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Psychological treatment of hypnotic-dependent insomnia in a primarily older adult sample

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ABSTRACT

Objective: This study tested cognitive behavior therapy (CBT) in hypnotic-dependent, late middle-age and older adults with insomnia.
Method: Seventy volunteers age 50 and older were randomized to CBT plus drug withdrawal, placebo biofeedback (PL) plus drug withdrawal, or drug withdrawal (MED) only. The CBT and PL groups received eight, 45 min weekly treatment sessions. The drug withdrawal protocol comprised slow tapering monitored with about six biweekly, 30 min sessions. Assessment including polysomnography (PSG), sleep diaries, hypnotic consumption, daytime functioning questionnaires, and drug screens collected at baseline, posttreatment, and 1-year follow-up.
Results: Only the CBT group showed significant sleep diary improvement, sleep onset latency significantly decreased at posttreatment. For all sleep diary measures for all groups, including MED, sleep trended to improvement from baseline to follow-up. Most PSG sleep variables did not significantly change. There were no significant between group differences in medication reduction. Compared to baseline, the three groups decreased hypnotic use at posttreatment, down 84%, and follow-up, down 66%. There was no evidence of withdrawal side-effects. Daytime functioning, including anxiety and depression, improved by posttreatment. Rigorous methodological features, including documentation of strong treatment implementation and the presence of a credible placebo, elevated the confidence due these findings.
Conclusions: Gradual drug withdrawal was associated with substantial hypnotic reduction at posttreatment and follow-up, and withdrawal side-effects were absent. When supplemented with CBT, participants accrued incremental self-reported, but not PSG, sleep benefits.

Chronic, clinically significant insomnia occurs in about 10% of the population (Ohayon, 2002). National panels have long cautioned against the use of hypnotics in the management of chronic insomnia (Institute of Medicine, 1979; National Institutes of Health, 1984, 1991), but hypnotic use continues to climb (Moloney, Konrad, & Zimmer, 2011).

Depending on dose and type, unwanted effects of hypnotics include physical and psychological dependence, residual sedation, cognitive impairment, and compromised psychomotor performance (Licata & Rowlett, 2008; Vermeeren & Coenen, 2011). In a tradeoff for modest therapeutic gains (Buscemi et al., 2007), hypnotic impairment exposes users to elevated risk for serious accidents (Shuto et al., 2010; Verster, Veldhuijzen, & Volkerts, 2004; Wang, Bohn, Glynn, Mogun, & Avorn, 2001).

The convergent influence of several factors causes the impact of hypnotics to be felt most strongly among older adults. First, insomnia is disproportionately represented among older adults, affecting about one third of people in this age group (Foley et al., 1995). Second, there is greater hypnotic exposure in older adults based on higher prevalence and persistence of hypnotic use in this group (Ashton, 1994; Balkrishnan, Rasu, & Rajagopalan, 2005; Morgan & Clarke, 1997; Stewart et al., 2006). Third, older adults

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are more vulnerable to the hazards associated with hypnotics than are younger adults. Age-related absorption and metabolic changes in later life can extend drug half-life in the body and promote excess drug accumulation, can heighten the risk of residual daytime cognitive and motor impairment, and can exacerbate sleep-disordered breathing, which is more common in older adults (Guilleminault, 1990; Moran, Thompson, & Nies, 1988; National Institutes of Health, 1984).

Psychological factors interact with the tolerance/dependence pattern often associated with the most common class of hypnotics, benzodiazepine receptor agonists, to prolong hypnotic dependence. Abrupt withdrawal may instigate exacerbation of insomnia and anxiety above baseline levels, termed rebound, after as short a period as 1 week of hypnotic use (Greenblatt, Harmatz, Zinny, & Shader, 1987). Resumption of hypnotics brings rapid relief from these acute symptoms, and psychological dependence on hypnotics is strengthened by this negative reinforcement paradigm. Accordingly, anticipation of rebound effects may discourage attempts to forego reliance on these medications, even when users no longer derive hypnotic benefits (Schneider-Helmert, 1988).

Psychological treatments for people with insomnia were introduced in the late 1960s. They have since been shown to be safe and effective and have gained broad acceptance (Morin et al., 2006). Hypnotic-dependent insomnia refers to current insomnia accompanied by chronic hypnotic use, and there would appear to be a unique and clinically significant role for psychological interventions in the treatment of hypnotic-dependent insomnia.

