

## INSOMNIA

# Three-Year Follow-Up of Insomnia and Hypnotics after Controlled Internet Treatment for Insomnia

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**Study Objectives:** To investigate the long-term effects of therapist-guided Internet-based insomnia treatment on insomnia severity and sleep medication use, compared with active control.

**Methods:** This study was an 8 week randomized controlled trial with follow-up posttreatment and at 6, 12, and 36 months, set at the Internet Psychiatry Clinic, Stockholm, Sweden. Participants were 148 media-recruited nondepressed adults with insomnia. Interventions were Guided Internet-based cognitive behavioral therapy for insomnia (ICBT-i) or active control treatment (ICBT-ctrl). Primary outcome was insomnia severity, measured with the Insomnia Severity Index. Secondary outcomes were sleep medication use and use of other treatments.

**Results:** The large pretreatment to posttreatment improvements in insomnia severity of the ICBT-i group were maintained during follow-up. ICBT-ctrl exhibited significantly less improvement posttreatment (between-Cohen  $d = 0.85$ ), but after 12 and 36 months, there was no longer a significant difference. The within-group effect sizes from pretreatment to the 36-months follow-up were 1.6 (ICBT-i) and 1.7 (ICBT-ctrl), and 74% of the interviewed participants no longer had insomnia diagnosis after 36 mo. ICBT-ctrl used significantly more sleep medication ( $P = 0.017$ ) and underwent significantly more other insomnia treatments ( $P < 0.001$ ) during the follow-up period.

**Conclusions:** The large improvements in the ICBT-i group were maintained after 36 months, corroborating that CBT for insomnia has long-term effects. After 36 months, the groups did not differ in insomnia severity, but ICBT-ctrl had used more sleep medication and undergone more other additional insomnia treatments during the follow-up period.

**Clinical Trial Registration:** The trial was registered, together with a parallel trial, at Clinicaltrials.gov as "Internet-CBT for Insomnia" registration ID: NCT01256099.

**Keywords:** CBT, guided self-help, insomnia, Internet, long-term follow-up, psychological treatment, psychotherapy

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## Significance

Over the past 30 years, research has repeatedly shown the benefits of cognitive behavioral therapy for insomnia (CBT-i) for the treatment of insomnia disorder. This report is the longest controlled follow-up of CBT-i thus far, showing that treatment gains are stable three years after treatment. Importantly, CBT-i also reduced use of sleep medications and other additional insomnia treatments, compared to a control treatment. This is a clinically significant finding since long term use of sleep medication is not recommended and sleep problems entail a great cost to society. We therefore suggest that CBT-i should continue to be considered treatment of choice for insomnia, and that efforts should be made to disseminate and increase accessibility to this much needed treatment.

## INTRODUCTION

Insomnia is defined as an inability to initiate and/or maintain sleep, with daytime dysfunction as a consequence. It is one of the most prevalent disorders known, and multiple studies have reported a prevalence of approximately 10% to 20%.<sup>1–3</sup> In addition to the substantial suffering of individuals with insomnia, this disorder also causes high societal costs because of sick leave, use of health care, and lost productivity.<sup>4,5</sup> Insomnia is associated with, and is a suspected contributing factor to, conditions such as cardiac disease, diabetes, anxiety, and depression.<sup>6,7</sup>

Current evidence suggests that both pharmaceutical and psychological treatments for insomnia are effective in the short term.<sup>8</sup> Psychological treatment in the form of cognitive behavioral therapy for insomnia (CBT-i) has stronger empirical support than medication in terms of long-term effectiveness<sup>9</sup> and is thus generally considered to be the treatment of choice.<sup>10,11</sup>

However, CBT-i therapists tend to be scarce.<sup>12,13</sup> Thus, different types of self-help treatments have been tested and found to be effective,<sup>14,15</sup> also for patients with multiple comorbidities.<sup>16</sup> Compared with unguided self-help, therapist support

provides better treatment outcomes for most psychiatric conditions,<sup>17</sup> including insomnia,<sup>16</sup> potentially because of the greater patient involvement in key therapeutic techniques.<sup>18</sup> Internet-based CBT-i (ICBT-i) is a form of self-help with increasing empirical support<sup>19</sup> that can be delivered with or without therapist guidance. In the current study, guided ICBT-i was used, and in this article, ICBT-i will henceforth refer to therapist-guided Internet-delivered CBT for insomnia.

