

Effects of digital cognitive behavioural therapy for insomnia on insomnia severity: a large-scale randomised controlled trial



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Summary

Background Although several large-scale randomised controlled trials have shown the efficacy of digital cognitive behavioural therapy for insomnia (dCBT-I), there is a need to validate widespread dissemination of dCBT-I using recommended key outcomes for insomnia. We investigated the effect of a fully automated dCBT-I programme on insomnia severity, sleep-wake patterns, sleep medication use, and daytime impairment.

Methods We did a parallel-group superiority randomised controlled trial comparing dCBT-I with online patient education about sleep. The interventions were available through a free-to-access website, publicised throughout Norway, which incorporated automated screening, informed consent, and randomisation procedures, as well as outcome assessments. Adults (age ≥ 18 years) who had regular internet access and scored 12 or higher on the Insomnia Severity Index (ISI) were eligible for inclusion, and were allocated (1:1) to receive dCBT-I (consisting of six core interactive sessions to be completed over 9 weeks) or patient education (control group). Participants were masked to group assignment and had no contact with researchers during the intervention period. The primary outcome was the change in ISI score from baseline to 9-week follow-up, assessed in the intention-to-treat population. This trial is registered with ClinicalTrials.gov (NCT02558647) and is ongoing, with 2-year follow-up assessments planned.

Findings Between Feb 26, 2016, and July 1, 2018, 5349 individuals commenced the online screening process, of which 1497 were ineligible or declined to participate, 2131 discontinued the screening process, and 1721 were randomly allocated (868 to receive dCBT-I and 853 to receive patient education). At 9-week follow-up, 584 (67%) participants in the dCBT-I group and 534 (63%) in the patient education group completed the ISI assessment. The latent growth model showed that participants in the dCBT-I group had a significantly greater reduction in ISI scores from baseline (mean score 19.2 [SD 3.9]) to 9-week follow-up (10.4 [6.2]) than those in the patient education group (from 19.6 [4.0] to 15.2 [5.3]; estimated mean difference -4.7 (95% CI -5.4 to -4.1 ; Cohen's $d -1.21$; $p < 0.001$). Compared with patient education, the number needed to treat with dCBT-I was 2.7 (95% CI 2.4 to 3.2) for treatment response (ISI score reduction ≥ 8) and 3.2 (2.8 to 3.8) for insomnia remission (ISI score < 8). No adverse events were reported to the trial team.

Interpretation dCBT-I is effective in reducing the severity of symptoms associated with the insomnia disorder. These findings support the widespread dissemination of dCBT-I. Future research is needed to identify the moderators of response and to improve targeting.

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Introduction

Insomnia has an estimated prevalence of around 10–15% in adults.^{1,2} Internationally, most treatment guidelines advocate the use of psychological interventions such as cognitive behavioural therapy for insomnia (CBT-I), either as a primary intervention or as an adjunct to short-term courses of medications.^{3,4} In reality, demand for face-to-face CBT-I exceeds supply. Many general practitioners are unable to prescribe this option, or there is a long waiting time until a trained therapist is available. Difficulties in access to guideline-recommended therapy have encouraged the development of online interventions, and a number of automated and therapist-guided versions of digital CBT-I (dCBT-I) are now available.

Randomised controlled trials (RCTs) of various versions of dCBT-I have shown reductions in the symptoms of insomnia and improvements in sleep-wake patterns, both in the short term and at 1-year follow-up ($n > 300$ adults);⁵ reductions in depressive symptoms ($n > 1000$ adults with insomnia and symptoms of depression);⁶ and improved functional health, psychological wellbeing, and sleep-related quality of life ($n > 1700$ adults).⁷ Additionally, in a sample of more than 3000 students, Freeman and colleagues⁸ found that dCBT-I was associated with significantly greater reductions in insomnia severity, paranoia, and hallucinations when compared with treatment as usual. Of the three large ($n > 1000$) RCTs, only the trial by Freeman and colleagues⁸

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Research in context

Evidence before this study

Treatment guidelines for chronic insomnia advocate the use of cognitive behavioural therapy for insomnia (CBT-I), yet the use of CBT-I has been limited by the availability of therapists. Self-guided and fully automated digital versions of CBT-I (dCBT-I) have been created, in part, to address this limitation, and numerous systematic reviews and meta-analyses have highlighted their efficacy. Three previous randomised controlled trials have evaluated the effects of dCBT-I in more than 1000 participants, and have shown significant reductions in the severity and symptoms of insomnia, as well as in associated aspects of health and wellbeing, including depressive symptoms, functional health, psychological wellbeing, and sleep-related quality of life.

Added value of this study

This study is one of the largest randomised controlled trials to examine the efficacy of a fully automated version of dCBT-I in a community-based sample of adults with significant levels

of insomnia. We included outcomes based on the recommended standard measures of insomnia for adults, namely changes in Insomnia Severity Index score and sleep-wake patterns prospectively assessed with use of sleep diaries, as well as assessing use of sleep medication. The findings indicate that dCBT-I is effective in reducing both night-time and daytime impairment associated with insomnia disorder, while being associated with reduced use of sleep medication.

