



# Guided internet cognitive behavioral therapy for insomnia compared to a control treatment – A randomized trial<sup>☆</sup>



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## ABSTRACT

**Aim:** To evaluate if internet-delivered Cognitive Behavioral Therapy for insomnia (ICBT-i) with brief therapist support outperforms an active control treatment.

**Method:** Adults diagnosed with insomnia were recruited via media ( $n = 148$ ) and randomized to either eight weeks of ICBT-i or an active internet-based control treatment. Primary outcome was the insomnia severity index (ISI) assessed before and after treatment, with follow-ups after 6 and 12 months. Secondary outcomes were use of sleep medication, sleep parameters (sleep diary), perceived stress, and a screening of negative treatment effects. Hierarchical Linear Mixed Models were used for intent-to-treat analyses and handling of missing data.

**Results:** ICBT-i was significantly more effective than the control treatment in reducing ISI (Cohen's  $d = 0.85$ ), sleep medication, sleep efficiency, sleep latency, and sleep quality at post-treatment. The positive effects were sustained. However, after 12 months the difference was no longer significant due to a continuous decrease in ISI among controls, possibly due to their significantly higher utilization of insomnia relevant care after treatment. Forty-six negative effects were reported but did not differ between interventions.

**Conclusions:** Supported ICBT-i is more effective than an active control treatment in reducing insomnia severity and treatment gains remain stable one year after treatment.

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## 1. Introduction

Insomnia means an inability to fall asleep, and/or waking up too early in the morning or during the night, resulting in non-restorative sleep and decreased day-time functioning (APA, 2013). When using stringent diagnostic criteria the point prevalence of insomnia in a general population is between 6% and 10% (Ford & Kamerow, 1989; Morin & Jarrin, 2013). The burden of disease is substantial, both for society (Daley, Morin, LeBlanc, Gregoire, & Savard, 2009) and for the individual, who not only suffers from the direct consequences of low quality sleep and worry about sleep, but also from an increased risk of, for example, depression (Buysse

et al., 2008; Ford & Kamerow, 1989) and hypertension (Suka, Yoshida, & Sugimori, 2003).

Pharmacological treatment is effective but only recommended for short term use. It may cause negative side-effects such as disturbed sleep architecture, memory and psychomotor impairment, rebound insomnia, and withdrawal effects (Wilson et al., 2010). In comparison, although data on possible negative effects of treatment are lacking, psychological treatment for insomnia in the form of cognitive behavioral therapy (CBT) has strong evidence (Riemann & Perlis, 2009) with sustained improvements. However, treatment access is low since qualified CBT-therapists are rare (Larsson, Kaldo, & Broberg, 2009) and expensive (van Straten & Cuijpers, 2008).

Self-help treatments with minimal guidance from a therapist could be one way to reduce the problems of availability and costs. Historically, the effects of self-help books for insomnia have been small to moderate and maintained at long-term follow-ups (van Straten & Cuijpers, 2008). A more recent form of guided self-help, internet-delivered Cognitive Behavioral Therapy with therapist

<sup>☆</sup> The trial was registered, together with a parallel trial, at [Clinicaltrials.gov](http://Clinicaltrials.gov) as "Internet-CBT for Insomnia" registration ID: NCT01256099.

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support (ICBT) has growing empirical support for a wide range of psychiatric conditions (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Hedman, Ljotsson, & Lindfors, 2012).

A number of studies have been conducted on internet-delivered self-help for insomnia since the first study in 2004 by Strom and colleagues (Strom, Pettersson, & Andersson, 2004), which despite a number of methodological problems showed promising results. Several studies with no therapist support, or with automated feedback only, have presented positive results (Lancee, van den Bout, van Straten, & Spoormaker, 2012; Ritterband et al., 2009; Ritterband et al., 2012), in one case also when compared to a non-guided internet-based placebo condition (Espie et al., 2012).

However, a meta-analysis demonstrates that for a range of conditions, therapist guided internet-treatments result in larger effects than non-guided versions (Spek et al., 2007). When it comes to ICBT for insomnia, the importance of therapist support is less clear. Studies of ICBT-i with automated feedback only have shown large effects (Ritterband et al., 2012; Espie et al., 2012). On the other hand, it has been shown that minimal therapist guidance can make a substantial difference when added to a self-help book (Jernelov et al., 2012), with the additive effect of support mediated by an increased involvement in the most important therapeutic methods (Kaldo, Ramerö, & Jernelöv, 2015). A recent study tested an ICBT program including 15–30 min of active therapist support each week (Van Straten et al., 2013). Effects were overall large, but the diagnostics relied on cut-offs and the comparison was a pure waitlist and not an active control treatment. Another study also showed positive results for therapist-supported ICBT but were less generalizable since it targeted patients with both insomnia and depression (Blom et al., 2015).

