Longitudinal comparison of internet-delivered Cognitive Therapy and Behavior Therapy for insomnia disorder

A randomized controlled trial

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LONGITUDINAL COMPARISON OF INTERNET-DELIVERED COGNITIVE THERAPY AND BEHAVIOR THERAPY FOR INSOMNIA DISORDER: A RANDOMIZED CONTROLLED TRIAL

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Insomnia is a common and chronic health condition and many insomnia sufferers rely on sleep medication. Internet-delivered CBT is an effective treatment method but knowledge of its long-term effects is limited. The aim of this study was to compare long-term effects of Cognitive Therapy and Behavior Therapy for insomnia disorder on sleep, daytime impairment, anxiety and depression up to 18 months after the treatment. 145 individuals were randomized into two groups, Cognitive Therapy and Behavior Therapy and follow-up measures were gathered at 6-, 12- and 18-months after the 10-week treatment. The results of the treatment were maintained for 18 months as regards daytime functioning, anxiety and depression. No statistically significant difference was found between CT and BT after 18 months. There was a statistically significant increase in insomnia severity during the follow-up, but the effect size was negligible. The beneficial effects of internet-delivered CT and BT produce thus comparable and long-lasting results for multiple outcomes.

Adequate sleep is a prerequisite for a balanced, healthy life in the long term. Many people suffer from difficulties initiating sleep, returning to sleep after interruption of sleep or waking up too early. Difficulties with sleep can also have consequences during the daytime in the form of worry for future sleep related problems as well as functional impairment due to lack of sleep. Approximately 25 % of adult population is currently dissatisfied with their sleep and 6-10 % of the population meet the criteria for insomnia disorder (Morin, Leblanc, Daley, Gregoire & Merette, 2006; Morin & Benca, 2012). In a Swedish sample, insomnia disorder was reported by 10.5 % in 18-84-year-old individuals (Mallon, Broman, Åkerstedt & Hetta, 2014). In addition to be a common disorder, insomnia is also persistent over time. As many as 74 % of individuals suffering from insomnia report the persistence of insomnia for at least one year (Seyffert et al., 2016). Suffering from insomnia is associated with psychological distress, impaired functioning during daytime, higher sick leave, greater consumption of health care services as well as accidents (Daley et al., 2009; Sivertsen, Øverland, Bjorvatn, Mæland & Mykletun, 2009). Insomnia increases the risk for developing other mental health issues, such as depression, anxiety and problems with substance-use (Baglioni et al., 2011; Breslau, Roth, Rosenthal & Andreski, 1996). Insomnia, if not treated, can become a chronic disorder (Morin et al., 2009). Chronic insomnia disorder is also associated with other health conditions such as diabetes, obesity, hypertension and cardiovascular disease (Seyffert et al., 2016).

Developing a treatment for insomnia disorder that is both effective, cost-effective and accessible for many is thus of great interest for the public health as well as for the individual suffering from an insomnia disorder. Cognitive behavior therapy for insomnia (CBT-I) is the treatment usually offered as the first-line therapy for adults since pharmacological treatment is recommended only for short-term use due to possible negative side-effects with prolonged use (Seyffert et al., 2016; van der Zweerde, Bisdounis, Kyle, Lancee & van Straten, 2019; Wilson et al., 2010). Society of Clinical

Psychology division 12 of the American Psychological Association (APA) recommends CBT-I as a psychological treatment for insomnia with strong research support (Society of Clinical Psychology division 12 of the APA, 2019). Internet-delivered CBT-I has become more popular with the increased digitalization in health care (Andersson, Titov, Dear, Rozental & Carlbring, 2019) and has shown effects equal to face-to-face therapy (Carlbring, Andersson, Cuijpers, Riper & Hedman-Lagerlöf, 2018).

Some research has been conducted on the long-term effects of CBT-I (Andersson, Rozental, Shafran & Carlbring, 2018) but most studies have focused on CBT-I as a full treatment, neglecting the unique contributions of its components Cognitive therapy (CT) and Behavior therapy (BT). Sunnhed et al. (2019) compared internet-delivered behavior therapy and cognitive therapy and found that both treatments had a significant effect on insomnia disorder compared to the waitlist condition, indicating that both therapy forms are effective as stand-alone therapies. The results persisted in a 6 month-follow up (Sunnhed et al., 2019).

However, whether the results of CT and BT as stand-alone, internet-delivered treatments are maintained in the long-term has not been previously studied. Knowledge of the long-term effects of BT and CT would create flexibility for health care professionals in choosing the most efficient and suitable treatment for patients with insomnia disorder. Thus, this study is based on the long-term outcomes of the Sunnhed et al. (2019) sample by focusing on the follow-up data collected 6-, 12- and 18-months after the 10-week treatment period of CT and BT respectively. [1]

Insomnia disorder

Every third or fourth adult is currently suffering from sleep related disturbances (Roth, 2007; Morin et al., 2015). Problems with sleep can be situational or recurrent and an untreated insomnia can become a chronic state. Individuals suffering from sleep disturbances report dissatisfaction with sleep duration and sleep quality, such as difficulties initiating or maintaining sleep, or waking up too early from sleep (DSM-5; American Psychiatric Association, 2013). Insomnia not only affects sleep at nighttime but also creates substantial distress and impairment in one's functioning during the day. Insomnia can be present on its own but more often it co-occurs with other psychiatric or medical disorders, such as depression or pain. Insomnia, if not treated, will make the individual more prone to adverse health outcomes such as diminished quality of life, physical illness and psychological distress (Morin et al., 2015). Approximately 6-10 % of adults suffering from insomnia meet the diagnostic criteria for insomnia disorder (Roth, 2007; Morin et al., 2015). Sleep disturbances can be diagnosed as insomnia disorder when they negatively affect the individual's daytime functioning, when the individual suffers from insomnia at minimum 3 nights per week, when the problem has persisted for 3 months and when sleep disturbances cannot be explained by any other medical or psychiatric condition (DSM-5; American Psychiatric Association, 2013).

Cognitive Behavior Therapy for Insomnia

Cognitive Behavior Therapy for insomnia (CBT-I) has been validated through over 400 clinical trials (van der Zweerde et al., 2019) and is regarded as the treatment of choice as a psychological treatment of insomnia disorder (van Straten et al., 2018; Zachariae, Lyby, Ritterband & O'Toole, 2016). The basic premise of CBT-I is that there is an interaction between cognitive and behavioral factors that maintain insomnia and that these factors

[1] A special thank you for Rikard Sunnhed for providing me with the data for this study as well as for his valuable help along the way.

can be altered. The aim of CBT-I is then to either neutralize or even reverse these maintaining psychological factors by teaching techniques to adjust sleep disruptive cognitions and behaviors that negatively impact normal sleep quality and quantity and thereby contribute to insomnia (Society of Clinical Psychology division 12 of the APA, 2019; Morin et al., 2015) CBT-I consists of two main treatment components, Cognitive Therapy (CT) and Behavior Therapy (BT). The focus of the therapy on these components respectively depends on the individual case conceptualization. The length of CBT-I treatment tends to be approximately 6 weekly sessions (Society of Clinical Psychology division 12 of the APA, 2019) thus making CBT-I a rather short-term therapy form. CBT-I has shown effects both in the short term and in the long term at 4-48 weeks follow-up (Zachariae et al., 2016).

Cognitive Therapy

Cognitive therapy is theoretically derived from the cognitive processing theory and is based on the cognitive model of insomnia (Harvey, 2002). The cognitive model suggests that cognitive arousal, such as worrying about one's sleep and dysfunctional beliefs about sleep resulting in daytime functional impairment, are the culprit for triggering arousal in the sympathetic nervous system. This autonomic arousal makes it harder to initiate and maintain sleep. As a coping mechanism, the individual starts to selectively pay attention to possible sleep-related threats and engage in safety behaviors such as going to bed early, taking a nap during daytime or using excess stimulants, in order to reduce insomnia anxiety and to avoid further difficulties with sleep and daytime functional impairment. The individual suffering from insomnia thus ends up in a vicious cycle which in turn increases worry and autonomic arousal. This vicious cycle maintains the symptoms of insomnia. The aim of cognitive therapy is to interfere with these maintaining factors by targeting the cognitive processes that maintain insomnia. The methods of cognitive therapy frequently include the use of behavioral experiments and cognitive restructuring of negative automatic thoughts about sleep (Harvey, 2002).

