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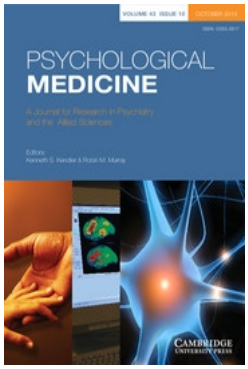

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ORIGINAL ARTICLE

Guided Internet-delivered cognitive behavioural treatment for insomnia: a randomized trial

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Background. Insomnia is a prevalent problem with a high burden of disease (e.g. reduced quality of life, reduced work capacity) and a high co-morbidity with other mental and somatic disorders. Cognitive behavioural therapy (CBT) is effective in the treatment of insomnia but is seldom offered. CBT delivered through the Internet might be a more accessible alternative. In this study we examined the effectiveness of a guided Internet-delivered CBT for adults with insomnia using a randomized controlled trial (RCT).

Method. A total of 118 patients, recruited from the general population, were randomized to the 6-week guided Internet intervention (n=59) or to a wait-list control group (n=59). Patients filled out an online questionnaire and a 7-day sleep diary before (T0) and after (T1) the 6-week period. The intervention group received a follow-up questionnaire 3 months after baseline (T2).

Results. Almost three-quarters (72.9%) of the patients completed the whole intervention. Intention-to-treat (ITT) analysis showed that the treatment had statistically significant medium to large effects (p<0.05; Cohen's d between 0.40 and 1.06), and resulted more often in clinically relevant changes, on all sleep and secondary outcomes with the exception of sleep onset latency (SOL) and number of awakenings (NA). There was a non-significant difference in the reduction in sleep medication between the intervention (a decrease of 6.8%) and control (an increase of 1.8%) groups (p=0.20). Data on longer-term effects were inconclusive.

Conclusions. This study adds to the growing body of literature that indicates that guided CBT for insomnia can be delivered through the Internet. Patients accept the format and their sleep improves.

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Key words: Behaviour therapy, cognitive therapy, Internet, sleep disorders, sleep initiation and maintenance disorders.

Introduction

Insomnia is characterized by difficulty initiating or maintaining sleep or non-restorative sleep. The disorder often persists for many years (Morin *et al*. 2009*a*) and is an important public health issue. The prevalence is high, with about a third of the population suffering from insomnia symptoms and about 10% fulfilling the criteria for a sleep disorder (Ohayon, 2002; Morin *et al*. 2006*b*). Insomnia also has a high burden of disease. People with insomnia often report a decline in cognitive abilities and mood swings due to fatigue, which impacts their daily life in various domains (Roth & Ancoli-Israel, 1999; Kyle *et al*. 2010). Not only is insomnia a significant public health problem in itself, but also many people with insomnia have co-morbid (mental) health problems or will develop co-morbid disorders in the future. Most often reported is the association with depression (Taylor *et al*. 2005; Staner, 2010). In addition, research over the past decade provides increasing evidence that insomnia contributes to the risk of developing heart disease (Redline & Foody, 2011) and is associated with increased mortality (Gallicchio & Kaleson, 2009). The societal costs due to insomnia are substantial. These costs are caused by increased health-care use, which is about three times higher among poor sleepers

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than among good sleepers. Most of the societal costs of insomnia (75%) stem from work absenteeism and poor work productivity (Daley *et al*. 2009*b*). In total, poor sleepers cost society about 10 times more than good sleepers (Daley *et al*. 2009*a*).

Treatment frequently consists of sleep medication such as benzodiazepines. Several meta-analyses have shown that benzodiazepines are effective in enhancing sleep in the short term (Buscemi *et al*. 2007), but also that there are important side-effects such as drowsiness, dizziness and light headedness. These side-effects increase the risk of (traffic) accidents and, especially in the elderly, the risk of falls. The other treatment option for insomnia is cognitive behavioral therapy (CBT). It has been demonstrated convincingly that CBT is at least as effective as benzodiazepines in the short term, whereas in the longer term CBT is more effective than sleep medication (Smith *et al*. 2002; Morin *et al*. 2009*b*). However, although CBT is the preferred treatment according to several guidelines (Siebern & Manber, 2011), it is often unavailable. There is a shortage of CBT therapists, and professionals are often unaware of the treatment facilities that do exist. Moreover, CBT is relatively costly in the short term compared with medication, even though the costs in the longer term (e.g. days away from work) may be reduced by CBT.

A recent development in the management of insomnia is to deliver the treatment over the Internet. During the past decade eHealth has been introduced in mental health care in general. Many Internet-delivered programmes have been developed for different disorders such as depression, alcohol and anxiety disorders (Andrews *et al*. 2010; Griffiths *et al*. 2010; Riper *et al*. 2011) and meta-analyses have demonstrated that these programmes are effective (Cuijpers *et al*. 2010). However, they seem to be much more effective when delivered with some form of guidance and coaching (Spek *et al*. 2007). Recently, the benefits of coaching in self-help treatments have also been demonstrated for insomnia (Jernelöv *et al*. 2012).

