



Impact of group treatment for insomnia on daytime symptomatology: Analyses from a randomized controlled trial in primary care

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ABSTRACT

Background: People typically seek primary health care for daytime symptoms and impairments they experience in association with their insomnia. However, few studies address the question of whether insomnia treatment can improve such symptomatology.

Objectives: To investigate whether a nurse-led group treatment program, based on the techniques of cognitive behavioral therapy for insomnia (CBT-I), improved daytime symptomatology in primary care patients with insomnia.

Outcomes: Fatigue (Fatigue Severity Scale [FSS]; main outcome), mood (General Health Questionnaire and Montgomery-Asberg Depression Rating Scale), health-related quality of life (Short-Form Health Survey), general daytime functioning, specific daytime symptoms (individual items from the Insomnia Severity Index and Uppsala Sleep Inventory), and dysfunctional beliefs (Dysfunctional Beliefs and Attitudes about Sleep).

Design: A randomized controlled trial including baseline and post-treatment assessment and a 1-year post-treatment follow-up of the intervention group.

Settings: Seven primary health care centers (Stockholm, Sweden).

Participants: One hundred and sixty-five primary care patients who meet the criteria for insomnia disorder (mean age 54 years, SD 16). Most were women (73%). Exclusion criteria: severe untreated illness, bipolar disorder, current stressful life event, night shift work, and untreated sleep disorder other than insomnia.

Methods: Data came from a randomized controlled trial of a 10-week nurse-led group treatment for insomnia based on CBT-I (n = 90). The control condition was treatment as usual (n = 75). In accordance with intention-to-treat principles, analyses included data on patients who completed baseline assessments (intervention n = 82, and control group n = 71; post-treatment dropout rate 20%). Fifty-four patients were included in the 1-year follow-up.

Results: Fatigue severity improved significantly more ($p < 0.001$) in the intervention than in the control group (intervention, total FSS score 37.2 [SD 11.9] to 31.0 [SD 13.4] vs. control 35.9 [SD 12.1] to 35.7 [SD 12.8]). This was true also for measurements on mood (psychological distress and depressive symptoms), health-related quality of life (mental functioning), general daytime functioning, specific daytime symptoms (worry about sleep, sleepiness, bodily tiredness, and difficulty concentrating) and dysfunctional beliefs. All improvements were maintained one year after group treatment.

Conclusions: Many aspects of the daytime symptomatology of insomnia were improved via nurse-led group treatment based on CBT-I in primary health care.

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What is already known about the topic?

- People typically seek primary health care for the daytime symptomatology (e.g., fatigue) they experience as a consequence of their insomnia.
- Cognitive behavioral therapy for insomnia (CBT-I) is the recommended treatment for insomnia but is not widely available to primary health care patients.
- Treatment recommendations are based on the effectiveness of CBT-I in improving sleep; less is known about whether it improves the daytime symptomatology of insomnia.

What this paper adds

- The daytime symptomatology of insomnia can improve as a result of nurse-led group treatment based on CBT-I in primary care.
- The improvements in daytime symptomatology were maintained one year after treatment.
- District nurses could successfully deliver group treatment for insomnia in primary health care after two days of training, and by using a semi-structured treatment manual.

1. Introduction

Insomnia is characterized by disturbed sleep and extensive daytime symptomatology that people attribute to their sleep difficulties (American Academy of Sleep Medicine, 2014). Daytime symptoms include fatigue, impairments in attention and difficulty concentrating, impaired daytime functioning, depressive mood, daytime sleepiness, reduced energy, and worry about sleep (American Academy of Sleep Medicine, 2014). Moreover, insomnia is related to depression (Mallon et al., 2000) and reduced quality of life (Leger et al., 2012).

Cognitive processes, such as dysfunctional beliefs and attitudes, play an important role in developing and maintaining insomnia. A vicious circle starts when poor sleep leads people to worry about and focus on their sleep. They begin to attribute daytime symptoms that have many possible causes (e.g., fatigue, difficulty concentrating) mainly or exclusively to poor sleep. This leads to even more worry, greater feelings of emotional distress, and mental and physical hyperarousal, which make it even harder to sleep. They then lie in bed, trying to force sleep to come, which leads to more worry and distress, more negative thoughts, and an even harder time relaxing and getting to sleep. Prompted by worry, distress, and negative thought, people develop behaviors to avoid sleeplessness and daytime symptoms, such as spending more time in bed, and canceling planned activities after a poor night's sleep. Such behaviors tend to maintain or even worsen insomnia symptoms (Harvey, 2002; Espie et al., 2006).