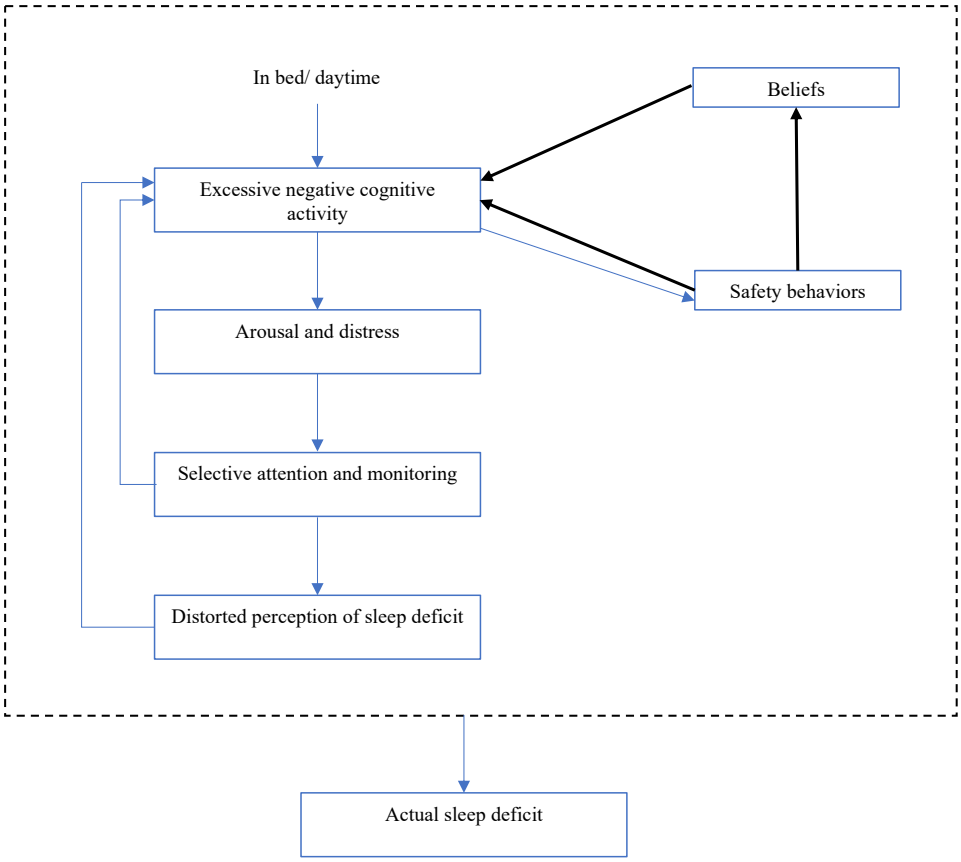

Figure 1. A cognitive model of the maintenance of insomnia (Harvey, 2002).
Note: arrow = leads to; bold arrow = exacerbates

Behavior Therapy

Behavior therapy integrates two distinct biological models of sleep, namely the circadian rhythm and the homeostatic system (Borbély, 1982). The circadian system can be seen as the biological clock of the body. It interacts with time cues in the environment such as the cycle of dark and light. The circadian system is responsible for regulating the sleep-wake pattern in humans. An individual's optimal sleep timing and duration are affected by the circadian rhythm. The homeostatic system is responsible for an individual's drive for sleeping and being awake, based on how long the individual has stayed awake or has been asleep. The longer the individual has stayed awake, the stronger the desire and drive for sleep. The accumulated sleep drive then determines the quality and quantity of our sleep. The aim of behavior therapy is to regulate these biological processes to optimize sleep by applying behavioral techniques. The two techniques used are sleep restriction and stimulus control. Sleep restriction targets the homeostatic system by limiting time stayed in bed to actual time of sleeping. Sleep restriction initially creates a slight sleep deprivation, which in turn affects the homeostatic system by increasing sleep drive, thus making it more likely to achieve greater sleep quality and quantity (Spielman, Saskin & Trophy, 1987). Stimulus control targets the circadian system by implementing methods to align sleep-related behavior with the circadian rhythm (Boozin, Epstein & Wood, 1991), thus aiming to optimize its function.

Internet-delivered therapy

Psychological treatment via the internet is a rather new phenomenon that started for a little more than two decades ago. Internet-delivered cognitive behavior therapy (ICBT) has been effectively used to treat mild to medium severity psychiatric conditions (Andersson, Carlbring & Hadjistavropoulos, 2017) and has shown equal overall efficacy when compared to face-to-face cognitive behavior therapy for different psychiatric and somatic conditions (Carl bring et al., 2018). ICBT is commonly structured as a combination of bibliotherapy and a therapist support function via an online platform or email, as well as other online features such as registration forms and tests. Clients will be screened with an initial questionnaire or a test, usually following up with a telephone interview, after which the chosen clients will be offered internet-based treatment during a fixed time frame (Andersson et al., 2008). The treatment is usually divided into weekly treatment modules including educational text material or videos about the condition as well as interactive assignments and self-report questionnaires. ICBT has thus similar structure as a manual based, diagnosis specific cognitive behavior therapy provided face-to-face (Vlaescu, Alasjö, Miloff, Carlbring & Andersson, 2016).

A recent review of 11 Swedish and 3 Dutch guided ICBT for multiple conditions (i.e. panic disorder, generalized anxiety disorder, social anxiety disorder and depression) investigated the long-term effects 2-5 years after the treatment. It was found that in spite of very long follow-up periods, the response rate of the participants was 74.1 % (*SD* = 13.1). Treatment lengths were on average 8-15 weeks, indicating that even short-term ICBT treatments can maintain their effect in the long-term up to 2-5 years.

Longitudinal studies on insomnia

Few papers have been published on the long-term effects of internet-delivered cognitive behavior therapy (ICBT) in general and on internet-delivered treatments for insomnia disorder specifically. A meta-analysis by van der Zweerde et al. (2019) on the effects of cognitive behavior therapy for insomnia investigated the long-term effects of 30 randomized controlled trials. Effects were defined as long-term when they were measured at least 12 weeks after the treatment. Studies on 3-, 6- and 12-months follow-up measures were included in the analysis. The study demonstrated that although the effects of cognitive behavior therapy for insomnia decline over time, the effects are clinically significant and last up to one year after the treatment. Similar results have previously been shown in a meta-analysis by Zachariae et al. (2016) that concluded the efficacy of both guided and unguided CBT-I on insomnia severity and that the effects of internet-delivered CBT-I were maintained at follow-up assessments up to 48 weeks.

Although the meta-analysis by van der Zweerde et al. included only controlled studies, some shortcomings can be found regarding the methodological approach of the included studies as well as regarding the comparison of the results. One major shortcoming in the analysis was that the included studies were not entirely comparable based on what type of treatments were included under the term CBT-I. For example, components that were identified as CBT-I included not only full CBT-I (including psychoeducation as well as behavioral and cognitive components), CT and BT but also relaxation and paradoxical intention (i.e. stop trying to fall asleep and thereby diminishing performance anxiety about sleeping; Society of Clinical Psychology division 12 of the APA, 2019). Another shortcoming was that the included studies used several different statistical methods and the results were reported on varying outcome measures, making comparison more challenging. Also, no studies in the meta-analysis reported effects after one year. The majority (97 %) of included studies were recruited from community samples as well as patients from care settings. Treatments were offered in varying formats (group format,

individual format and self-help). Furthermore, there was different handling of missing data across the studies (van der Zweerde et al., 2019). These methodological differences between the included studies makes it more difficult to draw general conclusions on the long-term effects on CBT-I. Due to the limitations in the van der Zweerde et al. (2019) meta-analysis it is of interest to explore some other studies that have been conducted within the field. More specifically, those randomized controlled trials that have reported long-term outcome measures up to 12-18 months after the active treatment phase using the Insomnia Severity Index (ISI; Bastien, Vallières & Morin, 2001**)** are of specific interest since ISI is commonly used as a measure of insomnia severity in more recent research (Sadeghniiat-Haghighi, Yazdi & Firoozeh, 2014). Also, excluding any studies with other than full CBT-I or its components CT and BT, such as those using relaxation techniques, as well as those studies where insomnia is secondary to some other somatic or psychological condition might be of interest.

Long-term outcomes up to one year

Two studies that fill the requirements mentioned above have been identified in the van der Zweerde et al. meta-analysis. Kaldo et al. (2015) evaluated internet-delivered CBT-I with brief therapist support against a control group that received internet-based active treatment but with less empirical support and lower effects (such as sleep hygiene, relaxation, mindfulness and stress management) to increase credibility. Long-term outcomes were measured 6 and 12 months after the 8-week active treatment period. It was found that CBT-I was significantly more effective than the active control and that the positive effects sustained up to 12 months [ISI, FU6 Cohen's *d*=1.71 (CI 1.33-2.08); FU12 Cohen's *d*=1.95 (CI 1.54-2.33)]. However, in the 12-month follow-up, the difference between the treatment group and the control group was no longer significant since outcomes on ISI were decreasing in the control group, possibly due to the individuals seeking other treatments for their insomnia. The study also highlights adverse effects. A limitation to this study is that other comorbidities were not excluded and that sleep medication use was unrestricted. In a study by Alessi et al. (2016), a manual-based CBT-I program (individual or in a small group setting) delivered by non-clinical sleep coaches improved sleep compared to the control group in older adults with chronic insomnia. The results were maintained throughout the 6- and 12-months follow-up period. No significant treatment effects were found regarding depression (measured by PHQ-9) between baseline and 6- or 12-months follow-up. Limitations to this study are that the active treatment group received not only CBT-I but also sleep hygiene, and that the treatment group mainly consisted of older male adults (98.2 % male, with mean respondent age *M*=74.1), making it uncertain to generalize the long-term results to other age groups and genders.

Ritterband et al. (2017) compared a fully automated, unguided internet-delivered 6-week CBT-I program (called SHUTi) with a control group who received online patient education about insomnia and collected follow-up data one year after the active treatment. Their results indicate that internet-delivered CBT-I has superior effects on all primary sleep outcomes compared to the control group and that treatment effects were maintained at the 12-month follow-up (ISI, *d*=2.32 [95% CI 2.01-2.63]). A limitation to this study is that, although multiple sleep related outcomes were included, it did not include any daytime outcome measures such as functional impairment or fatigue, which often are the main reason an individual seeks treatment for their insomnia symptoms (van der Zweerde et al., 2019).

