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Sleep-Related Safety Behaviors and Dysfunctional Beliefs Mediate the Efficacy of Online CBT for Insomnia: A Randomized Controlled Trial

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Abstract. Several trials have demonstrated the efficacy of online cognitive behavioral therapy (CBT) for insomnia. However, few studies have examined putative mechanisms of change based on the cognitive model of insomnia. Identification of modifiable mechanisms by which the treatment works may guide efforts to further improve the efficacy of insomnia treatment. The current study therefore has two aims: (1) to replicate the finding that online CBT is effective for insomnia and (2) to test putative mechanism of change (i.e., safety behaviors and dysfunctional beliefs). Accordingly, we conducted a randomized controlled trial in which individuals with insomnia were randomized to either online CBT for insomnia (n = 36) or a waiting-list control group (n = 27). Baseline and posttest assessments included questionnaires assessing insomnia severity, safety behaviors, dysfunctional beliefs, anxiety and depression, and a sleep diary. Three- and six-month assessments were administered to the CBT group only. Results show moderate to large statistically significant effects of the online treatment compared to the waiting list on insomnia severity, sleep measures, sleep safety behaviors, and dysfunctional beliefs. Furthermore, dysfunctional beliefs and safety behaviors mediated the effects of treatment on insomnia severity and sleep efficiency. Together, these findings corroborate the efficacy of online CBT for insomnia, and suggest that these effects were produced by changing maladaptive beliefs, as well as safety behaviors. Treatment protocols for insomnia may specifically be enhanced by more focused attention on the comprehensive fading of sleep safety behaviors, for instance through behavioral experiments. Key words: beliefs; CBT; insomnia; online; safety behaviors.

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Insomnia, that is, problems of getting to sleep and/or staying asleep, affects about 10% of the general population (Ohayon, 2002). In order to meet the criteria for a DSM-5 disorder, these sleep complaints need to be present for at least three months, cannot be better explained by another disorder, and have negative daytime consequences (American Psychiatric Association, 2013).

Among these daytime negative consequences, studies have documented low concentration, fatigue, and impaired cognitive functioning (Espie, Kyle, Hames, Cyhlarova,

& Benzeval, 2012; Kyle, Morgan, & Espie, 2010; LeBlanc et al., 2007; Roth & Drake, 2004), as well as an increased likelihood of experiencing physical complaints such as coronary artery disease (Mallon, Broman, & Hetta, 2002), diabetes (Mallon, Broman, & Hetta, 2005), and high blood pressure (Suka, Yoshida, & Sugimori, 2003). Furthermore, insomnia is related to an increased risk of developing other mental disorders such as depression and anxiety (Baglioni et al., 2011; Taylor, Lichstein, Durrence, Reidel, & Bush, 2005). In addition, insomnia is associated with

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substantial societal costs due to higher work absenteeism and decreased productivity (Daley, Morin, LeBlanc, Gregoire, & Savard, 2009).

Several meta-analyses showed that sleeping problems can be effectively treated with cognitive behavioral therapy for insomnia (CBT-I; Irwin, Cole, & Nicassio, 2006; Morin et al., 2006; Morin et al., 1999). CBT-I is as effective as sleep medication in the short term, and has more support for its efficacy in the long term (Rieman & Perlis, 2009; Smith et al., 2002). Moreover, CBT-I comes without the adverse side effects often associated with medication, such as headaches, drowsiness, and dizziness (Glass, Lanctot, Herrmann, Sproule, & Busto, 2005).

To reach a larger group of people and to create easier access to CBT-I, online versions of CBT-I for insomnia have been developed. Two meta-analyses demonstrated that selfhelp treatment for insomnia yields small to moderate effects (Cheng & Dizon, 2012; van Straten & Cuijpers, 2009), while a recent metaanalysis reported moderate to large effects (Ho et al., 2014). Moreover, recent studies showed that the efficacy of these online treatments is enhanced when patients received motivational feedback via the e-mail on their exercises and progress (Lancee, van den Bout, Sorbi, & van Straten, 2013), especially for the subgroup with depressive comorbidity (Lancee, Sorbi, Eisma, van Straten, & van den Bout, 2014).

While the evidence for (online) CBT-I is mounting, support for mechanisms by which the treatment works remains scarce. Indeed, in their recent meta-analysis on mediators of CBT-I, Schwartz and Carney (2012) concluded that although CBT-I appears to target the risk factors of insomnia, more research is needed to establish whether CBT-I works according to proposed mediators.

In a cognitive model of insomnia, Harvey (2002a) argued that thinking repetitively about possible sleep deficiencies and the consequences of impaired sleep contributes to arousal and distress, which consequently lead to selective attention and increased monitoring of sleep-related threats. These processes in turn result in an overestimation of the consequences of sleep difficulties, which causes even more impairment in sleep and daytime functioning. According to Harvey

(2002a), dysfunctional beliefs and safety behaviors fuel and exacerbate these processes and are therefore important maintaining factors of insomnia. This paper therefore aims to test the singular and joint meditational potency of these two constructs in the context of a randomized controlled trial (RCT) comparing online CBT-I and a waiting-list control condition.

Dysfunctional beliefs about sleep are erroneous assumptions, such as unrealistic expectations about sleep requirements, wrong attributions to the causes of insomnia, and unrealistic beliefs about the consequences of insomnia (Morin & Espie, 2003). These dysfunctional beliefs are hypothesized to trigger negative emotions that in turn lead to impaired sleep. For example, a patient that holds the belief "I need eight hours of sleep to adequately function during the day" will start to worry during the night if less than eight hours of available sleeping time remains. Following Harvey's (2002a) model, this worry/excessive toned cognitive activity will lead to distress which will result in a delay in sleep onset.

