

# Next Steps for Patients Who Fail to Respond to Cognitive Behavioral Therapy for Insomnia (CBT-I): the Perspective from Behavioral Sleep Medicine Psychologists

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## Abstract

**Purpose of Review** Cognitive behavioral therapy for insomnia (CBT-I) is a brief and effective non-pharmacologic treatment for insomnia that is recommended as the first-line treatment for chronic insomnia. Despite the benefits for many patients, 25–40% of patients do not have remission of their insomnia disorder. In this article, we discuss predictors of suboptimal response and a framework for assessing and mitigating factors that may interfere with treatment.

**Recent Findings** For patients with a suboptimal response to CBT-I, there is no established protocol to follow because of having no published studies of non-pharmacologic treatments directly targeting CBT-I non-responders. We present evidence-based treatments beyond CBT-I that may benefit patients who are suboptimal CBT-I responders including techniques for promoting adherence and other non-pharmacologic treatments including CBT to address psychiatric symptoms, mindfulness, exercise, bright light, and melatonin treatments. We also discuss the importance of assessment of comorbid sleep disorders and the potential use of hypnotic medications.

**Summary** There are other potential non-pharmacologic treatment that may be beneficial to patients with suboptimal response to CBT-I. However, further research is needed to guide treatment algorithms for patients who have suboptimal response to CBT-I in order to inform treatment decision making.

**Keywords** Cognitive behavioral therapy for insomnia (CBT-I) · Insomnia · Non-pharmacologic treatment · Comorbid · Hypnotic medications

## Introduction

Cognitive behavioral therapy for insomnia (CBT-I) is a brief and effective non-pharmacologic treatment for insomnia. In this treatment, patients attend approximately 4–6 sessions with a clinician trained in providing CBT-I. The sessions focus on education about the factors that control sleep and teach patients skills to manage their insomnia, including scheduling an appropriate sleep window (sleep restriction), reducing time awake spent in bed (stimulus control), reducing cognitive and physiological arousal (cognitive strategies and relaxation techniques), and reducing sleep-interfering behaviors (commonly referred to as sleep hygiene). These techniques lead to remission of insomnia disorder in 75–80% of patients with “primary” insomnia or insomnia in the absence of comorbidities [1] and 36% of patients with comorbid psychiatric or medical conditions [2]. Based on these data and others, the American College of Physicians published a position statement which recommended CBT-I as the first-line treatment for chronic insomnia [3]. Given that a significant number of patients, however, have at least residual insomnia symptoms, further treatment recommendations are needed in determining the next steps in their treatment for these patients. In this article, we have chosen to use the term “suboptimal responder” to include patients who also improve but do not meet clinical criteria for remission. The goal of this article is to discuss the factors that may contribute to suboptimal response to CBT-I and the evidence for the next steps in their care. We will discuss the following: (1) defining suboptimal response and what is known about how to predict suboptimal

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responders, (2) consideration of the external (patient related, environmental) factors that may contribute suboptimal response, (3) evaluating the internal (i.e., treatment related) factors that may contribute to suboptimal response, and (4) strategies to address suboptimal response.

### Defining CBT-I Non-responder and Predicting Who Will Have a Suboptimal Response

In clinical practice, patients are usually the ones who are alerting us when they have a suboptimal response with comments such as “I saw the psychologist but I’m still having trouble sleeping” or “I tried sleep restriction and it didn’t work” or by demonstrating lack of change or dropping out after several sessions of CBT-I. In the context of randomized trials of CBT-I, investigators set *a priori* criteria for patient response and remission. Most often, response has been defined as a decrease in severity on a validated instrument such as the Insomnia Severity Index [4] or by meeting a threshold of symptom improvement on sleep diaries (e.g., sleep onset latency < 30 min). There are only a few studies that have evaluated predictors of response to CBT-I. A recent meta-analysis compared trials of patients with comorbid insomnia and demonstrated that those who have comorbid medical and psychiatric illness have a lower response and remission rate with CBT-I [2•]. In addition, patients with comorbid psychiatric conditions were more likely to have remission of insomnia compared to patients with comorbid medical conditions [2•]. Recent data has highlighted poorer response to CBT-I among patients with insomnia with objective short sleep duration [5••]. Although it has been proposed that insomnia with objective short sleep duration is perhaps a subtype that would respond better to treatment with hypnotic medications, few studies have evaluated treatment in specific subgroups [6] of CBT-I non-responders. Importantly, several factors have been found to not be predictors of CBT-I response including age and insomnia severity [7, 8].