Long-term outcomes up to 18 months

Two fairly recent studies have been conducted on the long term-effects of CBT-I that analyze outcome measures beyond the one-year threshold. Batterham et al. (2017) investigated how internet-delivered CBT-I affects depressive symptoms and sleep in a randomized controlled trial. They found that the symptoms of depression, anxiety and insomnia decreased during the 6-week program and that the effects were sustained over a 18-month period (insomnia severity ISI, Cohen's *d*= 0.55; depression PHQ-9, Cohen's *d*=0.63; anxiety GAD-7, Cohen's *d*=0.47) compared to a control group that received a program on attention control. This study is an interesting one since they had a rather large Australian community selection (*N*=1149), but only 19 % attrition rate adds to the limitations of this study, making it difficult to draw any general conclusions of the long-term effects on sleep and depression. Another study that has included follow-up data up to 18 months after the treatment is that of Vedaa et al. (2019) who studied the long-term effects 18 months after the intervention period, comparing unguided internet-delivered CBT-I with web-based patient education in a randomized controlled trial in Norway. Outcomes were reported on sleep, daytime functioning and beliefs about sleep. Significant improvements were found from baseline to 18-month follow-up measured by Insomnia Severity Index (ISI), Cohen's *d*=2.04 [95% CI 1.66-2.42]. Additionally, improvements on all of the other outcome measures were maintained throughout the 18-month follow-up period. This study indicates that improvements acquired during the active treatment phase of (a fully automated) CBT-I can be maintained as long as 18 months after the treatment.

A more recently published study by Sunnhed et al. (2019) made a distinction between the components of CBT-I, comparing the effects of internet-delivered behavior therapy and cognitive therapy against a waitlist. Both treatments showed significant results (with moderate to large effect sizes) compared to the waitlist condition. The results of the interventions sustained in the 6-month follow-up for both treatment groups, indicating that the improvements made during the active treatment phase of 10 weeks were maintained throughout the follow-up period (Sunnhed et al., 2019).

Due to the limited amount of previous research available to this date on the long-term effects of insomnia treatment in controlled studies, more research needs to be conducted in this area. Long-term treatment effects are important to investigate since they can be in favor of therapy over medication (Cuijpers et al., 2103). Advocating CBT-I as the first line treatment instead of sleep medication would most likely cause less negative side effects in the long-term since sleep medication is known to cause dizziness, drowsiness, disturbed sleep architecture, memory, addiction as well as relapse when discontinued (van der Zweerde et al., 2019; Wilson et al. 2010). Pharmacological treatment can be regarded as effective but is only recommended for short-term use (Wilson et al., 2010). There is lack of evidence of the long-term benefits of sleep medication, thus CBT-I can be regarded as a safer treatment option in the long-term (Buscemi et al., 2007). An additional benefit of CBT-I over long-term sleep medication is that the purpose of CBT-I is to teach the insomnia sufferer methods and tools to manage insomnia symptoms throughout a lifetime, thus having long-term benefits.

There is currently limited research on the effects of short-term and long-term CBT-I on daytime functioning, even though impairments in the daytime functioning is the main reason why patients seek treatment for insomnia (Morin, LeBlanc, Daley, Grégoire & Merette, 2006). Ultimately, the overall purpose of an insomnia treatment is to improve functioning during the daytime, thus improving quality of life. On a societal level, this

will reduce costs for work absenteeism and increase work productivity (van der Zweerde et al., 2019).

Previously, the effects of CT and BT respectively, delivered over the internet, have not been studied in controlled trials. The Sunnhed et al. (2019) study was the first to highlight that both treatment components of CBT-I are effective and maintain their effects up to 6 months. A theoretical argument for comparing CT and BT is to study the differential effects of each treatment, in order to find out which treatment component of CBT-I yields the desired results, much like in a dismantling study. Being able to pinpoint exactly which treatment component (CT/BT) that decreases insomnia symptoms is crucial to be able to design better treatments for insomnia disorder. Gaining knowledge on the unique contributions of CT and BT as separate treatments takes us one step closer in creating new, more effective treatments in the future.

The clinical implication of comparing the long-term effects of CT and BT is having the ability to individualize the treatment for the specific needs of the individual patient, together with knowledge of the long-term effects of the respective treatment option, would further create more flexibility for the clinician as well as for the patient to choose a preferred treatment option. Another clinical implication of dividing the treatment components would be that CBT-I may come with adverse events. Examining negative effects of psychotherapy has been increasingly the focus of recent research (Rozental et al., 2018). BT has been known to improve sleep effectively and rapidly but comes also with some side effects. According to the study by Sunnhed et al. (2019), those who received BT experienced three times as much side-effects compared to the CT group, most likely due to BT focusing on initially decreasing the total sleep time during sleep restriction (Kyle et al., 2014). Adverse effects were reported in the form of fatigue/exhaustion, extreme sleepiness and irritability (Sunnhed et al. 2019). CT can be beneficial for patients with more cognitive distortion about their sleep and daytime functioning. Patients receiving CT are also generally more compliant (Sunnhed et al., 2019). Thus, studying the differential long-term effects of CT and BT as stand-alone therapies will make it easier for both patients and therapists to choose the preferred treatment method in the light of possible side effects.

Aim of the study

This study aims to investigate the long-term efficacy of cognitive therapy and behavior therapy for insomnia disorder. The study continues on the research of Sunnhed et al. (2019) by prolonging the follow-up period beyond 6 months. The aim is to study the long-term effects of internet-delivered Cognitive Therapy and Behavior Therapy for insomnia for multiple outcome measures. More specifically, to examine whether improvements in insomnia severity, daytime functioning, anxiety and depression from baseline to after the intervention period are maintained at the 18-month follow-up for CT and BT. The research questions are as follows:

- *Are the results of internet-delivered Cognitive Therapy and Behavior Therapy for insomnia maintained in the long term*?
- *Is there a statistically significant difference between CT and BT in the long term?*

Method

Participants and recruitment

Participants in the study were recruited through advertisements in the daily press and through social media. A web page was set up for the study, including information on the study design, treatment, data security and an introduction of the project group members (https://www.iterapi.se/sites/bis/). Participants were recruited during the time period from August 2016 to February 2017. Individuals wanting to be part of the study underwent three screening phases: a web-based screening questionnaire, a semi-structured telephone interview and a 7-day sleep diary. The participants that were eligible for inclusion were then randomized into two active treatment groups and a waiting list group. No compensation was given for participation.

Inclusion

To be included in the study, participants were encouraged to register themselves on the study's online platform. A prerequisite was a minimum 18 years of age, being a citizen of Sweden and being able to speak and write in Swedish. In the registration phase, participants would fill in a web-based screening questionnaire. At this first phase, the following criteria needed to be met in order for the candidate to become eligible for the next phase: sleep difficulties occurring minimum 3 nights per week during the last 3 months, despite having adequate opportunities for sleep, reaching a minimum total score of 11 on the Insomnia Severity Index (ISI), of which at least 2 items relating to nighttime symptoms (item 1-3) and at least 2 items relating to daytime impairment (items 5 and 7) (Bastien et al., 2001; Morin, Belleville, Bélanger & Ivers, 2011). Additionally, participants had to be able to commit to the 10-week treatment program, have the opportunity to read approximately 15 pages per week and commit to daily or weekly homework. Participants also needed access to a computer with an internet connection, a mobile phone and email.

Those participants who were accepted for the second phase were contacted for a semi-structured telephone interview. The interview was based on the Duke Structured Interview for Sleep Disorders (DSISD) and the MINI, and documented participants' sleep and any possible mental disorders. If somatic conditions were present, these needed to be stable and/or under treatment. Insomnia needed to be the most disabling and distressing condition, or if somatic or psychiatric comorbidities were present, insomnia still needed to be present, regardless of treatment. Inclusion criteria regarding medication was that possible sleep medication or SSRI dosage needed to be relatively stable during the last three months.

Those participants that were accepted to the third and final phase of the screening process would need to fill in a 7-day sleep diary. Inclusion criteria after assessing the sleep diaries was that the candidate had to have a minimum of three days of sleep difficulties (initiating sleep, maintain sleep or waking up too early) for a minimum of 30 minutes per night.

Exclusion

In the screening phase, candidates that suffered from severe depression (measured by more than 30 points on MADRS-S) or high suicidal ideation (measured by minimum 4 points on MADRS-S item 9) were excluded from the study.

In the second phase, candidates were assessed and excluded for the following conditions: if sleeping problems were caused by an obvious external condition (e.g. pregnancy, having small children, animals or distressing sounds in the environment), working night

shifts, rotating shift work more than 3 nights a week, high intake of caffeinated drinks or alcohol (measured as more than 4 beverages a day or more than 2 beverages after 6 pm) or if the candidate had received CBT-I within the last 5 years. Candidates who were consuming sleep-disturbing medication on a daily basis, had a history of psychotic or bipolar disorders, or had some other primary sleep disturbance (e.g. sleep apnea, restless legs syndrome, parasomnia, periodic limb movement disorder or circadian rhythm disorder) were also excluded in the second phase.

Randomization

Those participants who met the criteria for the study were randomized by a person within the study group, using randomization data provided by another person within the study group, into one of the three groups (BT, CT or waitlist) using an internet-based random generator (www.randomizer.org). The 219 participants that were diagnosed with insomnia disorder and met the study criteria were randomized into CT (n=72), BT (n=73) and waitlist (n=74). After randomization, the participants received a message regarding which group they had been allocated to. Participants in the BT and CT group were informed that they would be contacted by a therapist within two weeks in order to start the treatment. The waitlist group was informed about their inclusion in the study and that they would receive their treatment after 10 weeks during which they would need to fill in outcome measure questionnaires at pre-treatment, bi-weekly for the primary outcomes, as well as at post-treatment.

For the longitudinal follow-ups of 6, 12 and 18 months, a similar procedure was being used in order to gather follow-up data at every follow-up point. Participants were first sent an email with an instruction to fill in the follow-up questionnaires via a web link. If no reply was received, three automated reminder emails were sent at day 1, 3 and 5 after the initial email. If the participant did not fill in the follow-up questionnaires within a week from the last reminder, a person from the study project made a telephone call to the participant as a reminder. As a final step, after two weeks of not receiving follow-up information, a final telephone call was made and an additional gift card was offered in exchange for filling in the follow-up questionnaires. If no follow-up data was still not received after the final step, the participant was included in the analysis following the intention-to-treat principle.