Most authors recognize the importance of dysfunctional beliefs and therefore identifying and challenging these beliefs are nowadays a standard component of CBT-I (Harvey et al., 2014; Harvey, Sharpley, Ree, Stinson, & Clark, 2007; Morin & Espie, 2003). Multiple trials measured the effect of insomnia treatment on dysfunctional beliefs and found that such beliefs were indeed ameliorated by therapy compared to control conditions (Edinger, Wohlgemuth, Radtke, Marsh, & Quillian, 2001; Harvey et al., 2007). More importantly, changes in dysfunctional beliefs were correlated with treatment effect (Edinger et al., 2001; Espie, Inglis, & Harvey, 2001; Jansson-Frojmark & Linton, 2008; Morin, Blais, & Savard, 2002). However, only two groups performed specific mediation analyses (Espie et al., 2014; Okajima, Nakajima, Ochi, & Inoue, 2014). Surprisingly, Espie et al. (2014) found that dysfunctional beliefs mediated effects of treatment on a general insomnia measure, but not sleep efficiency. Another research group found no mediating effect of dysfunctional beliefs on the effects of treatment on insomnia severity (Okajima et al., 2014). Stated differently, while there is substantial support for the relationship between dysfunctional

beliefs and insomnia, specific evidence for its mediating role in CBT-I remains inconclusive.

Safety behaviors, that is, subtle avoidance behaviors intended to prevent a feared outcome, provide relief from distress in the short term, but eventually have negative consequences in the long term (Salkovskis, 1991). According to models in the anxiety literature (Clark, 1999; Kamphuis & Telch, 1998; Salkovskis, 1991) and Harvey's (2002a) insomnia-based model, safety behaviors prevent disconfirmation of patients' dysfunctional beliefs. For example, the belief that one needs eight hours a night to sleep may lead to the safety behavior of going to bed early so that there is an increased chance of sleeping for eight hours. This safety behavior will have the short-term benefit of being more rested in the morning, but it also prevents falsification of the belief that one needs eight hours of sleep for adequate functioning during the next day. The safety behavior thereby blocks opportunities to gain new insights about sleep learning by misattributing the prevention of sleep problems to the safety behavior. Notably, this may not apply to all safety behavior; for example, recent evidence shows that the careful use of safety behaviors can have beneficial effects for treatment (e.g., allowing some safety behaviors can motivate patients to do their exercises; Levy & Radomsky, 2014). In insomnia, these safety behaviors can occur both during the day and at night, and are not exclusively aimed at controlling overt behavior but also at controlling thoughts and imagery (Harvey, 2002a).

Safety behaviors in insomnia have only recently become the object of empirical scrutiny. Upon identification of safety behaviors in insomnia (Harvey, 2002b), it was demonstrated that people with insomnia report engaging in more safety behavior than people without insomnia (Jansson-Frojmark, Harvey, Norell-Clarke, & Linton, 2012; Ree & Harvey, 2004). Also, the need to engage in safety behavior (but not the intensity at which people engage in it) was associated with insomnia severity (Hood, Carney, & Harris, 2011). Moreover, two treatment studies showed that safety behaviors were ameliorated by CBT-I (Harvey et al., 2007; Jernelov et al., 2012). On the other hand, Woodley and Smith (2006) found insomnia severity unrelated to the use of safety behaviors and Gosling, Batterham, and Christensen (2012) reported that safety behaviors were not associated with the onset of sleep disturbance when controlling for ruminative style and somatic sensitivity. No mediation analyses have yet been conducted relating change in use of safety behaviors to treatment outcome.

In sum, both dysfunctional beliefs and safety behaviors are proposed as key mechanisms in the negative cognitive cycle of insomnia (Harvey, 2002a), but these assertions yielded inconclusive evidence (i.e., dysfunctional beliefs), or have not been tested empirically (i.e., safety behaviors) in therapy effect studies.

In the current investigation, we therefore aimed to (1) replicate the finding that online CBT-I is effective in the treatment of insomnia and (2) test the hypotheses that dysfunctional beliefs and safety behaviors mediate the effect of CBT-I. Accordingly, we conducted an RCT comparing online CBT-I to a waiting-list control group. Specific hypotheses include: (1) CBT-I is effective compared to a waiting list in ameliorating insomnia severity and sleep impairment assessed with a sleep diary, (2) CBT-I is effective compared to a waiting list in ameliorating dysfunctional beliefs and safety behaviors about sleep, and (3) dysfunctional beliefs and safety behaviors mediate the effect of CBT-I on insomnia severity and sleep measures.

Method

Participants

Participants were recruited from April 2013 to January 2014 via a popular-scientific website and a Facebook ad campaign. Enrollment took place in October 2013 and January 2014. An initial group of 109 interested individuals read information about the study, completed an informed consent form, and started the online questionnaire. Thirty-three interested volunteers were excluded based on the preselected inclusion/exclusion criteria (see Figure 1 for a Flowchart). Inclusion criteria were: (1) insomnia according to DSM-5 criteria; (2) Insomnia Severity Index (ISI) score 10 or higher (Morin, Belleville, Belanger, & Ivers, 2011); (3) being awake for at least 30 min at night for at least three nights a week; and (4) being 18 years or older. Exclusion

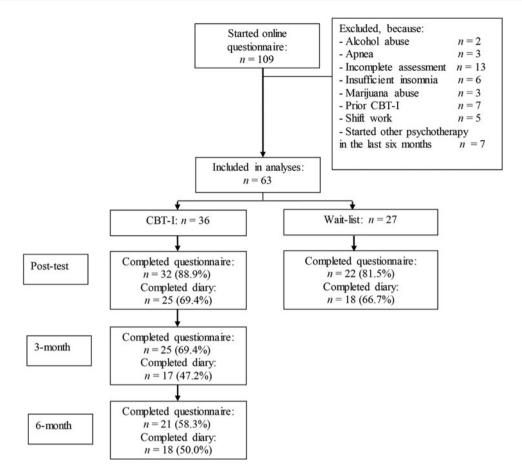


Figure 1. Flowchart.

criteria were: (1) possible sleep apnea (measured with the SLEEP-50 where the apnea subscale has a cutoff of >15; Spoormaker, Verbeek, van den Bout, & Klip, 2005), (2) shift-work, (3) earlier CBT for insomnia, (4) starting other psychotherapy in the last six months, (5) alcohol abuse (more than three glasses of alcohol a day for at least 21 days a month) or marijuana abuse (use more than once a week), (6) a diagnosis of schizophrenia or psychosis, and (7) current suicidal plans. Of the remaining people, 13 did not complete the questionnaires or failed to complete their diary on more than one day (out of seven). This resulted in a final sample of 63 participants. Baseline characteristics and descriptive statistics of the sample are displayed in Tables 1 and 2.