It is often the perception of daytime symptoms, especially fatigue, and the negative impact of such symptoms on quality of life that prompts people to seek treatment for their insomnia (Morin et al., 2006). Despite the importance of the daytime symptomatology of insomnia, most treatment research focuses on sleep, and clinical treatment guidelines are based on sleep outcomes (Riemann et al., 2017; Sateia et al., 2017; Wilson et al., 2010; Wilt et al., 2016). Expert consensus recommendations state that insomnia treatment studies should assess daytime symptomatology, and should do so by measuring fatigue, mood, quality of life, and dysfunctional beliefs and attitudes (Buysse et al., 2006). However, few studies focus on whether insomnia treatments improve daytime functioning and reduce daytime symptoms (Koffel et al., 2014; Riemann et al., 2017; Trauer et al., 2015; van Straten et al., 2017).

Most people seeking treatment for insomnia do so in primary health care (Morin et al., 2006). The recommended treatment is cognitive behavioral therapy for insomnia (CBT-I) (Riemann et al., 2017; Sateia et al., 2017; Wilson et al., 2010; Wilt et al., 2016). CBT-I aims to break patterns of maladaptive cognitions and behaviors involved in the

maintenance of insomnia. It includes educational components, behavioral techniques (e.g., sleep restriction), and cognitive techniques (e.g. methods for coping with worry and dysfunctional beliefs) (Morin, 1993).

However, CBT-I is not widely available to primary health care patients. Instead, hypnotic drugs are the usual treatment (Sateia et al., 2017; Sivertsen et al., 2010). To increase the availability of CBT-I in primary care, we evaluated whether a nurse-led group treatment based on CBT-I techniques and delivered in primary health care could improve insomnia. The program was specially designed to be led by district nurses, registered nurses with a 1-year master's degree in primary health care nursing. District nurses were chosen to lead the program because they are a large group of primary health care professionals with training in patient education and behavioral change. Treatment as usual was the control condition in the randomized controlled trial conducted to evaluate the group treatment. Analyses of trial results on insomnia severity, sleep variables, and hypnotic drug use have been reported previously (Sandlund et al., 2017).

In the present study, we aimed to investigate whether the nurse-led group treatment program for insomnia in primary care improved outcomes related to the daytime symptomatology of insomnia. These outcomes included fatigue (main outcome), mood, health-related quality of life, general daytime functioning, specific daytime symptoms, and dysfunctional beliefs related to the development and maintenance of insomnia.

2. Methods

2.1. Study design

This study includes analyses from a randomized controlled trial in primary care (2011–2014) that compared nurse-led group-treatment for insomnia (intervention) to treatment as usual. Seven primary health care centers in Stockholm County, Sweden, and 165 patients participated in the study. The trial was registered at [ClinicalTrials.gov](http://www.clinicaltrials.gov), identification number NCT01731223, <http://www.clinicaltrials.gov>. The study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting randomized trials (Moher et al., 2001). Earlier results of this study have been reported in a previous publication (Sandlund et al., 2017).

Ethical approval was obtained from the Regional Ethical Review Board in Stockholm, Sweden (Dnr 2011/194-31/1).

2.2. Participants and recruitment

Patients with insomnia were recruited to the study when they consulted their primary health care physician, who made a preliminary assessment of the patient's insomnia symptoms and health status. If the physician found the patient eligible, and if the patient was interested in participating in a group treatment program for insomnia, the physician sent the patient to an individual interview and structured assessment. The assessment was conducted by the nurse who led the group treatment program at that center. The nurse ensured that the patient met the eligibility criteria, confirming the insomnia diagnosis with a structured diagnostic interview guide for sleep disorders based on the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) (American Psychiatric Association, 2000). This guide was used to assess insomnia symptoms and symptoms of sleep disorders other than insomnia, such as obstructive sleep apnea, restless legs syndrome, periodic limb movement disorder, delayed sleep phase disorder, parasomnias, circadian rhythm disorders, and narcolepsy. The nurse also used a semi-structured interview guide to collect data on socio-demographic characteristics, as well as previous and current health problems and medications (Morin, 1993). Insomnia severity was assessed with the Insomnia Severity Index (ISI) (Morin, 1993).

Fig. 1 shows the flow of participants through the study, including

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