Inclusion and exclusion criteria are described as a flowchart in *Figure 2*.

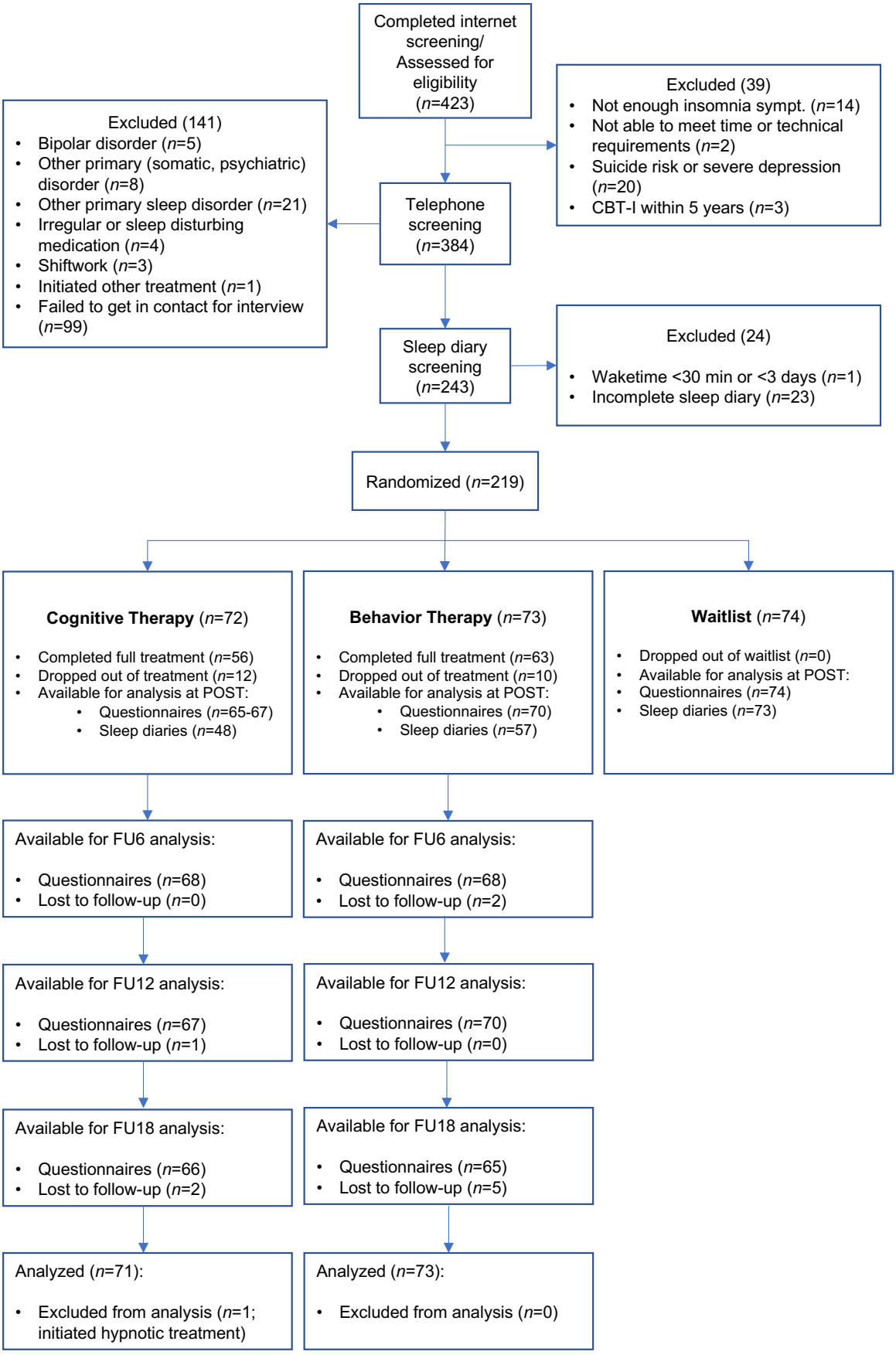

Figure 2. inclusion and exclusion criteria. Note: FU = follow-up

Sample and patient characteristics

Of the active treatment sample including CT and BT (*n*=145), the mean age was 51.7 years, and 73.1 % (*n*=106) were females. Across conditions, 43.4 % (*n*=63) reported use of sleeping pills and 46.2 % (*n*=67) used other type of medication. 24.8 % (*n*=36) stated a somatic and 15.2 % (*n*=22) a psychiatric comorbid disorder (Table 1).

Table 1

Participant characteristics at Baseline

	Cognitive Therapy (CT) *(n=72)*				Behavior Therapy (BT) *(n=73)*				Total *(n=145)*			
	%	*n*	*M*	*SD*	*%*	*n*	*M*	*SD*	*%*	*n*	*M*	*SD*
Gender (female)	76.4	55			69.9	51			73.1	106		
Age			51.5	12.5			51.8	14.5			51.7	13.5
Marital status												
Single	30.6	22			31.5	23			31.0	45		
Married/partner/separated	69.4	50			68.5	50			69.0	100		
Education												
High school	19.4	14			21.9	16			20.7	30		
University	80.6	58			78.1	57			79.3	115		
Employment												
Employed/student	83.4	60			75.3	55			79.3	115		
Unemployed	5.6	4			4.1	3			4.9	7		
Retired	11.1	8			20.5	15			15.9	23		
Insomnia duration (years)			12.0	10.7			11.1	10.3			11.5	10.5
Medication												
Sleep medication	40.3	29			46.6	34			43.4	63		
Other medication	45.8	33			46.6	34			46.2	67		
Comorbidity												
Somatic	33.3	24			16.4	12			24.8	36		
Psychiatric	16.7	12			13.7	10			15.2	22		

Instruments

Primary outcome measure

The participants' perception of their insomnia symptoms was measured by The Insomnia Severity Index (ISI; Bastien et al., 2001). ISI is a questionnaire consisting of seven items on a 5-point scale (scores 0-4). Total score is within the range of 0-28, with a cut-off of 15 to indicate clinically significant symptoms. ISI assesses both night-time and daytime symptoms, such as difficulty initiating and maintaining sleep, sleep satisfaction, how well rested the individual feels, how insomnia symptoms affect daytime functioning and how much insomnia causes worry. ISI has demonstrated sufficient internal consistency (Cronbach's alpha=.91) (Morin et al., 2011). The Swedish version of ISI has shown adequate internal consistency on the global four-item scale (Cronbach's alpha = .88) (Dragioti, Wiklund, Alföldi & Gerdle, 2015). ISI has also shown a 2-week test-retest reliability of 0.79 in adolescents (Chung, Kan & Yeung, 2011).

Secondary outcome measures

Two secondary outcome measures are included in this study. The Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear & Greist, 2002) was used to measure the participants' functional impairment. WSAS includes items regarding functioning at work, home, social and other private life activities and in interpersonal relationships (Mundt et al., 2002). The questionnaire includes five items rated on a 9-point scale (scores 0-8). Total score is within the range of 0-40, with a cut-off of 10 for clinically significant symptoms. WSAS has shown robust psychometric properties (Jansson-Fröjmark, 2014).

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was used to measure the participants' anxiety and depression. HADS includes two subscales, with 7 items for anxiety and 7 items for depression. The scale has shown acceptable psychometric properties (Olsson, Mykletun & Dahl, 2005; Norton, Cosco, Coyle, Done & Sacker, 2013). In Swedish samples the total HADS scale showed adequate reliability (Cronbach's alpha .90) as well as convergent and divergent validity (Lisspers, Nygren & Söderman, 1997). For the subtests HADS Anxiety and HADS Depression the internal consistencies were 0.80 and 0.82 and test-retest correlations were r=0.84 (p<.0001) and r=.71 (p<.0001) respectively (Andersson, Kaldo-Sandström, Ström & Strömgren, 2003).

Design

The original study by Sunnhed et al. (2019) was designed as a randomized controlled trial, comparing the effect of internet-delivered cognitive therapy and behavior therapy for insomnia disorder. The total number of participants that were to be included in the study was estimated with a priori analyses with G*Power 3.1.9 (Faul, Erdfelder, Lang & Buchner, 2007) under standard power conditions (80 %, two-tailed alpha 0.05) to detect a small effect between the three groups (Sunnhed et al., 2019). Participants were randomized into three conditions: a group that received cognitive therapy, a group that received behavior therapy and a control group consisting of participants on a waiting list. Both active treatments were 10 weeks long. The participants on the waiting list were allowed to choose one of the two treatment options and they received their chosen treatment after the active treatment groups (Sunnhed et al., 2019). Follow-up measures were conducted at 6-, 12- and 18-months post-treatment, but only the 6-month follow-up was included in the original study by Sunnhed et al. (2019.

As previously stated, the current study is a follow-up study based on the CT and BT treatments of the Sunnhed et al. (2019) sample. The follow-up data that is included in this study was collected 6-, 12- and 18-months after the 10-week treatment period for CT and

BT respectively (N = 145). Thus, only the active treatment groups were included in measuring longitudinal outcomes up to 18-months. The waitlist condition was excluded from this study.

Procedure

Both treatments were delivered via the internet over a period of 10 weeks. The treatment consisted of material in a self-help format and was delivered as pdf-files via the online platform. The material including all the information needed to apply the cognitive or behavioral techniques by themselves. On the online platform, the participants would also find registration sheets for the weekly exercises. The participants went through one module per week and received 15 minutes of telephone support weekly. During the support call, participants received feedback on their registered exercises and support in completing or comprehending the exercises. In the end of the telephone call, the participant received the next module for the upcoming week. The weekly support call was delivered by a registered clinical psychologist or a master student receiving clinical training. Prior to the treatment, all therapists involved in the treatment were required to read the 10 modules, a therapist manual as well as to participate in a therapist workshop.