### External Factors That May Contribute to Suboptimal Response

External factors are some of the first factors to consider when patients have a suboptimal response. For example, patients may be dealing with unstable medical or psychiatric disorders, changing doses of medications, severe pain, or hospitalizations. These factors would preclude the ability to participate in sessions and continue at home practice consistently. Patients with stable but uncontrolled medical conditions would also be better able to participate and benefit from treatment if their medical care is optimized. Other external factors that may interfere with treatment include logistical and

financial barriers such as unreliable transportation, insurance coverage and lack of child care and unstable work hours as these may interfere with attendance to sessions. Frequent business travel may also be challenging conditions for the patient to attend therapy or follow-up with the recommendations for behavior change such as a consistent sleep schedule. These medical, psychiatric, and logistical factors should be evaluated before beginning CBT-I, and if needed, a plan for mitigation should be put in place (e.g., problem solving transportation, delaying the start of treatment until a time with low travel frequency, if possible).

### Role of Treatment-Related Factors: Patient Adherence and Therapist Training

Patients may also have suboptimal response because they did not receive the adequate “dose” of the treatment. Adherence to CBT-I recommendations have been defined as attending sessions, completing homework (e.g., sleep diaries), and following recommendations for the sleep schedule in sleep restriction. Matthews and colleagues, in 2013, conducted a systematic review of adherence in CBT-I and demonstrated that patient attitudes and beliefs about CBT-I were consistent predictors of adherence whereas medical and psychiatric disorders were not associated with adherence in most studies. There is some evidence that adherence to sleep restriction and stimulus control (as measured by sleep diaries) was associated with better outcomes of CBT-I but this may be difficult to compare between studies because many studies do not contain objective measures of adherence.

Another area to consider in the suboptimal-responding patient is whether the patient received the intended treatment. There is evidence that although the behavioral therapy (BT) and cognitive therapy (CT) components of CBT-I both improve insomnia symptoms, the greatest remission rates are seen in patients who receive combined treatment (CBT-I) [9]. In addition, there is poor access to practitioners certified in CBT-I in many parts of the country and the world, which makes it likely that in some areas, patients who say that have attended CBT have not received the insomnia-specific aspects of treatment. There are currently 752 (659 in the USA) certified BSM practitioners [10]. The Society for Behavioral Sleep Medicine (SBSM) is in the process of re-establishing a credentialing exam that will include non-PhDs with mental health training who are eligible for certification. Clinical trials of CBT-I have demonstrated successful interventions using psychologists and also non-psychologists such as nurses with insomnia-specific training and supervision. Manber and colleagues developed and disseminated CBT-I to the VA [11] which greatly improved access to care. Even in the VA system, however, there are clinical areas with trained CBT-I providers that still have poor documentation in patient charts of

insomnia complaints and less than optimal referral rates for CBT-I. A recent survey of VA primary care providers demonstrated that even within hospital networks with access to CBT-I, most patients are still being provided with insufficient recommendations (e.g., sleep hygiene measures such as reducing caffeine) rather than making a referral to CBT-I [12].

### Treatment Options for Patients with Suboptimal Response to CBT-I

There are few studies that evaluate behavioral treatment options for patients who have suboptimal response to treatment. In the next paragraphs, we discuss some suggestions for consideration in the next steps including strategies for assessing patient preference and motivation for treatment, when you should assess for other sleep disorders and other possible behavioral treatments.

**Assessing Motivation and Patient Preferences** Given the importance of adherence to treatment recommendations, patient motivation is key and may be a main factor in suboptimal response. The treatment recommendations include setting regular bed times and wake up times, getting out of bed in the middle of the night when they cannot sleep, and reducing sleep interfering, although likely pleasurable, behaviors (e.g., having a smart phone or watching TV in bed). These changes may be more difficult for some than others, and patients' motivation to engage in treatment may be a limiting factor. Prior to initiating CBT-I, it is important to educate patients on the time and effort required in the treatment and whether they are able to commit to it given this information. It is possible, that even if they are interested, it may be appropriate to consider the strategy of a short-term hypnotic until a time they can devote to treatment (e.g., after final exams).

Monitoring patient engagement in treatment and adherence can determine whether adherence is a factor in suboptimal response. All patients should be monitored by sleep logs to determine their adherence and progress in CBT-I. Furthermore, actigraphy may also be helpful for assessing whether suboptimal response is related to patient non-adherence. Assessing patient preference is important.

