Guided internet cognitive behavioral therapy for insomnia compared to a control treatment – A randomized trial

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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, LèBlanc, 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...
support (ICBT) has growing empirical support for a wide range of psychiatric conditions (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Hedman, Ljotsson, & Lindefors, 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, Ranerö, & Jernelov, 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 wait-list 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 (Rozental 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-cotr; 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, 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), and via the public web site of the Internet Psychiatry Clinic (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) where 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).
2.1.2. Structured telephone interview

All individuals who were not initially excluded went through a structured and diagnostic telephone interview including: checking diagnostic criteria for insomnia (b) and depression (i), sociodemographic data, sleep difficulties, previous treatments (g), motivation and ability to take part in the study, specific questions on sleep related disorders, and a screening for a list of other psychiatric and somatic disorders and rating each as ‘not present’, ‘less probable’, and ‘probable’. Also, an interview-version of ISI was administered as described below.

Individuals who fulfilled inclusion criteria and completed the pre-treatment measures were included in the study and randomized. Table 1 presents the pre-treatment characteristics of all included participants (n = 148). Fig. 1 presents the flow of participants through recruitment, treatment and follow-ups.

2.2. Outcome measures

2.2.1. Primary outcome measure

2.2.1.1. Insomnia severity. The insomnia severity index (ISI; Bastien, Vallieres, et al., 2001; Bastien, Vallieres, et al., 2001), with 7 items rated from 0 to 4 on the severity of initial, middle and late insomnia; sleep satisfaction; interference of insomnia with daytime functioning; noticeability of sleep problems by others; and distress about sleep difficulties. The psychometric properties of ISI are adequate and it is sensitive to change (Bastien, Vallieres, et al., 2001), also when web-based (Thorndike et al., 2011).

Since some level of missing data could be expected in this study, especially on the web-based questionnaires (including ISI) at long term follow-ups (Lancee et al., 2012), the recommendations by Hedman et al. (2013) were followed by including an interview version of the primary measure to be administered at all assessment-points before and after treatment. This was based on the first five items in ISI, most closely covering the diagnostic criteria. These questions and their response options were read to the participants verbatim and the participant were asked to choose one response option. The five-item version of ISI had a Cronbach’s alpha of 0.83. Based on a regression analysis using data from both ISI and the interview version of ISI at the follow-ups (showing a strong and significant correlation of r = 0.83), a formula to transform interview-ISI values to ISI values were calculated to enable a replacement of missing ISI data.

2.2.2. Secondary outcome measures

2.2.2.1. Sleep diary. A sleep diary was used for one week at all assessment points. Each day, participants registered bed time, time of falling asleep, night time awakenings, time of waking up and time of getting out of bed. Also, subjective sleep quality was rated daily on a 1 to 5 point scale from very poor to very good. From these data sleep efficiency, sleep onset latency, total sleep time and sleep quality were calculated.

2.2.2.2. Stress. To measure the level of subjective stress, the Perceived Stress Scale 4 item version (PSS-4; Cohen, Kamarck, & Mermelstein, 1983), was used. Each item has the response alternatives 0 (never) to 4 (very often) and total score range from 0 to 16.

2.2.2.3. Sleep medications. Data from self-ratings, interviews and sleep diaries were cross-checked to determine the use of sleep medications before and after treatment. At post-treatment, complementary data on more specific changes in use of sleep medication during the treatment period were also collected.

2.2.3. Clinical significance – responders and remitters

Calculation of treatment response and remission rates follows previous recommendations (Morin et al., 2008); a responder was defined by a change in ISI score with 8 points or more compared to pre-assessment and participants with an absolute ISI score less than 8 were defined as remitters.