We have only been able to find two published studies comparing ICBT-i and face-to-face treatment. In one, ICBT-i was demonstrated to be noninferior to group CBT-i up to 6 mo after treatment,<sup>20</sup> whereas ICBT-i was less effective than individual CBT-i at the end of treatment in another study, which has not yet reported long-term effects.<sup>21</sup>

Thus far, studies of traditional face-to-face CBT for insomnia commonly employ a follow-up period of approximately 3, 6, or 12 mo,<sup>22</sup> with one exception which performed a 24-mo follow-up.<sup>23</sup> Studies of ICBT-i have, to the best of our knowledge, not had follow-up periods longer than 12 mo.<sup>14,19</sup>

Insomnia studies that report long-term follow-ups have largely demonstrated maintained treatment effects over time, but the effects of CBT-i on sleep medication usage are not

always reported. This observation, and the lack of follow-ups that are longer than 1 y, may be observed as a serious knowledge gap, considering that one proposed advantage of CBT-i compared with sleep medication is the long-term effects.<sup>9</sup>

The study presented in this article is a randomized controlled trial where ICBT-i is compared to an active, but low-intensity control treatment for insomnia. Previously, the pretreatment, posttreatment, 6- and 12-mo data have been reported.<sup>24</sup> In that report, the group receiving ICBT-i had a significantly larger treatment effect on insomnia severity than the control treatment group at the posttreatment and 6-mo assessments. At the 12-mo follow up, the control treatment group had attained similar results as the CBT-i group. This article also reported that the control group had used more other treatments for insomnia than the group receiving ICBT-i.

The aim of this randomized controlled trial was to perform a 36-mo follow-up of therapist-guided ICBT-i compared to an active control treatment, in order to evaluate if the positive effects of ICBT-i remained stable and if there were any differences between the groups regarding insomnia severity and sleep medication use.

## METHODS

This study was based on a randomized controlled trial that compared two active treatments. The study was performed at the Internet Psychiatry Clinic, which is part of the public psychiatric health care system in Stockholm County, Sweden. The study protocol was approved by the regional ethics review board in Stockholm, Sweden (2009/1810-31/3) and the trial was registered at Clinicaltrials.gov, registration ID: NCT01256099. Outcomes from pretreatment to the 12-mo assessment have been previously reported<sup>24</sup> and will only be presented briefly in this report when considered necessary for providing context and meaning to the 36-mo follow-up results reported in this article.

### Participants and Recruitment

Participants were recruited via advertisements and articles in daily newspapers, a website for clinical trials, and the clinic's website. Individuals interested in participating in the study provided informed consent and completed screening questionnaires via the Internet, followed by a telephone interview. Recruitment was performed jointly with another study that investigated the effects of insomnia treatment for patients with comorbid insomnia and depression.<sup>25</sup> In the study reported here, we investigated the preventive effects of insomnia treatment in a nondepressed sample. Applicants with ongoing depression were thus excluded from this study but included in a parallel study by Blom and colleagues.<sup>25</sup> Please refer to the first article regarding this study<sup>24</sup> for further details about the inclusion procedure.

The inclusion criteria were the following:

- a) aged 18 y or older;
- b) insomnia diagnosis according to the research criteria from American Academy of Sleep Medicine,<sup>26</sup> which encompass diagnostic criteria from the Diagnostic and Statistical Manual of Mental Disorders, 4th

- c) insomnia at a clinical level defined as greater than 10 points on the Insomnia Severity Index (ISI), according to Morin<sup>28,29</sup>;
- d) ability to read and write in Swedish;
- e) no comorbid sleep disorder that primarily required other treatment (e.g., sleep apnea or narcolepsy);
- f) no ongoing drug or alcohol abuse;
- g) a stable dosage of or no antidepressant medication during the 2 mo preceding inclusion;
- h) no somatic or psychiatric conditions that required acute care or were contraindicative of essential interventions in insomnia treatment (e.g., bipolar disorder);
- i) not fulfilling the DSM-IV-TR criteria for a current major depression episode, assessed in an interview using the depression segment from the Structured Clinical Interview for DSM-IV-TR (SCID-I)<sup>30</sup>;
- j) not working night shifts.