In a previously performed meta-analysis on self-help CBT for insomnia (van Straten & Cuijpers, 2009), we showed medium effects (e.g. sleep efficiency, Cohen's $d=0.42$). However, of the 10 included studies, only one provided the self-help through the Internet (Ström *et al*. 2004). Other studies on Internet-delivered CBT (Suzuki *et al*. 2008; Ritterband *et al*. 2009; Vincent & Lewycky, 2009; Espie *et al*. 2012; Lancee *et al*. 2012) have concluded that this treatment has positive effects, although the interventions in these studies were provided without personal guidance or coaching and some studies had small sample sizes.

In the current study we examined the effectiveness of an Internet-delivered CBT guided by a personal coach for adults with insomnia using a randomized controlled trial (RCT).

Method

Design

In our RCT people were randomized to either the intervention (Internet-based CBT) or to a wait-list control group. The wait-list control group received the intervention immediately after the post-test assessment.

Recruitment of patients

In a previous trial, for recruitment purposes, we created a popular scientific website on insomnia (www.insomnie.nl; Lancee *et al*. 2012). Because of the overwhelming response to this website, we had to create a waiting list. For the current trial we approached those on this waiting list (about 1 year later) by email, in batches of 100 to 200 people to prevent overloading the coaches. The email contained a link to a website with information on this particular trial. On this website, people could register for participation. We sent emails to the first 1500 people on this list as this was the maximum number of patients we could coach.

Inclusion and exclusion criteria

Inclusion criteria were: age $\geqslant$18 years and suffering from insomnia. Insomnia was defined according to DSM-IV criteria as difficulty initiating sleep or difficulty maintaining sleep and based on self-report. To be included people had to be awake for at least 30 min a night, for at least three nights a week, for at least 3 months (APA, 2000). Exclusion criteria were: severe symptoms of anxiety or depression. Anxiety was assessed with the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS; Spinhoven *et al*. 1997; Bjelland *et al*. 2002; Andersson *et al*. 2003), which contains seven items. Depression was assessed with the Center for Epidemiological Studies – Depression scale (CES-D; Beekman *et al*. 1997). People with a HADS score of $\geqslant$10 or a CES-D score of $\geqslant$30 were excluded. Use of sleep medication was allowed.

Procedure

A total of 275 people (18.3%) registered on the trial website (Fig. 1). They were sent an information folder, a consent form, a link to the baseline questionnaire and a 7-day sleep diary. Of these 275 who had registered, 137 (49.8%) returned the informed consent form, the sleep diary and the questionnaire. Of these 137 people, 19 (13.9%) exceeded the cut-off score for depression or anxiety and were excluded. The remaining 118