2.2.4. Other measures

2.2.4.1. Negative effects. A screening for negative treatment effects

Table 1
Pre-treatment characteristics of participants.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ICBT n = 73</th>
<th>ICBT-ctrl n = 75</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of women</td>
<td>59 (81%)</td>
<td>57 (76%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Age (sd)</td>
<td>47 (15.2)</td>
<td>49 (15.6)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Level of Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary school</td>
<td>5 (7%)</td>
<td>1 (1%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>High school</td>
<td>14 (19%)</td>
<td>18 (24%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>University</td>
<td>54 (74%)</td>
<td>56 (75%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Married or partner</td>
<td>49 (67%)</td>
<td>53 (71%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full or part time</td>
<td>58 (80%)</td>
<td>55 (73%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>On sick leave or unemployed</td>
<td>6 (8%)</td>
<td>4 (6%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Retired or other</td>
<td>9 (12%)</td>
<td>16 (21%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Current economic status 1 (very poor) – 5 (very good)</td>
<td>3.6 (0.81)</td>
<td>3.8 (0.98)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Years with sleep difficulties (sd)</td>
<td>10.8 (11.5)</td>
<td>10.2 (9.3)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Average number of self-reported co-morbid conditions (sd)*</td>
<td>1.8 (1.6)</td>
<td>1.9 (1.5)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Probable</td>
<td>2.2 (2.8)</td>
<td>4.2 (2.5)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Less probable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using one or more pharmacological and herbal remedies:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep medications</td>
<td>33 (45%)</td>
<td>37 (49%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Pain medications</td>
<td>11 (15%)</td>
<td>7 (9%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>5 (7%)</td>
<td>9 (12%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Allergy medications</td>
<td>11 (15%)</td>
<td>14 (19%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Other medications</td>
<td>16 (22%)</td>
<td>18 (24%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Neuropathic (alert)</td>
<td>10 (14%)</td>
<td>2 (3%)</td>
<td>p &lt; .05</td>
</tr>
<tr>
<td>Neuropathic (sleep)</td>
<td>7 (10%)</td>
<td>4 (5%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Neuropathic (other)</td>
<td>9 (12%)</td>
<td>9 (12%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Not using any drug</td>
<td>18 (25%)</td>
<td>23 (31%)</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

Note. Significance tests for continuous variables performed with t-test, otherwise Chi-2 is used.

* The probability of the participant actually having a diagnosis are estimated in the telephone interview and rated as Not present, Probable or Less probable.
was done in the interviews at all three assessments occurring after treatment. The interviewers asked all participants the question “Did the treatment lead to any negative consequences?”. If yes, they were asked to describe these consequences, and if the answer was unclear the interviewer asked the participant to be more specific. When all data had been collected, the answers from all three occasions were combined and grouped according to their thematic content.

2.2.4.2. Treatment satisfaction. The Client Satisfaction Questionnaire (CSQ-8; Attkisson & Zwick, 1982) measured overall patient satisfaction at the end of each treatment. Each item is rated from 1
to 4 and the total score ranges from 8 (low satisfaction) to 32 (high satisfaction). Internal consistency of the CSQ-8 has been reported to be high (Cronbach's alpha = 0.93).

2.2.4.3. Therapist contact. Therapist time was only measured for ICBT-i since the control treatment did not receive therapist guidance. The time therapists spent on reviewing and giving feedback to homework reports and sleep diaries, reading and writing answers to questions the participants had, and reminding inactive participants via messages and SMS was logged, as was the numbers of messages the participant sent to the therapist and vice versa.

2.2.4.4. Participant adherence. In the ICBT-i group, the number of activated modules and the number of homework reports was logged. To capture the overall engagement in each of the two interventions, all participants were asked at post-treatment how much of the self-help text they had read (with the options none, 25%, 50% 75%, and 100%) and how many hours a week they had spent working with the treatment methods.

2.3. Randomization and assessment points

This study was a randomized controlled trial with two arms (ICBT-i and ICBT-ctrl). The participants were randomized by people not involved in the study, using www.random.org as a true random number source and randomization clusters of different sizes. All outcome measures were assessed before and after treatment, and at 6 and 12 months after treatment.

Assessors and therapists were not blind to treatment condition.

2.4. Interventions

2.4.1. General description

Both treatments lasted eight weeks and consisted of eight modules, accessed on a secure web site. They were also similar on a range of other features: a module consisted of a text to read, control questions on the treatment and the theory behind it, behavioral assignments, sleep diary registrations and work sheets; the participants were expected to complete one module per week; participants had access to a discussion forum including the other participants in the same study arm; ISI and MADRS-S were filled out on a weekly basis and the therapist had access to this data which allowed monitoring of the participant's progress and alerted the responsible clinician if a participant scored 4 or more points on the suicidal ideation item in MADRS-S (item 9).

