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Improving insomnia in primary care patients: A randomized controlled trial of nurse-led group treatment

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ABSTRACT

Background: Insomnia is a common health problem, and most people who seek help for insomnia consult primary care. In primary care, insomnia treatment typically consists of hypnotic drugs, although cognitive behavioral therapy for insomnia is the recommended treatment. However, such treatment is currently available to few primary care patients.
Objectives: To evaluate the effects of a group treatment program for insomnia led by nurses in primary care.
Outcomes: were the Insomnia Severity Index, a 2-week sleep diary, and a questionnaire on frequency of hypnotic drug use.
Design: A randomized controlled trial with pre- and post-treatment assessment and a 1-year post-treatment follow-up of the intervention group.
Settings: Routine primary health care; 7 primary care centers in Stockholm, Sweden.
Participants: Patients consulting primary care for insomnia were assessed for eligibility. To be included, patients had to have insomnia disorder and be 18 years or older. Patients were excluded if they if they worked night shifts or had severe untreated somatic and/or mental illness, bipolar disorder, or untreated sleep disorder other than insomnia. One-hundred and sixty-five patients 20 to 90 years were included. Most were women, and many had co-existing somatic and/or mental health problems. The post-treatment dropout rate was 20%.
Methods: The intervention was a nurse-led group treatment for insomnia based on the techniques of cognitive behavioral therapy for insomnia. The nurses had 2 days of training in how to deliver the program. Ninety patients were randomized to the intervention and 75 to the control group (treatment as usual). Data from 82 in the intervention and 71 in the control group were analyzed in accordance with intention-to-treat principles. Fifty-four of the 72 in the intervention group who participated in the group treatment program were followed up after 1 year.
Results: Mean Insomnia Severity Index score decreased significantly from 18.4 to 10.7 after group treatment but remained unchanged after treatment as usual (17.0 to 16.6). The effect size was large (1.23). Group treatment also resulted in significant improvements in all sleep diary variables (sleep onset latency, total sleep time, time awake after sleep onset, number of awakenings, and sleep quality). It also reduced hypnotic drug use. Improvements were maintained 1-year post-treatment.
Conclusions: Patients with insomnia can be treated successfully with a nurse-led group treatment program in primary health care. The results support implementation of the treatment program, particularly given the need for increased access to non-pharmacological insomnia treatments.

1. Introduction

Insomnia is common, affecting 9% to 15% of the general population worldwide (Ohayon, 2002), and tends to persist over time once established (Mallon et al., 2000). To fulfill the diagnostic

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criteria for insomnia disorder, a person must experience both disturbed sleep and impaired daytime functioning related to disturbed sleep (American Psychiatric Association, 2013; American Academy of Sleep Medicine, 2014). Insomnia is more prevalent in women than in men. Prevalence is highest in middle age (40 to 49 years) and decreases thereafter (Mallon et al., 2014). A range of somatic and mental health disorders is associated with insomnia, including cardiovascular disease (Mallon et al., 2002), diabetes (Knutson et al., 2006), and psychiatric disorders (Taylor et al., 2003). Insomnia is also associated with reduced quality of life (Leger et al., 2012; Zammit et al., 1999). Together, these factors make insomnia a serious public health issue.

About 12.5% of people in the general population report that they need treatment for disturbed sleep (Sandlund et al., 2016), and most who seek help consult primary health care (Morin et al., 2006a). Primary care has a shortage of options for treating insomnia. One of the most common is the prescription of hypnotic drugs. Research suggests that such drugs should only be used as short-term treatments. This is because of their potential side effects and because their effectiveness seems to decrease over time (Buysse, 2013; Wilt et al., 2016). Sleep hygiene recommendations (general advice about environmental and behavioral factors that may help improve sleep) are also common (Sivertsen et al., 2010). Examples of such recommendations include keeping one's bedroom cool and dark and avoiding caffeine, nicotine, and alcohol close to bedtime. However, sleep hygiene recommendations are insufficient as the sole intervention for insomnia (Morgenthaler et al., 2006), likely because treatment for insomnia needs to address cognitive processes (e.g., worry) and maladaptive behaviors (e.g., irregular sleep habits) (Harvey, 2002).

