Combination Treatment for Chronic Insomnia Disorder in Adults:

An American Academy of Sleep Medicine Clinical Practice Guideline

Introduction: This guideline establishes clinical practice recommendations for combination treatment of chronic insomnia disorder in adults.

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 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.

18 19 **Conditional recommendation for:**

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1. In adults with chronic insomnia disorder, the AASM suggests the use of combination treatment with cognitive behavioral therapy for insomnia (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 with treatment, and/or patients who place lower value on reducing daytime symptoms with treatment, may reasonably select combination treatment vs CBT-I alone.

Keywords: chronic insomnia disorder, behavioral treatments, psychological treatments, pharmacologic treatments, combination therapy, clinical practice guideline

34 **Citation:**

INTRODUCTION

This clinical practice guideline (CPG) is intended to establish an American Academy of Sleep Medicine (AASM) guideline on combination treatment of chronic insomnia in adults and reflects the current recommendations of the 38 AASM. In 2017, the AASM issued a CPG on the pharmacological treatment of chronic insomnia in adults. A separate CPG was released by the AASM in 2020 to inform practice related to the use of behavioral-psychological 40 treatments for chronic insomnia in adults.² However, evidence-based guidance regarding the benefits and harms of combination treatment for chronic insomnia is lacking, despite pharmacological and behavioral-psychological

- 42 treatments commonly being used together in clinical practice. This CPG was therefore developed to address this
- 43 gap in knowledge.
- Chronic insomnia disorder occurs in roughly 1 in 10 adults.³ This disorder is characterized by difficulty falling 44
- 45 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 46
- cardiovascular disease, hypertension, diabetes, mental health and substance use disorders. 5-12 Other sleep disorders 47
- 48 (e.g., sleep apnea), medical conditions (e.g., chronic pain), and mental health disorders (e.g., depression) commonly
- 49 co-occur with chronic insomnia disorder. Clinical diagnosis of chronic insomnia disorder should be based on a
- 50 careful clinical history using accepted nosologies, such as the International Classification of Sleep Disorders
- 51 (ICSD)⁴ or the Diagnostic and Statistical Manual of Mental Disorders (DSM).¹³ No objective testing is required for
- 52 diagnosis, but best practice recommends objective sleep testing in patients with high suspicion of another sleep
- 53 disorder, such as a sleep-related breathing disorder.
- 54 The AASM issued a CPG on pharmacological treatment of chronic insomnia in 2017¹ and provided conditional
- 55 recommendations for medications to manage sleep onset insomnia (triazolam, ramelteon, zaleplon), sleep
- 56 maintenance insomnia (doxepin, suvorexant), and combined sleep onset and maintenance insomnia (temazepam,
- 57 zolpidem, eszopiclone). The task force (TF) emphasized that medications should be considered primarily in patients
- 58 unable to participate in CBT-I, with residual symptoms following an adequate trial of CBT-I, or as a temporary
- 59 adjunct to CBT-I in select cases. The TF also provided *conditional* recommendations against trazodone, tiagabine,
- 60 diphenhydramine, melatonin, tryptophan, and valerian due to insufficient evidence of efficacy, absence of high
- 61 quality data, and/or other considerations such as potential risks and patient values and preferences.
- 62 In 2020, the AASM developed a CPG focused on behavioral-psychological treatments for chronic insomnia.² In
- 63 this CPG, the TF provided a strong recommendation for multicomponent CBT-I due to substantial evidence of its
- 64 efficacy across multiple high-quality RCTs. Conditional recommendations were provided for multicomponent brief
- 65 therapies for insomnia and the single-component therapies stimulus control, sleep restriction therapy, and relaxation
- 66 therapy, which showed variable evidence of efficacy, but few undesirable effects. Sleep hygiene therapy, although
- 67 commonly used in clinical practice, received a conditional recommendation against its use as a single-component
- 68 treatment for chronic insomnia. Additionally, the TF found evidence that patients prefer behavioral-psychological
- 69 treatments for insomnia because these treatments are perceived to have better long-term efficacy, provide more
- 70 benefits for daytime symptoms, and have fewer side effects compared to pharmacological treatment.
- 71 The existing AASM CPGs comprehensively addressed pharmacological and behavioral-psychological treatments
- 72 used in isolation but left unaddressed critical clinical questions including whether, how, and when to combine these
- 73 treatment modalities. In clinical practice, these treatments are combined for many different reasons including
- 74 availability of behavioral-psychological treatments, patient and provider preference, cost, and convenience.
- 75 However, no evidence-based clinical guidelines exist to inform best clinical practices. With this guideline, we begin
- 76 to fill this knowledge gap by providing recommendations following a systematic review of the benefits and harms
- 77 of combination treatment for chronic insomnia in adults. We use the term "combination treatment" throughout this 78
- guideline and the accompanying systematic review to refer to the initiation of a behavioral-psychological treatment 79 concurrently with a pharmacological treatment. Most of the available data evaluated efficacy and safety outcomes
- 80 for concurrent initiation of combination treatment. However, we recognize that sequential treatment strategies (e.g.,
- 81 adding CBT-I to ongoing pharmacologic treatment) may be more common in clinical practice. We utilized the
- 82 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 2020 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 either lacked evidence at the time or were not widely used. 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. 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 Disclosures 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. Diary total sleep time (TST) and treatment side effects were considered important outcomes (Table 1).