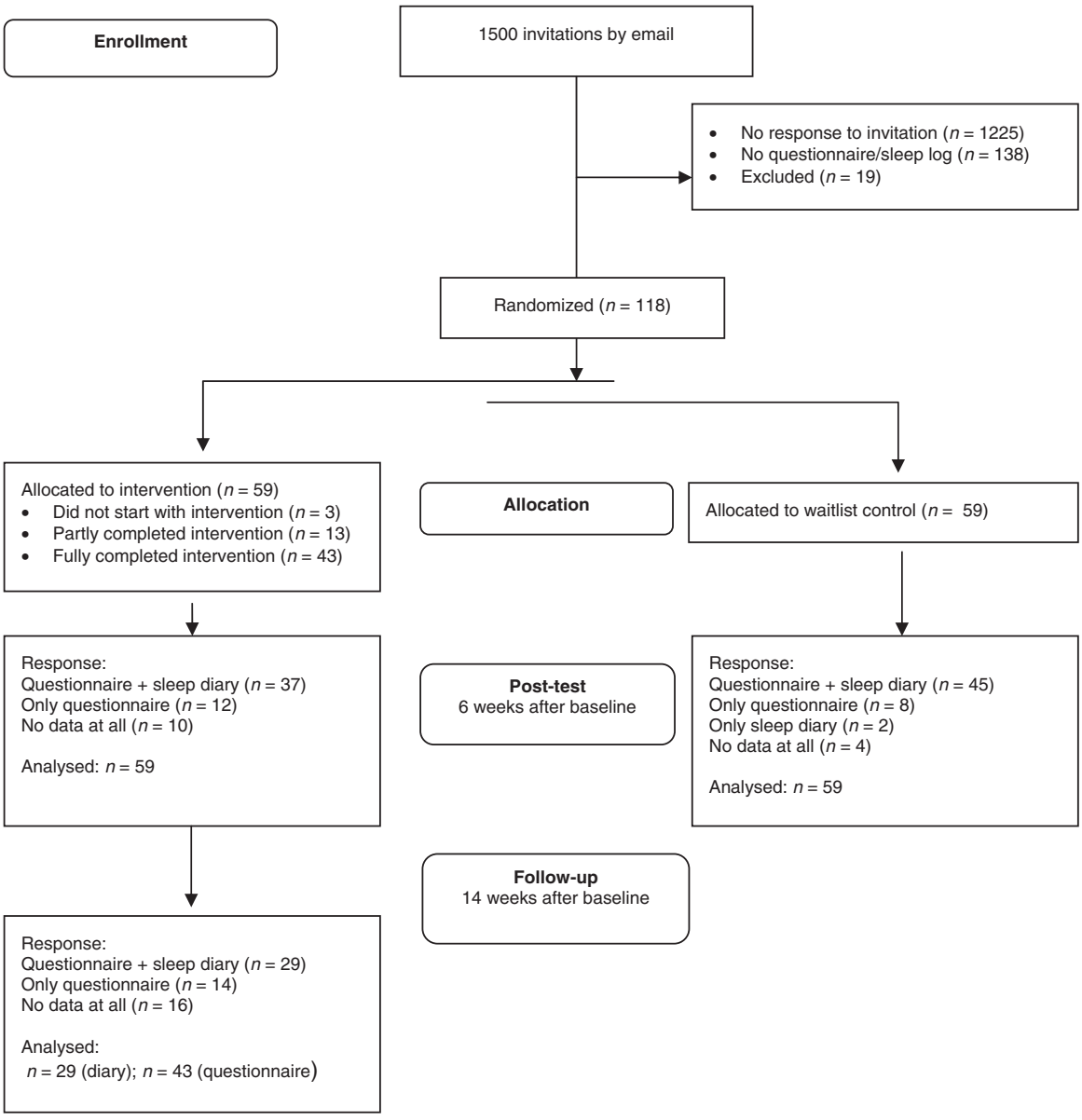

Fig. 1. Flow of participants through the study.

people (7.9% of the 1500 initially invited) were included in the trial. Half of them (n=59) were randomized to the guided Internet-based intervention and the other half (n=59) were randomized to the wait-list control group. Six weeks later they all received another email with a link to the post-test questionnaire and a 7-day sleep diary. Two weeks later the people in the wait-list control group could start the intervention. Eight weeks later we asked the intervention group to again complete a questionnaire and a sleep diary. At this time, the controls were only asked to complete a questionnaire about their experiences with the treatment.

Enrolment took place between May 2010 and September 2010. The study was approved by the Medical Ethical Committee of the Vrije Universiteit Medical Centre, Amsterdam, The Netherlands. The trial was registered on nederlandstrialregister.nl (number NTR2132).

Power and randomization

For pragmatic reasons we were not able to recruit for more than 5 months. Initially, we expected to be able to include only about 50 patients in this period. In other words, we expected to carry out a pilot study and hence no formal power analysis was performed. However, because recruitment was easier than expected, we continued inclusion until we met our full capacity to coach the patients in the intervention.

A randomization schedule was generated by the study coordinator (A.v.S.) by computer. We used blocks of 10 to enhance equal distribution between the groups. The actual randomization was performed by an independent researcher. All patients were informed by email about the randomization outcome.

Primary outcome measure

The patients were asked to complete a sleep diary for 7 days pre- and post-test, and at follow-up for the intervention group. From these diaries we calculated the sleep efficiency (SE), total sleep time (TST), sleep onset latency (SOL) and number of awakenings (NA). SE is calculated by dividing TST by the total time the person spent in bed (×100%). This SE might be considered as the true primary outcome because this measure can be used for patients presenting with different types of sleep problems (Morin, 2003). Patients were also asked to rate daily how sound their sleep had been the previous night and how refreshed they felt in the morning. Both questions could be answered on a 10-point scale ranging from 1 (not sound/refreshed at all) to 10 (very sound/refreshed).

Other outcome measures

All patients were asked to complete an online questionnaire pre- and post-test, and at follow-up for the intervention group. With this questionnaire we measured (along with demographics): the duration of sleep problems, overall sleep quality, use of sleep medication, anxiety, depression and quality of life. Overall sleep quality was measured with the Dutch version of the Pittsburgh Sleep Quality Index (PSQI). The questionnaire is well validated in different languages (Buysse *et al*. 1989; Backhaus *et al*. 2002) but Dutch validation studies are lacking. The PSQI is a self-rating questionnaire with 19 questions, and consists of seven subscales (sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medication and daytime dysfunction). Each subscale is scored on a scale of 0 to 3. The subscale scores can be summed to a total score ranging from 0 (good quality of sleep) to 21 (very poor quality of sleep). As mentioned earlier, the symptoms of anxiety were measured with the HADS and the symptoms of depression with the CES-D. The total score of the seven HADS items range from 0 (no symptoms of anxiety) to 21 (severe symptoms of anxiety). The total score of the 20 CES-D items range from 0 (no symptoms of depression) to 60 (severe symptoms of depression). Quality of life was assessed with one question (on a the visual analogue scale, VAS), which is part of the EuroQoL, in which the patients rate their quality of life on a scale from 0 (poor) to 100 (excellent) (Brooks, 1996). Online administration of questionnaires has been found to generate valid and reliable data with maintained psychometric properties.

After the treatment period all patients were asked to rate the intervention on several aspects. They could give an overall rating score for the treatment itself, and the feedback as provided by the coaches, each on a scale between 1 (very poor) and 10 (excellent). For each of the six lessons we asked whether the information in that particular lesson had been useful (yes/no). We also proposed two statements ('I gained new insights because of this treatment' and 'I'm better able to cope with my sleep problems because of the treatment') and asked if the patient agreed with those statements (answers on a five-point scale ranging from 'fully disagree' to 'fully agree'). These questions were developed by the research group.