Other comorbidities were allowed, and sleep medication use was unrestricted. Sleep apnea was assessed in the telephone interview, using questions on snoring, apneas, and the Epworth Sleepiness Scale.<sup>31</sup> Any suspicion of sleep apnea (e.g., extensive snoring but a lack of information about nightly apneas) meant exclusion and referral to sleep laboratory investigation. Narcolepsy was assessed in the interview with questions about sudden, uncontrollable sleep. Subjects who fulfilled the inclusion criteria and completed the pretreatment measurements were included and randomized ( $n = 148$ ). There were 81% females in ICBT-i and 76% females in ICBT-ctrl. The mean ages in the ICBT-i and ICBT-ctrl groups were 47 (standard deviation, hereafter SD, of 15.2) and 49 (SD 15.6) y old, and the participants had a mean (M) value of 10.8 (SD 11.5) and 10.2 (SD 9.3) y with sleep difficulties. The levels of depressive symptoms measured with the self-rated version of the Montgomery Åsberg Depression Rating Scale (MADRS-S)<sup>32</sup> were similar in both groups, ICBT-i:  $M = 12.6$ ,  $SD = 5.6$ ; ICBT-ctrl:  $M = 12.7$ ,  $SD = 6.0$ , i.e., symptom levels on average corresponding to mild depression. In ICBT-i, there were 33 users of sleep medication (45%) and 5 users of antidepressants (7%). The corresponding figures for ICBT-ctrl were 37 (49%) and 9 (12%). Further details regarding the baseline characteristics can be found in the first article.<sup>24</sup>

### Outcome Measures

#### Insomnia

The primary outcome measure was insomnia severity, which was measured using the Internet self-rating of the ISI<sup>33</sup>; if Internet data were missing, interview data were imputed (the imputation was performed as recommended by Hedman et al.<sup>34</sup>). The psychometric properties of ISI are adequate, it has been found to be sensitive to change,<sup>35</sup> also when delivered via the Internet,<sup>36</sup> and it has been validated across different cultures.<sup>37</sup> Insomnia was assessed via telephone interviews by blind assessors using the research criteria for insomnia.<sup>26</sup>

### **Sleep Medication**

The data regarding medication were retrieved from self-report questionnaires, interview data, and sleep diaries at all assessment points. Participants were asked, both in questionnaires and interviews, to provide sleep medication name, dose, and frequency of use (e.g., zopiclone, 7.5 mg, seven times per week). They were also asked to provide sleep medication data in the sleep diary at the preassessments and postassessments as well as the 6- and 12-mo follow-up. Also, at each assessment point, they were asked whether they had changed their sleep medication during the time period since the previous assessment, and if so, how. The data from all these sources were evaluated in detail for each participant, who were then defined as being frequent, regular, occasional, or nonusers of sleep medication at each assessment point. Frequent user meant using a meaningful dose of sleep medication four to seven times a week, regular user meant two to three times a week, and occasional user meant once a week or less. The sleep medication used was categorized into three types based on substance and expected effect on sleep: Category 1, hypnotics, such as zolpidem, zopiclone and propiomazine; Category 2, sedative antihistamines/antihistamines, e.g. hydroxyzine, alimemazine and ephedrine; and Category 3, melatonin.

To be able to compare the groups on how the use of sleep medications changed from baseline during the entire 3-y follow-up period, an index of change was calculated from the frequency variable previously described. Each of the four measurement points after the treatment were given a value depending on their relation to the baseline frequency of medicine use; a more frequent use yielded +1, a less frequent use yielded -1, and an equal level or missing data yielded 0. The sleep medication change index was then calculated for each patient by adding these values together.

### **Responders, Remitters, and Diagnosis**

Remission from insomnia was measured using the remission criterion which stipulates that the ISI score should be less than 8 points.<sup>33</sup> Participants were considered responders if the ISI score decreased by 8 or more points.<sup>29</sup> Insomnia diagnosis was assessed in structured diagnostic interviews at all assessment points.

### **Use of Other Treatments**

We collected data about the participants' additional efforts to treat insomnia with non-pharmacological treatments, such as psychotherapy (other than what was provided in this study), mindfulness, or counseling, during the entire follow-up period. These data were also retrieved from self-report questionnaires, interview data, and sleep diaries at all assessment points. For these treatments, we categorized the participants according to whether or not they tried other treatments during the follow-up period.

### **Randomization, Assessment Points, and Blinding**

Randomization between treatment groups in this trial was performed using [www.random.org](http://www.random.org) as a true random number source, with randomization clusters of different sizes. The randomization was performed by people who were otherwise not involved in the study.

Assessments were performed pretreatment, posttreatment, and after 6, 12, and 36 mo. The main outcome was the self-rated ISI, but to ensure validity of the complementary data collected in the 36-mo follow-up telephone interview, the assessors (one psychologist and one psychotherapist) were temporary staff who were not otherwise involved in the study and were blinded to the treatment allocation. The participants were, in the beginning of the interview, instructed not to reveal details about their treatment. The blinding was confirmed by asking the assessors if the blinding had been broken during the interview.

