https://doi.org/10.5664/jcsm.8986

JCSM | Journal of Clinical Sleep Medicine

SPECIAL ARTICLES

Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline

Jack D. Edinger, PhD[1,2]; J. Todd Arnedt, PhD[3]; Suzanne M. Bertisch, MD, MPH[4]; Colleen E. Carney, PhD[5]; John J. Harrington, MD, MPH[6]; Kenneth L. Lichstein, PhD[7]; Michael J. Sateia, MD, FAASM[8]; Wendy M. Troxel, PhD[9]; Eric S. Zhou, PhD[10]; Uzma Kazmi, MPH[11]; Jonathan L. Heald, MA[11]; Jennifer L. Martin, PhD[12,13]

[1]National Jewish Health, Denver, Colorado; [2]Duke University Medical Center, Durham, North Carolina; [3]Michigan Medicine, University of Michigan, Ann Arbor, Michigan; [4]Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts; [5]Ryerson University, Toronto, Canada; [6]University of Nebraska Medical Center, Omaha, Nebraska; [7]University of Alabama, Tuscaloosa, Alabama; [8]Geisel School of Medicine at Dartmouth, Hanover, New Hampshire; [9]RAND Corporation, Pittsburgh, Pennsylvania; [10]Harvard Medical School, Dana-Farber Cancer Institute, Boston Children's Hospital, Boston, Massachusetts; [11]American Academy of Sleep Medicine, Darien, Illinois; [12]David Geffen School of Medicine at the University of California Los Angeles, Los Angeles, California; [13]VA Greater Los Angeles Healthcare System, Geriatric Research, Education and Clinical Center, Los Angeles, California

Introduction: This guideline establishes clinical practice recommendations for the use of behavioral and psychological treatments for chronic insomnia disorder in adults.

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

Recommendations: The following recommendations are intended as a guide for clinicians in choosing a specific behavioral and psychological therapy for the treatment of chronic insomnia disorder in adult patients. Each recommendation statement is assigned a strength ("strong" or "conditional"). A "strong" recommendation (ie, "We recommend…") is one that clinicians should follow under most circumstances. A "conditional" recommendation is one that requires that the clinician use clinical knowledge and experience, and to strongly consider the patient's values and preferences to determine the best course of action.

1. We recommend that clinicians use multicomponent cognitive behavioral therapy for insomnia for the treatment of chronic insomnia disorder in adults. (STRONG)
2. We suggest that clinicians use multicomponent brief therapies for insomnia for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)
3. We suggest that clinicians use stimulus control as a single-component therapy for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)
4. We suggest that clinicians use sleep restriction therapy as a single-component therapy for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)
5. We suggest that clinicians use relaxation therapy as a single-component therapy for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)
6. We suggest that clinicians *not* use sleep hygiene as a single-component therapy for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)

Keywords: chronic insomnia disorder, behavioral treatment, psychological treatment, clinical practice guideline

Citation: Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2021;17(2):255–262.

INTRODUCTION

Chronic insomnia disorder is a common sleep disorder that leads to impairment in health and functioning.[1,2] This clinical practice guideline is intended to update the previously published American Academy of Sleep Medicine (AASM) guidelines on the psychological and behavioral treatments of insomnia.[3] This updated guideline, in conjunction with the accompanying systematic review (SR),[4] provides a comprehensive update of the available evidence and a synthesis of clinical practice recommendations for the psychological and behavioral treatments of chronic insomnia disorder. It is intended to optimize patient-centered care by providing actionable recommendations for the use of specific behavioral and psychological treatments in adults with chronic insomnia disorder. Separate clinical practice guidelines for pharmacologic treatment of chronic insomnia disorder are available.[5]

The treatment of chronic insomnia disorder should be based on a diagnosis established using ICSD-3 or DSM-5 criteria,[6,7] and a comprehensive clinical history. Historically, in some settings patients have been offered only sleep hygiene as treatment for their chronic insomnia disorder; however, standard of care should be to provide one of the recommended interventions discussed within the guideline to patients with chronic insomnia disorder, taking into consideration the accessibility and resource requirements when deciding on the most appropriate treatment for a given patient. Follow-up care to evaluate symptoms at the conclusion of treatment is indicated, and residual sleep-related symptoms should be evaluated and addressed.