The treatment

The Internet intervention was written (information, examples and assignments) by the first author (A.v.S.). It is based on a collection of other self-help materials for insomnia, textbooks and research literature. The first version of the intervention was discussed with the co-authors and several other sleep experts. The treatment consisted of six weekly lessons and included the different elements that are commonly incorporated in face-to-face CBT for insomnia (Edinger & Wolgemuth, 1999; Morin & Espie, 2003; Edinger & Means, 2005; Verbeek & Klip, 2005; Espie, 2006; Table 1). Every lesson contained information, examples of other people carrying out the treatment, and homework. After finishing the homework, the coach received a notification. Within 3 working days the coach provided online feedback on the homework. Patients could also send separate emails, for example when they had a question about the information provided. At the start of the study, feedback took about 20–30 min per person per lesson. During the study, as the coaches became more experienced, feedback took on average 15 min per person per lesson. The coaching was performed by A.v.S., four master's students in psychology, and one experienced CBT therapist (J.E.) who also trained and supervised the others. The aim of the feedback was to comment on the exercise, clarify information and motivate the patient to persist in carrying out the course and the requested behavioural changes.

Analysis

All post-test analyses were performed on the intention-to-treat (ITT) sample. Missing values were imputed using the multiple imputation procedure

Table 1. *Overview of the behavioural intervention for insomnia*

Lesson 1	Psycho-education about normal sleep and insomnia
Lesson 2	Sleep hygiene: information about behaviors that are known to promote or impede sleep (such as performing physical exercise or the use of caffeine)
Lesson 3	Sleep restriction and stimulus control: patients are taught to use the bedroom only to sleep and to restrict the time in bed to the average amount of night-time sleep
Lesson 4	Worrying and relaxation: audio files with progressive muscle relaxation exercises are offered and techniques to stop worrying
Lesson 5	Erroneous cognitions about sleep: the basics of cognitive therapy are explained and the most common erroneous ideas about insomnia are discussed
Lesson 6	Summary and plan for the future

implemented in SPSS version 20 (SPSS Inc., USA). We created 20 imputation sets. We then used statistical analyses to create pooled estimates of the 20 datasets. Standard deviations for the post-test mean scores were calculated separately because SPSS does not provide them. These were calculated by taking the natural logarithm of the standard deviation of each dataset, and taking the exponent of the summed result divided by the 20 datasets.

Comparisons between baseline values for the intervention and control groups were made with χ^2 tests (for dichotomous variables) or independent t tests (for continuous variables). To test the effectiveness of the intervention we first tested the differences in the post-test scores between the groups with linear regression while controlling for baseline scores and gender. The differences between the two groups were then expressed in effect sizes. We calculated Cohen's d by dividing the difference in post-test scores of the two groups by the pooled standard deviation. Cohen's d can thus be interpreted as the number of standard deviations the intervention group scores better than the control group (Cohen, 1988). A Cohen's d of 0.00–0.32 can be considered as small, 0.33–0.55 as medium, and>0.56 as large (Lipsey, 1990; Lipsey & Wilson, 1993).

Next, we wanted to test the clinical relevance of the intervention by comparing the intervention and control groups with regard to the percentage of patients who had (1) improved between baseline and post-test and (2) recovered post-test. However, no consensus consists on the definitions of 'improved' or 'recovered' for many of the variables studied. Instead of not studying clinical relevance at all, we arbitrarily defined 'improvement' and determined post-test thresholds as a proxy for recovery. For the PSQI we defined an improvement as a decrease in score of $\geqslant 3$ points. A score>5 is usually considered an indicator of relevant sleep disturbances (Buysse *et al*. 1989; Backhaus *et al*. 2002). However, only very few people scored below this cut-off. We therefore set the threshold at a score of 8. For SOL we defined improvement as a decrease of $\geqslant 30$ min. The post-test threshold for SOL was set at 30 min because there is some consensus that this can be considered 'normal' (Lichstein *et al.* 2003). Improvement for TST was defined as sleeping at least 1 h longer and the threshold was set at 6 h. For SE improvement was defined as at least a 10% increase and the threshold was set at 80%. For NA we defined improvement as waking up at least one time less and the threshold was defined as two awakenings. Feeling refreshed and soundness of sleep were both scored on a scale of 1 to 10. Improvement was defined as scoring at least 1 point higher and we set the threshold at 6. Improvement for anxiety was defined as $\geqslant 3$ points and for depression and quality of life as $\geqslant 5$ points. For the anxiety score on the HADS we used a threshold of $\leqslant 7$ (Olsson *et al.* 2005), for the depression score on the CES-D $\leqslant 16$ (Beekman *et al.* 1997) and for quality of life (EuroQoL) $\geqslant 60$.

Finally, we tested the robustness of the longer-term effects of the intervention. We did not impute the missing values of the follow-up scores but only used the data as provided by patients. We calculated the effects between post-test and follow-up within the intervention group with Cohen's d.

Results

Baseline characteristics

Most of the patients were female (70.3%), living with a partner (63.6%), born in The Netherlands (84.7%), had a high educational level (58.5%) and a paid job (70.3%; Table 2). There were significantly less females in the intervention group (59.3%) than in the wait-list control group (81.4%, $p<0.01$). There were also less people living with a partner in the intervention group (55.9%) than in the control group (71.2%), but this difference only reached borderline significance ($p=0.09$).