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

Table 1 – Critical and important outcomes used for decision-making

Outcome category	Specific outcome	Measure		
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, Pennsylvania 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		

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 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, October 2024. Scoping literature searches are performed on all published AASM CPGs on an annual basis 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.

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	Most patients should be offered the suggested
	recommended course of action. Adherence	course of action; however, different choices may
	to this recommendation could be used as a	be appropriate for different patients. The
	quality criterion or performance indicator.	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 can 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.

ADULTS WITH CHRONIC INSOMNIA DISORDER

Recommendations for specific interventions for the treatment of adults with chronic insomnia disorder are presented 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 Recommendations for:

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. 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.

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- 177 The overall certainty of evidence was low due to risk of bias and imprecision. The cost associated with combined
- 178 CBT-I and pharmacological treatment, compared to pharmacological treatment alone, was considered moderate.
- 179 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:

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).

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

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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. 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.

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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.

208 DISCUSSION

The current recommendations were developed to guide clinicians on the use of combination therapy for 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 to 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.^{1, 2, 17} Some of these guidelines also recommend shared decision-making with the patient to consider adding pharmacotherapy when CBT-I alone has been unsuccessful.¹⁷ The current CPG suggests the use of combination treatment over pharmacotherapy alone and suggests *against* the use of combination treatment over CBT-I alone in adults with chronic insomnia disorder. Based on the reviewed evidence, the TF also noted that interest holders (formerly referred to as stakeholders) who place a higher value on increasing TST with treatment, or a lower value on reducing daytime symptoms, may reasonably select combination treatment over CBT-I alone. 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 important, either as valued by the patient or as indicated by the clinician.¹⁶ However, patients' values and preferences may lead to implementing pharmacotherapy alone in other instances; for example, patients who weigh the lower cost of and commitment required by pharmacotherapy alone vs. CBT-I. Conversely, individuals concerned about pharmacotherapy dependence or side effects may prefer CBT-I alone.

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 optimally implement these recommendations. However, existing evidence indicates that access to CBT-I remains a problem in the general population²⁰ and is an even greater challenge in underserved or rural areas.^{21, 22} Digital CBT-I (dCBT-I) has shown promise in improving accessibility, but engagement and dropout rates remain challenges^{23, 24} and it is often not covered by health insurance carriers. Thus, pharmacotherapy alone is likely to continue to be first-line treatment for many practitioners 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.

It should be noted that 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 behavioral treatment 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 instruction

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 instruction alone is 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.²⁵ 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.²⁵ 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.²⁵ Given the currently-available evidence, the TF is unable to make recommendations regarding concurrent vs. 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 and sources of inequity to treatment access. CBT-I often requires multiple sessions with a trained provider, which may not be covered or may involve long wait times. 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 poses financial concerns, particularly with newer medications, that lack generic alternatives and increase treatment costs. Pharmacotherapy 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. 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. ²⁹ Information on important daytime side effects from combination treatments also needs to be more systematically integrated into RCTs. Additionally, long-term follow-up assessments are needed to better understand whether the durability of clinical effects are different for combination treatment vs. either treatment alone over time. ² Similarly, the observed clinically meaningful impact of combination treatment over CBT-I alone on increasing TST should be tested amongst insomnia phenotypes based on objective short sleep duration. ³⁰ 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. ²⁵ 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.

Limitations

The recommendations provided in this CPG should be considered in the context of limitations in the extant literature. Data are extremely limited regarding outcomes in patients from diverse racial/ethnic backgrounds, across sex/gender, socioeconomic strata, and with different medications and 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 homogenous 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. 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. Similarly, there was significant variation in how CBT-I was delivered across studies and which treatment components were included, making it difficult to draw conclusions about which specific components are most beneficial in combination therapy. We were also unable to identify a critical mass of studies that included single-component behavioral-psychological treatments or brief treatments of insomnia combined with pharmacological treatment.

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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