### **Interventions and Therapists**

The treatments were delivered using the same Internet-based technical platform—a secure website that had been previously used in a number of studies about Internet interventions, as well as in regular psychiatric care at the public health Internet Psychiatry Clinic in Stockholm, Sweden. Both treatments lasted for 8 w and consisted of eight modules, or chapters. More details about the treatments can be found in the article by Kaldo et al.<sup>24</sup>

#### **Insomnia Treatment (ICBT-i)**

The Internet-based treatment for insomnia consisted of eight modules, with the psychoeducative text provided in the form of a book. The material on the Internet platform consisted of reading instructions for each module, worksheets to be completed (e.g., cognitive reappraisal), a sleep diary to be completed, weekly homework assignments, exercises, and a secure, Email-like system for written contact with the therapist. The treatment encompassed an online discussion forum.

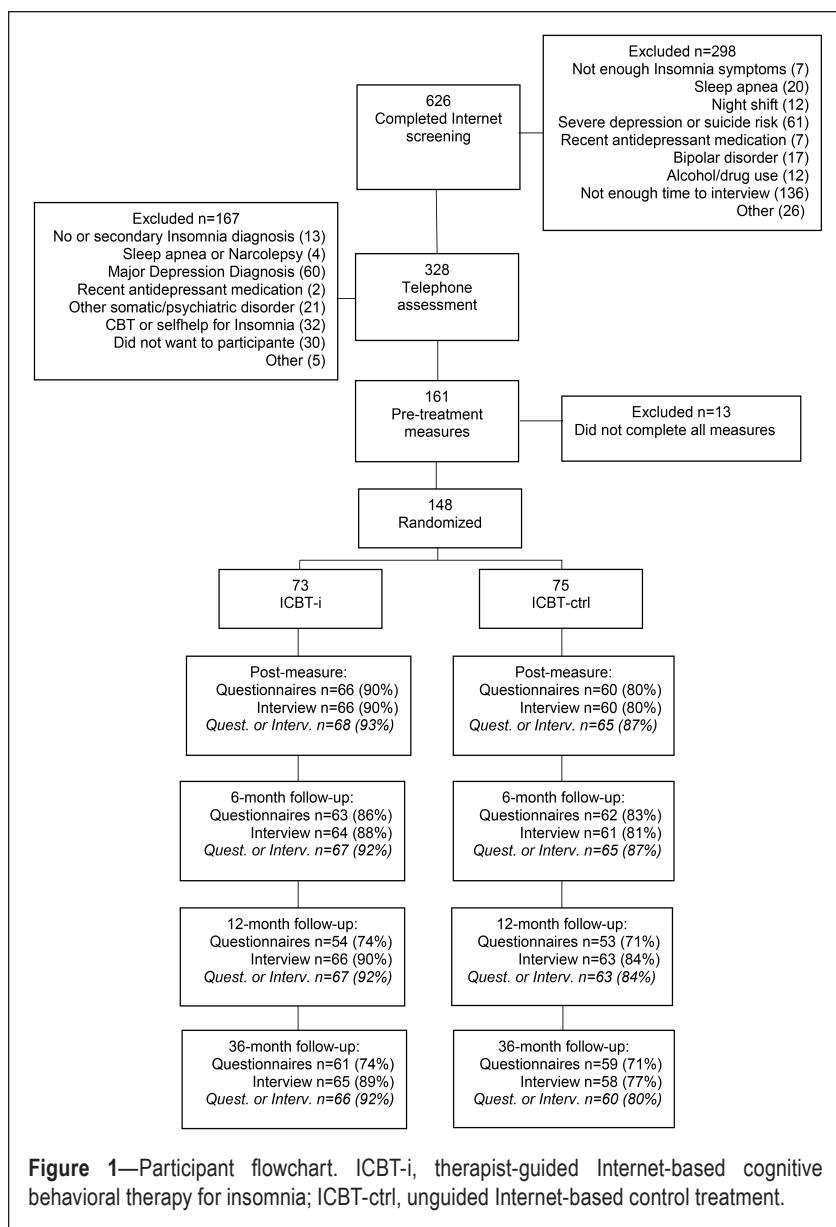
The treatment was mainly focused on state-of-the-art CBT-i: psychoeducation, sleep restriction, stimulus control, and cognitive reappraisal. Participants taking sleep medication were taught how to quit and were encouraged to include quitting or tapering in their treatment plan. The treatment also included a variety of other components common in CBT-i, such as relaxation training, daytime activity tips, and bedtime routines.