2.4.2. Insomnia treatment (ICBT-i)

The basis for the ICBT-i treatment was well-established CBT techniques for insomnia, with sleep restriction and stimulus control as the two most important methods [Harvey, Inglis, & Espie, 2002; Morin et al., 2006]. The treatment content was delivered both online and in a book (Jernelov, 2008) that had been previously shown to produce large effects on insomnia symptoms [Jernelov et al., 2012]. The printed material was divided into several modules (i.e., chapters) that included psychoeducative text and each module was accompanied by online material that consisted of reading instructions, a brief summary, sleep diary, weekly assignments, work sheets, weekly symptoms measures, homework reports and written communication with the therapist. The sleep diary and all worksheets existed both as printer friendly pdf-files and in digital forms that were filled out by the patients when reporting homework in the treatment platform. The modules in ICBT-i were: Introduction and facts about sleep; CBT for insomnia and sleep hygiene; education on sleep medication and tapering (given only to patients with sleep medication); sleep restriction and stimulus control; stress management; managing fatigue; handling negative thoughts about sleep; planning ahead.

The first, the second and the last modules were fixed, but the order of the remaining modules was determined by the therapist and participant together based on data from the pre-treatment assessment and the results of an interactive treatment guide filled out by the patient at the start of the treatment. Sleep restriction and stimulus control were never omitted from the treatment plan. The basic instructions for sleep restriction was to first calculate average time slept each night during one week to constitute the initial allowed time in bed (with no minimum time set beforehand). When weekly average sleep efficiency reached over 85%, the sleep window was increased by 15 min, but if it went below 80% the sleep window was decreased by 15 min.

Each module ended with a home-work report which the patient filled out and sent to their therapist. The therapist reviewed the home-work report, the sleep diary data, work sheets, and weekly insomnia and depression ratings. Written feedback was given within 48 h and the therapist then gave the participant access to the next module. Also, if the participant was inactive for 7 days, the system alerted the therapist to send a mobile phone text message (SMS) as a reminder and encouragement. If needed, another SMS was sent, followed by an e-mail then by telephone calls.

Therapists in the present study (n = 8) were in their final year of the Swedish 5-year university program for clinical psychologists and had training in CBT for at least 18 months. They all received a one-day course in CBT for insomnia and were supervised weekly by a licensed clinical psychologist with expertise in CBT for insomnia (KB).

2.4.3. Active control treatment (ICBT-ctrl)

The control treatment was designed to be an active intervention to control for the more general positive effects of participating in a treatment. To make ICBT-ctrl credible it was decided to incorporate some components with previously established specific effects on insomnia, but three strategies were used to make these less likely to be as effective as the ICBT-i program. First, the control treatment only included components with less empirical support and often low effects; sleep hygiene [Alexandru, Robert, Viorel, & Vasile, 2009], relaxation [Alexandru et al., 2009; Lichstein, Riedel, Wilson, Lester, & Aguillard, 2001], and mindfulness [Ong, Shapiro, & Manber, 2008], complemented with general stress management. Sleep restriction and stimulus control or other advice on how to more directly affect the sleep pattern were thus not included. Second, these methods were presented in a rather short and compact format and the exercises given to the patients were less frequent and intensive than usually recommended to reach full effect. For example, in relaxation only quick relaxation was used and mindfulness was only presented as one short exercise without clear-guidelines on how often to relax, and in neither case the use of continuous registrations was encouraged. Third, no therapist guidance was given in ICBT-ctrl in order to not provide the participants with expertise feedback on their homework or suggestions on methods not included in the program. Only support on technical questions and issues where given on demand, and an SMS was sent as a reminder at the start of treatment and when module two was activated.

In short, the control treatment included well-known CBT components to increase credibility and avoid nocebo-effects, but did not include the components considered the most effective for insomnia treatment, and also no therapist support.

The modules of the ICBT-ctrl were: psychoeducation on sleep, psycheducation on insomnia and setting treatment goals, sleep hygiene I (light, sound, temperature), sleep hygiene II (exercise, food, alcohol/nicotine/caffeine), applied relaxation, stress...
management, mindfulness, and treatment evaluation and maintenance. The treatment module for the upcoming week was opened each Sunday. Participants could work with the module material online, and were also encouraged to print out each module and the included registration sheets. At the end of each module, a homework report checklist was used by the participants to review their own homework. Also, in each weekly questionnaire, together with the ratings of insomnia and depression, participants reported which methods they had used and reflected on how these had worked out. Daily registrations in a sleep diary were recommended, as well as using these to explore patterns and factors that affected sleep. Participants were also encouraged to write comments in the discussion forum and for each module submit a post on a specific theme.