METHODS

The AASM commissioned a task force (TF) of sleep medicine and sleep psychology clinicians with expertise in 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 the guideline and SR documents. In accordance with the AASM's conflicts of interest policy, individuals were not 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, were required to recuse themselves from discussion or writing responsibilities related to the conflicts. All relevant conflicts of interest reported by the TF are listed in the Disclosures section.

The TF conducted a SR of the published scientific literature,[4] to answer two Patient, Intervention, Comparison, and Outcomes (PICO) questions related to the behavioral and psychological treatments for insomnia in adults. The review focused exclusively on efficacy of behavioral and psychological interventions of chronic insomnia disorder in adults, with and without comorbid conditions (**Table 1**), compared to a control or minimal intervention condition (PICO 1). The review also compared the effectiveness of different intervention delivery methods (eg, individual, group, telehealth, internet-based programs, telephone; PICO 2). The SR focused on the following critical patient-oriented, clinically relevant outcomes: patient reported sleep quality, sleep latency, wake after sleep onset and remission and responder rates. The TF considered remission and responder rates as the most influential critical outcomes for evaluating the quality of evidence. The review did not include comparisons of different interventions or combinations of pharmacotherapy with behavioral and psychological therapy.

These clinical practice recommendations were then developed according to The Grading of Recommendations Assessment, Development and Evaluation (GRADE) process was used to assess the evidence and assign a strength of recommendation,[8,9] based on the literature that provided data suitable for statistical analyses of the critical outcomes. The TF assessed the following four factors to determine the direction and strength of a recommendation: quality of evidence, balance of beneficial and harmful effects, patient values and preferences, and resource use. Details of these assessments can be found in the accompanying systematic review. Taking these major factors into consideration, each recommendation statement was assigned a strength ("strong" or "conditional"). When deemed necessary by the TF, additional information is provided in the form of "remarks" immediately following the recommendation statements. Remarks are based on the 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 recommendations in this guideline define interventions that should meet the needs of most patients in most situations. A "strong" recommendation is one that clinicians should follow for almost all patients (ie, something that might qualify as a quality measure). A "conditional" recommendation reflects a lower degree of certainty in the appropriateness of the patient-care strategy for all patients (**Table 2** shows the implications of recommendation strength). It requires that the clinician use clinical knowledge and experience, and strongly considers the individual patient's values and preferences to determine the best course of action. The ultimate judgment regarding any specific care must be made by the treating clinician and the patient, taking into consideration the individual circumstances of the patient, available treatment options, and resources. The AASM expects this guideline to have an impact on professional behavior, patient outcomes, and—possibly—health care costs. This clinical practice guideline reflects the state of knowledge at the time of publication and will be reviewed and updated as new information becomes available.

RECOMMENDATIONS

The following clinical practice recommendations are based on a systematic review and evaluation of evidence using the GRADE process. The implications of the strength of recommendations for guideline users are summarized in **Table 2** and the recommendations for interventions are summarized in **Table 3**. Remarks are provided as context for the recommendations and to guide clinicians in the implementation of these recommendations.

There was insufficient evidence to make recommendations for specific delivery methods (eg, individual, group, internet, self-help, video) for any of the treatments. For all treatments except for cognitive behavioral therapy for insomnia (CBT-I), there was insufficient data to evaluate efficacy within patient subgroups (ie, with or without comorbidities). In addition, there

Table 1—Descriptions of patient populations for subgroup analyses.