Power

This study was originally powered to include 100 participants (α of 0.05 and a power of 0.8 to detect Cohen's d effect sizes of 0.6 with a 20% dropout). However, due to financial and practical limitations we were forced to stop inclusion at 63 participants. Based on the posttest questionnaire data, in the current study we now achieved a power of 0.8 for an effect size of d = 0.65.

Materials

Online questionnaires. For online questionnaires, Thorndike et al. (2009) demonstrated the validity of both single-item and multiple-item presentation per webpage. We used multiple items per webpage (but never more than 15 items per webpage).

Table 1. Demographic and clinical characteristics at baseline

		(CBT-I	W	/ait-list	
		47.4	7 (14.37)	49.9	98 (13.71)	
Age	M (SD)		(,		, , , ,	F(1.53) = 0.43; p = 0.51
	,	n	%	n	%	, , , , , , , , , , , , , , , , , , , ,
Gender	Male	6	16.7	7	25.9	χ^2 (1) = 0.91; p = 0.37
	Female	30	83.3	20	74.1	, , , , , , , , , , , , , , , , , , , ,
Prescribed sleep medication	No	22	61.1	20	74.1	χ^2 (1) = 1.17; $p = 0.42$
•	Yes	14	38.9	7	25.9	, , , , , , , , , , , , , , , , , , , ,
Medication other than for sleeping	No	34	94.4	26	96.3	χ^2 (1) = 0.12; $p = 1.0$
	Yes	2	5.6	1	3.7	,,
In psychological treatment	No	35	97.2	27	100.0	χ^2 (1) = 0.76; $p = 1.0$
	Yes	1	2.8	0	0.0	,,
Insomnia due to a physical condition	No	31	86.1	25	92.6	χ^2 (1) = 0.60; p = 0.69
• •	Yes	5	13.9	2	7.4	,,
Currently employed	No	7	19.4	7	25.9	χ^2 (1) = 0.38; $p = 0.56$
7 1 7	Yes	29	80.6	20	74.1	
Years insomnia	< 1 year	5	13.9	4	14.8	χ^2 (3) = 4.01; $p = 0.26$
	1-5 years	5	13.9	9	33.3	, , , , , , , , , , , , , , , , , , , ,
	5–10 years	8	22.2	3	11.1	
	>10 years	18	50.0	11	40.7	

Note. CBT-I: n = 36; wait-list: n = 27. Age is based on n = 24 in the wait-list and n = 31 in the CBT-I condition.

Insomnia severity was measured with a Dutch translation of the seven-item ISI. The ISI is a widely used measure to index changes in insomnia severity, and favorable psychometric properties are documented (internal consistency $\alpha = 0.78$; Bastien, Vallières, & Morin, 2001; Morin, 1993). The total score ranges from 0 (no insomnia) to 28 (severe insomnia). The internal consistency (Cronbach's α) in the present study was 0.60 (which was comparable to the $\alpha = 0.61$ that was found in a validation study of the online version of the ISI; Thorndike et al., 2011). A cutoff of 10 was previously offered as the optimal indicator for clinical levels of insomnia in a community sample (Morin et al., 2011) and was used in this study.

Dysfunctional beliefs were assessed with the Dutch translation of the 16-item brief Dysfunctional Belief and Attitudes about Sleep scale—DBAS (Lancee & Kamphuis, in preparation; Morin, Vallieres, & Ivers, 2007). The English version of the DBAS shows adequate internal consistency ($\alpha = 0.79$; in the current study: $\alpha = 0.81$) and was significantly correlated with self-report measures of insomnia severity, anxiety, and depression. The sum of the DBAS score is averaged so that the total score ranges from 0 (no dysfunctional beliefs) to 10 (severe dysfunctional beliefs).

Sleep safety behaviors were measured with the Dutch translation of the 32-item Sleep-Related Behaviors Questionnaire—SRBQ (Lancee & Kamphuis, in preparation; Ree & Harvey, 2004). The total score ranges from 0 (no safety behaviors) to 128 (severe safety behaviors). The English version showed good internal consistency ($\alpha = 0.92$; in the current study: $\alpha = 0.83$) and could discriminate normal sleepers from people with insomnia. Furthermore, the SRBQ is correlated with daytime and nighttime complaints of insomnia.

Depression was measured using a Dutch translation of the 20-item Centre of Epidemiological Studies Depression scale (CES-D, range = 0—no depressive symptoms to 60—severe depressive symptoms; Bouma et al., 1995; Radloff, 1977). This scale has good internal consistency ($\alpha = 0.79-0.92$), and the validity of the Dutch scale is comparable to that of the original version (Bouma et al., 1995; Radloff, 1977). Cronbach's α was 0.89 in the current study.

Anxiety symptoms were assessed with the Dutch version of the seven anxiety items of the Hospital Anxiety and Depression Scale (HADS; Spinhoven et al., 1997; Zigmond & Snaith, 1983). The total score ranges from 0 (no symptoms of anxiety) to 21 (severe

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symptoms of anxiety). The reliability of the HADS is good ($\alpha = 0.80-0.84$; in the current study: $\alpha = 0.85$), as is the test–retest correlation (r = 0.89; p < 0.001).

The SLEEP-50 (Spoormaker et al., 2005) was used to exclude patients with possible sleep apnea. The apnea subscale has eight items ($\alpha = 0.51$) and the total scale ranges from 8 (no apnea indication) to 32 (severe apnea indication). A cutoff of ≥ 15 is optimal with a sensitivity of 0.85 and a specificity of 0.88.

Online sleep diary. We used a Dutch translation of the consensus sleep diary (Carney et al., 2012). Participants kept a sleep diary for seven days and recorded time to bed, time they tried to go to sleep, time of final awakening, time out of bed, sleep onset latency (SOL), wake after sleep onset (WASO), terminal wakefulness (TWAK), number of nightly awakenings, sleep quality (1 = "very bad" to 5 = "very good"), and use of sleep medication. From these variables, the time in bed (TIB = final arising time – time to bed), total sleep time (TST = TIB – SOL – WASO), and sleep efficiency (SE = [TST/TIB] × 100) were calculated.