Cognitive Therapy

CT used in this study (the 10-week treatment outline is presented in Table 2) is based on the premise that distorted cognitive processes are maintaining insomnia. These cognitions can present themselves as worry about one's sleep, unhelpful beliefs about sleep, attention bias regarding sleep-related threats, misperception of sleep and safety behaviors. The purpose of CT is then to minimize or even reverse these distorted cognitive processes and mechanisms and thus decrease their maintaining function for insomnia. This was done by cognitive restructuring that was mainly achieved by conducting behavioral experiments (Harvey, Sharpley, Ree, Stinson & Clark, 2007; Perlis et al., 2011).

Behavior Therapy

BT in this study consisted of sleep restriction, stimulus control and sleep hygiene (see treatment outline presented in Table 2). Sleep restriction is a technique that targets the proposal of insomnia being a result of excessive time in bed. Sleep restriction firstly aims at limiting time in bed to the actual sleep time, after which time in bed is gradually increased until time of sleep is being optimized (Spielman et al., 1987). Stimulus control is based on the premise of conditioning where temporal stimuli (at bedtime, in the bedroom) and environmental stimuli (worrying or being frustrated about one's sleep) have been paired together with respondent conditioning. This learned conditioning is incompatible with sleep and makes it harder to fall asleep. The purpose of stimulus control is then to recondition the sleep environment with sleep by increasing behaviors that are compatible with sleep, as well as limiting those behaviors that disturb sleep around the bedtime. Stimulus control can include techniques or a set of rules to follow, such as only going to bed when wanting to sleep, getting out of bed if one hasn't fallen asleep within 15 minutes or having a fixed time for getting out of bed each morning (Boozin et al., 1991). The purpose of sleep hygiene is to enhance sleep by providing information on environmental practices as well as general guidelines about health that promote sleep or can interfere with good sleep. The purpose of sleep hygiene is then to optimize these health and environment related factors for sleep, such as nutrition, exercise, substance use, room temperature, noise and light (Boozin et al., 1991; Perlis, Aloia & Kuhn, 2011).

Table 2

The 10-week treatment outline

	Cognitive therapy	Behavior therapy
1	Treatment introduction Sleep diary, self-help and worksheet registration 3-P: Conceptual model of insomnia Individualized case-conseptualization Treatment goals	Treatment introduction Sleep diary, self-help and worksheet registration 3-P: Conceptual model of insomnia Individualized case-conseptualization Treatment goals
2	Case conceptualization for daytime symptoms Identification of unhepful beliefs and Negative Automatic Thoughts (NAT)	Sleep restriction: Introduction
3	Challenging NAT through five common assumptions Challenging NAT via behavioral experiment (survey)	Sleep restriction
4	Challenging NAT (follow-up) Evaluate behavioral experiment (survey) Identifying and managing unwanted thoughts	Sleep restriction Stimuls control
5	Continued management of unwanted thoughts Identifying and managing selective attention/monitoring	Sleep restriction Stimuls control
6	Identifying and challenging estimatons of sleep and daytime symptoms Exploring progression and goal attainment Revision of case conseptualization	Sleep restriction Stimuls control Sleep hygiene Exploring progression and goal attainment Revision of case conseptualization
7	Identifying and challenging safety behaviors through behavioral experiment	Sleep restriction Stimulus control Sleep hygiene
8	Identifying and challenging assumptions about poor sleep Revision of case conseptualization	Sleep restriction Stimulus control Sleep hygiene Revision of case conceptualization
9	Relapse prevention and treatment consolidation Update on case conseptualization	Relapse prevention and treatment consolidation Update on case conseptualization
10	Exploring progression and goal attainment Termination of treatment	Exploring progression and goal attainment Termination of treatment

Treatments

In the original study by Sunnhed et al. (2019), the treatment attrition in the cognitive therapy group and behavior therapy group were 16.9 % and 13.5 % respectively, indicating non-significant difference. Cognitive therapy group completed 77.4 % and behavior therapy group 81.6 % of the exercises, thus with no significant difference. Furthermore, there was no significant difference in adherence to treatment measured as assigned modules, number of logins, number of support calls and module number at dropout. The only significant difference was regarding time spent on support calls, with CT having longer support calls (*M*=111.2 minutes, *SD*=42.4) than BT (*M*=97.2 minutes, *SD*=28.6) (Sunnhed et al., 2019).

Treatment credibility and expectancy were measured during the first week of therapy with Credibility/Expectancy Questionnaire consisting of six items (Devilly & Borkovec, 2000). Both therapies were rated high in credibility, with cognitive therapy scoring 19.2 on average (*SD*=3.9) and behavior therapy with 19.6 (*SD*=3.3) on a scale of 1-27. There were no statistically significant differences in credibility or expectancy between the therapies. Client Satisfaction Questionnaire (Attkisson & Zwick, 1982) was used to measure satisfaction in the therapy. Both groups reported high satisfaction in their designated therapy, with cognitive therapy averaging 25.7 (*SD*=4.5) and behavior therapy 25.1 (*SD*=5.7). No significant differences were found between the groups in terms of client satisfaction (Sunnhed et al., 2019).

Participants rated their experience of the treatment as well as their activity regarding the treatment on a scale from 1 to 5. There were no significant differences between the groups regarding how they perceived the amount of text, how much help they sought and received from their therapists, how they perceived the workload or how much time they invested in the therapy. CT group spent on average 1.56 hours (*SD*=0.5) and BT 1.25 hours (*SD*=0.4) per week on the respective treatment, indicating a significant difference. Further significant differences were found regarding how interesting the text was being perceived, with CT group rating the text more interesting and relevant (CT 3.95, *SD*=0.7; BT 3.69, *SD*=0.8). One significant difference was found on the perceived degree of work invested in the exercises, with BT group rating their investment higher than the CT group (BT 4.16, *SD*=0.8; CT 3.69, *SD*=0.7) (Sunnhed et al., 2019).

Statistical analysis

The statistical analysis was conducted by using mixed growth modeling with random effects to model person-specific change trajectories (Hesser, 2015). Each individual's change was thus modeled with repeated measures over time (Bollen & Curran, 2006). IBM SPSS version 26 was used as the statistical modeling program.

In total, the following 5 measurement points were analyzed for both treatments: pre-treatment, post-treatment, 6-month follow up, 12-month follow-up and 18-month follow-up. The growth model was based on available data for the intention-to-treat sample (*n*=144). For the primary and secondary outcome measures, statistical analysis was conducted by using piecewise growth models that compare both groups over the treatment period on two measurement points (pre-post) as well as on three measurement points during the follow-up phase (6-, 12- and 18-month follow-up). Piece 1 in the growth model was the time period from pre to post treatment, named as Time 1. Piece 2 in the model was the time period from post treatment to the 18-month follow-up, named as Time 2. Time 1 and Time 2 in the growth model represent averaged population change across treatment conditions. Two linear slopes were used to model change during the pre-post assessment (piece 1) and post to 18-month assessment (piece 2) for the primary outcome measure ISI and the secondary outcome measures WSAS, HADS Anxiety and HADS Depression.

Piecewise growth models were fitted to model linear change and to capture change and differential change as a function of treatment type. Both pieces were modeled with a random intercept, where piece 1 contained a fixed linear slope and piece 2 a random linear slope (Sunnhed et al., 2019; Hesser, 2015). Average population change across conditions was measured as a main effect of Time 1 and Time 2. The average differential rates of change per therapy during both phases was measured as an interaction effect of time and condition (CT/BT) by including treatment variables as a fixed predictor (CT=-0.5, BT=0.5) of change trajectories in the first and second piece.

Estimated means and standard error for the five measurement points were obtained from the growth model. Standard deviations were calculated with the help of standard error and *n* (*SD = SE * √n)*. Effect sizes (Cohen's *d*; Cohen, 1992) were calculated with the help of estimated means and pooled standard deviations. Between-group effect sizes under *d*=0.2 can be regarded as negligible, under *d*=0.5 as small, between *d*=0.5 and *d*=0.8 as moderate and above *d*=0.8 as large (Cohen, 1992). Within-group effect sizes under *d*=0.5 can be considered as negligible, under *d*=0.8 as small, between *d*=0.8 and *d*=1.1 as moderate and above *d*=1.1 as large (Öst, 2016).

Ethical considerations

The study was preregistered as a randomized controlled trial (RCT), with an approval number NCT0298467 (clinicaltrials.gov). The study has also been approved by the Regional Ethical Board in Stockholm, with the reference number 2016/856-3. All data that has been collected during the treatments as well as from the 6- and 12-month follow-up has been handled in accordance to the Personal Data Act (SFS 1998:204). Since data from the 18-month follow-up were gathered during the fall of 2018, The General Data Protection Regulation (GDPR; EU 2016/679) applies. This ensures that the participants' data will only be used for the purpose of the study. All participants have given their informed consent in the form of a digital signature when registering on the digital platform of the study. Participants who were included in the study were randomized into one of the three groups by an internet-based random generator (randomizer.org).

All participants of the project team were either registered psychologists, registered psychotherapists or psychologist students in the final phase of their education of 300 Higher Education credits. All project members were following professional secrecy according to Health and Medical Services Act (1982:763; 2017:30).

Since the waiting list condition received treatment right after the initial active treatments, no major negative impact was caused due to the postponed treatment for the waiting list group.