2.4. Treatment adherence

The self-help material assures a highly standardized way to deliver treatment. The self-help manual accounted for a major part of the therapeutic information the participants received during treatment, minimizing individual therapist influence. Furthermore, adherence to the treatment protocol in the group with guidance was ascertained through the use of a therapist manual and supervision.

2.5. Statistics

2.5.1. Analyzing outcome — linear mixed model

Hierarchical linear mixed effect modeling was used to perform significance tests for continuous outcome data. Mixed-effects models have several advantages compared to traditional statistical methods, in particular its superior ability to handle missing data (Gueorguieva & Krystal, 2004) and the inclusion of person-specific intercepts and change parameters (i.e., random effects) in the model. We used linear mixed models to examine the difference in rates of change between ICBT-i and ICBT-ctrl over the four assessment points. We did not expect the rates of change to be constant from pre-treatment to 12-months follow-up, but that the most pronounced changes would occur during treatment and any change after the post-treatment assessment would occur at slower pace. Initial visual inspection confirmed these expectations. We therefore fit the data to a basic model consisting of a two-part piecewise function. The first function, or piece, described a linear change from pre-to post-treatment and the second piece described a linear change from post-treatment to the follow-ups at 6 and 12 months.

Full information maximum likelihood estimation was used to fit the model. The strategy to find the best model for each outcome variable was to start with the basic model with group (coded as 0 for the ICBT-i group and 1 for the ICBT-ctrl group), time1 (for piece 1), time2 (for piece 2), group × time1, and group × time2 as fixed effects. Then random intercepts, random effects of time1 and time2, and a repeated measures effect were sequentially added and retained if they improved the model fit according to log-likelihood ratio tests for nested models.

Hypothesis-testing was then based on the estimates of the following effects obtained in the models: A significant interaction effect of time1 and group indicated difference in symptom reduction between the groups during treatment. A significant interaction effect of group and time2 indicated difference in durability of improvements gained during treatment. To test the group difference at each long-term follow-up assessment, the time variables were adjusted to move the intercept to each of these measurements points and then the effect of group (at the relocated intercept) were tested. The models also allowed for interpretation of the main (or simple) effects of time as tests of significant within-group effects for the two groups during the two time-periods, i.e. change from pre-treatment to post-treatment and from post-treatment to 12 months follow-up within each group. To obtain these effects for the ICBT-i group, the groups were recoded to 0 for the ICBT-ctrl and 1 for the ICBT-i group.

2.5.2. Missing data analysis

The modeling approach utilized all available data from all participants and measurement points, which made this an intent-to-treat analysis. Full information maximum likelihood estimation provides unbiased parameter estimates in the presence of missing data under the assumption of data missing at random (MAR) and outperforms traditional methods (e.g., last observation carried forward) in most missing data situations (Lane, 2008; Mallinckrodt, Clark, & David, 2001). The MAR assumption requires that all known correlates of data missingness (i.e. to what degree data is missing) are included in the analysis. We therefore performed sensitivity analyses where a number of covariates were added to the model for each outcome measure. All pre-treatment characteristics that correlated with either outcome or missingness and also significantly improved the model fit were included. Sensitivity analyses that deviated from the primary analyses are reported in the Results section.

Since more participants had completed the telephone-administered version of ISI than the internet-administered version, this measure was used to make a specific test of the relation between missingness and outcome.

2.5.3. Other statistical analyses and power

When deciding responder and remitter status, participants with missing data had their status carried forward from the last observation, and thus participants with only pre-treatment data available were defined as non-responders and non-remitters at all measurement points. Chi-2 tests, t-tests and Pearson’s r were also used to analyze observed data where appropriate. The original power calculations were made on an estimated difference of 0.6 (Cohen’s d) at post-treatment, with which an ordinary t-test would need 60 participants in each group to render a power of 90%. The use of mixed-effects models was not deemed to result in lower power than a t-test and thus the current sample size were judged to be satisfactory.

3. Results

3.1. Missing data and covariates included in the sensitivity analyses

The CONSORT flowchart (Fig. 1) provides information on the attrition at different measurement points.

The following pre-treatment characteristics were found to be correlated to data missingness and were thus candidates for inclusion in the sensitivity analyses: Use of antidepressants, use of naturopathics to improve sleep, and screening positive for Restless Legs Syndrome or Delayed Sleep Phase Syndrome. In addition, the pre-treatment variables that correlated with change in each specific outcome measure were candidates for inclusion in the sensitivity analysis for the respective measure.