Intervention

The online CBT-I treatment protocol that was administered was based on treatment manuals for face-to-face CBT-I (e.g., Morin & Espie, 2003; Verbeek & Klip, 2005). This treatment packaged the following modules: (1) psychoeducation; (2) progressive muscle relaxation; (3) sleep hygiene; (4) sleep restriction—restricting TIB to actual sleeping time; and (5) cognitive exercises—challenging the misconceptions about sleep. The treatment comprised six weekly sessions that each covered one or more modules. The basic treatment sessions spanned six weeks, but participants who took longer to complete the treatment (e.g., because of holiday) received feedback up to eight weeks. For a more elaborate description of the treatment content, please see Lancee, van den Bout, van Straten, and Spoormaker (2012).

The online program, first described in a study of Lancee et al. (2013), features an integrated diary that gives visual feedback on participants' sleep efficiency and total time spent awake. The online program enables the provision of feedback on treatment progress and assigned exercises. In a previous study (Lancee et al., 2013), motivational feedback

proved to enhance treatment effects (reminding and motivating are the most important aspects of the feedback). In the current study, similar feedback was provided by master's students of psychology under supervision of the first author. On average, the students spent 56.5 minutes (SD = 31.1) on giving feedback per participant for the full online treatment (i.e., all six lessons).

Procedure

The participants who met study criteria completed a questionnaire and received an online sleep diary, e-mailed to them at 6:00 am for seven consecutive days. After completing the diary, participants were randomized to either online CBT-I or the waiting-list condition. Twelve weeks later, both the CBT-I and waiting-list group received posttest questionnaires and a sleep diary. After completing the posttreatment sleep diary, participants in the waiting-list condition received an online CBT-I treatment. Participants in the online CBT-I condition also received three- and six-month follow-up questionnaires and diaries. The study was conducted in line with the Declaration of Helsinki, approved by the internal Ethical Review Board of the University of Amsterdam, and registered at Clinicaltrials. gov (NCT01955928).

Statistical analysis

The effects of the intervention were tested using multilevel regression analysis. Multilevel regression analysis is an intention-to-treat procedure that also allows participants with only one measurement in the analyses (Hox, 2002). One-way ANOVAs and chi-square tests showed that participants did not differ on any of the demographic or outcome variables at baseline (all ps > 0.2). However, participants in the online condition who did not respond to the posttest sleep diary had lower average scores on total sleep time at baseline (284 min versus 353 min). Therefore, total sleep time was added as a covariate in the multilevel regression analyses regarding the pretest—posttest measurements. At the three- and six-month follow-up no variables were associated with nonresponse. One outlier was removed from the diary analyses, as this respondent's sleep diary scores were below a z-score of 3.29 (sleep efficiency of this participant was 6.9% on average).

Because total sleep time was associated with nonresponse in the CBT-I condition, we used a multiple imputation procedure based on the missing at random assumption (Sterne et al., 2009). We used a monotone predictive mean matching procedure to generate 10 separate datasets and insert missing cases on the questionnaire and diary data. The posttest scores in Table 2 are the imputed values. To provide a comprehensive overview and to further show the possible influence of missing values on our analyses, we also included a completers analysis.

Within-group Cohen's ds were calculated on the imputed and completers data with $(M_{\rm prel} - M_{\rm post1})/\sigma_{\rm pooled}$. Between-group Cohen's ds were calculated on the difference in change scores divided by the pooled baseline standard deviation of the groups (Morris, 2008). A Cohen's d of 0.20 is generally considered small, that of 0.50 moderate, and that of 0.80 large (Cohen, 1988). A significance level of p < 0.05 (two-sided) was used throughout our study.

For the mediation analyses we used the bootstrapping method in the SPSS PROCESS tool of Hayes (2013). Bootstrapping is a nonparametrical procedure that produces an estimate of the sample based on several resamples. Mediation was tested by evaluating the 95% confidence interval of the indirect effect. The above procedure is preferred above the Sobel's test since often the sampling of the indirect effect is non-normally distributed (Hayes, 2013).

More specifically, we modeled our procedure after Vincent and Walsh (2013), that is, we used n = 5000 bootstrap resamples and the pretreat-

ment level of the dependent variable (i.e., ISI, SE, WASO, SQ) was added as a covariate in the model to predict posttreatment levels of the dependent variable. In view of the limited observed power, we performed both single (using either dysfunctional beliefs or safety behavior as mediator) and multiple mediation analyses (including both mediators). Our procedure differed from Vincent and Walsh (2013) in that we also added the pretreatment score of the mediator under investigation as covariate(s). We also calculated the effect sizes of the indirect effect with: 1 - c'/c. With this formula the proportion of the effect of the independent variable on the dependent variable that is accounted for by the mediator is calculated. Possible values lie between 0 and 1 (MacKinnon, Fairchild, & Fritz, 2007). In Figure 2, the mediation model is shown.

Results

Completion of modules

A module was deemed completed if the last exercise of this module was saved by the user. Twenty-seven (75.0%) of the participants in the CBT-I condition completed an adequate dose of the intervention (at least four modules; Lancee et al., 2013) and 17 (47.2%) completed all sessions of the intervention.

Baseline differences and nonresponse

Thirty-three (88.9%) participants in the CBT-I condition and 22 (81.5%) in the waiting-list condition completed the posttest questionnaire. The posttest diary was completed by 25

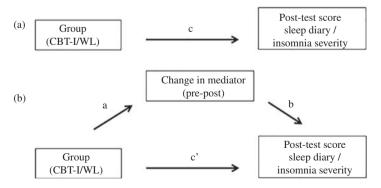


Figure 2. (a) Path c is the total effect of group on the outcome variables without the influence of the mediator variable. (b) Path a is the effect of group on the mediator variable, path b is the effect of the mediator on the outcome variable. Path ab is the indirect effect (or mediation effect). Path c' is the effect of the group controlling for the mediator variables.