For patients who are not adherent, motivational interviewing techniques [13] may be useful for assessing motivation and resolving ambivalence regarding engaging in CBT-I. For example, when initially presenting CBT-I to a patient, the clinician may consider asking open-ended questions about the patient's readiness to change their sleep behaviors and perceived barriers to change (e.g., "What do you think about making these changes to your sleep schedule?" "How will this fit into your current lifestyle?"). Open-ended questions give patients opportunities to express any concerns they have about engaging

in treatment, and discern any potential barriers to its success. Patients who present with ambivalence about making changes (e.g., not wanting to wake up on the same time on the weekdays and weekends) may be presented with decisional balance (e.g., "On the one hand, you want to improve your sleep, and on the other hand, you really like some of the habits you have right now. Where should we go from here?" or other techniques as outlined in motivational interviewing [13]). Although relaxing the treatment recommendations by "downgrading" the assignment (e.g., extending time in bed by 1 h on the weekends, allowing the patient to watch TV for 20 min before turning it off to sleep) may interfere to some degree with progress in treatment, it may increase their commitment to making other behavioral changes (e.g., maintaining a strict wake time on weekdays). It also may be helpful to troubleshoot and consider altering or downgrading aspects of the treatment that are difficult for the patient to complete, such as reducing the number of items on the sleep diary. Despite promise of using motivational interviewing as an adjunct approach to CBT-I, there is not a significant amount of research in this area. MI approaches have been used in obstructive sleep apnea (OSA) treatment [14]. More work needs to be done to determine if motivational interviewing enhances treatment success rates of CBT-I, particularly those with adherence problems.

**Assessment of Other Sleep Disorders** All patients seeking treatment for insomnia should complete basic screening in the clinical interview or using questionnaires to assess risk for comorbid sleep disorders such as circadian rhythm disorders, OSA, and Willis-Ekbom Disease/Restless Legs Syndrome (WED/RLS). For patients who have suboptimal response to behavior treatment despite good adherence to CBT-I, the possibility of further screening for comorbid sleep disorders should be discussed, such as an overnight polysomnogram. A recent review of comorbid OSA and insomnia demonstrated that between 35 and 77% of patients with insomnia presenting to sleep disorders, clinics also had comorbid OSA [15]. The insomnia populations with the highest prevalence of OSA included military personnel (60%) [16] and older adults (68.7%) [17]. Researchers have proposed treatments combining CBT-I with OSA [18, 19] which may address co-occurring symptoms such as fatigue. In addition to OSA, patients may have comorbid WED/RLS that affects progress in treatment. The finding of periodic limb movements (PLMs) on a diagnostic sleep study may lead the sleep physician to treat the PLMs and determine whether sleep quality improves.

**Psychotherapy for Depression or Anxiety** Several studies among patients with both insomnia and depression suggest that there is an antidepressant effect of CBT-I itself. In 2017, Carney compared CBT-I with antidepressant medication to

CBT-I and placebo with a sleep hygiene control [20]. Results of this study demonstrated CBT-I alone improved both sleep (objective and subjective) and depression whereas the other conditions improved depression and subjective insomnia symptoms but did not impact objective sleep variables. In addition, a 3-year follow-up of online CBT for depression compared with CBT-I demonstrated that long-term improvements for both mood and sleep were greatest in the group that received CBT for insomnia compared with CBT for depression [21]. These studies both support improvements in depression among participants with depression and insomnia. For those with persisting insomnia symptoms, however, it is unknown whether initiating antidepressant medication and/or CBT focused on depression would improve insomnia outcomes beyond completing CBT-I.

One recent study suggests that the cognitive components of CBT-I may be particularly helpful for patients with psychiatric disorders. In 2016, Belanger and colleagues conducted a secondary analysis of a randomized trial CBT-I that compared outcomes for patients with comorbid anxiety or depression to those without any psychiatric comorbidity [22]. In this study, participants with comorbid psychiatric disorders had better outcomes if they received both the cognitive and behavioral components together (rather than only the behavioral components alone). Therefore, greater attention to cognitive aspects may be beneficial for this population. There is less data about how to improve insomnia treatment for patients with anxiety disorders. A recent case series evaluated sequential treatment of CBT for insomnia and CBT for anxiety among patients with GAD and found that patients who first received CBT for the GAD symptoms and second received the CBT for insomnia had greater improvements in worry and insomnia [23].

**Using Technology to Reduce Barriers** There is growing evidence in support of the use of technology-delivered CBT-I. The use of technology-assisted treatment for insomnia may reduce logistical barriers for some patients such as transportation [24] or engage a selection of patients who prefer this modality. Both telephone-based and web-based CBT-I have demonstrated to be effective for improving insomnia symptoms. A recent large trial with 1-year follow-up demonstrated internet-delivered CBT-I was not inferior to face to face CBT-I [24].

### Adjunct Behavioral Sleep Medicine Treatments

For patients who have not responded to CBT-I, there are other treatment options available. Evidence, however, is limited in their use for patients with suboptimal response to CBT-I. We discuss mindfulness, exercise, use of bright light therapy, and melatonin.

**Mindfulness** Mindfulness-based cognitive therapy (MBCT) has recently been adapted to treat insomnia, and a new clinical manual became available this past year [25]. Mindfulness refers to conscious non-judgmental awareness of the present moment. The meditation and cognitive strategies used in MBCT may be particularly helpful for insomnia patients with active minds and hyperarousal that prevent them from initiating or returning to sleep. A meta-analysis of six randomized clinical trials determined that mindfulness-based strategies are effective in treating sleep disturbances compared to control groups and specifically reduced total wake time and sleep onset latency and increased sleep quality and sleep efficiency [26].

