from using sleep hygiene instructions alone as a component of combination therapy. The AASM CPG on behavioral-psychological treatments for insomnia issued a conditional recommendation against sleep hygiene alone because of its lack of efficacy compared to other treatments. By extension, the TF judged that sleep hygiene instructions alone are unlikely to be an efficacious component of combination treatment.

This CPG addressed combination treatment only when both treatments were started concurrently. Research studies using this design were the most common and provide the clearest assessment of outcomes. However, sequential treatment—for instance, adding pharmacotherapy when CBT-I response is not adequate or vice versa—may better represent actual clinical practice [16]. A recent randomized sequential clinical trial has offered insight into the question of sequencing pharmacological and behavioral-psychological insomnia treatments [28]. Specifically, this clinical trial found that a treatment sequence in which behavioral treatment is

followed by zolpidem resulted in higher insomnia remission rates than zolpidem followed by behavioral treatment [28]. In addition, a treatment sequence in which zolpidem was followed by trazodone showed greater lengthening of TST than all other sequences, including those in which behavioral treatment was combined with zolpidem [28]. Given the currently-available evidence, the TF is unable to make recommendations regarding concurrent versus sequential combination treatment. Therefore, we recommend that clinicians (1) facilitate access to CBT-I for the community they serve by advocating for its inclusion in sleep and outpatient centers and by leveraging as many in-person, telehealth, and dCBT-I resources as possible and (2) use shared decision-making at the individual patient level to understand both the upstream determinants (e.g., cost, commitment) and downstream effects (e.g., remission rate, TST) of implementing CBT-I alone, pharmacotherapy alone, or their combination.

Social determinants of health play a crucial role in treatment feasibility. Cost and insurance coverage can be significant barriers to treatment access and sources of inequity. CBT-I often requires multiple sessions with a trained provider, which may not be covered or may involve long wait times [29]. Digital CBT-I may require subscription fees as well as access to broadband internet and technological literacy. Patients from lower socioeconomic backgrounds may also face disproportionate challenges in accessing CBT-I due to logistical constraints (e.g., transportation, work schedules, childcare). Over-reliance on pharmacotherapy in these populations, due to lack of CBT-I availability and affordability, could perpetuate disparities in long-term insomnia management and outcomes. Therefore, expanding access to affordable, evidence-based behavioral-psychological interventions remains a critical public health goal to address health equity-related factors that contribute to poorer outcomes for certain populations. Pharmacotherapy may be more accessible broadly, but it poses financial concerns, particularly with newer medications that lack generic alternatives and increase treatment costs [1, 30, 31]. Additionally, adherence differs between interventions: Some patients struggle with the structured behavioral changes of CBT-I, while others may be reluctant to take sleep medications long term.

This CPG also has important research implications. The most important research gap we identified was for adequately-powered comparative effectiveness trials that apply contemporary standards for clinical trial conduct and reporting. Sufficiently powered RCTs examining the comparative effectiveness of combination treatment should include systematic assessments of daytime functioning impact and comorbid clinical outcomes, such as depression, substance misuse, pain, or hypertension, and be tested in key subpopulations [32]. Information on important daytime side effects from combination treatments also needs to be more systematically integrated into RCTs. This CPG addressed mainly short-term outcomes, given the designs of the included studies.

Longer-term follow-up assessments are needed to better understand whether the durability of clinical effects are different for combination treatment versus either treatment alone over time [2]. However, such studies are difficult to conduct and their utility is limited by the likelihood that patients and providers who perceive any treatment to be ineffective are likely to move on to a different treatment. Similarly, the observed clinically meaningful impact of combination treatment over CBT-I alone on increasing TST should be tested among insomnia phenotypes based on objective short sleep duration [33].

Future RCTs should also address design issues with important clinical implications, such as the sequential (CBT-I followed by pharmacotherapy) versus concurrent (CBT-I plus pharmacotherapy) delivery of combination treatment and other novel clinical trial designs [28]. In addition, many hypnotic agents remain untested in combination treatment, including dual orexin receptor antagonists (DORAs). Specific hypnotics may have differential effects when combined with CBT-I for specific patient populations [1]. Moreover, sufficient evidence was available only for CBT-I as the behavioral-psychological treatment, thus future studies that include other multicomponent and single-component behavioral-psychological treatments are needed. If addressed, these research gaps could well shift the recommendations in this CPG for combination treatment. Future research is also needed to identify the prevalence of combined pharmacological and behavioral-psychological treatments for chronic insomnia in clinical practice, as current evidence is limited.

Limitations

The recommendations provided in this CPG should be considered in the context of limitations in the extant literature. The most notable limitation is the small number of studies that compared single and combination treatment modalities. The small number of studies can reduce the precision of meta-analysis results, and led us to combine outcomes within broad categories (e.g., daytime symptoms) that would ideally be considered separately. Data are also extremely limited regarding outcomes in patients from diverse racial/ethnic backgrounds, across sex/gender, socioeconomic strata, and with different medications, medical, and psychiatric comorbidities. Therefore, we cannot confidently extrapolate these recommendations to patients from diverse backgrounds. Furthermore, most trials included

small sample sizes, were conducted at single academic centers, and enrolled largely homogeneous populations, further limiting generalizability.