Patient Population*	Description
Patients with insomnia and no comorbidities	Patients diagnosed with chronic insomnia disorder: a) in the absence of identified sleep-disruptive comorbidities; or b) who met criteria for "primary insomnia" based on earlier diagnostic systems (eg, DSM-IIIR, DSM-IV and DSM-IV-TR)
Patients with insomnia and psychiatric comorbidities	Patients diagnosed with both chronic insomnia disorder and concurrent psychiatric comorbidities (eg, depression, posttraumatic 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 (eg, cancer, fibromyalgia, osteoarthritis)

*Study populations that do not meet the above descriptions or were a combination of the patient populations were not included in the subgroup analyses.

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

Strong Recommendation "We recommend…"	Almost all patients should receive the recommended course of action. Adherence to this recommendation could be used as a quality criterion or performance indicator.
Conditional Recommendation "We suggest…"	Most patients should receive 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 his or her values and preferences.

The ultimate judgment regarding the suitability of any specific recommendation must be made by the clinician.

were fewer than three studies meeting our inclusion criteria for the use of cognitive therapy, paradoxical intention, mindfulness, biofeedback and intensive sleep retraining; as a result, no recommendations are made about these treatments. A detailed review of the data for all interventions can be found in the accompanying systematic review.

Cognitive behavioral therapy for insomnia (CBT-I)

Recommendation 1: We recommend that clinicians use multicomponent cognitive behavioral therapy for insomnia for the treatment of chronic insomnia disorder in adults. (STRONG)

Remarks: This recommendation is based primarily on studies in which CBT-I was delivered by a trained professional to patients with and without comorbid conditions.

The TF made a strong recommendation in favor of CBT-I based on a large body of moderate quality evidence from 49 studies, including multiple, recent, large RCTs, showing clinically meaningful improvements in critical outcomes, patients highly preferring behavioral and psychological treatments, and favorable information on cost-effectiveness of CBT-I.

The TF assessed whether CBT-I improved patient-reported critical outcomes: remission rate, responder rate, sleep quality, sleep latency and wake after sleep onset. The TF identified 66 randomized controlled trials (RCTs) in adult patients diagnosed with chronic insomnia disorder that compared CBT-I to wait-list, minimal interventions, or placebo therapies. Forty-nine of the studies provided data suitable for meta-analyses for at least one critical outcome. Meta-analyses demonstrated clinically significant improvements in remission and responder rates with CBT-I compared to control conditions. Of these 49 studies, 11 studies included patients with insomnia and no comorbidities, six studies included patients with insomnia and comorbid psychiatric conditions and 12 studies included patients with insomnia and comorbid medical conditions. Each of these patient groups was analyzed separately. Twenty studies included a mix of patients with and without comorbidities and were not separately analyzed. Meta-analyses of sleep quality demonstrated clinically significant mean improvements in patients with insomnia and no comorbidities and patients with insomnia and comorbid psychiatric conditions. Meta-analyses of sleep latency and wake after sleep onset demonstrated clinically significant mean improvements in patients with insomnia and comorbid psychiatric conditions and in patients with insomnia and no comorbidities. Meta-analyses of remission and responder rates were clinically significant for all three subgroups. The overall quality of evidence was moderate due to imprecision. The quality of evidence was moderate for sleep latency, remission and responder rates. Benefits of CBT-I include treatment gains that are potentially durable over the long term without the need for additional interventions. CBT-I may reduce the need for pharmacologic therapy and thereby reduce patient risk of drug-related adverse events. The principal harms associated with CBT-I are symptoms of daytime fatigue and sleepiness, mood impairment (eg, irritability), and cognitive difficulties (eg, attention problems) during treatment; however, these undesirable effects are primarily restricted to the early stages of treatment, when behavioral therapies are introduced, and improve over time, typically resolving by the end of treatment. Based on clinical experience, the TF determined that the benefits of CBT-I strongly outweighed the short-term undesirable effects for adults with chronic insomnia disorder. Clinicians should also note that when sleep restriction therapy is used as a component of CBT-I, this treatment may be contraindicated in certain populations such as those working in high risk occupations (eg, heavy machinery operators or drivers) or those predisposed to mania/hypomania or with poorly controlled seizure disorders. While cost of treatment varies by delivery method, the cost-effectiveness of CBT-I is favorable, as CBT-I is a time-limited treatment, and the limited available data suggests significant costs of untreated chronic insomnia disorder. The clinical consensus of the task force was that CBT-I is preferred because it has superior long-term effectiveness and improvement in symptoms with minimal side effects as compared to control conditions. Based on their clinical experience, the TF determined that the vast majority of well-informed patients would choose CBT-I for the treatment of chronic insomnia disorder.

