## **EDITORIAL**

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"The coming years hold out promising opportunities for learning more about the mechanisms underlying successful treatment of insomnia..."

<sup>1</sup>Department of Psychology, University of Arizona, Tucson, AZ 85721–0068, USA <sup>2</sup>Department of Psychiatry & Behavioral Sciences, Stanford University, Stanford, CA 94305, USA \*Author for correspondence: Tel.: +1 520 621 5705 E-mail: bootzin@u.arizona.edu



# Future outlook of nonpharmacological treatments for insomnia in adults: clinical trial progress

CLINICA

INVESTIGATI

## Richard R Bootzin\*1 & Rachel Manber<sup>2</sup>

Meta-analyses [1,2], treatment guidelines [3] and a NIH State-of-the-Science Conference statement in 2005 [4] have concluded that the most widely evaluated nonpharmacological treatment for chronic insomnia in adults, cognitive-behavior therapy for insomnia (CBT-I), is efficacious. CBT-I is a multicomponent treatment consisting of stimulus control therapy, sleep restriction therapy, cognitive therapy, psychoeducation about sleep and sleep hygiene, arousal reduction procedures, such as relaxation and meditation, and methods for changing sleep–wake circadian rhythms such as the scheduling of exposure to bright light. See Bootzin and Epstein [5] for descriptions of the CBT-I components.

Both hypnotics and CBT-I improve sleep [2]. An advantage that CBT-I has over the prescription of hypnotics is that following CBT-I, improvement is maintained for as long as 2 years after treatment is discontinued [4]. In contrast, after treatment with hypnotics ends, insomnia symptoms tend to reappear. One major challenge for the use of CBT-I is a shortage of clinicians trained to provide it. This has stimulated a number of new efforts to make CBT-I more available. New directions include:

- Implementing large-scale training programs for clinicians by national providers such as the Veterans Health Administration;
- Designing and evaluating abbreviated treatments that could be delivered by those with limited CBT-I training and could be used in primary care settings;
- Designing and evaluating self-help treatments (books, videos, internet programs, and phone apps) that can reach many more individuals than those who seek out treatment from clinicians.

A second major challenge to delivering CBT-I and making it available to more people is enhancing the existing treatment by expanding treatment to those who have sleep disturbances that are comorbid with other sleep, health and mental health problems; and evaluating new nonpharmacological interventions that may be more efficacious than or enhance the currently available interventions.

#### Disseminating treatment by training practicing clinicians

Training courses and text books are available to licensed clinicians as a resource to familiarize them with CBT-I, but competent delivery of CBT-I to complex and diverse patient populations requires hands on learning through consultation with

Keywords: CBT-I • cognitive behavioral therapy • insomnia • nonpharmacological • stimulus control therapy • training and feedback from expert clinicians. For example, Behavioral Sleep Medicine certification requires the equivalent of a 1-year postdoctoral sleep fellowship, usually undertaken by prelicensed professionals, during which trainees receive close supervision when treating a large number of patients. Another model for training is the large ongoing dissemination project that targets licensed mental health clinicians in the Veterans Health Administration, the largest integrated healthcare system in the USA. Following a training workshop an expert leads small-group consultation calls, reviews taped therapy sessions, rates therapists' skills and provides feedback to therapists in training for 4 months. Initial program evaluation revealed that patient outcomes are comparable to those obtained in randomized clinical trials [6] and sustainability of the initiative is evidenced by continued use 6 months post-training [7]. The challenges met by this initiative are relevant to future dissemination efforts [8]. Prime among them are the costs of the availability of time for training and the need to minimize disruptions to clinicians' ongoing workload and to the system in which they work. The challenge for training more clinicians is to develop cost-effective consultation models and new technologies.

#### Abbreviated CBT-I

There has been a recent emphasis in training nurses and others who work in primary care settings to use abbreviated (usually limited to behavioral components of CBT-I) group treatment for insomnia complaints [9]. A promising variation on this treatment has been to use a 1-day workshop as an intervention delivered simultaneously to as many as 30 individuals with insomnia at a time. Evaluation of the workshop revealed that 50% of those attending the workshop had not previously sought treatment and that compared with wait-list controls, those receiving the workshop experienced reduction in insomnia severity from baseline to 3 months after the workshop [10]. This intensive educational approach may be a good method to reach individuals with insomnia symptoms who do not seek clinical therapy.