Many previous studies on ICBT-i are uninformative on the long term effects since most studies had no or only short follow-ups (2–14 weeks). One six months follow-up showed durable effects, but the waitlist had then received the intervention and could no longer serve as a control (Ritterband et al., 2009). The 48 week follow-up in a study by Lancee et al. (2012), although positive, also lacked an untreated control-group and showed attrition rates of 38%–65%.

Another general shortcoming of previous research is that even though the importance of reducing sleep medications has been stressed (Ritterband et al., 2009; Van Straten et al., 2013), previous studies have seldom included use of sleep medication as an outcome, and some studies that did measure it showed no decrease (Espie et al., 2012; Van Straten et al., 2013).

In general, the reporting of negative treatment effects, or adverse events, has been a neglected aspect of psychological treatments so far (Barlow, 2010), and this is also true for both CBT and ICBT. In face-to-face treatment it has been estimated that about 5–10% of all patients are afflicted by negative effects, and there has recently been a call for regularly probing for these events also in internet-based interventions (Rozenental et al., 2014).

In summary, even though a number of studies generally show positive effects for internet interventions for insomnia, there is still a lack of knowledge on long term effects, how a therapist-guided internet intervention compares to an active control treatment, effects on sleep medication use, and possible negative treatment effects.

The aim of this study was to evaluate if therapist guided internet-delivered CBT for insomnia (ICBT-i) was more effective compared to an active internet-delivered control treatment (ICBT-ctrl; not including the most efficacious CBT-i-methods), in reducing insomnia symptoms and improving sleep parameters directly after treatment, after six months, and after a year. In addition, the within-group long term stability of gains of ICBT and the effects on sleep medication were evaluated. We also wanted to screen for

possible negative treatment effects, and to apply rigorous methods for handling missing data.

## 2. Methods

This study was undertaken as a randomized controlled trial comparing two active treatments and is reported in accordance with the CONSORT statement for non-pharmacological trials (Boutron, Moher, Altman, Schulz, & Ravaud, 2008). The study was conducted at the Internet Psychiatry Clinic, part of the public health care in the Stockholm County, Sweden. The study protocol was approved by the regional ethics review board in Stockholm, Sweden (2009/1810-31/3). The trial was registered at [Clinicaltrials.gov](http://Clinicaltrials.gov), registration ID: NCT01256099.

### 2.1. Participants and recruitment

Participants were recruited via advertisements and articles in daily newspapers, via a website for clinical trials in Sweden ([www.studie.nu](http://www.studie.nu)), and via the public web site of the Internet Psychiatry Clinic ([www.internetpsykiatri.se](http://www.internetpsykiatri.se)). Individuals interested in participating signed informed consent and completed eighteen screening questionnaires via the internet. The screening questionnaires included the Insomnia Severity Index (ISI; Bastien, Vallières, & Morin, 2001), a self-report version of the Montgomery Åsberg Depression Rating Scale (MADRS-Svanborg & Åsberg, 1994), Alcohol Use Disorders Identification Test (AUDIT; Saunders, 1993), the Drug Use Disorders Identification Test (DUDIT; Berman, Bergman, Palmstierna, & Schlyter, 2005), questions on demographic data (e.g. age, gender, education), practical pre-requisites for participating in the study, and a checklist screening for sleep disorders, somatic disorders, behavioral medicine conditions, and psychiatric conditions.

Inclusion criteria were:

- a) 18 years or older,
- b) Insomnia diagnosis according to the research criteria from American Academy of Sleep Medicine (Edinger et al., 2004), assessed in a structured diagnostic interview,
- c) Insomnia at a clinical level defined as more than 10 points on ISI according to Morin (1993),
- d) Ability to read and write in Swedish and no foreseeable practical problems to participate in the study,
- e) No comorbid sleep disorders primarily requiring other treatment (e.g. sleep apnea or narcolepsy),
- f) A consumption of alcohol/drugs deemed to not substantially affect sleep or interfere with treatment,
- g) Not started to use or changed the dose of antidepressant drug during the last 2 months,
- h) No somatic or psychiatric conditions requiring acute care or being contraindicative of essential interventions in insomnia treatment (e.g. bipolar disorder),
- i) Not fulfilling the DSM-IV criteria for current Major Depression episode,
- j) Not working night shifts.

Other comorbidities were allowed. Sleep medicine use was unrestricted.

#### 2.1.1. Initial screening

All criteria except (b), (g), and (i) were reviewed on basis of the screening questionnaires. AUDIT-scores above 19 for men and above 14 for women, and a DUDIT-score above 8 and 2 respectively, were reviewed more thoroughly and led to exclusion if addiction or abuse was apparent (f). Scores above 30 on the MADRS-S total score and above 3 on the item on suicidal ideation led to exclusion (h).

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