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		Baseline	Posttest	Coh	en's d
	Group	Mean (SD)	Mean (SD)	Within-group	Between-group
Questionnaire					
Insomnia severity	CBT-I	18.19 (3.88)	12.26 (5.77)	-1.21***	-1.05*
	WL	18.33 (3.59)	16.34 (6.01)	-0.40*	
Dysfunctional beliefs	CBT-I	5.70 (1.28)	4.33 (1.95)	-0.83***	-1.49***
Ž	WL	5.20 (1.50)	5.91 (1.76)	0.43 ns	
Sleep safety behavior	CBT-I	48.06 (16.31)	37.06 (19.79)	-0.61***	-0.97***
1 2	WL	42.48 (13.06)	45.83 (20.16)	0.20 ns	
Depression	CBT-I	17.08 (8.92)	14.40 (10.02)	-0.28*	-0.50*
•	WL	17.63 (9.11)	19.47 (11.19)	0.18 ns	
Anxiety	CBT-I	6.42 (3.06)	6.07 (4.23)	-0.09 ns	-0.49 ns
	WL	6.52 (3.43)	7.76 (4.41)	0.31*	
Diary		,	,		
Sleep efficiency	CBT-I	67.33 (14.46)	79.47 (10.86)	0.98***	1.00**
1	WL	66.97 (13.42)	65.16 (15.41)	-0.12 ns	
Total sleep time	CBT-I	331.1 (78.15)	375.84 (59.71)	0.56***	0.62 ns
1	WL	337.8 (76.37)	334.31 (79.00)	-0.04 ns	
Sleep onset	CBT-I	44.05 (36.44)	32.21 (35.23)	-0.12 ns	-0.60 ns
1	WL	42.86 (29.83)	51.08 (37.871)	0.24 ns	
Wake after sleep onset	CBT-I	60.99 (38.54)	38.09 (29.25)	-0.67**	-0.91*
1	WL	61.16 (37.56)	72.77 (48.66)	0.27 ns	
Terminal wakefulness	CBT-I	51.74 (32.72)	31.00 (22.95)	-0.73*	-0.45 ns
	WL	62.70 (36.19)	57.63 (41.01)	0.13 ns	
Number of awakenings	CBT-I	2.08 (1.00)	1.78 (1.10)	-0.28 ns	-0.26 ns
2	WL	2.43 (1.65)	2.48 (1.35)	0.03 ns	
Sleep quality	CBT-I	2.76 (0.49)	3.14 (0.52)	0.76***	0.79*
1 1 2	WL	2.80 (0.48)	2.79 (0.51)	-0.02 ns	

Note. Missing posttest scores are imputed with predictive mean matching (CBT-I: n = 36; wait-list: n = 27). *p < 0.05; **p < 0.01; ***p < 0.001.

(69.4%) in the CBT-I condition and by 18 (66.7%) in the waiting-list condition. In the CBT-I condition, the three- and six-month questionnaires were completed by 25 (69.4%) and 21 (58.3%) participants, respectively, and the three- and six-month diaries by 17 (47.2%) and 18 (50.0%), respectively.

As mentioned previously, people in the CBT-I condition who did not fill out the posttest diary had a lower score on total sleep time at baseline (284 min versus 353 min). There were no other statistically significant differences with respect to demographic or clinical variables between the responders and nonresponders.

Efficacy: intention-to-treat analyses

Table 2 displays the imputed mean scores and corresponding Cohen's deffect sizes. At posttest, we found significant interaction effects (Time \times Group) between the CBT-I and waiting-list condition for the following variables: insomnia

severity (ISI), b = 3.80; SE = 1.50; p = 0.013, efficiency, b = -7.89; SE = 2.92; p = 0.006, WASO, b = 27.65; SE = 11.21; p = 0.014, sleep quality, b = -0.41; SE = 0.16; p = 0.012, dysfunctional cognitions (DBAS), b = 1.89; SE = 0.42; p < 0.001, safety behaviors (SBRQ), b = 14.19; SE = 3.83; p < 0.001, and depressive symptoms, b = 5.25; SE = 2.03; p = 0.010. These effects indicate that CBT-I is more effective than the waiting-list condition. The effects in the CBT-I condition were maintained or improved at three- and sixmonth follow-ups. The improvements between posttest and six-month follow-up were most notable for insomnia severity, anxiety, and depressive symptoms (Table 3).

There was a trend toward a significant interaction effect for total sleep time, b = -24.19; SE = 13.57; p = 0.075, and anxiety symptoms, b = 1.86; SE = 0.98; p = 0.058. No significant interaction effects

Table 3. Intention-to-trea	t sample: three- and	six-month follow-up	s for the CBT-I condition
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	Three-m	onth	Six-mo	nth
	Mean (SD)	d	Mean (SD)	d
Questionnaire				
Insomnia severity	11.45 (5.95)	1.34***	10.48 (5.21)	1.68***
Dysfunctional beliefs	4.36 (2.08)	0.55***	3.90 (1.66)	0.79***
Sleep safety behavior	34.81 (21.21)	0.19***	30.96 (17.63)	0.70***
Depression	12.04 (9.38)	0.78***	10.80 (6.77)	1.22***
Anxiety	5.62 (4.96)	0.70***	4.26 (3.07)	1.01***
Diary	, ,		, ,	
Sleep efficiency	81.48 (5.75)	-1.29**	78.53 (8.70)	-0.94***
Total sleep time	400.10 (33.86)	-1.15***	382.21 (45.37)	-0.80*
Sleep onset latency	21.90 (11.14)	0.54***	24.19 (16.11)	0.43**
Wake after sleep onset	35.56 (12.74)	0.89**	35.76 (15.69)	0.86**
Terminal wakefulness	32.86 (23.69)	0.66*	45.78 (26.66)	0.20 ns
Number of awakenings	1.67 (0.86)	0.44 ns	1.75 (1.03)	0.32 ns
Sleep quality	3.25 (0.42)	-1.08**	3.07 (0.67)	-0.54*

Note. Missing posttest scores are imputed with predictive mean matching (CBT-I: n = 36). d is a withingroup Cohen's d with the baseline levels as a reference.

for: SOL. b = -9.40: SE = 7.40; p = 0.204, TWAK, b = 6.55;SE = 9.88; p = 0.507, and number of nightly awakenings, b = -0.53; SE = 0.35: p = 0.132.