**Exercise** Exercise is one of the most beneficial interventions for health, including for sleep quality. To date, there have been several studies that have shown that exercise substantially improves sleep quality and vitality in insomnia [27]. Interestingly, the effects of exercise on sleep are as large as those of CBT-I and hypnotic medications [28]. Exercise may be used as an adjunct to combat the fatigue and sleepiness associated with sleep restriction. One randomized controlled trial demonstrated that patients instructed to increase physical activity in addition to engaging in sleep restriction demonstrated greater improvements in sleepiness, fatigue, and sleep efficiency than those of sleep restriction alone [29]. Recent evidence supports the idea that chronic exercise engagement is beneficial for sleep in patients with insomnia. A 6-month exercise program in Finnish overweight and obese men with chronic insomnia significantly reduced objective sleep onset latency, subjective difficulty initiating sleep, and depressive symptoms [30].

The literature is somewhat mixed regarding the effects of an acute bout of exercise on sleep the following night. Previous work has demonstrated that acute bouts of exercise are related to significant reductions in sleep onset latency and wake time after sleep onset and increases in total sleep time and sleep efficiency, but most of these studies were conducted among non-insomnia populations [31]. On the other hand, a recent small study of the acute effects of a single morning or evening exercise session did not improve subjective sleep quality in older patients with difficulty initiating sleep or early morning awakenings. Morning exercise, however, did decrease the number of stage shifts throughout the night and number of wake epochs during the second half of the night in patients with difficulty initiating sleep [32].

**Use of Bright Light and Melatonin** Circadian factors may play a role in insomnia in the development and maintenance of insomnia for some patients. Evidence suggests that those with evening chronotype are more likely to report non-restorative sleep [33] and that sleep onset insomnia may be related to phase delay in some patients. Further, patients who shift their

chronotypes toward morningness during behavioral sleep interventions experience greater improvements in depression, positive affect, and sleep quality [34]. Thus, it may be helpful to use circadian, including light therapy and melatonin, as adjunct treatments to CBT-I to address circadian factors among patients who may have a phase advance or delay component [35]. Use of bright light therapy is considered a treatment standard for circadian rhythm sleep wake disorders [36] but is not considered an option based on the American Academy of Sleep Medicine insomnia practice parameters [37]. Light is mentioned in the recently released European guidelines for the diagnosis and treatment of insomnia as an area in need of further evaluation [38]. A recent meta-analysis of 15 studies demonstrated a small to medium effect size for the use of light therapy for treating insomnia. These positive studies, however, had mostly small sample sizes. In addition, there was inconsistency in the number of days, light intensity, timing, and duration used across studies. The impact of melatonin on insomnia was also evaluated in a recent meta-analysis [39] and reported there are five randomized placebo-controlled studies of the use of insomnia. For both light and melatonin studies, the outcomes are expressed in minutes of change in sleep diaries or questionnaires rather than response and remission criteria, which limits the usefulness of the findings. Further, there is no consensus on what is the optimal dose or timing in insomnia and none of these studies have specifically focused on patients with suboptimal response to CBT-I. Given the costs and side effect profiles for bright light therapy and melatonin are low, it may be a useful adjunct in an insomnia patient with suboptimal response who is interested in additional behavioral treatments.

### Considering Referral to Discuss Hypnotic Medication

Patients with suboptimal response to CBT-I may benefit from a trial of hypnotic medication. There is preliminary evidence that patients with suboptimal response to CBT-I may benefit from referral to a sleep medicine physician to discuss a trial of hypnotic medication. There is recent, preliminary evidence from a sequential treatment trial in which patients were assigned to BT or zolpidem and then those who did not remit, were reassigned to the other treatment or trazodone [40]. Results suggested that those who received BT then were randomized to switch to zolpidem, had a higher remission rate than those who remained in BT, or were assigned to trazodone. The results are preliminary but suggest an important role for sequential treatment for those who have suboptimal response to behavioral therapies.

### Conclusion

In summary, despite the benefits of CBT-I to a large number of patients, a substantial number of patients fail to remit or

respond to the treatment. More research is needed to predict and focus additional therapies to improve sleep and quality of life of these patients. We recommend evaluating non-responders first in their adherence, motivation and ability to participate in treatment, and responding in a patient-centered manner in planning the next steps, whether it be exploring pharmacologic treatment, adjunctive behavioral treatments, or psychotherapy.

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### Compliance with Ethical Standards

**Conflict of Interest** Kelly Glazer Baron and Stephanie Hooker declare no conflicts of interest.

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- Of major importance

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