Behaviour Research and Therapy 67 (2015) 45–54

Contents lists available at ScienceDirect

Behaviour Research and Therapy

journal homepage: www.elsevier.com/locate/brat

A randomized-controlled trial of an early minimal cognitive-behavioural therapy for insomnia comorbid with cancer☆

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ARTICLE INFO

Article history:
Received 11 July 2014
Received in revised form
13 January 2015
Accepted 23 February 2015
Available online 25 February 2015

Keywords:
Cancer
Insomnia
Acute
Cognitive-behavioural therapy
Early minimal intervention

ABSTRACT

Objective: This study aimed to provide preliminary evidence on the efficacy of an early minimal cognitive-behavioural therapy for acute insomnia (mCBT-I) comorbid with cancer.
Method: Thirty-eight patients (92% female; M_{age} 57; all Caucasian) with various types of cancer and having insomnia symptoms for less than 6 months were randomized to a self-administered mCBT-I condition ($n = 20$; 6 short booklets + 3 phone consultations with a psychologist, over 6 weeks) or a no-treatment condition ($n = 18$). Measures were completed at pre-treatment and post-treatment, as well as at 3- and 6-month follow-ups.
Results: All sleep parameters and the average dosage of hypnotics were significantly improved from pre- to post-treatment among treated participants, but not in control participants. mCBT-I was also associated with a significantly greater reduction of anxiety and depression symptoms, maladaptive sleep habits, and erroneous beliefs about sleep, as well as with a significantly greater improvement of subjective cognitive functioning. A greater proportion of mCBT-I participants than controls met the criteria for a clinical remission at post-treatment. Therapeutic gains of mCBT-I were well sustained up to 6 months after the intervention.
Conclusions: This study supports the efficacy of an early minimal CBT-I to treat acute insomnia comorbid with cancer.

Insomnia is highly prevalent among individuals with cancer. Rates of insomnia found in cancer patients are two to three times higher than in the general population (Morin, LeBlanc, Daley, Gregoire, & Merette, 2006; Ohayon, 2002). A population-based longitudinal study ($n = 991$) conducted by our research team showed that as many as 59% of cancer patients report insomnia symptoms during the peri-operative period (Savard, Villa, Ivers, Simard, & Morin, 2009). While the prevalence of insomnia generally declined over time, 36% of patients continued to experience insomnia at the 18-month follow-up (Savard, Ivers, Villa, Caplette-Gingras, & Morin, 2011).

Insomnia, especially when it becomes chronic, is associated with several daytime sequelae, including fatigue (Lichstein, Means, Noe, & Aguillard, 1997), poor concentration and memory (Fortier-Brochu, Beaulieu-Bonneau, Ivers, & Morin, 2012), decreased work productivity (Daley, Morin, LeBlanc, Gregoire, & Savard, et al., 2009), and impaired quality of life (Chevalier et al., 1999; Zammit, Weiner, Damato, Sillup, & McMillan, 1999). In the long-term, insomnia may lead to psychological disturbances such as depression, anxiety, and substance use disorders (Breslau, Roth, Rosenthal, & Andreski, 1996; Buysse et al., 2008; Chang, Ford, Mead, Cooper-Patrick, & Klag, 1997; Ford & Kamerow, 1989; Jansson-Fröjmark & Lindblom, 2008; Morphy, Dunn, Lewis, Boardman, & Croft, 2007; Neckelmann, Mykletun, & Dahl, 2007), and is associated with an increased utilization of health care services and hospitalization (Daley, Morin, LeBlanc, Gregoire, & Savard, 2009; Léger, Guilleminault, Bader, Levy, & Paillard, 2002). Despite the significance of their consequences and the fact that they are often a persistent condition in the context of cancer, sleep difficulties are typically overlooked in clinical care.

Cognitive-behavioural therapy for insomnia (CBT-I) is now considered the treatment of choice for chronic insomnia with no

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http://dx.doi.org/10.1016/j.brat.2015.02.003
0005-7967/

psychological or medical comorbidity (National Institutes of Health, 2005). One advantage of CBT-I over pharmacotherapy is that it is associated with a larger sustainment of therapeutic gains over time (Morin, Bootzin, et al., 2006; Morin, LeBlanc, et al., 2006). The efficacy of CBT-I for chronic insomnia comorbid with cancer has been supported in several randomized controlled trials (RCT) (Epstein & Dirksen, 2007; Espie et al., 2008; Fiorentino et al., 2009; Garland et al., 2014; Savard, Simard, Ivers, & Morin, 2005). However, a major limitation for the routine implementation of CBT-I in cancer clinics is the scarcity of mental health professionals formally trained in this approach, as well as the costs associated with the treatment sessions. In addition, our experience suggests that the number of CBT-I sessions offered (usually around 6), although not that numerous, is still too demanding for many patients, especially during the active phase of treatment. Thus, a high proportion of cancer patients do not receive any appropriate treatment for their sleep difficulties or are prescribed pharmacotherapy only, which is associated with many side effects, risks, and limitations (Hall, 1998; Morin, 1993, 2001; National Institutes of Health, 2005). Moreover, although it is recommended that individuals limit the duration of their hypnotics use to a period of two to four weeks (National Institutes of Health, 2005), the average duration amounts to several years among cancer patients (Casault, Savard, Ivers, Savard, & Simard, 2012).