We explored whether there was a relationship between interview-ISI scores and data missingness. At post-treatment and 6-month follow-up the effect of missingness was non-significant (t(124) = −0.157; p = 0.88 and t(123) = 0.123; p = 0.22), but after 12 months the telephone data revealed a significantly (t(127) = 2.31; p = 0.023) higher level of insomnia symptoms for participants with missing data (n = 23; m = 8.5; SD = 3.0) compared to those having filled out the questionnaires (n = 106; m = 6.7; SD = 3.4). We therefore used interview-ISI data to impute missing data in ISI and also included interview-ISI as a possible candidate in the sensitivity analyses for the other measures.
3.2. Treatment adherence, treatment satisfaction, and therapist time

The ICBT-i treatment consisted of a total of 8 modules, but the module on sleep medication was only opened to patients with sleep medications. An average of 6.8 (SD = 1.7) modules were made available and the participants completed the homework report for 5.4 (SD = 2.4) modules. The homework report of the most important module on sleep restriction and stimulus control were filled out by 60 of the 73 participants (82%).

Since the participants in ICBT-ctrl automatically gained access to a new module each week, and no homework report or therapist contact was included, adherence measured as number of modules or homework reports could not be estimated for this group. However, on the question on how much of the treatment text they read, ICBT-i read on average 84.2% (SD = 19.6%) and ICBT-ctrl read 87.3% (SD = 19.9%) which did not differ significantly (t(122) = 0.86; p = .39). The self-reported number of hours spent on treatment each week was significantly higher for the ICBT-i (M = 6.1; SD = 4.5) compared to ICBT-ctrl (M = 4.4; SD = 4.1; t(122) = 2.20M p = .03).

At the post-treatment measurement, the treatment satisfaction measured with the CSQ-8 was significantly lower for the control treatment (M = 18.7; SD = 5.3) than for the insomnia treatment (M = 27.3; SD = 4.5; t(122) = 9.63, p < .001).

The therapists spent on average 1.91 h (SD = 1.00; CI-95% = 1.67 to 2.14) in total on each patient in the ICBT-i condition. The number of messages sent by the therapists was on average 17.7 (SD = 6.4) and the participants sent on average 18.7 (SD = 10.5) messages (including homework reports). Telephone contact was utilized only very few times to reach inactive participants that had neither responded to written messages in the treatment platform, nor to SMS. These telephone calls were not therapeutic in nature and were not registered.

3.3. Primary outcome – insomnia severity

The piecewise model that best fit the data for ISI included two random effects; the intercept and the slope of the first piece between pre-treatment and post-treatment. Fig. 2 shows both the observed means and the estimated means from the piecewise model. The differences between the observed means and the estimated means are due to the model’s correction for missing data in the latter and the fact that the second estimated time-piece describes the overall linear trend from post-treatment to 1-year follow-up. As more thoroughly presented in Table 2, ICBT-i produced a significantly greater reduction in ISI compared to ICBT-ctrl during treatment, and after 6 months the participants in ICBT-i still experienced a significantly lower level of insomnia. However, after treatment the two groups converged significantly and at the 12-month follow-up the difference was no longer significant. This was mainly due to continued improvement in ICBT-ctrl, since no significant deterioration was found for ICBT-i.

Large to very large within groups effect sizes were observed in both groups at post, FU6 and FU12: Cohen’s d (CI-95%) for ICBT-i were 2.07 (1.66–2.46), 1.71 (1.33–2.08), and 1.95 (1.54–2.33) for each respective time-point, and the corresponding effects for ICBT-ctrl were 1.09 (0.75–1.43), 1.22 (0.87–1.56), and 1.50 (1.13–1.86) respectively.

3.4. Clinical significance – responders and remitters

The results are presented in Table 3. The general findings in the continuous outcome variable were replicated for the categorical data of responders and remitters, with significant group differences at post and 6-month follow-up but not after 12 months. The proportion of responders in ICBT-i did not differ much between the three measurement points after treatment (45%–52%), which was also the case for remitters (37%–47%). This confirms that the effects were stable.

3.5. Secondary outcomes and sensitivity analyses

Table 2 presents the observed means and standard deviations for ISI and secondary outcomes together with the estimated means and effect sizes based on estimated data. Table 2 also presents the results of the linear mixed models significance tests for interaction (time × group) within each time-piece and direct comparisons of the groups at both follow-ups.