Table 2. *Baseline characteristics of the sample (n=118)*

	All (*n*=118)	Intervention (*n*=59)	Control (*n*=59)	*p* value
Demographics				
Female (%)	70.3	59.3	81.4	<0.01
Age (years), mean (S.D.)	49.4 (12.9)	48.7 (13.8)	50.1 (11.9)	0.54
Born in The Netherlands (%)	84.7	83.1	86.4	0.61
Living with partner (%)	63.6	55.9	71.2	0.09
High educational level (%)	58.5	62.7	54.2	0.35
With paid job (%)	70.3	69.5	71.2	0.84
Sleep characteristics				
Years with insomnia, mean (S.D.)	11.8 (10.2)	11.1 (9.6)	12.6 (10.7)	0.45
Overall sleep quality, mean (S.D.)	12.0 (2.2)	12.4 (2.1)	11.7 (2.2)	0.08
SOL (min), mean (S.D.)	57.1 (47.2)	68.7 (56.3)	45.4 (32.5)	<0.01
TST (h), mean (S.D.)	5.5 (1.0)	5.5 (1.0)	5.5 (1.0)	0.84
SE (%), mean (S.D.)	67.5 (11.7)	67.7 (11.7)	67.3 (11.7)	0.84
NA, mean (S.D.)	1.9 (1.1)	1.7 (0.8)	2.2 (1.2)	0.02
Refreshed, mean (S.D.)	5.7 (1.0)	5.6 (1.0)	5.8 (0.9)	0.25
Soundness of sleep, mean (S.D.)	5.5 (1.0)	5.5 (1.0)	5.4 (1.0)	0.52
Use of sleep medication (%)	30.5	28.8	32.2	0.69
Other health outcomes				
Anxiety, mean (S.D.)	4.6 (2.4)	4.4 (2.6)	4.8 (2.2)	0.41
Depression, mean (S.D.)	12.4 (6.8)	12.0 (6.6)	12.8 (7.0)	0.52
Quality of life, mean (S.D.)	68.6 (14.5)	70.8 (13.8)	66.5 (15.0)	0.11

SOL, Sleep onset latency; TST, total sleep time; SE, sleep efficiency; NA, number of awakenings; S.D., standard deviation.

On average, it took patients almost an hour to fall asleep (mean SOL=57.1 min), they slept for 5½ h (TST), woke almost twice during the night (NA=1.9) and slept 67.5% of the time that they were in bed (SE). They rated the soundness of sleep and the feeling of being refreshed as insufficient (5.7 and 5.5 respectively). On average, their sleep problems had existed for 11.8 years (S.D.=10.2).

In general, it took people in the intervention group longer to fall asleep (SOL 68.7 min) than those in the control group (45.4 min; $p<0.01$), mainly because the number of people lying awake for a very long time ($\geqslant$ 2 h) was higher in the intervention group ($n=10$) than in the control group ($n=2$). Furthermore, people in the intervention group woke less often during the night (NA=1.7) than people in the control group ($p=0.02$). There were no significant differences with respect to the use of sleep medication, depression, anxiety or quality of life.

Adherence and satisfaction

Three of the 59 patients (5.1%) in the intervention group did not start the treatment, six (10.2%) completed one or two lessons, seven (11.9%) completed between three and five lessons, and the majority (72.9%; $n=43$) completed all six lessons. Most of the patients that dropped out of treatment did not provide any reasons. Some indicated that they were too busy. The treatment was rated as a 7.3 (S.D.=1.2) on a scale from 1 to 10, and the feedback as a 7.6 (S.D.=1.2). The third lesson, which was about stimulus control and sleep restriction, was viewed as useful most often (by 79.6% of the patients). All the other lessons were viewed as useful by about 60% of the patients. About two-thirds (61.2%) of the patients agreed with the statement 'I gained new insights because of this treatment', and about two-thirds (65.3%) agreed with the statement 'I'm better able to cope with my sleep problems because of the treatment'.

Post-test effects of the intervention: continuous outcomes

The overall post-test response was 86.4% ($n=102$) for the questionnaire, and 71.2% ($n=84$) for the sleep diary. The non-response for the sleep diary was significantly higher in the intervention group ($n=22$; 37%) than in the control group ($n=12$; 20%; $p=0.04$). Furthermore, those who returned the sleep diary were more often born in The Netherlands (89% *v.* 74%, $p=0.03$) and they had a shorter SOL at baseline (48.9 min *v.* 78.0 min, $p<0.01$). There were no other significant differences between the responders and

