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Internet-vs. group-delivered cognitive behavior therapy for insomnia: A randomized controlled non-inferiority trial

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ABSTRACT

The aim of this study was to compare guided Internet-delivered to group-delivered cognitive behavioral therapy (CBT) for insomnia. We conducted an 8-week randomized controlled non-inferiority trial with 6-months follow-up. Participants were forty-eight adults with insomnia, recruited via media. Interventions were guided Internet-delivered CBT (ICBT) and group-delivered CBT (GCBT) for insomnia. Primary outcome measure was the Insomnia Severity Index (ISI), secondary outcome measures were sleep diary data, depressive symptoms, response- and remission rates. Both treatment groups showed significant improvements and large effect sizes for ISI (Within Cohen's *d*: ICBT post = 1.8, 6-months follow-up = 2.1; GCBT post = 2.1, 6-months follow-up = 2.2). Confidence interval of the difference between groups post-treatment and at FU6 indicated non-inferiority of ICBT compared to GCBT. At post-treatment, two thirds of patients in both groups were considered responders (ISI-reduction > 7p). Using diagnostic criteria, 63% (ICBT) and 75% (GCBT) were in remission. Sleep diary data showed moderate to large effect sizes. We conclude that both guided Internet-CBT and group-CBT in this study were efficacious with regard to insomnia severity, sleep parameters and depressive symptoms. The results are in line with previous research, and strengthen the evidence for guided Internet-CBT for insomnia.

Trial registration: The study protocol was approved by, and registered with, the regional ethics review board in Linköping, Sweden, registration number 2010/385-31.

1. Introduction

Insomnia is a disorder of difficulty initiating and/or maintaining sleep, with impaired daytime functioning as a consequence. It is a common disorder with around 10–30% point prevalence reported in various studies (Kim, Uchiyama, Okawa, Liu, & Ogihara, 2000; Mellinger, Balter, & Uhlenhuth, 1985; Ohayon & Roth, 2003). Insomnia causes serious suffering and is a substantial economic burden to society due to sick leave and utilization of health care resources (Daley, Morin, LeBlanc, Gregoire, & Savard, 2009; Sivertsen, Overland, Bjorvatn, Maeland, & Mykletun, 2009; Walsh, 2004). There is also increasing evidence that disturbed sleep is a predictor for many other health problems, of which depression, anxiety and substance abuse are among the most studied (Baglioni et al., 2011; Breslau, Roth, Rosenthal, & Andreski, 1996; Ohayon & Roth, 2003; Taylor et al., 2007). Evidence based treatment for insomnia consists of pharmacotherapy and/or psychotherapy. Pharmacotherapy has moderate to large effects but is mainly intended for short term use (Nowell et al., 1997), and symptoms often recur after treatment (Riemann & Perlis, 2009). Cognitive behavioral therapy (CBT) has been found effective both in the short and long term (Okajima, Komada, & Inoue, 2014). Two reviews of sleep medication and psychotherapies have concluded that sleep medication and CBT are equally effective short term, but that CBT is more effective in the long term (Mitchell, Gehrman, Perlis, & Umscheid, 2012; Riemann & Perlis, 2009).

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Even though CBT for insomnia is broadly considered treatment of choice, few patients suffering from insomnia receive CBT due to a lack of trained therapists (Edinger, 2009; Espie, 2009; Larsson, Kaldo, & Broberg, 2010). Many studies have been conducted to investigate new ways of disseminating CBT. Group therapy, bibliotherapy, telephone therapy and Internet therapy have all proven effective (Espie et al., 2007; Ho et al., 2015; Jansson & Linton, 2005; Jernelöv et al., 2012; Koffel, Koffel, & Gehrman, 2015; Ström, Pettersson, & Andersson, 2004; van Straten et al., 2013), also for insomnia comorbid with depression (Blom et al., 2015). Internet-delivered CBT (ICBT) is a growing field (Hedman, Ljótsson, & Lindefors, 2012). Therapist guided ICBT has a potential to be more therapist-efficient than both individual and group-CBT (GCBT): less therapist time is normally needed per patient, thus each therapist can treat more patients during a certain time period (Andersson, 2009; Barak, Klein, & Proudfoot, 2009). Another advantage of ICBT is that therapy is not restricted to a specific time or geographical place. This implies that therapy is available also to patients living far away from a clinic, or without the possibility to come during office hours (Andersson, 2014).

