CHAPTER 1

INTRODUCTION AND BACKGROUND FOR A CBT-I PROGRAM

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Since the first edition of this CBT-I training manual, new sleeping pills have appeared on the market and the non-drug treatment of insomnia has rapidly evolved into a formal treatment called CBT-I (cognitive behavioral therapy for insomnia.

Nevertheless, the old adage "the more things change, the more things stay the same" holds true for insomnia. CBT-I is still more effective than sleeping pills. Even with the new generation of sleeping pills, which have flourished in the marketplace due to direct consumer advertising, sleeping pills continue to exhibit many of the same drawbacks and side effects- along with newly documented dangers. Indeed, in three head-to-head comparisons that compared the efficacy of CBT-I to sleeping pills, the score is 3 to 0 in favor of CBT-I. Other studies continue to show that insomnia patients prefer CBT-I to sleeping pills.

Sleeping pills are no longer considered a safe or appropriate treatment for chronic insomnia because they:

- can have serious side effects that far outweigh their benefits;
- can have serious risks that increase morbidity and mortality;
- are only moderately effective for insomnia and stop working over time;
- undermine self-efficacy by strengthening the belief that the cure for insomnia comes from external factors.

KEY CONCEPT: *Most importantly, sleeping pills don't cure insomnia because they don't treat the causes of insomnia. Consequently, if poor sleepers rely on sleeping pills, their sleep may improve while they take medication, but insomnia will return usually return if they stop taking the medication, thereby sustaining the cycle of insomnia and sleeping pills.*

CBT-I is the most effective behavioral intervention for any health problem for adults. It produces large effect sizes that average .8 and often exceed 1.0 compared to an average CBT effect size of .7 for depression, panic disorder, and generalized anxiety disorder and .65 for headaches. Numerous studies have shown that CBT-I is safer and works better

than sleeping pills in the long run. For example, an analysis of over 20 studies showed that CBT-I helped people fall asleep faster than sleeping pills and without any side effects. Another major review study showed that CBT-I is effective for older adults while another review showed that, in people over 60, the side effects of sleeping pills outweigh their small benefits. In fact, seniors were twice as likely to experience a side effect such as short-term memory loss, headaches, daytime fatigue, nausea, motor vehicle crashes and dizziness. A National Institutes of Health "State of the Science" conference on insomnia found no evidence that CBT-I produces any side effects.

There have been three studies that have directly compared sleeping pills to CBT-I. In all three, CBT-I was more effective. Gregg D. Jacobs, Ph.D. and colleagues conducted one of these studies at Harvard Medical School with funding from the National Institutes of Health. The study compared CBT-I to the most widely prescribed sleeping pill, Ambien, and demonstrated that CBT-I was more effective in the short-term (4 weeks) and in the long-term (one year). Moreover, Ambien was only moderately effective while it was taken, and any benefit disappeared after patients discontinued the medication. This study also found that 80% of patients treated with CBT-I fell asleep faster and half fell asleep as quickly as normal sleepers.

Use of CBT-I in over 10,000 sleep clinic patients at the Harvard and UMass Medical Schools consistently shows that 90% of patients reduce or eliminate sleeping pills with CBT-I. CBT-I has been recommended as the preferred treatment for chronic insomnia by the New England Journal of Medicine and the Lancet and by the National Institutes of Health, Consumer Reports, the American Psychological Association, and the American College of Physicians.

A study by Dr. Charles Morin of Laval University in Quebec, Canada showed that 85% of long-term (on average, 19 years) elderly, nightly users of benzodiazepine sleep medications were able to eliminate sleep medication altogether using CBT-I combined with the techniques described in chapter five for sleep medication tapering. Studies have also shown that discontinuation of sleeping pills is associated with improvements in cognitive functioning.

The most recent research on CBT-I indicates not only that it reduces insomnia in patients with a variety of co-morbidities such pain, fibromyalgia, depression, PTSD, and substance abuse but that it also produces improvements in these co-morbidities. In fact, CBT-I doubles the improvement rates of depression compared to antidepressant medication alone in depressed patients with insomnia.

Still, the treatment of insomnia has been hindered by the fact that, although insomnia is the most prevalent sleep disorder, it receives the least amount of federal research funding of any sleep disorder. Insomnia lags far behind other sleep disorders such as sleep apnea, which receive a far greater percentage of the total funding for sleep disorders from the National Institutes of Health.

Equally problematic is that, for numerous reasons, the vast majority of Americans do not have access to CBT-I. First, due to a lack of training opportunities, there are only a few thousand well-trained CBT-I specialists in the United States. Second, sleep clinics are often directed by pulmonologists who specialize in treating sleep apnea, not insomnia. Third, many doctors and patients are not familiar with CBT-I because, unlike sleep medications, it is not advertised.

Section Focus: Press Release

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STUDY FINDS COGNITIVE BEHAVIOR THERAPY MORE EFFECTIVE THAN SLEEPING PILLS FOR TREATING INSOMNIA

Benefits of Non-Drug Techniques Top Most Popular Sleeping Pill, Ambien

BOSTON – A study by researchers at Beth Israel Deaconess Medical Center (BIDMC) and Harvard Medical School has found cognitive behavioral therapy (CBT-I) is more effective than sleeping

pills in treating chronic sleep-onset insomnia.

The findings, which appear in the Sept. 27 issue of the *Archives of Internal Medicine*, show non-drug techniques yield better short and long-term results than the most widely prescribed sleeping pill, zolpidem, commonly known as Ambien. It is the first placebo-controlled trial to evaluate the separate and combined effects of CBT-I and pharmacological therapies in treating insomnia in young and middle-aged adults.