Brief therapies for insomnia (BTIs)

Recommendation 2: We suggest that clinicians use multicomponent brief therapies for insomnia for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)

The TF made a conditional recommendation in favor of BTIs based on a small body of moderate quality evidence from 7 studies showing clinically meaningful improvements in several critical outcomes, consideration that many patients prefer brief treatments, and the potential for BTIs to require only limited resources.

The TF assessed whether BTIs improved patient-reported critical outcomes: remission rate, responder rate, sleep quality, sleep latency and wake time after sleep onset. The TF identified 11 RCTs in adult patients diagnosed with chronic insomnia disorder that compared BTIs to wait-list,

Table 3—Summary of interventions.

Intervention	Treatment Type*	Description
STRONG RECOMMENDATION FOR USE		
Cognitive behavioral therapy for insomnia (CBT-I)	Multicomponent	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).
CONDITIONAL RECOMMENDATIONS FOR USE		
Brief therapies for insomnia (BTIs)	Multicomponent	BTIs include abbreviated versions of CBT-I (typically 1–4 sessions) emphasizing the behavioral components. BTIs 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 pretreatment 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 wake-time. 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 (eg, abdominal breathing, progressive muscle relaxation; autogenic training) and cognitive arousal (eg, guided imagery training; meditation) that may perpetuate sleep problems.
CONDITIONAL RECOMMENDATION AGAINST USE		
Sleep hygiene	Single-component	A set of general recommendations about lifestyle (eg, diet, exercise, substance use) and environmental factors (eg, 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.
NO RECOMMENDATIONS		
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.
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 (eg, 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.

(continued on following page)

Table 3—Summary of interventions. (continued)

Intervention	Treatment Type*	Description
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 therapies	Multicomponent or single-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).

*Multicomponent = this treatment is a combination of approaches, single-component = this treatment is delivered in isolation.

minimal interventions, or placebo, out of which 7 RCTs provided data suitable for meta-analyses for at least one critical outcome. Meta-analyses showed clinically significant improvements in remission rate, responder rate and sleep quality.

The overall quality of evidence was moderate due to imprecision. In addition to benefits of treatment, BTIs may use fewer resources than CBT-I as fewer treatment sessions are required. Similar to CBT-I, the TF determined that the undesirable effects of BTIs are minimal and short-term, and that the balance of benefits vs harms favors the use of BTIs over control conditions. Clinicians should also note that when sleep restriction therapy is used as a component of BTIs, this treatment may be contraindicated in certain populations such as those working in high risk occupations (eg, heavy machinery operators or drivers) or those predisposed to mania/hypomania or with poorly controlled seizure disorders. Based on their clinical experience the TF determined that the vast majority of well-informed patients would choose BTIs for the treatment of chronic insomnia disorder.

Stimulus control

Recommendation 3: We suggest that clinicians use stimulus control as a single-component therapy for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)

The TF made a conditional recommendation in favor of stimulus control as a single-component therapy based on a small body of low quality evidence from 8 studies showing clinically meaningful improvements in one critical outcome, consideration that some patients may prefer stimulus control, and the potential for stimulus control to require only limited resources compared to multicomponent or multistep single-component approaches.