As previously noted, sequential treatment, where medication or behavioral-psychological therapy is added only after the other has been initiated, is likely to be the more common real-world scenario. However, studies of sequential approaches are few in number and were excluded from the current analyses and formal decision-making process. Similarly, the use of CBT-I to facilitate discontinuation of hypnotic medication is an important clinical topic, but was outside the scope of this CPG. The range of pharmacological agents in eligible studies was narrow, with most trials focusing on benzodiazepine receptor agonists. No eligible studies investigated DORAs or melatonin receptor agonists. Trazodone was used in one study. Although this medication is not FDA-approved for this indication, it is among the most widely-prescribed insomnia medications in the US [34–36] and therefore worthy of study. However, our analyses did not permit us to make conclusions about the relative efficacy of different medications used in combination with CBT-I. Similarly, there was significant variation in specific CBT-I treatment components and delivery methods across studies, making it difficult to draw conclusions about which specific components are most beneficial in combination therapy. Using manualized multicomponent CBT-I appears most appropriate [37–40]. We were also unable to identify a critical mass of studies that combined pharmacological treatment with single-component behavioral-psychological treatments, brief treatments of insomnia, or newer psychological treatments for insomnia (e.g., acceptance and commitment therapy).

Additionally, few studies systematically collected data on adverse events, and long-term outcomes remain largely unstudied. Cost-effectiveness analyses were also unavailable. Given these gaps, clinicians are encouraged to thoughtfully incorporate individual patient characteristics, preferences, and values—such as prior experience with behavioral-psychological treatments, perceptions about long-term medication use, or considerations about cost/accessibility—when determining the most appropriate treatment strategy.

Conclusion

This CPG recommends that clinicians use combination therapy (CBT-I plus medication) over pharmacotherapy alone for adults with chronic insomnia disorder but recommends against using combination therapy over behavioral-psychological treatment (CBT-I) alone. However, patients who prioritize increasing sleep duration as a key clinical outcome and those who place lower value on reducing daytime symptoms, may preferentially select combination therapy. Overall, we encourage individualized clinical decision-making, weighing patient values and preferences, social determinants, and treatment accessibility. While combination therapy may be optimal for some, ensuring equitable access to CBT-I and addressing cost-related barriers to care are necessary for improving insomnia management across diverse populations.

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Declarations

Conflict of interest Dr. Buysse is a consultant for BeHealth (2016-current), Eisai, Inc (2019-current), Pear Therapeutics (2019-current), National Cancer Institute (2019-current), Idorsia Pharmaceuticals Ltd (2021-current), Sleep Number (2021-current), Synchronicity Pharma (2025-current); received research support from Sleep Number (2023-2025); is Board President at the Sleep Research Society (2025-2026); and receives compensation from the following intellectual property materials: the Pittsburgh Sleep Quality Index (1989-current), Pittsburgh Sleep Quality Index Addendum for PTSD (PSQI-A) (2005-current), Brief Pittsburgh Sleep Quality Index (B-PSQI) (2021-current), Daytime Insomnia Symptoms Scale (2007-current), Pittsburgh Sleep Diary (1994-current), Insomnia Symptom Questionnaire (2009-current), RU_SATED (copyrights held by University of Pittsburgh) (2021-current), the Consensus Sleep Diary (copyright held by Ryerson University) (2012-current). Dr. Arnedt consulted for Purdue Pharma (2021-2022), Eisai, Inc. (2021-2022), Idorsia Pharmaceuticals Ltd (2022), and received compensation from the following intellectual property materials: telephone-delivered insomnia therapy treatment manuals (copyright held by University of Michigan) (2013-2024). Dr. Fernandez-Mendoza serves on the Society of Behavioral Sleep Medicine's guideline development expert panel (2023-current) and on the Sleep Research Society's Board of Directors (2024-current). Dr. Falck-Ytter is a paid consultant for the AASM and an affiliated member of the United States Grading of Recommendations Assessment, Development and Evaluation Network and the Evidence Foundation. Dr. Hyer is employed by the AASM. Ms. Kazmi was formerly employed by the AASM. She was employed by the AASM at the time of her work on this guideline.Dr. Singh serves on the AASM Guideline Advisory Panel; the Hypersomnia Foundation's medical advisory

board (2018-current); has served on the Society of Anesthesia and Sleep Medicine Board of Directors (SASM) (2020-current) and is President-elect of SASM (2024-2026). Dr. Wickwire is a consultant for Nox Health (2023-current) and ResMed Corp. (2022-current); has served as a consultant for Axsome Therapeutics, Eisai, Inc., Ensodata, Idorsia Pharmaceuticals Ltd, Merck Sharp & Dohme Corporation, and Primasun; receives research support from Merck Sharp & Dohme Corporation (2020-current), and ResMed Foundation (2022-2027); owns stock in WellTap (2011-current); and serves on the AASM Board of Directors (2022-current).
Dr. Buenaver, Dr. Chang, Dr. Patel, and Dr. Zhou have no relevant conflicts of interest to disclose.

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