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Efficacy: treatment and study completers only

Completers analyses only included individuals who completed an adequate dose of the online treatment (at least four sessions) and filled out the posttest diary or questionnaire. Table 4 displays the mean scores of the completers and corresponding Cohen's d effect sizes (Supplemental Table S1 displays the completers' follow-up data). Again, we observed significant interaction effects (Time × Group) for the following variables: insomnia severity SE = 1.66;p = 0.005. b = 4.60;(ISI), sleep efficiency, b = -7.57; SE = 3.39; p =WASO, b = 26.19; SE = 12.38; p = 0.034, sleep quality, b = -0.37; SE = 0.18; p = 0.035, dysfunctional cognitions (DBAS), b = 2.16; SE = 0.43; p < 0.001, safety behaviors (SBRQ), b = 17.14; SE = 4.04; p < 0.001, depressive symptoms, b = 6.39; SE = 2.14; p = 0.002, and anxiety symptoms, b = 2.46; SE = 1.03; p = 0.016. As before, these results indicate that CBT-I is more effective than the waiting-list condition.

Now there was trend toward a significant interaction effect on number of nightly awakenings, b = 0.63; SE = 0.38; p = 0.097. The following variables showed no significant interaction effect: total sleep b = -17.13; SE = 16.44; p = 0.298, SOL, b = 9.39; SE = 8.05; p = 0.244, TWAK, b = 6.34; SE = 11.18; p = 0.571.

Clinical significant change

At baseline, all participants had clinical levels of insomnia based on the ISI (cutoff ≥ 10) (Morin et al., 2011). Of the participants that completed the posttest, 12 (37.5%) scored below the cutoff in the CBT-I condition and 3 (13.6%) in the waiting-list condition. The proportions of the two conditions attaining scores below the cutoff were not significantly different, χ^2 [1] = 3.70; p = 0.14. On the follow-ups, 13 (52.0%; three-month) and 12 participants (57.1%; six-month) scored below cutoff in the CBT-I condition.

A change of eight or more on the ISI is considered a clinical meaningful change in insomnia severity (Morin et al., 2011). Of the participants that completed the posttest, a trend emerged showing that CBT-I participants were more likely to achieve a meaningful change in insomnia with 13 participants (40.6%) meeting criteria for meaningful change in the CBT-I condition, and 4

p < 0.05; **p < 0.01; ***p < 0.001.

Table 4. Completers sample: pretest to posttest means and corresponding Cohen's d

		Baseline	Posttest	Coh	en's d
	Group	Mean (SD)	Mean (SD)	Within-group	Between-group
Questionnaire					
Insomnia severity	CBT-I	18.12 (4.30)	11.56 (6.23)	-1.23***	-1.06**
•	WL	18.23 (3.79)	15.95 (6.21)	-0.44 ns	
Dysfunctional beliefs	CBT-I	5.65 (1.38)	4.07 (1.82)	-0.98***	-1.43***
,	WL	5.36 (1.56)	5.88 (1.77)	0.31 ns	
Sleep safety behavior	CBT-I	44.56 (16.52)	31.04 (17.60)	-0.79***	-1.08***
1	WL	42.95 (14.15)	46.09 (19.97)	0.18 ns	
Depression	CBT-I	15.36 (8.11)	11.56 (8.02)	-0.47**	-0.70**
•	WL	17.68 (9.17)	19.91 (10.98)	0.22 ns	
Anxiety	CBT-I	6.00 (2.63)	4.96 (4.08)	-0.30 ns	-0.88*
•	WL	6.27 (3.10)	7.77 (4.33)	0.40*	
Diary		,	,		
Sleep efficiency	CBT-I	70.03 (13.33)	79.35 (11.36)	1.22***	0.56*
-	WL	64.22 (13.95)	65.97 (15.38)	0.12 ns	
Total sleep time	CBT-I	355.47 (71.76)	385.48 (50.03)	0.96**	0.23 ns
_	WL	324.03 (75.73)	336.92 (79.66)	0.17 ns	
Sleep onset	CBT-I	37.09 (37.99)	30.96 (37.56)	-0.19*	-0.26 ns
-	WL	42.82 (33.81)	46.08 (36.61)	0.09 ns	
Wake after sleep onset	CBT-I	63.49 (34.66)	39.49 (28.57)	-0.76*	-0.99*
-	WL	61.16 (37.56)	72.91 (45.67)	0.28 ns	
Terminal wakefulness	CBT-I	49.25 (29.55)	31.22 (21.77)	-0.69*	-0.19 ns
	WL	68.33 (37.37)	56.65 (35.96)	-0.32 ns	
Number of awakenings	CBT-I	2.27 (1.14)	1.76 (1.76)	-0.34*	-0.48 ns
2	WL	2.40 (1.46)	2.52 (1.34)	0.09 ns	
Sleep quality	CBT-I	2.80 (0.46)	3.13 (0.48)	0.71**	0.83*
• •	WL	2.78 (0.43)	2.75 (0.48)	-0.08 ns	

Note. The completer sample is based on the participants that completed the posttest and completed at least four modules of the intervention (questionnaire, CBT-I: n = 25; wait-list: n = 22; diary, CBT-I: n = 22; wait-list: n = 18).

(18.2%) in the waiting-list condition ($\chi^2[1] = 3.04$; p = 0.07). At the follow-up assessments, 11 (44.0%; three-month) and 10 participants (47.6%; six-month) achieved a clinical meaningful change in the CBT-I condition, respectively.

Medication and use of other treatment during the trial

Of the participants that completed the posttest, 10 (31.2%) used prescribed sleep medication and also 10 (45.5%) in the waiting-list condition. These proportions were not significantly different, $\chi^2[1] = 1.13$; p = 0.39.

During the trial, alternative treatment was sought by six (18.8%) participants in the CBT-I condition (n = 1, sleep medication; n = 2,

general practitioner; n = 1, sleep center, n = 1, acupuncture, n = 1, physical therapy) and eight participants (29.6%) in the waiting list (n = 4, sleep medication; n = 1, self-help via smartphone app; n = 1 general practitioner; n = 1 psychologist; n = 1, tai-chi).