The most common pattern was the same as can be seen for ISI in Fig. 2; ICBT-i was superior to ICBT-ctrl at post and 6-months follow-up, but after 12 months the ICBT-ctrl participants had experience decrease in their symptoms to such extent that no significant differences were observed. The only exceptions were for sleep latency, where ICBT-ctrl remained inferior to ICBT-i also after one year, and for sleep time and stress (PSS-4) that did not differ at any time-point.

The sensitivity analyses, where all pre-treatment covariates that correlated with either missingness or outcome (or both) and also contributed significantly to the model according to log-likelihood ratio tests where added, did not change the results of the significance tests except in one case; Sleep Quality 6 months after treatment. Here the sensitivity test indicated a type II error, since the sensitivity analysis showed that ICBT-i was significantly superior to ICBT-ctrl when covariates were included in the model to correct for the effects of missingness.

In addition to the analyses presented in Table 2, the effects of time for the ICBT-i group were tested. All measures, except for the PSS-4 (p = .077), indicated significant improvement during the first time-piece (pre-post). Sleep time was thus significantly increased for the ICBT-i, even though no difference from the control treatment was found, as reported above. There were no significant effects during the second time-piece (post – FU12), indicating that no further improvement or deterioration for the participants in ICBT-i occurred.

3.6. Sleep medication and other treatments

During the year after treatment, 35 out of 68 (52%) of the participants in the control group had utilized sleep medications or
Table 2
Primary and secondary outcomes and effect sizes.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Control treatment</th>
<th>Between groups effect sizes est. (CI-95)</th>
<th>Linear mixed models</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>M est.</td>
<td>SD</td>
<td>M</td>
</tr>
<tr>
<td>ISI (0–28)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>16.8</td>
<td>16.8</td>
<td>3.8</td>
</tr>
<tr>
<td>Post</td>
<td>8.3</td>
<td>8.6</td>
<td>4.1</td>
</tr>
<tr>
<td>FU6</td>
<td>9.5</td>
<td>8.8</td>
<td>5.4</td>
</tr>
<tr>
<td>FU12</td>
<td>8.9</td>
<td>9.1</td>
<td>4.1</td>
</tr>
<tr>
<td>Sleep efficiency (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>70.6</td>
<td>70.6</td>
<td>11.9</td>
</tr>
<tr>
<td>Post</td>
<td>84.7</td>
<td>84.0</td>
<td>9.4</td>
</tr>
<tr>
<td>FU6</td>
<td>83.2</td>
<td>83.3</td>
<td>9.5</td>
</tr>
<tr>
<td>FU12</td>
<td>82.6</td>
<td>82.5</td>
<td>10.6</td>
</tr>
<tr>
<td>Sleep latency (min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>57.1</td>
<td>59.9</td>
<td>43.9</td>
</tr>
<tr>
<td>Post</td>
<td>27.4</td>
<td>29.1</td>
<td>24.8</td>
</tr>
<tr>
<td>FU6</td>
<td>35.2</td>
<td>29.3</td>
<td>26.9</td>
</tr>
<tr>
<td>FU12</td>
<td>27.7</td>
<td>29.6</td>
<td>17.2</td>
</tr>
<tr>
<td>Sleep time (h)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>5.85</td>
<td>5.85</td>
<td>1.00</td>
</tr>
<tr>
<td>Post</td>
<td>6.61</td>
<td>6.61</td>
<td>0.96</td>
</tr>
<tr>
<td>FU6</td>
<td>6.78</td>
<td>6.65</td>
<td>1.01</td>
</tr>
<tr>
<td>FU12</td>
<td>6.58</td>
<td>6.69</td>
<td>0.95</td>
</tr>
<tr>
<td>Sleep quality (0–4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>2.74</td>
<td>2.74</td>
<td>0.59</td>
</tr>
<tr>
<td>Post</td>
<td>3.30</td>
<td>3.22</td>
<td>0.86</td>
</tr>
<tr>
<td>FU6</td>
<td>3.12</td>
<td>3.17</td>
<td>0.90</td>
</tr>
<tr>
<td>FU12</td>
<td>3.16</td>
<td>3.12</td>
<td>0.74</td>
</tr>
<tr>
<td>PSIS-4 (0–14)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>5.8</td>
<td>5.8</td>
<td>3.1</td>
</tr>
<tr>
<td>Post</td>
<td>5.0</td>
<td>5.1</td>
<td>3.3</td>
</tr>
<tr>
<td>FU6</td>
<td>5.2</td>
<td>4.9</td>
<td>3.6</td>
</tr>
<tr>
<td>FU12</td>
<td>4.5</td>
<td>4.8</td>
<td>3.5</td>
</tr>
</tbody>
</table>