Table 3. *Post-test effects on sleep and other health outcomes*

	Pre-test mean score (S.D.)		Post-test mean score (S.D.)[a]			Cohen's d[c]	
	Intervention (n=59)	Control (n=59)	Intervention (n=59)	Control (n=59)	p value[b]	Point estimate	95% CI
Sleep characteristics							
Overall sleep quality (PSQI)	12.4 (2.1)	11.7 (2.2)	8.9 (2.6)	11.6 (2.5)	<0.01	1.06	0.67 to 1.44
SOL	68.7 (56.3)	45.4 (32.5)	39.9 (40.0)	41.5 (38.3)	0.14	0.04	−0.32 to 0.40
TST	5.5 (1.0)	5.5 (1.0)	6.2 (1.0)	5.6 (1.1)	<0.01	0.57	0.20 to 0.94
SE	67.7 (11.7)	67.3 (11.7)	79.2 (10.8)	68.2 (12.3)	<0.01	0.95	0.57 to 1.33
NA	1.7 (0.8)	2.2 (1.2)	1.7 (1.0)	2.3 (1.2)	0.15	0.54	0.18 to 0.91
Refreshed	5.6 (1.0)	5.8 (0.9)	6.3 (1.1)	5.9 (0.9)	<0.01	0.40	0.03 to 0.76
Soundness of sleep	5.5 (1.0)	5.4 (1.0)	6.3 (1.0)	5.5 (0.8)	<0.01	0.88	0.51 to 1.26
Other health outcomes							
Anxiety	4.4 (2.6)	4.8 (2.2)	3.2 (2.8)	4.7 (2.9)	<0.01	0.53	0.16 to 0.89
Depression	12.0 (6.6)	12.8 (7.0)	8.8 (7.1)	11.8 (6.4)	0.04	0.44	0.08 to 0.81
Quality of life	70.8 (13.8)	66.5 (15.0)	74.0 (14.7)	65.1 (16.2)	0.04	0.58	0.21 to 0.94

PSQI, Pittsburgh Sleep Quality Index; SOL, sleep onset latency; TST, total sleep time; SE, sleep efficiency; NA, number of awakenings; S.D., standard deviation; CI, confidence interval.

[a] Based on imputed means.

[b] Based on linear regression with baseline values and gender as covariates.

[c] Post-test comparison of control and intervention groups based on imputed mean scores.

the non-responders for other baseline variables or demographics.

The post-test scores of the patients in the intervention group were significantly (p<0.05) better than those of the control group on all sleep estimates and other health outcomes, after correcting for baseline values and gender, with the exception of SOL (p=0.14) and NA (p=0.15; Table 3). The effect sizes for overall sleep quality (the PSQI score), TST, SE, soundness of sleep and quality of life were large (Cohen's d=1.06, 0.57, 0.95, 0.88 and 0.58 respectively). The effect sizes for NA, feeling refreshed, anxiety and depression were medium (Cohen's d between 0.40 and 0.54). The effect size for SOL was almost absent (d=0.04). The 95% confidence intervals around the effect sizes are all fairly wide.

Post-test data on the use of sleep medication were available for 102 (86.4%) of the 118 included patients. There was no statistically significant difference in response between those patients who used sleep medication at baseline (response rate 91.7%) and those that did not (response rate 84.1%; p=0.27). In the intervention group the use of sleep medication decreased from 28.8% at baseline to 22.4% at post-test (−6.4%). In the control group it increased from 32.2% at baseline to 34.0% at post-test (+1.8%). The post-test difference between the intervention and control group did not reach statistical significance (p=0.20).

Clinical relevant changes: percentage of patients who improved or scoring below a threshold

We arbitrarily defined improvement, and set thresholds for each of the outcome variables as proxy measurements for recovery. The effects were largest on overall sleep quality and SE: about 60% of the patients in the intervention group improved compared to around 15% in the control group (Table 4). Furthermore, about 50% of the patients in the intervention group scored below the post-test cut-off whereas this was the case for only 9.5% (sleep quality) and 18% (SE) of the control group. The percentage of patients scoring below the cut-off for TST, feeling refreshed and sleeping soundly were also significantly higher in the intervention than in the control group, and they also improved more often. For SOL, NA and anxiety, the differences between the groups were not statistically significant. Patients in the intervention group did improve more often on depression and quality of life than patients in the control group but there was no difference in the percentage of patients scoring below the threshold as this percentage was already high in the control group.

Effects at follow-up

The response at follow-up was 49% (n=29) for the sleep diary and 73% (n=43) for the questionnaire.

Table 4. *Clinically relevant changes: percentage of patients who improved and percentage of patients scoring below predefined thresholds at post-test*

		Percentage of patients[a]			
	Definition	Intervention	Control	OR[b]	95% CI
Sleep characteristics					
Overall sleep quality (PSQI)					
Improved	⩾3 difference	60.2	16.6	6.9	2.5–18.8
Scoring below threshold	⩽8 at post-test	49.1	9.5	16.5	4.6–58.7
SOL (min)					
Improved	⩾30 min difference	42.7	22.0	1.9	0.6–6.6
Scoring below threshold	⩽30 min at post-test	55.8	43.7	3.3	1.0–10.9
TST (h)					
Improved	⩾1 h difference	38.5	15.1	3.7	1.2–11.3
Scoring below threshold	⩾6 h at post-test	64.4	41.9	3.4	1.1–10.6
SE (%)					
Improved	⩾10% difference	61.9	14.6	14.9	3.5–63.6
Scoring below threshold	⩾80% at post-test	53.6	18.0	8.8	2.3–33.8
NA (*n*)					
Improved	⩾1 difference	21.0	12.9	2.9	0.7–12.1
Scoring below threshold	⩽2 at post-test	63.2	49.3	1.3	0.5–3.5
Refreshed (scale 1–10)					
Improved	⩾1 difference	41.9	13.1	4.8	1.5–15.7
Scoring below threshold	⩾6 at post-test	72.8	49.7	4.7	1.3–17.0
Soundness of sleep (scale 1–10)					
Improved	⩾1 difference	41.0	13.4	10.4	2.2–50.2
Scoring below threshold	⩾6 at post-test	68.1	26.2	7.6	2.2–25.6
Other health outcomes					
Anxiety (HADS)					
Improved	⩾3 difference	29.2	20.8	2.0	0.7–5.9
Scoring below threshold	⩽8 at post-test	95.7	89.9	2.3	0.4–12.1
Depression (CES-D)					
Improved	⩾5 difference	43.1	24.6	3.1	1.1–8,6
Scoring below threshold	⩽16 at post-test	89.8	79.9	1.8	0.5–6.3
Quality of life (Scale 1–10)					
Improved	⩾10 difference	47.6	25.1	5.1	1.7–15.3
Scoring below threshold	⩾60 at post-test	88.0	76.6	1.7	0.5–5.5