Deterioration and adverse events

In line with the consensus statement on negative effects of Internet interventions (Rozental et al., 2014), we report the participants that deteriorated at posttest. In the CBT-I group 3 (9.3%) participants deteriorated on the ISI and in the waiting-list group 7 (31.8%). None of the deteriorations were clinical meaningful (change ISI \geq 8). Furthermore, no patients reported adverse events; however, we only asked the people that dropped out from

^{*}p < 0.05; **p < 0.01; ***p < 0.001.

the study if they had experienced such events during therapy.

Mediation analysis

We conducted mediation analyses for the dependent sleep variables that showed a significant interaction effect (Time × Group) at posttest (i.e., insomnia severity, sleep efficiency, WASO, sleep quality). Dysfunctional beliefs and safety behaviors were the mediator variables in two separate analyses (please see Supplemental Table S2 for the zero-order correlations).

As can be seen in Table 5, dysfunctional beliefs (proportion of the effect explained by the mediation 94%) and safety behaviors (92%) mediated the treatment effects of CBT-I on insomnia severity (ISI), as well as on sleep efficiency (proportion explained respectively 45% and 41%). No mediation effects were found on WASO or on sleep quality. Mediation effect size estimates are based on MacKinnon et al. (2007).

For insomnia severity and sleep efficiency we also conducted joint meditational analyses, including both potential mediators in a single model (Table 5). Dysfunctional beliefs, b = -3.67, 95% BI [-9.12, 0.16] and safety behaviors, b = -1.57, 95% BI [-6.96, 2.31], were not significant mediators on sleep efficiency in this model. However, together they mediated the effect, b = -5.25, 95% BI [-12.03, -0.72], proportion explained: 54%. For insomnia severity, the total mediation effect, b = 4.43, 95% BI [2.08, 7.03], proportion explained 80%, was carried by safety behaviors, b = 3.06, 95% BI [1.18, 5.80], and not by dysfunctional beliefs, b = 1.37, 95% BI [-0.42, 3.86].

Discussion

A first aim of the present study was to test whether online CBT-I was effective in treating insomnia. We found that online CBT-I showed moderate to large statistically significant effects on insomnia severity, sleep efficiency, sleep quality, anxiety, and depression scores compared to a waiting list. Moreover, this CBT-I treatment format also dysfunctional beliefs ameliorated sleep safety behaviors. After treatment, 40.6% of the participants in the CBT-I condition achieved a clinical meaningful change on the ISI against 18.2% in the waiting-list condition. The effects of online CBT-I were maintained at the three- and sixmonth follow-up.

A second aim was to test the extent to which dysfunctional beliefs and safety behaviors might mediate the effects of CBT-I on insomnia severity and sleep diary measures. The singular mediator analyses indicated that both dysfunctional beliefs and safety behaviors mediated the effect of CBT-I on insomnia severity (ISI) and sleep efficiency, but not WASO and sleep quality.

The observed treatment outcomes are in line with previous studies on online treatment of insomnia (Cheng & Dizon, 2012; Ho et al., 2014; van Straten & Cuijpers, 2009). However, the effects appeared somewhat smaller than effects in a couple of recent studies (Espie, Kyle, Williams, et al., 2012; Lancee et al., 2012; Ritterband et al., 2009; van Straten et al., 2014), as well as in a recent study using the same treatment program (e.g., posttest within-group Cohen's d on insomnia severity of 1.6 versus 1.2; Lancee et al., 2013). A possible explanation could be that in the current study feedback was provided by master's students of psychology instead of by an insomnia expert such as in a previous investigation (Lancee et al., 2013). However, in another similar study (van Straten et al., 2014) large results were acquired with studentbased feedback. Furthermore, no significant interaction effects were observed for total sleep time, number of nightly awakenings, TWAK, and SOL, possibly due to power issues. In addition, the proportion achieving a clinical meaningful change (18%) in the waiting list was rather high, conceivable as a consequence of the high percentage (30%) seeking other treatment during the trial.

Our mediation analyses provided additional support for the hypothesis that change in dysfunctional beliefs and safety behaviors explains CBT-I's treatment effects. As such, they fall in line with findings observed by several authors regarding dysfunctional beliefs (Edinger et al., 2001; Espie et al., 2001; Harvey et al., 2007; Jansson-Frojmark & Linton, 2008; Morin et al., 2002) and safety behaviors (Espie et al., 2014; Harvey et al., 2007; Jernelov et al., 2012). They are in contrast to the null findings on insomnia severity reported Okajima et (2014)al. and

Table 5. Safety behaviors (SRBQ) and dysfunctional beliefs (DBAS) as mediators of online CBT for insomnia outcome Downloaded by [York University Libraries] at 03:16 07 November 2015