Note. All statistical tests are performed on estimated values.
M Est. = Estimated mean (in italics); ISI = Insomnia Severity Index (missing data imputed from the interview version of ISI when applicable). PSS-4 = Perceived Stress Scale – 4 item version.
Initial diff in change denotes the interaction between time and group during piece 1 (pre-post). Follow-up diff in change denotes the interaction of time and group during piece 2 (post-FU12). FU6 group diff and FU12 group diff denotes the difference between groups at FU6 and FU12 respectively.

Table 3
Responders and remitters in each group.

<table>
<thead>
<tr>
<th>Post</th>
<th>FU6</th>
<th>FU12</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICBT-i N (%)</td>
<td>ICBT-ctrl N (%)</td>
<td>ICBT-i N (%)</td>
</tr>
<tr>
<td>Responders</td>
<td>37 (51%)</td>
<td>18 (24%)</td>
</tr>
<tr>
<td>Non-responders</td>
<td>36</td>
<td>57</td>
</tr>
<tr>
<td>Statistics</td>
<td>Chi-2(1) = 11.3; p = .001</td>
<td>Chi-2(1) = 5.5; p = .019</td>
</tr>
<tr>
<td>Remitters</td>
<td>31 (43%)</td>
<td>11 (15%)</td>
</tr>
<tr>
<td>Non-remitters</td>
<td>42</td>
<td>64</td>
</tr>
<tr>
<td>Statistics</td>
<td>Chi-2(1) = 14.1; p &lt; .001</td>
<td>Chi-2(1) = 4.4; p &lt; .036</td>
</tr>
</tbody>
</table>

Note. Responder — change in ISI >7. Remitter — ISI<8. Missing data replaced according to the last observation carried forward principle.
than in the treatment group (8/69; 12%), but not significantly so (Chi-2(1) = 2.1; p = .15).

3.7. Negative effects

In ICBT-i 15 patients reported one negative effect and four patients reported two. For the control treatment the corresponding figures were 11 and 6. The total number of negative effects reported did not differ between the treatments (t(34) = 0.94; p = .36). Table 4 provides an overview of the themes of reported negative experiences.

4. Discussion

This study shows that therapist-guided ICBT for insomnia was superior to an active but unguided control treatment immediately after treatment and six months afterwards, and resulted in a stable reduction of insomnia symptoms also after one year. The primary outcome measure, self-rated insomnia severity, was significantly reduced for ICBT-i compared to the control group and the improvements remained stable during the first year after treatment. The effect of ICBT-i was very large and significantly larger than the effect for the active control treatment immediately afterwards and after six months. During the follow-up period, the control group showed increasingly lower symptoms and at the 12-months follow-up the difference between the two groups was no longer significant.

The positive effects of the treatment were also mirrored in the sleep diary measures; sleep latency was more than halved to 29.7 min, sleep time increased with 45.6 min and sleep efficiency improved from 70.6% to 84.7%, all together being similar to previous studies (Espie et al., 2012; Lancee et al., 2012; Ritterband et al., 2009; Van Straten et al., 2013). Sleep latency was the only parameter where ICBT-i was still superior over the control treatment after one year, while the participants in ICBT-i did not sleep longer than controls at any time-point. The latter is not surprising since CBT for insomnia in general does not show very strong effects longer than controls at any time-point. The latter is not surprising considering findings by Kyle et al. (2014) where more objective and systematic measures of these factors showed clear deterioration during sleep restriction. These findings should be explored further in future research in line with the recommendations of Rozental et al. (2014).

To our knowledge, this is the first study to compare ICBT-i to an active control treatment for insomnia. The participants’ adherence to each intervention was similar in the proportion of self-help material being read. Participants in ICBT-i spent more time on working with the treatment methods, but participants in the control treatment still reported a fairly high degree of treatment engagement with about an average of 35 min a day. The active control treatment also performed rather well at post-treatment, which is not so surprising since it included some credible and effective methods such as sleep hygiene, relaxation, mindfulness, and keeping a sleep diary (Alexandru et al., 2009; Lichstein et al., 2001; Ong et al., 2008). But the control treatment also improved significantly more than ICBT-i after the post-treatment assessment. This may be due to a combination of spontaneous recovery, a delayed effect of treatment since all participants had access the treatment material during six months after post-treatment measures, and the observed higher utilization of additional treatments for insomnia during the follow-up period.