To further the evidence for ICBT, it needs to be compared directly to traditional treatment. Previous studies on guided ICBT for other conditions show that guided ICBT has been equivalent to face-to-face treatment (Andersson, Cuijpers, Carlbring, Riper, & Hedman, 2014). Although a recent meta-analysis indicates that self-help CBT for insomnia is as effective as face-to-face treatment with CBT (Ho et al., 2015), to our knowledge, there are no published studies directly comparing ICBT for insomnia to face-to-face treatment.

The aim of this study was to compare guided Internet-delivered CBT to group-CBT in a randomized controlled non-inferiority trial, investigating treatment effects post treatment and after six months. The primary aim was to investigate the effects on insomnia, a secondary aim was to investigate the effects on participants' level of depression and sleep medicine use. Given the aforementioned results from previous research, the hypothesis was that ICBT is not inferior to GCBT and that achieved results would be sustained over the follow-up period.

2. Method

2.1. Participants and recruitment

This study was open to adults living in the region of Östergötland County, Sweden. The participants were recruited via a national recruitment website (www.studie.nu), a radio program and ads in local newspapers. The study protocol was approved by, and registered with, the regional ethics review board in Linköping, Sweden, registration number 2010/385-31.

Inclusion criteria were:

a) 18 years or older
b) Insomnia diagnosis according to the research criteria from the American Academy of Sleep Medicine (Edinger et al., 2004), with more than 10 points on Insomnia Severity Index, ISI (C.M. Morin, 1993), which is the recommended cutoff to detect insomnia cases (C. M. Morin, Belleville, Belanger, & Ivers, 2011)
c) Ability to participate in group meetings
d) Ability to read and write in Swedish.

Exclusion criteria were:

e) Comorbid sleep disorders urgently requiring other treatment (sleep apnea or narcolepsy)
f) Ongoing alcohol or drug abuse
g) Change in antidepressant medication within the past 2 months
h) Comorbid disorders directly contraindicative of essential interventions in insomnia treatment (e.g., bipolar disorder) or urgently requiring other treatment (e.g. severe depression and suicidal ideation, i.e. having >30 p on the self-report version of the Montgomery Åsberg Depression Rating Scale (MADRS-S) (Montgomery & Asberg, 1979), (Svanborg & Åsberg, 1994) or > 3 p on the suicide ideation item 9 or diagnosed with severe depression or suicidality at assessment)
i) Other on-going psychological treatment
j) Night-shift work

Comorbidities were allowed, apart from what is mentioned in exclusion criteria e, f and h. There was no restriction on sleep medication use.

2.1.1. Initial screening

Participants applied via a secure website, received information about the study and gave their consent. They filled out a number of screening questionnaires including: contact information, background data, specific questions on sleep related disorders, questions on other psychiatric and somatic disorders, ISI, MADRS-S and the Alcohol Use Disorders Identification Test (AUDIT) (Saunders, Aasland, Babor, De La Fuente, & Grant, 1993). AUDIT was input to the assessment of alcohol and drug abuse.

2.1.2. Structured telephone interview

Participants not excluded after the initial screening were interviewed by telephone. The interview encompassed: checking diagnostic criteria (inclusion criteria b) for insomnia using 1, an interview version of ISI, 2, a question on adequate opportunity and circumstance for sleep, and 3, questions on daytime fatigue (Epworth Sleepiness Scale, ESS (Johns, 1991)); checking motivation and ability to take part; a follow up on findings from the initial screening regarding sleep related disorders, other psychiatric and somatic disorders and use of medicines. Patients not excluded at this stage were booked for a live assessment.

2.1.3. Live assessment

The live assessment took 15–50 min and focused on: checking the diagnostic criteria for insomnia; asking about daytime functioning using ESS; assessing depressive symptoms using the depression section of the Structured Clinical Interview for DSM-IV, SCID-I (First, Gibbon, Spitzer, Williams, & Benjamin, 1999). When indicated in the initial screening or telephone interview participants were asked about suicidal ideation, alcohol consumption, medication, bipolar disorder and sleep disorders other than insomnia. All interviews were reviewed in a meeting where the principal investigator, (GA) made the final decision on inclusion based on the interviews and screening data. Participants excluded at this stage were offered to get the Internet version of the treatment outside of the study, or referred to other caregivers when relevant (see Fig. 1).

2.2. Randomization and assessment points

Treatment was provided in two arms, group therapy (GCBT) and therapist guided Internet-delivered therapy (ICBT). Participants, (n = 48) were randomized to treatment conditions (n = 24 per group) by university staff not involved in the study, using a free randomization service online (www.randomizer.org). The group therapy participants were divided into three groups with 8, 9 and 7