



Internet-delivered cognitive-behavioral therapy for insomnia and comorbid symptoms

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ABSTRACT

Background: Cognitive-behavioral therapy for insomnia (CBTi) is considered the standard treatment. The internet has proven to be a useful and successful tool of providing CBTi. However, few studies have investigated the possible effect of unguided internet-delivered CBTi (ICBTi) on comorbid psychological symptoms and fatigue.

Methods: Based on a randomized controlled trial, we investigated whether unguided ICBTi had an effect on comorbid psychological symptoms. Adults with insomnia ($n = 181$; 67% women; mean age 44.9 years [SD 13.0]) were randomized to ICBTi ($n = 95$) or to an online patient education condition ($n = 86$) for a nine-week period.

Results: The results from mixed linear modelling yielded medium to large between-group effect sizes from pre- to post-treatment for symptoms of anxiety or depression ($d = -0.57$; 95% CI = 0.79–0.35) and fatigue ($d = 0.92$; 95% CI = 1.22–0.62). The ICBTi group was reassessed at a 6-month non-randomized follow-up, and the completing participants had on the average a significant increase (from the post-assessment) on symptoms of anxiety or depression, while the reduction in symptoms of fatigue (on post-assessment) was maintained. However, due to high dropout attrition and no control group data, caution should be made regarding the long-term effects. In conclusion, the present findings show that unguided ICBTi positively influence comorbid symptoms in the short-term, thereby emphasizing the clinical relevance of unguided ICBTi.

Trial registration: [ClinicalTrials.gov](https://clinicaltrials.gov) identifier: NCT02261272

1. Introduction

Insomnia is the most common sleep disorder and impairs quality of life for millions of individuals worldwide (Ohayon, 1997; Pallesen et al., 2001). Reduced daytime functioning is an important aspect of the insomnia diagnosis, as insomnia affects mood, social functioning, work, cognitive functioning, and often leads to fatigue (American Psychiatric Association, 2013). Additionally, mental illnesses, such as depression and anxiety are commonly comorbid with insomnia (Ohayon, 2007; Sanchez-Ortuno and Edinger, 2012). Traditionally insomnia has been viewed as a symptom of mental illnesses, but there is a growing body of

literature indicating that insomnia may represent an independent disorder that can worsen and cause mental problems (Harvey, 2001). For instance, the symptoms of insomnia often persist after the comorbid disorder has been successfully treated, and it has been argued that this emphasizes the necessity of a separate treatment that focuses mainly on the symptoms of insomnia (Harvey, 2001; Sanchez-Ortuno and Edinger, 2012). Today, cognitive behavioral therapy for insomnia (CBTi) is considered the gold standard treatment (Morin et al., 2006, Wilson et al., 2010). CBTi has shown good results in reducing insomnia symptoms (Okajima et al., 2011), and some studies have examined if CBTi yields similar improvements regarding comorbid psychological

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symptoms and disorders, such as depression and anxiety (e.g., Bélanger et al., 2016; Ho et al., 2015).

The prevalence of insomnia is steadily growing and the need for effective treatment is urgent (Pallesen et al., 2014). To date, the availability of CBTi is still insufficient, due to economic costs and lack of qualified personnel offering this treatment face-to-face (Edinger and Means, 2005). As a means of enhancing the availability of CBTi, internet-delivered CBTi (ICBTi) (e.g. Ritterband et al., 2009) has been developed and found to be very effective in improving patients' sleep (Cheng and Dizon, 2012; Zachariae et al., 2016). Research also indicates that ICBTi may improve patient's comorbid symptoms (Ye et al., 2015; Christensen et al., 2016). Ye et al. (2015) conducted a meta-analysis, which included ten qualified RCTs on Internet-based CBTi interventions. The analysis revealed overall positive results; the combined effect sizes for comorbid depression and anxiety were -0.36 and -0.35 , respectively. An RCT from Australia (Christensen et al., 2016) also examined the effect of internet-based CBTi (SHUTi) on symptoms of depression in individuals with insomnia and sub-clinical depression. The results at six weeks and at six months indicated that the participants who received the SHUTi treatment ($n = 574$) had a significantly lower level of depression symptoms, compared to participants who used an internet-based placebo control program.

The Sleep Healthy Using the Internet (SHUTi) program is an example of a sophisticated online adaptation of CBTi which have shown significant results (Ritterband et al., 2009; Ritterband et al., 2012). In the first clinical trial of SHUTi (Ritterband et al., 2009), findings indicated that nearly three out of four patients were in remission six months after treatment, which is similar to what is typically found in face-to-face CBTi. Further, the results indicated that the SHUTi intervention reduced comorbid psychological symptoms (Thorndike et al., 2013).