As an alternative, more minimal forms of CBT-I could be implemented. In the context of insomnia with no comorbidity, minimal therapy (i.e., bibliotherapy, video, television program, web-based therapy) has been found to produce greater effects than a control condition (Currie, Clark, Hodgins, & El-Guebaly, 2004; Espie et al., 2012; Mimeault & Morin, 1999; Morawetz, 1989; Morin, Beaulieu-Bonneau, LeBlanc, & Savard, 2005; Oosterhuis & Klip, 1993; Riedel, Lichstein, & Dwyer, 1995; Ritterband et al., 2009; Ström, Pettersson, & Andersson, 2004; van Straten, Cuijpers, Smit, Spermon, & Verbeek, 2009; Vincent & Lewycky, 2009). There is also some evidence suggesting that a self-help CBT-I could be as effective as professionally-administered therapy (Bastien, Morin, Ouellet, Blais, & Bouchard, 2004). However, some research has found that the addition of some form of therapist support improves treatment efficacy (Mimeault & Morin, 1999; Riedel et al., 1995). In the context of cancer, preliminary data ($n = 11$) have shown that an intervention combining a 60-min video and 6 short booklets was feasible and acceptable by breast cancer patients with insomnia (average insomnia duration: 86 months) (Savard, Villa, Simard, Ivers, & Morin, 2011). These results are consistent with those of Ritterband et al. (2012) in 28 cancer survivors with a diagnosis of chronic insomnia (i.e., ≥6 months), comparing a web-based CBT-I treatment to a waiting list control condition.

The use of minimal interventions would be especially relevant for the management of acute insomnia. CBT-I administered soon following the onset of insomnia symptoms has the potential to prevent sleep difficulties from becoming chronic during the cancer care trajectory. Moreover, an early intervention may help reduce the negative impact of insomnia on patients' quality of life, in addition to limiting its direct and indirect costs. However, the efficacy of such an approach needs to be empirically tested.

The main goal of this study was to assess the efficacy of a self-administered minimal CBT-I (mCBT-I) combining a bibliotherapy with brief phone consultations for the management of acute insomnia comorbid with cancer. Secondary objectives were to assess the effect of this intervention on hypnotic consumption, anxiety, depression, and fatigue symptoms, quality of life, subjective cognitive functioning, maladaptive sleep habits, and erroneous beliefs about sleep. It was expected that, at post-treatment and at the 3- and 6-month follow-ups, participants receiving mCBT-I would show significantly greater improvements in subjective sleep parameters (sleep diary parameters and ISI score) compared to controls (CTL). It was also expected that treated participants would show a significantly greater reduction of hypnotic consumption, psychological distress, fatigue, maladaptive sleep habits, and erroneous beliefs about sleep, as well as greater increases in quality of life and subjective cognitive functioning.

Method

Participants

Eligibility criteria

Inclusion criteria were: (a) a diagnosis of non-metastatic cancer; (b) acute insomnia symptoms (i.e., <6 months) as assessed with the *Insomnia Interview Schedule* (Morin, 1993); (c) score on the *Insomnia Severity Index* (ISI; Morin, 1993) of 8 or greater; (d) aged between 18 and 75 years old; and (e) able to readily read and understand French. Exclusion criteria were: (a) regular hypnotic medication usage (i.e., ≥3 nights per week) for more than 6 months; (b) diagnosed by a physician with or treated for a sleep disorder other than insomnia (e.g., sleep apnea, periodic limb movements); (c) severe cognitive impairments (e.g., Alzheimer's disease) or a comorbid medical condition known to alter sleep (e.g., multiple sclerosis) as noted in the medical chart, observed at recruitment, or reported by the patient; (d) severe psychiatric disorder (e.g., major depressive disorder) as assessed with the Prime-MD (Spitzer et al., 1994); and (e) already involved in a psychotherapy addressing sleep difficulties.

Recruitment

Most participants were solicited in person between March 2004 and November 2005 at their pre-operative visit to the ambulatory care unit of L'Hôtel-Dieu de Québec and at the Hôpital du Saint-Sacrement (CHU de Québec). Some other participants were recruited by phone through other studies conducted in our laboratory. The study was approved by the ethics review board of both hospitals and of Laval University.

Of the 722 patients approached at the clinics or by phone, 37 refused the screening, and 612 were excluded (see Fig. 1). The main reasons for exclusion were an ISI score <8 ($n = 302$) and chronic insomnia (i.e., ≥6 months; $n = 187$). Of the 73 potentially eligible patients, 27 refused to participate in the study, thus giving a participation rate of 63%. Eight of the 46 patients who accepted to participate in the RCT were excluded following the clinical interview, leaving a total of 38 participants. Three participants in the mCBT-I condition dropped out before completing all pre-treatment measures. Statistical analyses were therefore based on a sample of 35 participants. Three additional participants dropped out of the study at post-treatment and 2 at the 6-month follow-up (3 in the mCBT-I group and 2 in the CTL group).

Sample size justification and power analyses

Sensitivity power analyses were performed with G*Power 3.1.5 using standard conditions (alpha = 5%, power = 80%), a sample size of 35 participants, 4 time assessments, and an expected dropout rate of 10% per assessment (about 90 df for Time and Group × Time interactions). Under these conditions, an effect size $f = 0.21$ could be detected (between small = 0.10 and moderate = 0.25; Cohen, 1988).

Randomization and allocation concealment

The randomization sequence was prepared by a biostatistician using a random permuted-block procedure (SAS 9.3 PROC PLAN) with block sizes varying from 4 to 8 to minimize between-group imbalance during the study. The allocation sequence was