#### **Active Control Treatment (ICBT-ctrl)**

The control treatment was designed to be a credible insomnia treatment, thus including some methods that were expected to have a general but small effect on health and sleep, but without techniques with stronger evidence for treating insomnia (sleep restriction and stimulus control). This treatment was only delivered online and included no therapist support, but had a discussion forum via which the participants could communicate with each other. The treatment encompassed a sleep diary, psychoeducation about sleep, sleep hygiene and limited versions of relaxation training, stress management, and mindfulness.

#### **Therapists**

Therapist support was available only for the ICBT-i group. Eight therapists in their final year of a 5-y Master of Science university program for clinical psychologists participated in the study. They were all educated and trained in CBT for at least 18 mo, including supervised face-to-face treatments. The therapists participated in a 1-day course in CBT for insomnia



and received weekly supervision by a licensed clinical psychologist with expertise in CBT for insomnia (KB).

### Statistical Analyses

Statistical analyses were performed using the SPSS version 22 software package (IBM Inc., Armonk, NY, USA).

Hierarchical linear mixed-effect modeling was used to perform significance tests of the primary outcome, insomnia severity (ISI), where missing self-rated data were replaced by imputed interview data when possible (see Kaldo et al.<sup>24</sup> and Hedman et al.<sup>34</sup> for information about the imputation method). We used full maximum likelihood estimation to fit the model. All included and randomized participants were part of the outcome analyses according to the intent-to-treat, and the mixed models approach is a valid and recommended choice in treating missing data.<sup>38</sup> Group differences at the 36-mo follow-up were analyzed by moving the intercept to 36 mo (156 w) after the end of treatment.

The dichotomous outcomes, such as diagnosis, responders and remitters, and use of other treatments, were analyzed using  $\chi^2$  or Fisher exact testing. The sleep medication change index, described in the Outcome Measures section, represents a number of follow-up time-points and is seen as an interval scale, thus suitable for an independent samples *t*-test to compare the groups on sleep medication use over the follow-up period.

The observed data from questionnaires and interviews were used to calculate Cohen *d* effect sizes for repeated measures with pooled SDs.

## RESULTS

### Attrition and Model Fit

See Figure 1 for a flowchart that shows the attrition at the different assessment points. Interview data was used to impute missing questionnaire data for 2 participants in ICBT-i and 5 in ICBT-ctrl at the postassessment, 4 (ICBT-i) and 3 (ICBT-ctrl) at the 6-mo follow-up, 13 (ICBT-i) and 10 (ICBT-ctrl) at the 12-mo follow-up and 5 (ICBT-i) and 1 (ICBT-ctrl) at the 36-mo follow-up. All randomized participants were included in the analyses according to intent-to-treat principles using mixed-effect modelling to handle remaining missing data.

The best-fitting hierarchical linear mixed-effect model for insomnia outcome consisted of two time pieces, pretreatment to post-treatment (timepiece 1) and posttreatment to 3-y follow-up (timepiece 2). The model was tested for potential covariates using baseline variables that correlated with outcome pretreatment to posttreatment and/or missingness. None of the tested baseline variables improved the model, separately or combined.

The final model was a simple timepiece 1, timepiece 2, group, group\*timepiece 1 and group\*timepiece 2 model with random intercept.

### Insomnia Severity

Both groups improved significantly in terms of ISI from pre-assessment to postassessment ( $P < 0.001$ ). There was a significant interaction pretreatment to posttreatment, with an advantage for ICBT-i ( $P < 0.001$ ). The mixed-model analysis of ISI at the 36-mo follow-up indicated that the improvements attained by participants in the ICBT-i group were maintained, as illustrated in Figure 2 and Table 1. However, from posttreatment to 36-mo follow-up, there was a significant interaction effect to the advantage of the ICBT-ctrl group ( $P < 0.01$ ). This finding was explained by the fact that the ICBT-i group had no significant change ( $P = 0.7$ ) from posttreatment to 36-mo follow-up, whereas the control treatment group improved significantly ( $P = 0.001$ ) during this time. There was no significant

difference between treatment groups at the 36-mo follow-up assessment ( $P = 0.7$ ). See Figure 2.