Considerable scientific evidence suggests that non-pharmacological interventions such as cognitive behavioral therapy are effective in treating insomnia (Morin et al., 2006b; Trauer et al., 2015). Additionally, cognitive behavioral therapy for insomnia (CBT-I) may be more effective than hypnotic drugs (Mitchell et al., 2012). In many countries, national guidelines recommend non-pharmacological treatments such as CBT-I as the standard first-line treatment for insomnia (Wilson et al., 2010; Swedish Council on Health Technology Assessment, 2010). CBT-I is a package of straightforward and practical cognitive and behavioral techniques developed in the field of cognitive behavioral therapy specifically to treat insomnia (Morin, 2004). CBT-I aims to change maladaptive cognitions and behaviors. It includes educational, cognitive, and behavioral components that address both nighttime and daytime symptoms (Morin, 2004).

Despite its effectiveness and the guidelines that call for its use, CBT-I is still rarely available to primary health care patients. The scientific evidence for CBT-I is mainly based on treatment performed by psychologists (Wang et al., 2005), and insomnia treatment studies in the context of nursing practice have mostly been of quasi-experimental design and conducted outside primary health care (Page et al., 2006; Hellstrom and Willman, 2011). Nevertheless, one study in primary health care evaluated brief nurse-led behavioral treatment for older people with insomnia, which showed positive results on sleep variables (Buysse et al., 2011). That treatment consisted of two sessions and two telephone calls and comprised sleep education and two behavioral techniques. The few other studies that have been conducted in primary care have evaluated nurse-led strictly manual-guided group CBT-I (Bothelius et al., 2013; Espie et al., 2007, 2001a).

To give more patients access to the first-line treatment for insomnia, we developed a group treatment program based on CBT-I techniques to be used by district nurses for primary health care patients with insomnia. District nurses are registered nurses who work at primary health care centers. They have completed a 1-year master's degree in primary health care that includes training in health-related behavioral change and patient education. District nurses are thus well suited to lead group treatment sessions in primary care. In the current trial, the nurses used a semi-structured manual to guide the group treatment program, which included cognitive and behavioral techniques, such as relaxation, worry time, arguing against unhelpful thoughts, sleep restriction, and stimulus control.

In this randomized controlled trial, we evaluated the effects of a nurse-led group treatment program for patients with insomnia that was based on CBT-I techniques. We compared the effects of group treatment with the effects of treatment as usual. Both recruitment of patients to the study and the treatment program were conducted entirely in primary health care settings. Specific aims were to investigate the effects of the program on (a) insomnia severity (Insomnia Severity Index), (b) sleep (sleep diary variables), (c) clinically important insomnia outcomes (e.g., a $\geq$ 8-point reduction in Insomnia Severity Index), and (d) hypnotic drug use. To investigate whether treatment effects were sustained over time, we conducted a 1-year post-treatment follow-up of patients in the intervention group.

2. Methods

2.1. Study design

The study was a randomized controlled trial that compared the effects of the nurse-led group treatment with the effects of treatment as usual in routine primary health care in Stockholm County, Sweden. The trial was conducted between August 2011 and June 2014 at seven geographically diverse primary health care centers that had purchaser-provider contracts with the Stockholm County Council. Participating centers received no extra financial or other resources. To measure treatment effects, outcome variables were assessed at baseline and post-treatment. Patients in the intervention group who participated in the group treatment were included in a 1-year post-treatment follow-up. The study followed the Consolidated Standards of Reporting Trials (CONSORT) (Moher et al., 2001).

Prior to conducting this study, approval was obtained from the Regional Ethical Review Board in Stockholm, Sweden (Dnr 2011/194-31/1). The trial was registered at ClinicalTrials.gov, identification number NCT01731223, http://www.clinicaltrials.gov

2.2. Participants and recruitment

Patients seeking help for insomnia at the seven participating primary health care centers were continuously recruited to the study by their physicians. Physicians asked patients that they believed fulfilled the study's eligibility criteria if they were interested in participating in the study. Those who were interested were referred to the participating district nurse for a multi-part structured screening assessment to ensure insomnia diagnosis and confirm eligibility.

The structured screening assessment took the form of a 45-min individual interview. To confirm the insomnia diagnosis, the nurse used a standardized diagnostic manual "Structured diagnostic interview for sleep disorder according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV)." (American Psychiatric Association, 2000) The nurse also used a semi-structured interview guide to gather data on clinical sleep history (the duration, frequency, and severity of nighttime and daytime symptoms); whether the patient experienced sleeping difficulty despite opportunities for sleep (e.g., adequate time periods and circumstances); and current and previous somatic and mental health problems, treatments, and medications (Morin, 1993). Guided by the diagnostic manual (American Psychiatric