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Cognitive-behavior therapy singly and combined with medication for persistent insomnia: Impact on psychological and daytime functioning

Charles M. Morin [a, b, *], Simon Beaulieu-Bonneau [a, b], Lynda Bélanger [a, c], Hans Ivers [a], Montserrat Sánchez Ortuño [d], Annie Vallières [a, b], Josée Savard [a, c], Bernard Guay [b], Chantal Mérette [a, b]

[a] Université Laval, Québec, Canada
[b] Centre de recherche de l'Institut universitaire en santé mentale de Québec, Québec, Canada
[c] Centre de recherche du Centre hospitalier universitaire de Québec, Québec, Canada
[d] University of Murcia, Murcia, Spain

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ABSTRACT

While impairment of daytime functioning due to poor sleep is often the main determinant for seeking treatment, few studies have examined the clinical impact of insomnia therapies on daytime outcomes. The main objective of this study was to evaluate the impact of cognitive-behavior therapy (CBT), alone and combined with medication, on various indices of daytime and psychological functioning. Participants were 160 individuals with chronic insomnia who received CBT alone or CBT plus medication (zolpidem) for an initial six-week therapy, followed by an extended six-month therapy. Participants treated with CBT initially received maintenance CBT or no additional treatment and those treated with combined therapy initially continued with CBT plus intermittent medication (prn) or CBT without medication (taper). Measures of anxiety and depressive symptoms, fatigue, quality of life, and perceived impact of sleep difficulties on various indices of daytime functioning were completed at baseline, after each treatment stage, and at six-month follow-up. Following acute treatment, significant improvements of fatigue, quality of life (mental component), anxiety, and depression were obtained in the CBT alone condition but not in the combined CBT plus medication condition. Following extended treatment, further improvements were noted for the subgroup receiving extended CBT relative to that with no additional treatment, and for the subgroup receiving CBT and intermittent medication relative to that with CBT but no medication. Improvements were well maintained at the 6-month follow-up. These findings indicate that insomnia-specific therapy is effective at improving daytime and psychological functioning in the short term, and that maintenance therapy produces an added value to optimize long-term outcomes. Trial registration: www.clinicaltrials.gov (#NCT 00042146).

1. Introduction

Chronic insomnia is characterized by both difficulties sleeping at night and problems with daytime functioning or significant distress; the presence of these two features is essential to make the diagnosis of insomnia (American Academy of Sleep Medicine, 2014; American Psychiatric Association, 2013; Edinger et al., 2004). Common daytime problems reported by individuals with insomnia include fatigue or low energy, cognitive problems such as difficulty concentrating or remembering things, mood disturbances, and decreased motivation, all of which can contribute to significant functional impairments at work, at home, or on the road (Buysse et al., 2007; Edinger et al., 2004; Roth et al., 2006). Subjective reports of daytime impairments are not always corroborated by objective findings from neurobehavioral testing (Fortier-Brochu, Beaulieu-Bonneau, Ivers, & Morin, 2012), not unlike the discrepancies between subjective and objective measures of sleep parameters (Krystal, 2007; Riedel & Lichstein, 2000). Yet, the perception of daytime impairments can be a major source of distress for individuals with insomnia and is often the

* Corresponding author. Université Laval, École de Psychologie, 2325, rue des Bibliothèques, Québec, Québec, G1V 0A6, Canada.
E-mail address: cmorin@psy.ulaval.ca (C.M. Morin).

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main determinant prompting them to seek treatment (Davidson, Aime, Ivers, & Morin, 2009; Gagnon, Belanger, Ivers, & Morin, 2013).

While there is extensive evidence showing that psychological and pharmacological therapies are effective for improving sleep (Buysse, 2013; Krystal, 2009; Morin et al., 2006; National Institutes of Health, 2005), there is surprisingly little evidence that these treatments or the sleep improvements they produce have a significant impact on daytime functioning. Drug studies often incorporate measures of cognitive functioning but this is usually done to demonstrate that there is no residual daytime impairment associated with the drug under investigation. Likewise, few investigations of psychological therapies (mostly CBT) for insomnia have incorporated measures of daytime functioning and in most cases these have been used as secondary outcomes (Morin et al., 2006). Moreover, these studies have yielded inconsistent findings. For instance, some studies found a significant decrease in depressive symptoms following CBT (Belleville, Guay, Guay, & Morin, 2007; Dirksen & Epstein, 2008; Quesnel, Savard, Simard, Ivers, & Morin, 2003), while others did not find any difference between CBT and control conditions (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001; Espie, Inglis, Tessier, & Harvey, 2001; Jacobs, Pace-Schott, Stickgold, & Otto, 2004; Rybarczyk et al., 2005; Taylor et al., 2014). These studies also report similarly mixed results regarding improvements in anxiety (state, trait, or worry), fatigue, and health-related quality of life.