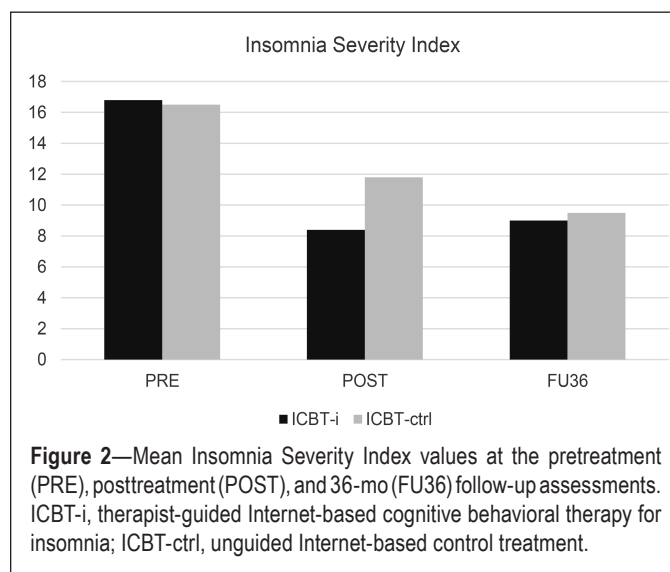
The mean, SD, within-group effects sizes, remitters, and responders are presented in Table 1. Chi-square analysis of remitters ( $ISI < 8$  points) and responders ( $ISI\text{-change} > 7$  points) indicated a significant difference posttreatment (remitters:  $\chi^2 = 14.1$ ;  $P < 0.001$ , responders:  $\chi^2 = 11.3$ ;  $P = 0.001$ ). At the 36-mo follow-up,  $\chi^2$  analyses indicated a non-significant difference (remitters:  $\chi^2 = 2.7$ ;  $P = 0.10$ , responders:  $\chi^2 = 2.1$ ;  $P = 0.14$ ). Insomnia diagnosis assessed in the 36-mo interviews indicated that 17 participants (26%) in ICBT-i and 15 participants (26%) in ICBT-ctrl had insomnia; this difference was not significant ( $\chi^2 = 0.001$ ,  $P = 0.97$ ). Assuming all participants that were missing from the interview assessment had an insomnia diagnosis, these figures are 25 (34%, ICBT-i) and 32 (43%, ICBT-ctrl), and there was no significant difference between the groups ( $\chi^2 = 1.1$ ,  $P = 0.29$ ).

### Use of Sleep Medication

The total sleep medication use and frequency of use at each assessment point is found in Table 2. During the entire period from the posttreatment to the 36-mo assessment, sleep medication use decreased significantly more in ICBT-i ( $M = -0.97$ ,  $SD = 1.9$ ) than in ICBT-ctrl ( $M = -0.28$ ,  $SD = 1.6$ ;  $t = -2.4$ ,  $df = 146$ ,  $P = 0.017$ ) according to analysis of the sleep medication change index. A sensitivity analysis including only sleep

medication from Category 1 did not change the result in a significant way ( $P = 0.015$ ).

The clearly dominant types of sleep medication were from Category 1 (hypnotics), representing 87% to 90% of the total sleep medication used (i.e., varying from 87% to 90% at the different assessment points), evenly distributed between the groups. Zopiclone represented approximately 50% of



**Figure 2**—Mean Insomnia Severity Index values at the pretreatment (PRE), posttreatment (POST), and 36-mo (FU36) follow-up assessments. ICBT-i, therapist-guided Internet-based cognitive behavioral therapy for insomnia; ICBT-ctrl, unguided Internet-based control treatment.

**Table 1**—Insomnia severity: means, effect sizes, remitters and responders pretreatment to 36-mo follow-up (observed data).

|           | Insomnia Severity Index |                      |                     | Effect size within group (Cohen <i>d</i> )<br>Pre-FU36 (95% CI) | Remitters  |            | Responders |            |
|-----------|-------------------------|----------------------|---------------------|---|------------|------------|------------|------------|
|           | Pre Mean (SD)<br>n      | Post Mean (SD)<br>n  | FU36 Mean (SD)<br>n |   | Post n (%) | FU36 n (%) | Post n (%) | FU36 n (%) |
| CBT-i     | 16.8 (3.8)<br>n = 73    | 8.3 (4.1)<br>n = 68  | 9.0 (4.9)<br>n = 66 | 1.58 (1.1–2.1)  | 31 (43%)   | 35 (48%)   | 37 (51%)   | 40 (55%)   |
| ICBT-ctrl | 16.5 (3.8)<br>n = 75    | 11.8 (4.4)<br>n = 65 | 9.5 (4.7)<br>n = 60 | 1.67 (1.1–2.24)   | 11 (15%)   | 26 (35%)   | 18 (24%)   | 32 (42%)   |

FU36, 36-mo follow-up; ICBT-i, therapist-guided Internet-based cognitive behavioral therapy for insomnia; ICBT-ctrl, unguided Internet-based control treatment; SD, standard deviation. Remitters =  $ISI < 8$ ; Responders =  $ISI\text{-change} > 7$ .