Data security

All data regarding the participants has been handled via a secure online platform (Vlaescu et al., 2016) ensuring that the participants were treated anonymously throughout the study. All data were coded to ensure anonymity, the participants receiving a code-id to use in all interaction within the online platform. The platform was electronically encrypted and the participants had the opportunity to either use their own email address as login or to create a new one via http://www.cyber-rights.net that ensures anonymity with encrypted emails. The only emails the participants would receive were reminders to complete the weekly exercises, to fill in questionnaires and to inform of a new module at the online platform. The participant would need to log into the online page with an anonymous code-id and a password of their choice. To ensure even better security, one-time enter codes sent by sms were being used.

Adverse events

Individuals who receive a treatment for insomnia disorder report adverse events due to the treatment (Rozental et al., 2014). Participants in this study were asked at post-treatment to rate if any of 14 adverse events had been occurred during the treatment, based on a method that has been utilized in prior research (Kyle, Morgan, Spiegelhalder & Espie, 2011). As many as 29 % of the total sample reported adverse events at post-treatment, with 14.1 % in the CT group and 43.2 % in the BT group. Individuals receiving CT reported fatigue/exhaustion, irritability, low mood, feelings of agitation and euphoria.

Individuals receiving BT reported fatigue/exhaustion, extreme sleepiness and irritability (Sunnhed et al., 2019). From an ethical standpoint, these findings are important since the participants were not informed of possible adverse events caused by the treatment prior to the treatment. Adverse events found in this study may have negatively impacted the participants' daily functioning, impairing their ability at work as well as in their personal life. Therefore, future studies on insomnia treatment should take this into consideration by informing the participants of any possible side effects of the treatment prior to enrolment, thereby giving the participants a possibility to be excluded from the study if desired.

Results

Primary outcome

ISI

Table 3 shows estimated means and results from piecewise growth models investigating change over the pre-post assessment (Time 1) and over the follow-up period at 6-, 12- and 18-months (Time 2) for primary and secondary outcomes. As observed in Table 3, the predictor in the growth model that tested change during pre-post assessment as well as during the follow-up period was statistically significant for both Time 1 ($p<.001$) and for Time 2 ($p=.012$), indicating that the improvement that was made during the active treatment phase was not sustained throughout the follow-up period for the primary outcome measure ISI. Although statistically significant, the increase in the mean ISI scores was relatively small as seen on the estimated means from post-treatment throughout the follow-up period in Table 3. According to the growth estimate, CT group had an increase of 1.22 points and BT group increased 1.35 points from post-treatment to 18-month follow-up. The predictor in the growth model that tested change between CT and BT during Time 1 and Time 2 showed no statistical significance ($p=.079$ and $p=.892$ respectively), indicating that neither the change during the active treatment phase nor during the follow-up period was dependent on the group.

Table 3

Estimated means and results from linear growth models

	Estimated means															Results from linear growth models		
	Baseline			Post			FU6			FU12			FU18			Effect of the predictor		
Variable	*N*	*M*	*(SD)*	*N*	*M*	*(SD)*	*N*	*M*	*(SD)*	*N*	*M*	*(SD)*	*N*	*M*	*(SD)*	Predictor	Estimate *(S.E)*	*p*
ISI																		
CT	71	19.96	(4.38)	71	9.52	(4.04)	71	9.93	(3.71)	71	10.33	(4.38)	71	10.74	(5.65)	Time 1	- 3.920 (0.144)	.000
BT	73	19.01	(4.36)	73	9.85	(4.10)	73	10.30	(3.67)	73	10.75	(4.36)	73	11.20	(5.72)	Time 2	0.071 (0.028)	.012
																Time 1 on group	0.508 (0.289)	.079
																Time 2 on group	0.008 (0.056)	.892
WSAS																		
CT	71	23.34	(8.09)	71	9.48	(7.58)	71	9.95	(6.66)	71	10.42	(7.16)	71	10.89	8.93	Time 1	-5.070 (0.265)	.000
BT	73	20.88	(8.12)	73	9.39	(7.52)	73	9.59	(6.66)	73	9.79	(7.18)	73	9.99	(8.97)	Time 2	0.056 (0.045)	.212
																Time 1 on group	0.946 (0.531)	.075
																Time 2 on group	- 0.044 (0.090)	.621
HADS Anxiety																		
CT	71	9.31	(3.62)	71	6.93	(3.45)	71	6.93	(3.20)	71	6.93	(3.29)	71	6.94	(3.71)	Time 1	- 1.022 (0.097)	.000
BT	73	8.77	(3.59)	73	6.04	(3.42)	73	6.21	(3.16)	73	6.38	(3.25)	73	6.55	(3.76)	Time 2	0.014 (0.106)	.356
																Time 1 on group	- 0.136 (0.194)	.484
																Time 2 on group	0.028 (0.031)	.379
HADS Depression																		
CT	71	6.46	(3.03)	71	4.06	(2.86)	71	4.17	(2.61)	71	4.28	(2.61)	71	4.38	(2.95)	Time 1	- 0.979 (0.089)	.000
BT	73	6.25	(3.08)	73	3.75	(2.90)	73	3.79	(2.56)	73	3.83	(2.56)	73	3.87	(2.99)	Time 2	0.012 (0.013)	.357
																Time 1 on group	- 0.036 (0.178)	.839
																Time 2 on group	- 0.011 (0.027)	.676

Note. The growth model uses available data for the intention-to-treat sample (*n*=144). Time 1 and Time 2 in the growth model are the time coefficients that represent population change on average across treatment conditions, where Time 1 has been coded for the active treatment phase and Time 2 for the follow-up phase. Treatment assignment was coded as a group variable (CT=-0.5 and BT=0.5). The model estimate is the unstandardized regression coefficient and it can be interpreted as an effect size on the original time scale where one time-unit is one month for all the outcome measures during Time 1 and Time 2. The means and the unstandardized mean difference (unstandardized effect size) were derived from the growth model estimates. CT= Cognitive Therapy, BT= Behavior Therapy, S.E.=standard error, ISI=Insomnia Severity Index, WSAS= Work and Social Adjustment scale, HADS = The Hospital Anxiety and Depression scale, Time 1= first piece of the linear growth model measuring change from baseline to post-treatment,
Time 2 = second piece of the linear growth model measuring change from post-treatment to 18-month follow-up.

Table 4 describes the associated within-group effect sizes for ISI outcomes, derived from the model-implied means, between baseline and post-treatment, baseline and 18-month follow-up and post-treatment and 18-month follow-up for CT and BT groups. Effect sizes for post-treatment compared to the 18-month follow-up was *d*=-0.25 for the CT group and *d*=-0.27 for the BT group.

Table 4

Effect size, within-group (Cohen's d)

	Baseline-post *d*	Baseline-FU18 *d*	Post-FU18 *d*
Insomnia Severity Index			
CT	2.48	1.84	-0.25
BT	2.17	1.55	-0.27
Work and Social Adjustment Scale			
CT	1.46	1.46	-0.17
BT	1.27	1.27	-0.07
HADS Anxiety			
CT	0.67	0.65	-0.003
BT	0.78	0.60	-0.14
HADS Depression			
CT	0.81	0.70	-0.11
BT	0.84	0.78	-0.04

Note: Within-group effect sizes are calculated from the estimated means and standard deviations derived from the growth model. CT= Cognitive Therapy, BT= Behavior Therapy.

Table 5 describes effect sizes between the treatment groups at post-treatment and at 18-month follow-up. Between-group effect sizes were calculated comparing CT group mean to BT group mean at the two measurement points. A positive effect size indicates that CT had higher ISI mean and thus worse outcome on the variable, whereas a negative effect size indicates that CT had lower ISI mean and thus better outcome. The difference comparing CT and BT at the 18-month follow-up was *d*=-0.08, indicating better outcome for the CT group.

Table 5

Effect size, between-group (Cohen's d)

	ISI	WSAS	HADS Anx	HADS Dep
Post	-0.16	0.01	0.26	0.11
FU18	-0.08	0.10	0.10	0.17

Note: Between-group effect sizes are calculated from the estimated means and standard deviations derived from the growth model. Between-group effect sizes are reported as CT compared to BT. A positive figure refers to CT having higher scores on the variable and thus worse outcome. A negative figure refers to CT having lower scores on the variable and thus better outcome.

Secondary outcomes

WSAS

As observed in Table 3, the predictor in the growth model that tested change during pre-post assessment was statistically significant for Time 1 ($p<.001$), indicating an improvement in WSAS measures as a result of the active treatment phase. For time 2 the predictor was not significant ($p=.212$), indicating that the improvement measured by WSAS that was made during the active treatment phase was sustained throughout the follow-up period. The predictor in the growth model that tested change between the active treatment groups during Time 1 and 2 showed no statistical significance ($p=.075$ and $p=.621$ respectively), indicating that neither the improvement made during the active treatment phase nor during the follow-up period was dependent on which treatment the individuals received.

Effect size for post-treatment compared to the 18-month follow-up was $d=-0.17$ for the CT group and $d=-0.07$ for the BT group (Table 4). The difference between CT and BT at the 18-month follow-up was $d=0.10$, indicating better outcome for the BT group (Table 5).

HADS Anxiety and HADS Depression

As observed in Table 3, the predictor in the growth model that tested change in HADS Anxiety during pre-post assessment was statistically significant for Time 1 ($p<.001$), thus improvement in HADS Anxiety measures was attained as a result of the treatment. For Time 2 the predictor was not significant ($p=.356$), indicating that the improvement in HADS Anxiety that was made during the active treatment phase was sustained throughout the follow-up period. The predictor in the growth model that tested change between the active treatment groups during Time 1 and 2 showed no statistical significance ($p=.484$ and $p=.379$ respectively), indicating that the improvement made during the active treatment phase was not dependent on treatment type during the treatment and the follow-up.