The TF assessed whether stimulus control as a single-component treatment improved patient-reported critical outcomes: remission rate, responder rate, sleep quality, sleep latency and wake time after sleep onset. The TF identified 8 RCTs in adult patients diagnosed with chronic insomnia disorder that compared stimulus control to wait-list, minimal interventions, or placebo, all of which provided data suitable for meta-analyses for at least one critical outcome. These studies demonstrated clinically significant improvements in remission rate.

The overall quality of evidence was low due to imprecision and risk of bias. Based on their clinical experience, the TF determined that the potential benefits of stimulus control outweighed the likely minimal risk and determined that this treatment may be appealing due to the sleep improvements it produces. The TF noted that stimulus control may need to be adapted for safety in some patient populations, such as those at high risk for falls, with mobility issues, or using sedative-hypnotics. The use of stimulus control may result in some cost and resource use savings compared to multicomponent therapies such as CBT-I, but such savings would be negligible compared to other single-component therapies. Based on their clinical experience and limited available literature, the TF determined that the majority of well-informed the patients would choose stimulus control as a treatment for chronic insomnia disorder.

Sleep restriction therapy

Recommendation 4: We suggest that clinicians use sleep restriction therapy as a single-component therapy for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)

The TF made a conditional recommendation in favor of sleep restriction therapy as a single-component therapy based on a small body of low quality evidence from 6 studies showing clinically meaningful improvements in several critical outcomes, consideration that some patients prefer sleep restriction

therapy, and the potential for sleep restriction therapy to require only limited resources.

The TF assessed whether sleep restriction therapy as a single-component treatment improved patient-reported critical outcomes: remission rate, responder rate, sleep quality, sleep latency and wake after sleep onset. The TF identified 6 RCTs in adult patients diagnosed with chronic insomnia disorder that compared sleep restriction therapy to wait-list, minimal interventions, or placebo out of which 4 RCTs provided data suitable for meta-analyses for at least one critical outcome. These studies demonstrated clinically significant improvements in responder and remission rates.

The overall quality of evidence was low due to imprecision and risk of bias. Potential harms may occur in the early phases of treatment such as increased daytime sleepiness and difficulties with concentration, but these effects typically dissipate as treatment progresses and time in bed is extended as sleep improves. Patients may find it challenging to adhere to sleep restriction therapy due to shortened time in bed or the resulting increase in daytime sleepiness or fatigue. In some cases (eg, older adults, chronic pain, depression), patients may find it difficult to identify meaningful activities to fill the additional time out of bed that is required by the sleep restriction protocol. Clinicians should note that this treatment may be contraindicated in certain populations such as those working in high risk occupations (eg, heavy machinery operators or drivers) or those predisposed to mania/hypomania poorly controlled seizure disorders or excessive daytime sleepiness. The use of sleep restriction therapy may result in some cost and resource savings compared to multicomponent therapies such as CBT-I, but resource use is likely similar to other single-component therapies. Based on their clinical experience, the TF determined that the vast majority of well- informed patients would choose sleep restriction therapy as a treatment of chronic insomnia disorder if the treatment rationale is adequately explained and the patient is monitored by a clinician during treatment.

Relaxation therapy

Recommendation 5: We suggest that clinicians use relaxation therapy as a single-component therapy for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)

The TF made a conditional recommendation in favor of relaxation therapy as a single-component therapy based on a small body of low quality evidence from 5 studies showing clinically meaningful improvements in one critical outcome, consideration that some patients prefer relaxation therapy, the fact that most mental health providers are trained to deliver this form of treatment, and the potential for relaxation therapy to require only limited resources.