De Mediator vari	Dependent variable (DV)	Effect of IV on M (a)	Effect of M on DV (b)	Indirect effect (ab)	Direct effect (c')	Total effect (c)
Single mediator analyses	nalyses		000	130 / 10 H M / 030 OF C 1	000	02 6
DBAS ISI		b = -1.05, t = -3.91**	b = -2.29, t = -5.26**	b = 3.78, 93% BI [1.87, 0.33]	b = -0.20, t = -0.14 ns	b = 5.58, t = 2.24*
SE		b = -1.86,	b = 2.41,	b = -4.48,95% BI $[-10.62, -1.04]$	_	b = -9.92,
		t = -3.61***	t = 2.60*			t = -3.14**
WASO	•	b = -1.87,	b = -2.74,	b = 5.11, 95% BI $[-7.20, 23.40]$	b = 27.41,	b = 32.51,
		t = -3.70***	t = -0.79 ns		t = 2.18*	t = 3.03**
SO		b = -1.83,	b = 0.04,	b = -0.07, 95% BI $[-0.30, 0.07]$	b = -0.41,	b = -0.48,
		t = -3.67***	t = 0.93 ns		t = -2.62*	t = -3.60***
SBRQ ISI		b = -13.33,	b = -0.27,	b = 3.57, 95% BI [1.53, 6.03]	b = 0.31,	b = 3.88,
		t = -3.35**	t = -6.55***		t = 0.25 ns	t = 2.49*
SE		b = -15.41,	b = 0.25,	b = -3.90, 95% BI $[-9.82, -0.26]$	b = -5.63,	b = -9.53,
		t = -3.35**	t = 2.37*		t = -1.64 ns	t = -2.98**
WASO	•	b = -15.51,	b = -0.45,	b = 6.91, 95% BI $[-4.90, 25.35]$	b = 24.16,	b = 31.06,
		t = -3.44**	t = -1.15 ns		t = 1.96 ns	t = 2.87**
SO		b = -15.14,	b = 0.01,	b = -0.14,95% BI $[-0.61,0.05]$	b = -0.28,	b = -0.43,
		t = -3.39**	t = 1.83 ns		t = -1.73 ns	t = -2.89**
Multiple mediator analyses	r analyses					
DBAS ISI		b = -1.67,	b = -0.82,	b = 1.37,95% BI $[-0.42,3.85]$	b = -0.74,	b = 3.69,
		t = -3.90***	t = -1.55 ns		t = -0.57 ns	t = 2.29*
SE		b = -1.91,	b = 1.92,	b = -3.67, 95% BI $[-9.12, 0.16]$	b = -4.53,	b = -9.78,
		t = -3.67***	t = 1.50 ns		t = -1.27 ns	t = -3.04**
SBRQ ISI		b = -14.02,	b = -0.22,	b = 3.06, 95% BI [1.18, 5.80]	b = -0.74,	b = 3.69,
		t = -3.43**	t = -3.95***		t = -0.57 ns	t = 2.29*
SE		b = -15.63,	b = 0.10,	b = -1.57, 95% BI $[-6.96, 2.31]$	b = -4.53,	b = -9.78,
		t = -3.36**	t = 0.70 ns		t = -1.27 ns	t = -3.04**

Note. Independent variable (IV) = "Group"; DBAS, dysfunctional beliefs and attitudes about sleep scale; ISI, insomnia severity index; SRBQ, sleep-related behaviors questionnaire; SE, sleep efficiency; SQ, sleep quality; WASO, wake after sleep onset. *p < 0.05. **p < 0.01. ***p < 0.00I.

sleep efficiency reported by Espie et al. (2014). When testing the joint model, i.e., when including both dysfunctional beliefs and safety behaviors into the mediation analyses, only safety behaviors remained a significant mediator for insomnia severity.

These findings underscore the importance of paying attention to safety behaviors in insomnia treatment. To challenge these safety behaviors, Harvey and Eidelman (2011) advocated the use of behavioral experiments. They described several useful experiments, such as the use of clock-watching at night. In this exercise, patients are asked to act as usual for the first three nights (i.e., watching their clock when they are awake). In the subsequent three nights, they are asked to refrain from their clock-watching. Before conducting the experiment patients write down their predictions and afterwards the outcomes are discussed. These experiments help the patients to understand that the safety behavior and underlying beliefs are not helpful and, in most cases, fuel insomnia. Since our data point toward the importance of these safety behaviors we think further investigation of such behavioral experiments is warranted.

Some limitations need to be acknowledged when appraising the present findings. We used a pre-post change score for the mediator variables (dysfunctional beliefs/safety behavior). Arguably, our argument would be less theoretical if the mediators were measured at a separate time-point that succeeded the independent variable (group) and preceded the dependent variable (i.e., ISI). Furthermore, with the present level of power (i.e., a 0.8 probability to detect an effect size of 0.65), no significant treatment effects were detected for SOL, TWAK, or total sleep We therefore did not conduct mediation analyses for these variables. Future studies on CBT-I may include more participants to allow for mediational analyses on these diary sleep variables. Likewise, the predominance of the meditational potency of safety behaviors over dysfunctional belief needs to be crossvalidated in future studies.

Other methodological limitations of this study were that we did not include objective measurements (e.g., polysomnography), that insomnia was not diagnosed by a clinician, and that we had a self-selected sample of people interested in an online treatment study.

On the other hand, we note that subjective measurements (i.e., diaries) are the standard outcome measures in most treatments trials (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006), and we believe that the inclusion of objective measurements and/or clinician-based diagnoses would have weakened the ecological validity of the online design. Furthermore, we made an effort to use the best possible online selection criteria by using DSM-5 insomnia criteria in addition to a score of 10 on the ISI (Morin et al., 2011). Likewise, one could argue that the present sample was a self-selected set of individuals who were online and interested in treatment. Again, this may be the case, but this likely reflects the potential users of these treatment formats.

Also, this trial suffered from some dropout. We had 11-19% missing data in the posttest questionnaire and 31-33% in the diary. These missing data may have influenced the results because participants in the CBT-I condition with low total sleep time scores dropped out more often from the posttest measurements. Our multilevel and multiple imputation intention-to-treat analyses mitigate these concerns somewhat (Hox, 2002; Sterne et al., 2009). However, from a clinical viewpoint, it is particularly important that individuals with the most severe insomnia do complete the treatment. This may be particularly important for total sleep time since insomniacs that sleep the fewest hours have a higher risk for hypertension (Vgontzas, Liao, Bixler, Chrousos, & Vela-Bueno, 2009). Limiting these dropouts in the future is therefore of major importance.

Finally, as these mediation analyses were performed in an online treatment study, we cannot be sure that our findings generalize to face-to-face therapy. These concerns are mitigated by the fact that both types of treatment use the same protocol, it is likely that the treatments achieve their effects in a similar manner.

Taken together, this study contributes to the now substantial evidence for the efficacy of online CBT for insomnia. Future studies may compare online CBT-I to active treatments, including face-to-face treatments, and focus more on the mechanisms of change. Indeed, we hold that the main contribution of this paper lies in the identification of two

potential mediating factors of treatment effectiveness: dysfunctional beliefs and safety behaviors. As a primary candidate variable deserving more attention, we would like to nominate the (fading out of the) use of safety behaviors.

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Disclosure statement

The authors have declared that no conflict of interest exists.

Supplemental data

Supplemental data for this article is available via the supplemental tab on the article's online page at http://dx.doi.org.10.1080/16506073. 2015.1026386

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