This relative lack of attention to daytime variables may result from the fact that health regulatory agencies require new drugs to show efficacy on selected sleep parameters, not daytime functioning, whereas most psychological therapies target sleep-related behavioral and scheduling factors, not daytime functioning per se. There is also a common assumption that daytime and psychological functioning will necessarily improve following sleep improvements. The lack of attention to the daytime component of chronic insomnia may explain why only 40–50% of individuals receiving insomnia treatment achieve remission (Morin et al., 2009); if therapy only targets nighttime sleep difficulties, it may be no surprise that daytime functioning does not improve. In order to optimize current therapies for insomnia, it would be important to investigate the extent to which those therapies have a clinical impact in improving psychological and daytime functioning. The inclusion of measures of waking correlates, more specifically mood, fatigue, and quality of life, in insomnia treatment studies has been part of the essential recommendations of an expert consensus for a standard research assessment for insomnia (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006).

The objective of this paper was to examine the impact of insomnia therapies, CBT alone and CBT combined with medication, on several indices of psychological and daytime functioning such as mood, fatigue, health-related quality of life, and cognitive functioning. A secondary objective was to compare if an extended treatment, incorporating maintenance CBT or intermittent medication, would enhance daytime outcomes relative to acute interventions.

2. Methods

The results were derived from a larger study that evaluated the short- and long-term effects of CBT, singly and combined with medication, for persistent insomnia, and compared the efficacy of maintenance strategies to optimize long-term outcomes. Additional information on the study design and methodology, and the main findings for the sleep outcome variables are available elsewhere (Morin et al., 2009, 2014).

2.1. Participants

Inclusion criteria were to be aged 30 years or older and meeting diagnostic criteria for chronic insomnia based on a combination of DSM-IV (American Psychiatric Association, 1994) and ICSD-2 criteria (American Academy of Sleep Medicine, 2005). These criteria were further operationalized as follows: (a) difficulties initiating and/or maintaining sleep, defined as a sleep onset latency and/or wake after sleep onset greater than 30 min, with an average sleep time of less than 6.5 h at least 3 nights per week (according to daily sleep diaries); (b) insomnia duration greater than 6 months; and (c) significant distress or impairment of daytime functioning (rating of at least 2 on item 5 or 7 of the *Insomnia Severity Index*). Exclusion criteria were: (a) presence of a serious medical condition (e.g., cancer) directly related to the onset and course of insomnia; (b) use of medications known to alter sleep (e.g., steroids); (c) lifetime diagnosis of a psychotic or bipolar disorder; (d) current diagnosis of major depression, unless treated and in remission; or more than two past episodes of major depression; (e) history of suicide attempt; (f) alcohol or drug abuse within the past year; (g) sleep apnea (apnea/hypopnea index > 15), restless legs, or periodic limb movements during sleep (movement index with arousal > 15 per hour); and (h) night-shift work or irregular sleep patterns. Patients with stable medical (e.g., hypertension) or selected psychiatric (e.g., generalized anxiety disorder) disorders were included in the study provided that these conditions were not judged to be the primary cause of insomnia. Patients using prescribed or over-the-counter sleep medications no more than twice weekly were enrolled after they withdrew from medications. Individuals using alcohol as a sleep aid were required to discontinue this practice at least two weeks prior to baseline assessment.

Of the 486 individuals who completed telephone screening for eligibility, 242 completed second-stage screening consisting of a clinical sleep/insomnia evaluation (Morin, 1993), the Structured Clinical Interview for DSM-IV (SCID-IV) (First, Spitzer, Gibbon, & Williams, 1997), a medical history and physical examination, and polysomnography (PSG). Eighty-two persons were excluded after this screening for various reasons, leaving 160 who were enrolled in the study (97 women, 63 men), with a mean age of 50.3 years ($SD = 10.1$; range = 30 to 72) and a mean education level of 14.7 years ($SD = 3.5$) (see Morin et al. (2009) for a complete participants flow). All patients were Caucasian, and most were married or living with a partner (68.1%), and were employed (73.3%). The majority (73.8%) reported mixed sleep-onset and maintenance insomnia. The average insomnia duration was 16.4 years ($SD = 13.6$). All patients were sleep-medication free prior to entering the study, but 63 (39.4%) had used sleep medication previously. In terms of comorbidity, 24 patients (15.0%) presented a comorbid psychiatric disorder, and there was no significant difference between conditions (13.8% vs 16.3% for CBT and CBT plus medication conditions, respectively), $X^2(1) = 0.20$, $p = 0.66$. The most prevalent diagnoses were specific phobia ($n = 9$), generalized anxiety disorder ($n = 8$), and social phobia ($n = 3$). Small samples size for each diagnosis within condition precluded statistical testing for group differences. In the total sample, 92 patients (57.5%) presented at least one comorbid medical disorder (most commonly a cardiovascular condition).

2.2. Procedure

Participants were randomized to one of two acute treatments: (a) CBT ($n = 80$) or (b) CBT plus medication ($n = 80$). After completing this six-week treatment, they were randomized a second time to an extended treatment for the next six months. CBT patients were randomized to either extended CBT (CBT) or no