Implications of all the available evidence

Evidence supports the broad dissemination of dCBT-I in the general adult population, although it remains unclear how to optimally disseminate and target such interventions. Although a rapid implementation of new evidence-based innovations is important, it is also important to monitor the degree to which the efficacy shown in trials translates into clinical effectiveness, and to identify the optimal balance between therapist-delivered and self-guided interventions.

included the Insomnia Severity Index (ISI) in the assessments, and none included sleep diaries. The ISI and sleep diaries are recommended key outcome measures for studies and clinical trials of insomnia,⁹ and omitting these measures limits the comparability of the magnitude of benefits among different dCBT-I models, or comparisons with other insomnia interventions such as face-to-face interventions. Furthermore, Freeman and colleagues' study⁸ was done on a student sample (mean age 25 years), which also limits generalisability, and attrition in that study was high, with only 18% of participants completing the dCBT-I intervention. In addition, the use of a treatment-as-usual control group (as in Freeman and colleagues' trial) reduces comparability across trials and can lead to inflated effect estimates. Thus, there is a need to investigate the effect of dCBT-I in comparison with a more robust and controlled condition. To our knowledge, no previous large-scale trial has investigated how automated dCBT-I programmes affect participants' use of sleep medication. This factor is important because sleep medication is recommended as a short-term solution only, but often becomes a long-term treatment by default.

To date, most RCTs of dCBT-I have been done on subpopulations in English-speaking countries, such as the USA, the UK, or Australia. To validate broad dissemination of dCBT-I, investigation of the effect of the intervention in non-English speaking countries, as well as in the general adult population, and with use of a pragmatic approach with minimal exclusion criteria, is necessary.

To address crucial knowledge gaps regarding dCBT-I, we did an RCT using a fully automated screening and intervention programme among adults recruited from the general population in Norway. We examined the

effects of dCBT-I compared with an online patient sleep education programme on self-reported insomnia symptoms, sleep-wake patterns, use of sleep medication, and other key markers of health and wellbeing, such as daytime fatigue, psychological distress, and perceived physical and mental health.

Methods

Study design and participants

We followed the CONSORT guidelines for a parallel-group, superiority RCT, comparing fully automated dCBT-I (a Norwegian-language version of Sleep Healthy Using the Internet [SHUTi]) with online patient education about sleep.

For the purpose of recruitment, the RCT was publicised in several ways. Information about the trial and about its website was made available in waiting rooms at general practitioner or family doctor surgeries and at primary care and municipal health-care facilities throughout Norway (eg, prompt mental health-care clinics, which are similar to Improving Access to Psychological Therapies clinics in England, and Healthy Life Centres in Norway [Frisklivssentraler]). A link to the trial website was made available through the websites of other relevant institutions (eg, Healthy Life Centre websites and the website of the Norwegian Competence Centre for Sleep Disorders). During the recruitment period, the Norwegian University of Science and Technology, the Norwegian Institute of Public Health, and the Central Norway Regional Health Authority publicised the RCT (eg, through news about the trial on their websites and Facebook), and interviews with members of the research team were published in local and national newspapers.

A website was made publicly available during the recruitment period, and potential participants could register and complete an online screening test to assess their eligibility for inclusion. Individuals with regular internet access were eligible to participate if they were aged 18 years or older, and scored 12 or higher on the ISI¹⁰ (a score considered to have a high accuracy for diagnosing insomnia disorder [unpublished data]). Individuals were excluded if they met one or more of the following criteria: scored more than 10 on the Epworth Sleepiness Scale¹¹ (suggestive of sleep apnoea and hypersomnia); were at risk of sleep apnoea, based on pre-selected screening questions (self-reported regular snoring and breathing problems with difficulties staying awake during the day); had a self-reported medical condition for which an automated dCBT-I programme might be contraindicated (ie, epilepsy, bipolar disorder, schizophrenia or psychotic disorders, or recent cardiac surgery); or were currently engaged in night-time shift work.

Eligible individuals were subsequently shown two on-screen notifications. The first stated that the online intervention included some text-heavy elements, and that if they had reading difficulties or a reading disability (eg, dyslexia), they might find sections of the programme difficult to follow (individuals were offered an option to opt-out at this point). The second notification highlighted that the intervention required many individuals to actively change their patterns of behaviour, and again offered an opt-out or an option to delay entry to the trial if the individual was unsure about whether they could set aside sufficient time to participate in the full course of therapy (six sessions over 6–9 weeks). Following these notifications, potential participants were asked to indicate whether they wished to continue and be included in the randomisation process. A positive answer resulted in the individual being directed to the online consent form, which had to be signed electronically. After completion of the consent procedure, individuals were assigned personal login details to access the baseline assessment. All participants gave written informed consent. The trial protocol was prospectively approved by the Regional Committees for Medical and Health Research Ethics in South East Norway (2015/134). All personal data collected in this trial were anonymised. The trial protocol has been published elsewhere.¹² The patient user group for the Central Norway Health Trust (Regionalt brukertvalg, Helse Midt-Norge) was consulted about the trial design and the original protocol (as submitted for funding), and their feedback informed the aims of the trial and the study design (eg, the assessments included and online screening procedure). The group also endorsed and supported the final research protocol as submitted for ethical approval.¹²