As can be observed in Table 4, the effect size for post-treatment compared to the 18-month follow-up was $d=-0.003$ for the CT group and $d=-0.14$ for the BT group. The difference between CT and BT at the 18-month follow-up was $d=0.10$, indicating better outcome for BT as seen in Table 5.

For measures on HADS Depression, the predictor for Time 1 was not significant ($p<.001$) and thus decrease in HADS Depression measures was attained as a result of the treatment (Table 3). For Time 2 the predictor was not significant ($p=.357$), indicating that the decrease in HADS Depression was sustained throughout the follow-up period. The predictor in the growth model that tested change between the active treatment groups during Time 1 and 2 showed no statistical significance ($p=.839$ and $p=.676$ respectively), indicating that the improvement made during the active treatment phase was not dependent on treatment type during the treatment and the follow-up.

Effect size for post-treatment compared to the 18-month follow-up was $d=-0.11$ for the CT group and $d=-0.04$ for the BT group (Table 4). The difference between CT and BT at the 18-month follow-up was $d=0.17$, indicating better outcome for BT (Table 5).

Discussion

The aim of the study was to investigate the long-term effects of internet-delivered Cognitive Therapy and Behavior Therapy for insomnia on multiple outcome measures. The specific interest of this study was to examine whether improvements in insomnia severity, daytime functioning, anxiety and depression from baseline to after the intervention period are maintained at the 18-month follow-up for CT and BT respectively.

The overall finding was that the results after a 10-week internet-delivered insomnia intervention are maintained long-term for a period of up to 18 months on outcome measures estimating daytime functioning, anxiety and depression. A statistically significant decrease at 18-months follow-up was found only for the outcome that measures insomnia severity, although the deterioration in the result was considered negligible (CT *d*=-0.25, BT *d*=-0,27). Furthermore, both CT and BT produced comparable effects on most outcome measures in the long term for a period of up to 18 months, indicating that both CT and BT are effective as stand-alone treatments for insomnia disorder.

Research question 1: *Are the results of internet-delivered Cognitive Therapy and Behavior Therapy for insomnia maintained in the long term?*

Primary outcome

The results showed that the effects of internet-delivered Cognitive Therapy and Behavior Therapy for insomnia are maintained in the long term, up to 18 months, on most measures except for the primary outcome Insomnia Severity Index (ISI). The change in ISI during pre-post assessment as well as from post to 18-month follow-up was statistically significant for both time periods, indicating that the improvement in insomnia severity during the 10-week treatment phase was not maintained throughout the follow-up period. Although the change is statistically significant, the increase in the mean ISI scores was relatively small from post-treatment to 18-month follow-up (CT *d* = -0.25, BT *d* = -0,27). Within-group effect sizes under 0.5 can be considered negligible (Öst, 2016). Also, the estimated mean ISI scores at the 18-month follow-up (Table 3) did not reach the cut-off for clinically significant symptoms of insomnia disorder (Bastien et al., 2001). Effect sizes on ISI from baseline to 18-month follow-up were large, with effect size for CT being *d*=1.84 and for BT *d*=1.55.

These findings are in line with those of previous longitudinal studies. Kaldo et al. (2015) found somewhat similar within-group effect sizes on ISI at 6- and 12-months follow-up (FU6 *d*=1.71, FU12 *d*=1.91). In this study, the participants in the waitlist condition improved in the long-term as regards their insomnia symptoms and the authors hypothesized that some of the participants seeked treatment elsewhere, for example started using sleep medication. However, this explanation should not be valid in the current study since sleep medication use was assessed in the follow-up questionnaires. Ritterband et al. (2017) and Vedaa et al. (2019) on the other hand reported even larger within-group effect sizes at 12- and 18-months follow-up with effect sizes beyond the 2.0 threshold. Vedaa et al. sample had similar demographics (gender, marital status and education) than in this study, making it interesting to compare the results. On the other hand, Vedaa et al. reported that those participants that were lost to 18-month follow-up had higher ISI score at baseline than that of the completers, decreasing somewhat the validity of their result.

It is possible that the slightly larger effect size of CT compared to BT after 18 months is also affected by the content of the treatment. CT uses behavioral experiments that are targeted at changing dysfunctional beliefs about one's sleep, whereas BT is based on sleep restriction, stimulus control and sleep hygiene, thus having more direct effects on sleep. BT is regarded as effective but comes also with unwanted side-effects, which makes compliance more difficult in the long-term after an active treatment phase in case of relapse. In the study by Sunnhed et al. (2019) the participants also rated text material for CT as more interesting, making it more likely for the participant to adhere to CT than to BT in case of relapse.

Secondary outcomes

On all of the secondary outcomes Work and Social Adjustment Scale (WSAS), The Hospital Anxiety and Depression Scale (HADS Anxiety and HADS Depression) the results showed that the effects of internet-delivered Cognitive Therapy and Behavior Therapy for insomnia are maintained in the long term for a period of up to 18 months. The change in WSAS, HADS Anxiety and HADS Depression during pre-post assessment was statistically significant, indicating statistically significant improvements in daytime functioning, anxiety and depression after the treatment period. For the follow-up time period the change was not statistically significant, indicating that the improvements that were made during the treatment phase were also maintained throughout the 18-month follow-up period. Within-group effect sizes from baseline to 18-month follow-up were largest for WSAS (CT d=1.46, BT d=1.27), indicating that the 10-week insomnia treatment has long-term benefits not only on sleep but also on how the individual perceives their daytime functioning. Effect sizes for HADS Anxiety and HADS Depression were moderate for both CT and BT, ranging from d=0.60 to d=0.78, indicating that insomnia treatment has moderate effects also on decreasing anxiety and depression. There was very little change during the follow-up period on all three secondary outcomes for both treatment groups, with within-group effect sizes from post to 18-month follow-up ranging from d=-0.003 to d=-0.17, indicating that the benefits on daytime functioning, anxiety and depression after an insomnia treatment stay fairly stable for a period of up to 18 months after the treatment.

Other longitudinal studies on insomnia treatment have reported long-term effects on daytime functioning (or similar, such as daytime fatigue), anxiety and depression, although assessments have been conducted using other questionnaires. Alessi et al. (2016) found that improvements on sleep were maintained up to 12 months but they found no significant effects on depression (measured by PHQ-9). Batterham et al. (2017) on the other hand found in their study that improvements on depression and anxiety were maintained for 18 months after the insomnia treatment (PHQ-9 d=0.63; GAD-7 d=0.47). These effect sizes are comparable to the findings of this study and are in line with the finding in this study that insomnia treatment has least effect on anxiety compared to the other measurements. In Sunnhed et al. (2019), the effect sizes for WSAS, HADS Anxiety and HADS Depression at the 6-month follow-up were reported as a difference between CT and BT groups, i.e. no within-group effect size was reported which makes it difficult to compare the results.

The finding that insomnia treatment greatly increased daytime functioning with large effect sizes is in line with the fact that most insomnia sufferers seek help due to impaired functioning during daytime (van der Zweerde et al., 2019). The somewhat larger effect size for CT compared to BT might indicate that the treatment that targets dysfunctional beliefs about sleep (i.e. CT) has greater effect during daytime by decreasing worry about sleep.

Small effect sizes during the follow-up period for WSAS, HADS Anxiety and HADS Depression can be an indication of the stability of daytime functioning, anxiety and depression over a long period of time as a result of the insomnia treatment. However, there is also a possibility for "social desirability bias" (Grimm, 2010) in the long term where the participants reply to the questionnaires without sufficient reflection and instead choose the same answers as in the previous measurements. High test-retest correlations of the outcome measures should on the other hand minimize this bias.

Research question 2: *Is there a statistically significant difference between CT and BT in the long term?*

Primary outcome

On the primary outcome ISI the results showed that there was no statistical significance between CT and BT during Time 1 or 2 (p=.079 and p=.892 respectively), indicating that there was no statistically significant difference between the groups in the long term. Between-group effect size for ISI post-treatment was d=-0.16 and at the 18-month follow-up d=-0.08, indicating that the slightly better outcomes for CT were negligible.

Previous studies have generally been investigating the effects of CBT-I as a unified treatment, with components from both cognitive and behavior therapy. Sunnhed et al. (2019) compared CT and BT as stand-alone treatments. The finding that there was no statistically significant difference between the groups in the long-term in this study is in line with Sunnhed et al. study where the 6-month follow-up results were comparable for both groups, although the results were slightly in favor for CT on ISI. The difference between the groups at the 6-month follow-up was marginal, with an effect size of d=-0.039. ISI baseline mean values for CT were slightly higher than that of BT (CT M=19.96, BT M=19.01) (Sunnhed et al. 2019), whereas the results in the current study indicate that there was greater difference in within-group effect sizes from baseline to the 18-month follow-up in CT group (CT d=1.84, BT d=1.55), indicating that CT group made greater progress in terms of improved sleep in the long-term compared to the BT group.

A possible explanation for this might be the cognitive restructuring of sleep-related dysfunctional beliefs that are the focus of CT. It is more likely that once the dysfunctional beliefs about sleep are challenged and replaced with new, more functional cognitions, they will maintain in the long term. Cognitive restructuring with the help of behavioral experiments thus reduces the amount of safety behaviors and decreases worry about one's sleep (Harvey, 2002).