"Sleeping pills are the most frequent treatment for insomnia, yet, CBT-I techniques clearly were more successful in helping the majority of study participants to become normal sleepers. The pills were found to be only moderately effective compared to CBT-I and lost their effectiveness as soon as they were discontinued," said study leader Gregg Jacobs, Ph.D., insomnia specialist in the Sleep Disorders Center of BIDMC and an assistant professor of psychiatry at Harvard Medical School.

"Our results suggest CBT-I should now be considered the first line treatment for insomnia, which is experienced on a nightly basis by one-third of the nation's adult population," added Jacobs.

Insomnia affects more than 70 million Americans and is one of the most common complaints brought to physician's offices. Those with the condition experience difficulty initiating or maintaining sleep, often resulting in impaired daytime functioning. In the National Sleep Foundation's 2002 Sleep in America poll, 35 percent of all adults experienced symptoms every night, with 58 percent reporting insomnia at least a few nights per week.

For the study, researchers conducted a randomized, placebo-controlled clinical trial involving 63 young and middle-aged adults with chronic sleep-onset insomnia. Interventions included behavioral and relaxation techniques, pharmacotherapy (using Ambien), or combined therapy compared with placebo.

Researchers measured sleep twice during an eight-week treatment period: at mid-treatment when pharmacotherapy subjects were still taking a nightly does of Ambien and at the end of the eight-week treatment period when Ambien subjects gradually tapered their medication and then discontinued it entirely. The main outcome measure was sleep-onset latency as shown by patient diaries. Secondary measures included sleep efficiency and total time as derived from the diaries, objective measures of variables using objective sleep recordings, and an assessment of daytime functioning.

Amongst the findings, CBT-I and combination groups showed the greatest changes in sleep-onset latency at mid-treatment, both registering a 44 percent reduction. Pharmacotherapy subjects showed a modest 29 percent reduction in latency, followed by 10 percent for the placebo group. At the end of the eight-week treatment period, CBT-I and combination treatment yielded a 52 percent reduction on sleep-onset latency; these improvements were maintained at long-term follow-up.

The moderate improvements observed in the Ambien group at mid-treatment were not maintained after the drug was gradually tapered and then discontinued. In fact, by the end of the eight-week treatment phase, insomnia returned toward baseline levels and did not differ from the placebo group. CBT-I and combined therapy also produced the greatest improvements in sleep efficiency and number of normal sleepers by the end of treatment on measures of sleep onset latency and sleep efficiency. There was no advantage of combined therapy over CBT-I alone. No significant differences

emerged amongst groups in total sleep time, though all exhibited increases. The results from the objective sleep recordings paralleled the sleep diary results.

Despite the fact sleeping pills are the most frequently prescribed treatment for insomnia, and newer generation medications are being introduced to the U.S. market, they are not recommended for long-term treatment. This is due to numerous and well-documented side effects such as dependency. Prior studies also indicate that insomnia patients prefer non-drug approaches.

Study co-authors include Edward Franz Pace-Schott, MS, BIDMC psychiatry; Robert Stickgold, PhD, BIDMC psychiatry; Michael W. Otto, PhD, Massachusetts General Hospital and Harvard Medical School.

This research was funded by grants from the National Institutes of Health.

Beth Israel Deaconess Medical Center is a major patient care, teaching and research affiliate of Harvard Medical School, and ranks third in National Institutes of Health funding among independent hospitals nationwide. BIDMC is clinically affiliated with the Joslin Diabetes Center and is a research partner of Dana-Farber/Harvard Cancer Center. BIDMC is the official hospital of the Boston Red Sox. For more information, visit www.bidmc.harvard.edu.

Key Concept: *The success of the CBT-I is based on a central theme: insomnia can only be treated by addressing the underlying causes. In most instances, the primary causes of chronic insomnia are sleep thoughts (cognitions) and sleep behaviors (habits) which are learned and can be unlearned.* Some examples include:

- negative, distorted thoughts and beliefs about insomnia;
- feelings of loss of control over sleep;
- spending excessive time in bed;
- going to bed too early or sleeping too late;
- trying to control sleep rather than letting it happen;
- lying awake in bed, frustrated and tense.

The CBT-I program described in this manual is based on over three decades of research and clinical practice at the Harvard Medical School and University of Massachusetts Medical School involving over 10,000 patients. It is a six-week program that consists of five two-hour group sessions or five 30-45-minute individual treatment sessions (three weekly sessions followed by two bi-weekly sessions). The group format is more cost-effective for both patients and the clinician and offers the advantage of social

support, reinforcement and modeling. The individual format allows for more one-on-one interaction, feedback, and flexibility in scheduling of treatment sessions. Group sizes range from five to eight patients. A typical treatment session consists of presentation of new CBT-I techniques and discussion of both newly presented material and patients' practice of previously learned CBT-I techniques.

CBT-I differs from other forms of CBT and other psychological therapies because it:

- Produces rapid improvement in sleep in five treatment sessions over six weeks.
- Is more physiologically, behaviorally, and quantitatively based.
- Involves a primary symptom that is concrete and measurable using a sleep diary. This allows the clinician and patient to see compliance with treatment goals, and objective changes in the presenting symptom, on a weekly basis.
- Is attractive for patients because it is "not all in my head" and, therefore, serves as an ideal segue to other CBT treatments.

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CHAPTER 2

SLEEP AND INSOMNIA: BASIC CONCEPTS