In the current study, a Norwegian translated version of the SHUTi was used to examine whether the treatment would have similar effects outside English speaking countries. The preliminary results showed that the SHUTi treatment improved the participants' sleep overall (Hagatun et al., 2017). Based on the lack of knowledge about how such unguided interventions affect comorbid disorders, the aim of the present paper was to examine how the SHUTi intervention affected symptoms of psychological distress and fatigue.

2. Methods

2.1. Participants and procedures

The study protocol was approved by the Regional Committees for Medical and Health Research Ethics in Western Norway (2012/1934 REK, South East B). Details of the study procedure are reported in another forthcoming paper (Hagatun et al., 2017), and therefore only briefly summarized here: Participants were recruited through the media, and completed an online screening before they went through a screening interview by phone. Inclusion criteria were: minimum 18 years old and meeting the diagnostic criteria for insomnia. Exclusion criteria were: night work, presence of another sleep disturbance or mental problem/disorder (e.g. moderate or severe depression) that might impair sleep. Included participants were randomly allocated to either SHUTi or a web-based patient education condition over 9 weeks. Participants in the SHUTi group were followed-up after 6 months.

2.2. Interventions

The SHUTi program is a fully automated interactive online self-help program (Ritterband et al., 2009), based on traditional face-to-face CBTi. SHUTi comprises six weekly online modules, including sleep hygiene, sleep restriction, stimulus control, and cognitive restructuring. The program is mainly based on informative text for the participants to read, and the treatment content, CBTi, is then elaborated and rehearsed

through interactive exercises, quizzes, animations, video vignettes, and expert explanations. In addition, the participants are assigned homework for practicing the content taught in that week's core. An essential aspect of the SHUTi program is that it provides personalised treatment recommendations, which are automatically generated, based on the information that each participant registers through the online sleep diaries and questionnaires. More detailed descriptions of the SHUTi program have been published elsewhere (Ritterband et al., 2009; Thorndike et al., 2008).

The control intervention of the current study comprised a patient education web site, containing information meant to resemble the kind of information individuals with insomnia may receive when they visit a general practitioner concerning their insomnia symptoms (Sivertsen et al., 2010). At this site, the participants could read about the symptoms of insomnia, potential causal and maintaining factors, as well as suggestions for strategies to improve sleep, including simple sleep hygiene strategies, as well as some of the most basic behavioral recommendations used in stimulus control. Hence, the information is mainly based on the treatment principles of CBTi. Although there is some overlap between the patient education intervention and the SHUTi intervention, the two interventions are very different in terms of the share volume of the self-help material and the therapeutic approach; while interactivity and personalised feedback are key elements in the comprehensive self-help intervention in SHUTi, the information provided in the patient education intervention was brief and static. Hence, all information in the patient education intervention was presented as text, without any elements of interactivity or feedback, and took about 30 min to read through. The participants in the patient education group were offered access to ICBTi (SHUTi) after completing the first post-assessment (after nine weeks), albeit no further data were collected from these participants.

2.3. Measurements

Symptoms of anxiety and depression were measured by The Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983), and the Chalder Fatigue Scale (Chalder et al., 1993) was used to measure physical and mental symptoms of fatigue at baseline, post treatment and the 6-month non-randomized follow-up. Only the total HADS score was used, as research indicate that the HADS subscales' ability to differentiate between depression and anxiety is suboptimal (Cosco et al., 2012).

2.4. Statistical analyses

To examine the effect of the SHUTi program compared to the patient education website, a linear mixed model for repeated-measures analysis was performed using the intention to treat principle, such that all participants with baseline data were included in the analysis. In all, 24 of the randomized participants were not included in the analyses, as they never completed any questionnaire (see also Fig. 1). None of these 24 participants were aware of treatment allocation and none of them received any form of treatment. Not including these drop-outs in the analyses is therefore not considered a threat to the internal validity of the study. No constraints were imposed on the covariance structure for repeated measures (type = unstructured, R-matrix only). Mixed model analysis uses maximum likelihood estimation and can handle data that are missing at random (MAR) on dependent variables. Although there are no conclusive tests to prove the assumption of MAR, it is generally considered to be a more realistic assumption as compared to missing completely at random (MCAR). For the analysis, time (pre vs. post), group (SHUTi vs. control), and the interaction effect time x group were included in the model. A statistically significant ($p < 0.05$) interaction effect would indicate that the effect of time was different between the SHUTi and control group.

An additional mixed model analysis was performed including data

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