Secondary outcomes

On the secondary outcomes WSAS, HADS Anxiety and HADS Depression the results showed that there was no statistically significant difference between CT and BT in the long term. The predictor that tested change between the treatment groups was non-significant on all three variables during Time 1 and Time 2, indicating that the improvements neither during the treatment phase nor during the follow-up were dependent on which treatment the individual received. Thus, both CT and BT resulted in comparable results in the long-term. Between-group effect sizes for WSAS, HADS Anxiety and HADS Depression at post-treatment were d=0.01, d=0.26 and d=0.11, respectively. Greatest difference between the groups after the 10-week treatment was thus on measurements on anxiety, with slightly less anxiety in BT group. Effect sizes at 18-month follow-up were d=0.10 for WSAS, d=0.10 for HADS Anxiety and d=0.17 for HADS Depression, with slightly better outcomes in the BT group. Between-group effect

sizes on all three variables on both assessment points were thus negligible to small (Cohen, 1992), despite the fact that BT group had lower scores on all secondary outcome measures.

Long-term results on the secondary outcomes follow the same trajectory that was found in Sunnhed et al. (2019), namely that BT group had slightly better outcomes at the 6-month follow-up. The long-term results in this study indicate that BT continued having slightly better outcomes on WSAS, HADS Anxiety and HADS Depression throughout the entire follow-up period of 18 months. One possible explanation to BT group having better outcomes on all the secondary variables might be found in the role of effort justification. Since BT group experienced more adverse events as a result of the treatment and thus greater effort involved in therapy, it is possible that the positive long-term outcomes came through the reduction of cognitive dissonance (Axsom & Cooper, 1985). However, the study should be replicated in order to draw any final conclusions.

Methodological strengths and weaknesses in the study

Despite being a randomized controlled trial, some methodological weaknesses can be found in the study. Firstly, with a rather homogenous sample with the majority of participants being well-educated females of higher age (*M*=51.7), it is difficult to generalize the results to a larger population. Text material for CT was rated as more interesting by the participants which in turn might reflect the fact that perhaps more educated, resourceful people find the text more interesting and thus engage more in the treatment, compared to individuals with lower education degree. The sample was also self-referred and thus not comparable to patients in regular care, limiting the generalization of the results.

Some limitations to this study can be found in the statistical analysis that was conducted. Firstly, the growth model in order to fit the data was chosen as a result of an ocular observation of the observed means graphs on the four outcome variables. The observed means on ISI, WSAS, HADS Anxiety and HADS Depression seemed to follow a linear growth trajectory in two distinct pieces, thus a piecewise linear growth model was chosen as the statistical analysis for all four outcome variables. A closer look on ISI estimated means shows that for that specific outcome measure, a quadratic growth model might have been an even better fit. Quadratic growth model was nevertheless left out of the scope of this study. Another statistical limitation to this longitudinal study was that the therapist effects were not accounted for in the rate of change (Magnusson, Andersson & Carlbring, 2018). However, since accounting for therapist effects requires more sophisticated statistical methods, this approach was disregarded in the analysis.

Another methodological limitation to this study was the lack of data collection from the waitlist condition during the follow-up period. Not having a control group during the 18-month follow-up period decreases the internal validity of the study. On the other hand, being able to gather long-term data from a control group during such a long time would have been not only challenging but also unethical since this would have required the control group to be left without treatment for 18 months. A limitation regarding the outcome measures was that no objective sleep measure, such as actigraphy or polysomnography, was utilized. Instead, the outcome measures rely solely on the subjective assessment of the participants. Neither was therapist compliance measured or assessed in any way, raising the possibility of treatment contamination. Furthermore, it is possible that only those participants who received good results after the treatment continued to fill in the questionnaires during the follow-up period since it is more likely

that those who did not benefit from the treatment dropped out, which in turn decreases the validity of the study.

Treatment length and therapist support are two aspects of the treatment that can be debated in terms of cost-effectiveness. The 10-week treatment with telephone support in this study can be regarded as long and resource consuming compared to the 6 weeks that is usually recommended in clinical practice (Society of Clinical Psychology division 12 of the APA, 2019). A shorter treatment would increase the construct validity of this study since longer treatment may be unnecessary. Treatment length and therapist support affect also the generalizability of the results. Although the results of this study indicate that both CT and BT as stand-alone therapies produce comparable results after a 10-week treatment, it remains yet unknown weather a 6- to 8-week program would have yielded similar results.

The study being a randomized controlled trial with a well-planned design and power calculation to ensure sufficient amount of participants can be regarded as strengths of this study. Growth model was chosen as the statistical analysis method since this is regarded as the state-of-the art statistical analysis method when it comes to longitudinal studies. Another feasible approach would have been deploying repeated measures ANOVA, but this method of analysis was disregarded due to the fact that it compares means of the population, whereas growth model considers growth trajectories of each individual participant, making the growth model analysis more accurate and sensitive to individual differences. Additionally, growth model is based on intention-to-treat principle, thus includes full information maximum likelihood estimation on all participants in the study.

Treatments

The findings in this study show that CT and BT produce comparable results for multiple outcomes. It is thus of interest to discuss the differences between the treatments beyond treatment outcome. In BT the exercises are more repetitive and demanding in terms of planning and the amount of engagement required. CT on the other hand is more varied in terms of written material and type of exercises, which in turn requires more time spent on the treatment. This finding might be of importance when choosing the treatment since people have different resources and limitations at different points in life. For instance, being an insomniac parent with small children who wake up multiple times during the night might be considered a life circumstance that makes it challenging to engage in BT (with sleep restriction) at that point of time.

Individuals who underwent BT experienced remarkably more negative side effects compared to those who underwent CT (Sunnhed et al., 2019), most likely due to the initial restriction of total sleep time. These adverse events may decrease compliance with BT home assignments, putting CT in an advantage. The evidence suggests that psychological treatments can cause adverse events in the short-term but there is still lack of evidence on adverse events in the long-term. In the current study, the data on negative side effects were gathered only at post-treatment and not during the follow-up period, which makes it difficult to discuss adverse events in the long-term. It is most likely that the negative side effects eventually subsided once the treatment was completed since they were a bi-product of the treatment. Nevertheless, it is important that health care professionals take negative side effects and time constraint issues into consideration when discussing possible treatment options with their patients, in order to ensure the best possible fit for the individual patient.

Limitations to longitudinal studies

A question that arises when investigating long-term efficacy of a short-term internet-delivered CBT is how to ensure that the long-term outcome is a result of the treatment and not affected by other factors. A change in life situation or receiving treatment for some somatic or psychological health condition that as a by-product positively affects sleep, daytime functioning, anxiety or depression, would decrease the validity of the results. In many longitudinal studies the treatment seeking of the participants during the follow-up period has not been documented (Andersson et al., 2018). Since this study was a controlled trial, the participants were asked to report on sleep medication use and treatment seeking also during the follow-up period. Nevertheless, no such analysis has been conducted for the follow-up data beyond 6 months at this point, which can be regarded as a limitation to the validity of the long-term results.

It is also possible that individuals who know they are part of a longitudinal study report outcomes in a more positive light out of social pressure. On the other hand, the randomization of the participants into two treatment groups should diminish the difference between CT and BT group - an assumption that seems to be confirmed in the long-term results of this study since no significant difference was found between the treatment groups.

One possible bias negatively affecting the follow-up results is that the participants may recall their previous answers to the questionnaires, thus tending to answer somewhat similarly throughout the entire follow-up period. On the other hand, since there was as long as 6 months interval between the follow-up time points, this assumption should hold little relevance.

Future Research

The findings in this study indicate that both internet-delivered CT and BT produce comparable results in the long-term for a period of up to 18 months. Having two internet-delivered treatment options that produce comparable results makes it possible for more individuals to receive help for their insomnia through the internet and creates flexibility to choose the preferred treatment that best suits the individual and the current life circumstances. Future research should therefore focus on defining moderators and mediators in CT and BT, in order to increase our understanding of the mechanisms of change in each treatment. This way we could in the future choose the most appropriate and effective treatment in each individual case. Another interesting research topic would be to investigate if higher ISI baseline scores and sleep medication use at baseline correlate with higher drop-out rates at 18-month follow-up; a correlation that was found by Vedaa et al. (2019).

Longitudinal data in this study was gathered on multiple outcome measures, nevertheless no sleep diaries were kept by the participants after the treatment phase. Future research should therefore consider adding this as an outcome measure also during the follow-up period, in order to ensure more qualitative data on sleep, beyond questionnaires such as ISI. Also, future studies could incorporate other possible outcome measures beyond sleep, functional impairment, anxiety and depression, that were the focus of this study. Other long-term functional outcome measures suggested would be measuring sick leave, sleep medication use and other measures on general health. To further increase the validity of the research, additional more objective outcome measures could be utilized, such as actigraphy or polysomnography.

To address the generalization limitation of the findings of this study, future research should examine other groups with greater variety on gender, age and educational background. It would be helpful to also examine patients in general health care to see if the findings in this study apply to patients in clinical settings.

Booster-sessions are commonly used a few weeks or months after the treatment in order to enhance, maintain and prolong the results of CBT, at a relatively low additional cost. It would be interesting to conduct a long-term follow-up study on insomnia with an additional booster-session after the treatment phase to see whether the results are sustained even beyond the 18-month follow-up threshold.

Conclusion

The overall conclusion of this study is that the beneficial effects of internet-delivered CT and BT produce substantial, comparable and long-lasting results on outcomes that measure sleep, daytime impairment, anxiety and depression. These findings are in line with previous research that demonstrate long-term effects of insomnia treatment on multiple outcome measures for a period of up to 18 months. We also know that these results can be reached without any additional booster-sessions.

The current study adds to previous findings by demonstrating that CT and BT produce comparable effects as stand-alone therapies, thus creating higher flexibility for therapists as well as for the patients in choosing and implementing the preferred treatment. This knowledge creates not only flexibility but also possibilities for cost-effectiveness and savings potential within health care as well as in the society, by being able to help many insomnia sufferers with easily accessible and individualized treatment methods. Being able to offer an optimized treatment method for the patient creates less need for long-term sleep medication use and instead teaches the patient new psychological tools to manage insomnia.

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