The TF assessed whether relaxation therapy as a single-component treatment improved patient-reported critical outcomes: sleep quality, sleep latency and wake after sleep onset, remission rate, and responder rate. The TF identified 12 RCTs in adult patients diagnosed with chronic insomnia disorder that compared Relaxation Therapy to wait-list, minimal interventions, or placebo, out of which 5 RCTs provided data suitable for meta-analyses for at least one critical outcome. These studies demonstrated clinically significant improvements in responder rate and sleep quality.

The overall quality of evidence was low due to risk of bias and imprecision. The TF determined that the modest benefits of relaxation likely outweigh the minimal potential harms and burdens. Based on their clinical experience, the TF determined that relaxation therapy can be delivered at relatively low cost and with minimal additional resources, given that many therapists and clinical providers have training in relaxation therapy. As a result, this treatment is widely available across clinical settings. Based on their clinical experience, the TF determined that majority of well-informed patients would choose relaxation therapy as a treatment for chronic insomnia disorder.

Sleep hygiene

Recommendation 6: We suggest that clinicians *not* use sleep hygiene as a single-component therapy for the treatment of chronic insomnia disorder in adults. (CONDITIONAL)

*Remarks: Although sleep hygiene is **not** recommended as a single-component approach (ie, the only treatment) for patients with chronic insomnia disorder, sleep hygiene may be included in multicomponent interventions.*

The TF made a conditional recommendation against use of sleep hygiene as a single-component therapy based on indirect evidence showing that sleep hygiene was less effective than other treatments when used alone. Only two RCTs, which provided low quality evidence, showed clinically meaningful improvements in one critical outcome with sleep hygiene alone. Furthermore, allocation of resources for sleep hygiene alone may divert resources and delay the use of other single- or multicomponent behavioral interventions that are more effective.

The TF assessed whether sleep hygiene, as a single-component treatment, improved patient-reported critical outcomes: remission rate, responder rate, sleep quality, sleep latency and wake after sleep onset. The TF identified three RCTs in adult patients diagnosed with chronic insomnia disorder that compared sleep hygiene to wait-list, minimal interventions, or placebo, of which one RCT provided data suitable for posttreatment comparisons of sleep hygiene and wait-list control for at least one critical outcome. The study demonstrated a clinically significant higher responder rate in the sleep hygiene group compared to control, although within the same study CBT-I was superior to sleep hygiene alone. Those who 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 overall quality of evidence was low due to imprecision and risk of bias. The potential benefits of sleep hygiene as a single-component therapy were considered by the TF to be minimal and not more favorable compared to control conditions overall. When sleep hygiene was used as a control group in studies of other interventions, it was less beneficial than active treatments. Sleep hygiene education is considered inexpensive; however, no formal cost analyses have been conducted, and this

minimally effective treatment may divert resources away from more effective ones. The TF judged that any resources utilized for a treatment without sufficient evidence may be considered unfavorable. Based on their clinical experience, the TF determined that the vast majority of well-informed patients would not choose sleep hygiene or benefit from it as a single-component therapy for the treatment of chronic insomnia disorder.

DISCUSSION

The current recommendations were developed to guide treatment decision-making as clinicians work with adult patients with chronic insomnia disorder. The recommendations provided are based on a systematic review of the clinical trial literature that included meta-analyses of extracted data when possible. The TF used the GRADE process for assessing the evidence collected during the review to formulate the recommendations.