PSQI, Pittsburgh Sleep Quality Index; SOL, sleep onset latency; TST, total sleep time; SE, sleep efficiency; HADS, Hospital Anxiety and Depression Scale; CES-D, Center for Epidemiological Studies – Depression scale; NA, number of awakenings; S.D., standard deviation; OR, odds ratio; CI, confidence interval.

[a] Based on imputed values $n=59$.

[b] Based on logistic regression analyses with gender and baseline values as covariates.

There were no statistically significant baseline differences between the group who did complete a sleep diary at follow-up and those who did not, although people who did not return the diary had borderline significantly higher anxiety and depression scores ($p=0.09$ and $p=0.10$ respectively).

We compared the observed follow-up scores for patients in the intervention group with post-test scores to obtain some indication of the robustness of effects in the long term (Table 5). None of the improvements or deteriorations were statistically significant and all were very small. Most notable were the continued small improvements in overall sleep quality and quality of life (Cohen's $d=0.25$ and 0.21 respectively).

Discussion

In this RCT we studied the effectiveness of a guided Internet-based CBT for adults with insomnia. First, we showed that adherence was good (72.9% completed the intervention) and that the patients were satisfied with the information they received, the assignments,

Table 5. *Within-group comparison of post-test and follow-up for the intervention group*

	Post-test mean (S.D.)[a]	Follow-up mean (S.D.)[b]	Cohen's *d*[c]	
			Point estimate	95% CI
Sleep characteristics				
Overall sleep quality (PSQI)	8.9 (2.6)	8.3 (2.1)	0.25	−0.15 to 0.64
SOL	39.9 (40.0)	44.4 (38.9)	−0.11	−0.56 to 0.33
TST	6.2 (1.0)	6.1 (1.0)	−0.10	−0.55 to 0.35
SE	79.2 (10.8)	78.1 (12.4)	−0.10	−0.54 to 0.35
NA	1.7 (1.0)	1.8 (1.1)	−0.10	−0.54 to 0.35
Refreshed	6.3 (1.1)	6.4 (1.4)	0.08	−0.36 to 0.53
Soundness of sleep	6.3 (1.0)	6.4 (1.3)	0.09	−0.35 to 0.54
Other health outcomes				
Anxiety	3.2 (2.8)	3.0 (3.5)	0.06	−0.33 to 0.46
Depression	8.8 (7.1)	8.0 (7.0)	0.11	−0.28 to 0.51
Quality of life	74.0 (14.7)	77.1 (15.0)	0.21	−0.19 to 0.60

PSQI, Pittsburgh Sleep Quality Index; SOL, sleep onset latency; TST, total sleep time; SE, sleep efficiency; NA, number of awakenings; S.D., standard deviation; CI, confidence interval.

[a] Based on imputed means.

[b] Observed values only.

[c] Within intervention group comparison of reported post-test and follow-up means.

the feedback from the coaches and the effects of the intervention. Second, we did not find any effect of the intervention on SOL and NA, possibly because of baseline differences and because SOL had some outliers. Third, the treatment had significant effects ($p<0.05$) on all the remaining sleep estimates (sleep quality, TST, SE, sleeping soundly and feeling refreshed in the morning) and on the secondary outcomes (symptoms of anxiety and depression, quality of life). The effect sizes were medium to large (Cohen's *d* between 0.40 and 1.06). Patients in the intervention group more often improved and reached recovery than those in the control group. The use of medication decreased in the intervention group by 6.8% and increased in the control group by 1.8%. However, these analyses were performed on the sample of completers and were not statistically significant. Finally, the completers-only sample did not show any significant improvement or deterioration in the longer term (3 months).

There were some baseline differences between the intervention and baseline groups (gender, SOL, NA). We therefore used gender as a covariate in all the statistical tests on post-test differences, and we also included baseline values as covariates. The post-test response was high, with 88.1% of the patients providing some or all of the data. Although there were some baseline differences between post-test responders and non-responders, the risk of bias is probably low because the non-response percentage was small and these data were estimated using multiple imputation. However, the follow-up data should be interpreted with caution. As the non-response percentage for the sleep diary was 51%, we decided not to impute the data but to show the results for the responders only. Hence these data may be biased, and suggest that more research on the longer-term effects of Internet treatments for insomnia is necessary.