**Table 2**—Sleep medication use.

| Time | Group     | n  | Users Total, n (%) | Frequent User, n (%) | Regular User, n (%) | Occasional User, n (%) |
|------|-----------|----|--------------------|----------------------|---------------------|------------------------|
| PRE  | ICBT-i    | 73 | 37 (50%)           | 16 (22%)             | 9 (12%)             | 12 (16%)               |
|      | ICBT-ctrl | 75 | 41 (55%)           | 21 (28%)             | 11 (15%)            | 9 (12%)                |
| POST | ICBT-i    | 68 | 15 (22%)           | 10 (15%)             | 2 (3%)              | 3 (4%)                 |
|      | ICBT-ctrl | 66 | 32 (48%)           | 16 (24%)             | 7 (11%)             | 9 (14%)                |
| FU6  | ICBT-i    | 67 | 17 (25%)           | 9 (13%)              | 4 (6%)              | 4 (6%)                 |
|      | ICBT-ctrl | 65 | 23 (35%)           | 12 (18%)             | 7 (11%)             | 4 (6%)                 |
| FU12 | ICBT-i    | 67 | 17 (25%)           | 7 (10%)              | 4 (6%)              | 6 (9%)                 |
|      | ICBT-ctrl | 63 | 24 (38%)           | 13 (21%)             | 6 (10%)             | 5 (8%)                 |
| FU36 | ICBT-i    | 66 | 19 (29%)           | 13 (20%)             | 1 (2%)              | 5 (8%)                 |
|      | ICBT-ctrl | 60 | 28 (47%)           | 20 (33%)             | 3 (5%)              | 5 (8%)                 |

FU6, 6-mo follow-up; FU12, 12-mo follow-up; FU36, 36-mo follow-up; ICBT-i, therapist-guided Internet-based cognitive behavioral therapy for insomnia; ICBT-ctrl, unguided Internet-based control treatment; POST, posttreatment assessment; PRE, pretreatment; frequent user, 4 to 7 nights/week; regular user, 2 to 3 nights/week; occasional user, 1 night/week or less.

Category 1, and zolpidem and propiomazine approximately 25% each. Category 2 (sedative antiallergens/antihistamines, mainly hydroxyzine) represented 11% to 17% evenly distributed between groups, and Category 3, melatonin, represented 2% to 4%. During the entire follow-up period, 17% to 24% used two sleep medication types simultaneously. Sedative antidepressants (mirtazapine) were recorded as sleep medication if the participant presented it as such. However, only one participant used mirtazapine as a sedative at one time point, and then together with zopiclone, and it is therefore not presented as its own category. Mirtazapine presented by the participant as an antidepressant was also rare (five participants at the 12-mo follow-up, one at the 36-mo follow-up) and evenly distributed between the groups. No participants reported using benzodiazepines as sleep medication and very few used it for other purposes, and then very occasionally, typically once during the 2 w previous to assessment (three participants at posttreatment, four at the 6-mo follow-up, two at the 12-mo follow-up, and one at the 36-mo follow-up, both groups represented). No participants reported using antipsychotics.

### Use of Other Treatments

In ICBT-i, 11 participants (15%) had tried some other insomnia treatment (e.g., mindfulness or yoga) from the posttreatment to 36-mo assessment, compared with 32 (43%) in ICBT-ctrl. This difference was significant ( $\chi^2 = 13.6$ ,  $P < 0.001$ ).

## DISCUSSION

To the best of our knowledge, this study is the longest reported follow-up of CBT-i in a randomized trial presented to date. The results indicate that the improvements in insomnia attained directly after treatment were maintained after 3 y and must be considered large when compared with previous studies regarding ICBT-i.<sup>19</sup> Participants in the active control treatment exhibited less reduction in insomnia severity at posttreatment and after 6 mo,<sup>24</sup> but there was no group difference after 1 and 3 y. This finding could, at least in part, be attributed to a combination of the initial effects of the active control treatment and a significantly higher consumption of sleep medication and other insomnia treatments during the 3-y follow-up period.