Psychological and behavioral treatments for chronic insomnia disorder comprise a variety of behavioral and cognitive "nonpharmacologic" treatments for chronic insomnia disorder. CBT-I is generally regarded as the treatment of choice, has the most evidence available in the literature and is the only approach to receive a Strong recommendation. The following considerations should inform use of this intervention. First, CBT-I is a multicomponent intervention, and the exact treatment components vary across studies. All studies included sleep restriction therapy, stimulus control and some form of cognitive therapy; however, the cognitive component varied widely. Whether or not relaxation strategies or sleep hygiene were included in the CBT-I regimen varied across studies as well. It was beyond the scope of this CPG to recommend a specific CBT-I protocol, and these variations did not appear to systematically impact the effectiveness of the treatment. In-person one-on-one delivery of CBT-I by a trained CBT-I provider is the most widely evaluated delivery method and is generally considered the best available treatment. While the number of trained CBT-I providers is growing, health care professionals may have difficulty identifying such providers and connecting patients with them. Additionally, patients may face barriers to accessing CBT-I, including higher out-of-pocket costs as compared to medications, or locating a skilled provider in their geographic region. Since CBT-I is typically provided by mental health professionals, there may also be a perceived stigma in seeking care. In light of variability in access and costs, clinicians should discuss different CBT-I delivery modalities with their patients (eg, in person individual treatment, group treatment, internet-based programs), and align the delivery modality based on availability, affordability, treatment format, duration and the patient's preferences and values.

Whereas CBT-I is the treatment of choice for most patients, BTIs, sleep restriction therapy, stimulus control, and relaxation therapy are also potentially useful interventions with minimal undesirable effects, and thus all received Conditional recommendations. These recommendations are based on a variable number of studies across these therapies. In addition, there were some interventions for which insufficient evidence was available to make recommendations as single-component treatments (paradoxical intention, intensive sleep retraining, biofeedback, cognitive therapy and mindfulness). In some instances, research is limited because some therapies are relatively new to the insomnia treatment literature (eg, intensive sleep retraining) while other, single-component therapies (eg, cognitive therapy) have been incorporated into CBT-I, resulting in an absence of studies comparing the single-component therapy to control over time. Thus, it seems doubtful that the efficacy of some single-component therapies will be further evaluated in future research. The TF felt that these therapies should still be considered as viable treatment alternatives when CBT-I is not available or not desired by, or appropriate for, the patient. Challenges with finding providers skilled in delivering BTIs or single-component therapies remain, as many providers do not receive training in any sleep-specific modalities. While sleep hygiene is not recommended to be used by itself, as a single-component therapy, due to the lack of evidence for its efficacy, certain common-sense principles of sleep hygiene (eg, avoiding excessive caffeine or alcohol) may nevertheless be helpful in a comprehensive treatment approach, and consideration of sleep hygiene factors is a common element of CBT-I. The principles of sleep hygiene are now widely available to patients as general health information, and clinician time should be allocated to delivery of interventions with the best evidence. As such, clinical care devoted to sleep hygiene as a single-component approach may impact the availability of clinical care devoted to more effective single- or multicomponent treatments Based on these evidence-based recommendations, clinicians should spend time and resources offering CBT-I, BTIs or one of the single-component therapies discussed above to patients with insomnia disorder, rather than providing sleep hygiene alone. Education of front-line providers on more effective alternatives to sleep hygiene is needed.

Some of the challenges patients face when undergoing any of these psychological treatments include the ability to attend sessions and adhere to treatment recommendations. In most cases, a noticeable improvement in insomnia symptoms is not immediate (as is the case with pharmacological interventions), and CBT-I treatment typically ranges from 4–8 visits, both of which may serve as barriers to treatment completion. Patients may also get discouraged if immediate results are not observed. It is important for the treating provider to recognize these challenges and help set realistic expectations before starting treatment. When discussing treatment options for chronic insomnia disorder, patients should be reminded that psychological and behavioral insomnia therapies typically produce gradual improvements in insomnia symptoms, but the benefits are durable beyond the end of treatment. Available evidence suggests that the initial undesirable effects (eg, sleepiness and fatigue) are typically mild and resolve quickly for most patients. In selecting appropriate treatments, clinicians should additionally consider comorbid medical and psychiatric conditions that may change the balance of benefits vs harms (eg, the potential adverse effects of treatment-induced sleep deprivation on seizure disorder or bipolar disorder).