There is a growing body of literature on psychological management of hypnotic-dependent insomnia, but much of it is poorly controlled and important gaps remain. Thirteen studies investigated this subject and all reported positive results with respect to sleep improvement or reduced hypnotic use. But ten (Baillargeon et al., 2003; Espie, Lindsay, & Brooks, 1988; Kirmil-Gray, Eagleston, Thoresen, & Zarcone, 1985; Lichstein & Johnson, 1993; Lichstein et al., 1999; Morin, Colecchi, Ling, & Sood, 1995; Morin, Stone, McDonald, & Jones, 1994; Riedel et al., 1998; Taylor, Schmidt-Nowara, Jessop, & Ahearn, 2010; Zavesicka, Brunovsky, Matousek, & Sos, 2008) are of diminished interest due to several factors: uncontrolled case study, constricted range of dependent variables, small *N*, inclusion of over-the-counter hypnotics, or nonrandom assignment to conditions.

There are three methodologically mature studies in this domain (Belleville, Guay, Guay, & Morin, 2007; Morgan, Dixon, Mathers, Thompson, & Tomeny, 2003; Morin et al., 2004). All tested cognitive behavior therapy packages comprised of some combination of sleep hygiene, cognitive therapy, stimulus control, sleep restriction, and relaxation.

We have learned from the above studies that people with insomnia can successfully withdraw from hypnotics, and incremental sleep improvement occurs with supplemental psychological treatment. However, important questions remain. (1) Among the methodologically mature studies, only Morin et al. (2004) obtained polysomnography data to verify sleep status. (2) Only Morin et al. (2004) obtained drug screens to verify medication status. (3) Only Morin et al. (2004) focused on older adults. (4) A placebo-controlled trial has not been conducted.

The present clinical trial addressed these four concerns with hypnotic-dependent insomnia to more clearly understand the role of psychological treatment in the management of this disorder with primarily older adults. Volunteers who had current insomnia combined with hypnotic dependence were randomly assigned to three treatment conditions: multi-component cognitive behavior therapy (CBT) comprising relaxation, stimulus control, and sleep hygiene instructions plus scheduled medication withdrawal, placebo biofeedback (PL) plus scheduled withdrawal, or scheduled withdrawal (MED) only. The CBT and PL groups received eight, 45 min weekly treatment sessions before commencing drug withdrawal. All three groups were given the same drug withdrawal protocol: slow tapering monitored with about six biweekly, 30 min sessions, but the length of the drug withdrawal period varied greatly based mainly on the initial dosage level.

Method

Participants

We recruited volunteers from the community through media announcements. Participants were compensated with $300 distributed between posttreatment and 1-year follow-up. This study was approved by the University and Hospital IRBs.

A clinical interview and sleep diaries were used to determine sleep status. To satisfy the diagnosis of hypnotic-dependent insomnia, inclusion criteria were derived from a combination of the Diagnostic and Statistical Manual of Mental Disorders (4th ed.) (DSM-IV) criteria for insomnia (American Psychiatric Association, 1994) and the International Classification of Sleep Disorders criteria for hypnotic-dependent sleep disorder (American Sleep Disorders Association, 1997). The key criteria were: complaint of current difficulty initiating or maintaining sleep lasting at least 6 months, complaint of impaired daytime functioning, and use of prescription sleep medication at least 3 times/week for 6 months. We added the following empirically derived quantitative criteria (Lichstein, Durrence, Taylor, Bush, & Riedel, 2003): sleep onset or awake time during the night must exceed 30 min at least three times per week on the baseline sleep diaries.

Exclusion criteria were age less than 50 years old, history of seizures, consuming more than four alcoholic beverages per week or consuming alcohol at bedtime even once per week; cognitive impairment, a score below 26 on the Mini-Mental State Exam (Folstein, Folstein, & McHugh, 1975) or below 18 (Murden, McRae, Kaner, & Bucknam, 1991) if the participant had less than a 9th grade education; sleep intrusive, unstable medical/psychiatric disorders as per the Structured Clinical Interview for DSM-IV, Axis I (First, Spitzer, Gibbon, & Williams, 1997) and Axis II (First, Gibbon, Spitzer, Williams, & Benjamin, 1997), the Cornell Medical Index (Brodman, Erdmann, Wolff, & Miskovitz, 1986), and follow-up clinical interviews; consuming illicit drugs or sleep active medications, such as sedatives, stimulants, and steroids, besides the designated hypnotics; and presence of other sleep disorders, particularly periodic limb movements (arousal index $>$ 15) or sleep apnea (apnea/hypopnea index $>$ 15).

Research setting and apparatus

The study was conducted at two settings, the Psychological Services Center, The University of Memphis, and the Sleep Disorders Center (accredited by the American Academy of Sleep Medicine), Methodist Healthcare of Memphis.

A Nihon Koden #4312 polygraph was used for the all-night sleep studies (PSG). Monitoring consisted of two electroencephalography (EEG) measures, two electrooculography (EOG), and chin electromyography (EMG) according to standard placements (Rechtschaffen & Kales, 1968) to score sleep stages. Supplementary channels included oxygen saturation level, bilateral anterior tibialis EMG, heart rate (EKG), thoracic strain gauge, and a nasal/oral thermistor.