#### Self-help treatments

In addition to dissemination of full and abbreviated CBT-I to clinicians, there has been a recent interest in the use of self-help methods as a means of increasing access to treatment for those with insomnia symptoms. Self-help methods are those that a person can use independently at home, such as books, audiotapes, videos, television programs, cell phone apps and the Internet. Only small-to-moderate effect sizes were found in a meta-analysis of studies of self-help treatments for insomnia [11]. Thus, self-help produces improvement, but less improvement than found in individual and group insomnia therapy

formats provided by clinicians [2]. Although seven out of the ten studies of self-help CBT-I offered additional support by means of e-mail, telephone or face-to-face encounters, studies that included persons with psychiatric comorbidities produced less improvement than studies in which they were excluded [11], possibly because the additional support offered in these studies was limited and a thorough ongoing assessment of mental health status was not included [5].

The use of the Internet for providing treatment continues to evolve. More recent programs produce better outcomes than earlier attempts. A noteworthy internet CBT-I program was developed and evaluated by Lee Ritterband and colleagues [12]. The investigators recruited a small sample of individuals who went through a threestep screening process. Potential participants filled out an online interest form, then had a 15-min telephone interview followed by a semistructured personal interview. Those with sleep disorders other than insomnia or who had major medical or psychiatric problems were ineligible to participate. The investigators reported large effects for sleep improvement compared with a no-treatment control condition. In a subsequent pilot study of an Internet program for sleep problems of cancer patients, Ritterband and colleagues found that the Internet program produced greater improvement in sleep and fatigue compared with those in the wait-list control condition [13].

Another study taking a new approach to the Internet is that of Colin Espie and colleagues using an automated media-rich web application [14]. They found large effect sizes in sleep outcomes along with small-to-moderate effect sizes on daytime consequences of insomnia. The use of technology as a means of expanding access to treatment for insomnia is likely to continue. Outcomes, particularly for sleep measures, have already begun to document improvements [14]. Several efforts to develop self-help and clinician-assisted phone apps are underway (e.g., CBTiCoach available on the Veterans Health Administration intranet), as are ongoing efforts to integrate devices that provide objective estimates of sleep and using them to enhance the administration of CBT-I.

#### Treating comorbid disorders

During the past decade there has been considerable attention to treating sleep disturbance that is comorbid with mental illness, including depression posttraumatic stress disorder, recovering alcoholics, and other psychiatric disorders [15], cancer [16], and chronic pain [17]. There have been pilot studies for a number of other comorbid problems such as chronic obstructive pulmonary disease, coronary artery disease and hearing impairment that support the conclusion that CBT-I improves sleep even in those with health and mental health comorbid problems. In some cases the benefits of CBT-I extend beyond sleep; for example, adding CBT-I to an antidepressant medication leads to higher rates of remission from depression among patients with comorbid insomnia and depression [18].

#### New treatments

The overall evidence for the effectiveness of CBT-I is impressive, but not strong enough for us to be complacent and satisfied with the therapies that are currently available. Thus it is encouraging that new treatments and treatment components are being developed and evaluated. The inclusion of mindfulness meditation integrated into CBT-I therapy is a welcome example; initial results suggest large pre- to post-treatment effect sizes for measures of sleep continuity, insomnia severity and presleep arousal [19].

One of the most innovative of the new treatments is Intensive Sleep Retraining (ISR), from Jodie Harris, Leon Lack and colleagues [20]. Individuals with insomnia spent 25 h of sleep deprivation in a sleep laboratory and were given 50 opportunities, one each half hour, to fall asleep for no more than 3 min. Seventy nine participants were randomly assigned to one of four treatments: a sleep hygiene control condition; ISR; 4 weeks of stimulus control therapy (SCT); and the combination of ISR followed by SCT.

ISR produced faster but eventually equivalent improvement to SCT on sleep and daytime functioning. The combined treatment produced both faster initial treatment gains and larger effect sizes than SCT or ISR alone. This suggests that it may be possible to kick-start improvement with ISR and obtain additional improvement by following it with SCT or other components of CBT-I.

### Conclusion

The clinical trial literature provides evidence of considerable interest in the nonpharmacological treatment of insomnia. CBT-I is an effective treatment and there are many intriguing and fruitful efforts to strengthen its effects and to increase access to it. The coming years hold out promising opportunities for learning more about the mechanisms underlying successful treatment of insomnia, increasing the availability of CBT-I to those with comorbid health and mental health problems, and using the principles of CBT-I for prevention of insomnia during periods of vulnerability for sleep perturbation.

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