REFERENCES

1. Daley M, Morin CM, LeBlanc M, Grégoire JP, Savard J. The economic burden of insomnia: direct and indirect costs for individuals with insomnia syndrome, insomnia symptoms, and good sleepers. *Sleep*. 2009;32(1):55–64.
2. Fernandez-Mendoza J, Shea S, Vgontzas AN, Calhoun SL, Liao D, Bixler EO. Insomnia and incident depression: role of objective sleep duration and natural history. *J Sleep Res.* 2015;24(4):390–398.
3. Morgenthaler T, Kramer M, Alessi C, et al. American Academy of Sleep Medicine. Practice parameters for the psychological and behavioral treatment of insomnia: an update. An American Academy of Sleep Medicine report. *Sleep*. 2006;29(11): 1415–1419.
4. Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med.* 2021:17(2):263–298.
5. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(2):307–349.
6. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. Washington, DC: American Psychiatric Association Publishing; 2013.
7. American Academy of Sleep Medicine. *International Classification of Sleep Disorders*. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
8. Guyatt G, Oxman AD, Akl EA, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol.* 2011;64(4): 383–394.
9. Morgenthaler TI, Deriy L, Heald JL, Thomas SM. The evolution of the AASM clinical practice guidelines: another step forward. *J Clin Sleep Med.* 2016; 12(1):129–135.

ACKNOWLEDGMENTS

The task force thanks and acknowledges the early contributions of Charles M. Morin, PhD and Vanessa Gonzalez, MPH. Dr. Morin served as a member of the task force during the initial stages of the systematic review, which served as the basis for this clinical practice guideline, and Ms. Gonzalez was the staff for the initial phase of the project. The task force also thanks Daniel J. Buysse, MD; Rachel Manber, PhD; and Colin E. Espie PhD, DSc, FRSM, FBPsS for serving as external reviewers of the document and providing valuable feedback.

SUBMISSION & CORRESPONDENCE INFORMATION

Submitted for publication November 5, 2020
Submitted in final revised form November 5, 2020
Accepted for publication November 5, 2020
Address correspondence to: Jack D. Edinger, PhD, National Jewish Health, 1400 Jackson St, Denver, CO 80206; Email: EdingerJ@NJHealth.org

DISCLOSURE STATEMENT

The development of this paper was funded by the American Academy of Sleep Medicine. Dr. Martin serves on the AASM Board of Directors. Ms. Kazmi is employed by the AASM. Mr. Heald was employed by the AASM during his work on this paper, but his employment by the AASM ended in July 2020. The following include all the conflicts managed throughout guideline development. Dr. Edinger received funding from Merck for an insomnia research study, and his research program was loaned portable PSG recorders from Philips/Respironics to support a NIMH funded research grant. Dr. Arnedt was loaned an FDA-cleared device treatment for insomnia by Ebb (2018–present), served as a consultant to Magna Seating Systems Engineering until 2016 to develop a report on drowsy driving, served on a contract project with NHTSA on drowsy driving (2018–present) and was a co-investigator for a study funded by the NBA contracted with the University of Michigan to evaluate the validity of commercially available devices to measure sleep (ended 2019). Dr. Bertisch was a co-investigator on an insomnia research project funded by Merck (ended 2017), serves as an unpaid member of the Board of Directors of the Alliance of Sleep Apnea Partners, a non-profit patient centered group. Dr. Lichstein is a member of the insomnia advisory board for Merck, the topic of which is unrelated to the behavioral treatments of insomnia. Dr. Sateia served as a consultant for Physicians Seal for melatonin – 30 minutes consultation in 2018. Dr. Troxel was a co-investigator on a study about the prevalence and risk factors for nocturia using data from the British Healthy Workers (ended March 2020), served as a consultant for Guidepoint, as a subject matter expert on sleep to industry clients (January 2018–present), has received research funding from the National Institutes of Health, was principal investigator on a grant funded by Feelmore Labs to review a clinical trial design and protocol for an investigational neurostimulation device (ended June 2020), and serves on the scientific advisory board for Feelmore Labs.