We recruited our patients through a waitlist, which comprised people who had indicated 1 year earlier that they were interested in participating in an insomnia study. Those people that responded to our invitation were still, or again, suffering from insomnia. Thus, it is thus likely that our sample was skewed towards higher insomnia severity. Baseline sleep estimates indeed indicate severe problems: SOL of almost 1 h, TST of 5.5 h and SE of 68%, which on average had lasted for 12 years. Even though this might indicate that our group is not representative for all insomnia patients, it might consist of the patients most in need for treatment.

The effects of our intervention are promising. Two previous meta-analyses on self-help for insomnia showed, for example, an effect size of 0.40 (Cheng & Dizon, 2012) and 0.42 (van Straten & Cuijpers, 2009) for SE whereas in the current study the SE effect size was much higher ($d=0.95$). One reason for our positive results might be that the patients in the intervention received regular weekly feedback from their personal coach. This might also have been responsible for our

high adherence rates and overall satisfaction with the intervention. In general, higher effects are demonstrated for guided web-based interventions than for unguided ones (Spek *et al.* 2007; Richards & Richardson, 2012). However, it has been argued that unguided interventions might in future become as beneficial as guided interventions once the websites are more interactive and technically better, for example including automated personalized feedback based on text or answers on quizzes and questionnaires. Some studies on unguided Internet-delivered insomnia treatments also show promising results (e.g. Ritterband *et al.* 2009; Espie *et al.* 2012) but, to date, only one study has compared guided with unguided self-help for insomnia (Jernelöv *et al.* 2012). That study supports the notion that guidance increase effectiveness. We recommend replication of that study using Internet-guided treatment and also examining the cost-effectiveness of the two approaches.

The effects of face-to-face treatments for insomnia are well studied and their results are summarized in reviews (e.g. Morin *et al.* 2006*a*). Although no formal meta-analysis has been performed and no overall estimate for face-to-face treatments is available, the effects seem to be of the same order of magnitude as those of our study. Unfortunately, there are very few studies that directly compare face-to-face treatments with self-help or Internet treatments. In our previous meta-analysis on self-help, we demonstrated that those few studies that exist do not demonstrate a clear difference in effect (van Straten & Cuijpers, 2009). The comparability of effects between face-to-face treatments and self-help (Internet) treatments has been demonstrated for anxiety and depression (Cuijpers *et al.* 2010). We need further studies examining accessibility, effects and costs, to demonstrate which intervention should be used when and for whom.

In our opinion people with co-morbidity should be included in insomnia treatment trials because co-morbidity tends to be the rule rather than the exception. In particular, co-morbidity with mental disorders is very common. People with insomnia are about 10 times more likely to have depression and 17 times more likely to have an anxiety disorder than people without insomnia (Taylor *et al.* 2005). In our study we excluded people with severe anxiety or depressive disorders because the most effective treatment strategy for people with co-morbid insomnia and more severe mental health problems is not known. This is an important topic that requires further investigation. We did include people who reported moderate symptoms of anxiety and depression. These symptoms improved during the intervention period with medium effect sizes (Cohen's d=0.53 and 0.44). This might indicate that insomnia is one of the causes of mental health problems or that there are other underlying mechanisms that lead to disruption of both mood and sleep (Turek, 2005; Fairholme *et al.* 2012). This significant finding stresses the importance of insomnia treatment, as it might be useful to reduce moderate symptoms of depression or anxiety.

There are several limitations to this study. First, the diagnosis of insomnia was based purely on self-report and was not confirmed by a clinician. This means that it is possible that some people in our sample did not suffer from full-blown insomnia or suffered other sleep disorders (e.g. sleep apnoea). In future we would prefer this intervention to be delivered through general practitioners (GPs). This means that the GPs might screen out mild cases and those with other serious sleep or medical disorders. However, we would like to stress that our method of recruitment did not result in a sample of only mild cases. The fact that 72.9% of the patients completed the intervention (and put in considerable effort in completing the exercises) seems to indicate that those people were indeed in need of help. A second limitation is that the sleep estimates were based on sleep diaries and not on more objective measures such as polysomnography or actigraphy. The use of both subjective and objective measures has been recommended because people with insomnia often over- or underestimate their actual sleep time (Buysse *et al.* 2006; Van den Berg *et al.* 2008). However, using polysomnography is costly and imposes a burden on the patients. Therefore, sleep diaries are currently the most widely used outcome measure in insomnia treatment studies (Morin, 2003). Sleep diaries are also generally well accepted because it is the subjective complaint that prompts patients to seek treatment. The third limitation is that we did not measure daytime consequences of insomnia. As it is already an effort for patients to keep a sleep diary, we wanted to keep the number of remaining questions as low as possible. However, now that this intervention has proved to be effective with regard to sleep estimates, a next step would be to investigate the consequences of these improvements for daytime functioning. This is ultimately the most important outcome for patients but is also essential in demonstrating possible cost-effectiveness. Almost two-thirds of our sample had a paid job, and loss of work productivity is one of the most common consequences of insomnia but also the most costly (Dailey *et al.* 2009*a*). The self-help study of Jernelöv *et al.* (2012) is one of the few to demonstrate positive effects on daytime functioning after self-help treatment.

In summary, this study adds to the growing body of literature that indicates that guided CBT for insomnia can be delivered through the Internet. We suggest that it is time for large-scale implementation projects.

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Declaration of interest

None.

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