The long-term reduction in sleep medication use observed in the ICBT-i group is important because medication is only recommended for short-term use and has potentially serious side effects.<sup>9,39</sup> The original study reported that sleep medication use in ICBT-i decreased significantly and substantially from preassessment to postassessment (from 45% to 10%). When examining the entire follow-up period, sleep medication use decreased significantly more in the ICBT-i group, compared to baseline. Similar results were also reported in a previous study using the same treatment manual,<sup>16</sup> although with a much shorter follow-up period. Most of the sleep medication used was of a type that is effective in the short term but can lead to habituation and dependence, so called z-drugs (zolpidem and zopiclone). Given the lack of access to psychological treatments for insomnia, these drugs are widely prescribed and used beyond the recommended short term.<sup>40</sup> The ICBT-i manual included a module that specifically targeted sleep

medicine use, and the therapists were encouraged to support participants with tapering. Our current findings are an addition to the area of tapering that has been previously discussed by Schutte-Rodin et al.<sup>41</sup> and Taylor et al.,<sup>42</sup> and we propose that future studies of CBT-i continue to target and evaluate the use of sleep medication.

Previous studies have demonstrated that participants on waiting lists exhibit little spontaneous recovery from insomnia, with effect sizes of less than a Cohen  $d$  value of 0.50.<sup>14,43</sup> In addition, studies have demonstrated that individuals with insomnia tend to have sleep difficulties for a very long time, typically more than 10 y,<sup>16,24,44,45</sup> which indicates chronicity. Thus, we propose that it is unlikely that the similarities between the groups after 3 y can be attributed to a general spontaneous recovery over time, but are instead due to more specific factors in this control treatment group, such as being active help-seekers, receiving a partially effective control treatment, and using significantly more additional insomnia treatments and sleep medication than the ICBT-i group. Because of the lack of follow-ups longer than 1 y and the fact that comparisons to control groups after the posttreatment or 3-mo follow-up are rare, this is largely an unexplored area. In our study, the active control treatment presented a moderate-to-large within-group reduction of symptoms ( $d = 1.09$ ) directly at posttreatment,<sup>24</sup> potentially because the treatment consisted of a number of methods that are somewhat effective for insomnia, e.g., relaxation and keeping a sleep diary, in addition to a few mindfulness exercises. Mindfulness has, in a more comprehensive form known as Mindfulness-Based Stress Reduction, recently been indicated to have a positive effect on insomnia, but with a 3-mo delay compared with CBT-i.<sup>46</sup>

A low-intensity treatment, such as the control treatment in this study, has its merits: it is relatively simple to provide because there is no active support, the methods presented are non-invasive, and lack the type of side effects that have been reported for sleep restriction.<sup>47</sup> Directly after treatment, this low-intensity treatment had a moderate effect on insomnia. Disadvantages are that the participants in this group had a much slower recovery and, perhaps most importantly, used both more other insomnia treatments and more sleep medication over the 3-y follow-up period than the group receiving full CBT-i. We therefore think that CBT-i should still be seen as the preferred treatment for insomnia, but that the effects of briefer and/or non-guided interventions for insomnia should be further studied.

There are some limitations to this study. One limitation is that we did not use sleep diaries for the 36-mo assessment. Given the great difficulties in retrieving the sleep diary data from study participants, we wanted to maximize the chances of obtaining data about the primary measure (ISI) and use of other treatments by not burdening the participants with a sleep diary. The data on sleep medication were measured with self-reports at each assessment point. Information about medication use between assessments can thus only be inferred. Registry data on sleep medication consumption would have been preferable to compare the two groups over the entire 3-y period. Still, we believe that data presented are a good indication of the overall sleep medication usage during this period, and we can see no

reason why the precision of the measure should differ between the two groups in any systematic way.

Excluding patients with diagnosed major depression implied that depression levels in this sample were fairly low compared to some other recent insomnia studies, even though symptom levels pretreatment indicated mild depression on average. This limits the generalizability regarding which patients benefit from treatment in the long term.

## CONCLUSIONS

The 3-y follow-up in this study is the longest follow-up period of CBT for insomnia thus far. The results show that the large improvements in the ICBT-i group observed posttreatment were maintained throughout the 36-mo follow-up period. The active control treatment had produced moderate-to-large improvements posttreatment. After 1 and 3 y, ICBT-ctrl had reached the same low levels of insomnia symptoms as ICBT-i. However, participants in the control treatment group used significantly more other insomnia treatments and sleep medication during the follow-up period compared with ICBT-i.

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