There are some limitations to this study. First, no untreated control group was used. However, previous studies reviewed in the introduction have shown that the absolute majority of within group effects of wait-lists lie below a Cohen’s d of 0.50 which is markedly lower even than the control treatment in this study. Second, no complete blinding was used since participants in the control treatment did receive information that they were allocated to a condensed version of the full treatment and would not receive support. This procedure was used in order to minimize possible nocebo effects, that could occur if participants were to perceive the intervention received as inferior to an expected treatment. To

---

**Table 4**

<table>
<thead>
<tr>
<th>Themes of self-reported negative effects</th>
<th>ICBT-i</th>
<th>ICBT-ctrl</th>
</tr>
</thead>
<tbody>
<tr>
<td>The use of the sleep diary caused increased stress, worry and focus on sleep difficulties</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>The technical platform or the treatment were perceived as being complicated and/or stressful</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Disappointed in not better during treatment, increased hopelessness</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Sleep restriction, or the use of the sleep diary in the control intervention, induced less sleep or lower quality of sleep when applied</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Stricter bedtimes use in sleep restriction resulted in unwanted change of habits or perception of a reduced freedom during the day</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Sleep restriction gave extra time out of bed which was spent on eating, resulting in a weight gain</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Sleep restriction induced less sleep and lower concentration resulting in a mistake at work, although rather benign.</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Previous panic attacks returned when using sleep restriction</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
minimize this risk, the information given was that the condensa-
tion of the treatment was done to make it equally effective but less
effortful. According to adherence estimations, control participants
took an active part in their treatment, and the comparatively large
effects, also relative to wait-lists in previous studies, indicate that
placebo- and/or specific effects of the semi-effective methods used
were larger than possible nocebo effects. However, nocebo effects
can still not be ruled out. Since the outcomes were based on self-
reports, the effects of non-blind assessors should be minimal.
Third, although the overall attrition rates were low, sleep diary
showed 30%–45% missing data. Even though state-of-the-art
methods for handling missing data were used, the results from
sleep diary data should be interpreted with some caution.

Finally, the study was not designed to evaluate the specific effect
of therapist support, and hence no conclusion regarding such ef-
fects can be drawn. The control treatment lacked both therapist
support and some of the most effective techniques. However, it is
interesting to compare the effects in this study to the previous
study by Jernelov et al. (2012) where the same self-help manual
delivered as a book together with telephone support showed a
somewhat larger effect than that found in the present study on
insomnia severity (d = 2.46 compared to d = 2.07) and sleep pa-
rameters. This might indicate that highly structured phone calls on
a set time each week are better not only than no support at all, but
also than therapist contact through text messages via the internet.
However, since a number of previous trials have utilized automated
feedback rather than therapist support and received large effects
(Ritterband et al., 2012; Espie et al., 2012), it is still not clear if
therapist support is needed in ICBT for insomnia even though this
seems to be the case for ICBT in general (Spek et al., 2007).

In conclusion, in this study ICBT for insomnia including brief
therapist support is more effective in reducing insomnia severity
than an active control treatment, and treatment gains remain one
year after treatment. Together with previous studies, it strengthens
the evidence for this kind of intervention and calls for an increased
focus on implementation.

Conflict of interest for any author

None.

Acknowledgments

This study has received funding from the Södertörn-Königs-
Foundation (SLS-156621), AFA Sickness Insurance Research Fund
(2999/09-721), The regional agreement on medical training and
clinical research (ALF) between Stockholm County Council and
Karolinska Institutet.

We would like to give special thanks to Monica Hellberg for
being an invaluable logistic resource and to Hugo Hesser for life
saving advice on the statistical analyses; Michele Storm, Jennie
Eriksson, Linda Algärd, Lisa Bohman, Anna Etzler, Lovisa Egnell,
Karin Frankeł & Astrid Jonsell, for their work as online therapists;
Kristina Jungmarker, Hans Lundgren, and Tryggve Strömgen
for their work with the follow-ups; and finally Per Carlbring, who
allowed us to use his research website to post information about
the study.

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