Randomisation and masking

Individuals who met all eligibility criteria and provided online written informed consent were randomly allocated

	Description of session	Participants in dCBT-I group who completed session (n=868)
Core 1: overview	Reviews the nature of insomnia and how the programme works; the participants identify their sleep problems and set up personal treatment goals	748 (86%)
Core 2: behaviour and sleep 1	Focuses on how behavioural changes can improve sleep, with a special emphasis on sleep restriction	641 (74%)
Core 3: behaviour and sleep 2	Focuses on how behavioural changes can improve sleep, with a special emphasis on stimulus control	563 (65%)
Core 4: sleep and thoughts	Focuses on addressing and changing beliefs and thoughts that might impair sleep (eg, excessive worrying about the possible consequences of insomnia)	503 (58%)
Core 5: sleep hygiene	Teaches about lifestyle and environmental factors that might interfere with sleep (eg, caffeine and nicotine intake, and electronic media use in bed)	448 (52%)
Core 6: relapse prevention	Focuses on integrating the behavioural, educational, and cognitive components from the former cores to develop strategies to avoid future episodes of poor sleep from developing into full-blown chronic insomnia	402 (46%)
No data were available on the number of participants in the patient education control group who read the content in its entirety. dCBT-I=digital cognitive behavioural therapy for insomnia.		
Table 1: Description and completion rates of dCBT-I sessions during the intervention period		

(1:1) to receive either dCBT-I or patient sleep education, with no stratification. The randomisation procedure was integrated into the study platform and fully automated; the research team did not have access to the computerised process and could not influence randomisation in any way. All statistical analyses were done by a researcher (ORFS) who was masked to group allocation.

Participants were masked to their group assignment, although it is possible that many were able to deduce the condition to which they were allocated on the basis of programme content. As the interventions were fully automated and delivered online, there was no contact between researchers and participants during the intervention period. If technical problems arose with delivery of the online programme or completion of assessments (eg, forgetting the username or password), a technician could assist the participant via email or telephone.

Procedures

The content of the dCBT-I and patient education interventions were translated into Norwegian language by clinical sleep specialists in Norway and have been tested in a smaller-scale study by the investigators.¹³

The dCBT-I programme (SHUTi)¹⁴ consists of six fully automated and interactive online sessions designed to be completed within a 9-week intervention period (table 1). The sessions cover the primary topics addressed in face-to-face CBT-I,¹⁵ including sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention. By using information and feedback from the individual, elements of the SHUTi programme are tailored to the user (as described by Thorndike and colleagues).¹⁶

The patient education programme is similar to the control interventions used in other RCTs of dCBT-I,

For the study website see <https://sovmestring.no>

including previous trials of SHUTi.^{5,13} The patient education website provides fixed information about the prevalence, causes, and consequences of insomnia, the symptoms of insomnia, when to seek input from a health professional, as well as basic lifestyle, environmental, and behavioural recommendations that might help to improve sleep (ie, sleep hygiene education). The content included in the patient education programme was based on a review of established insomnia education websites.⁵ There are both similarities and important differences between the patient education programme and the SHUTi programme. Both provide the user with cognitive behavioural therapy principles and offer a method to keep ongoing sleep diaries, but the SHUTi programme does so through online tools and weekly interactive sessions, whereas the patient education programme does so through provision of printable documents.

At baseline and 9-week follow-up, all participants were asked to complete 10 days of sleep diaries within a 14-day period (including daily self-rating of sleep–wake patterns).¹⁷ From the sleep diary, we extracted information on sleep onset latency (min), wake time after sleep onset (min), early morning awakening (min; defined as the time between final awakening and getting out of bed), total sleep time (h), time in bed (h), and sleep efficiency (total sleep time as a percentage of time in bed). Participants also completed the ISI, a seven-item self-report instrument with good psychometric properties, which assesses core symptoms of insomnia (with a higher score indicative of greater severity) and is validated for online use. The ISI can continuously measure insomnia severity, and can also be used to assess remission (score <8) and response to interventions (reduction of ≥ 8 points from baseline).¹⁵

Because the ISI was used to assess eligibility for participation, we supplemented this insomnia measure with the Bergen Insomnia Scale (BIS),¹⁸ a six-item rating scale (with higher scores representing greater symptomatology) that assesses the severity of symptoms of insomnia that are listed in the diagnostic criteria of the Diagnostic and Statistical Manual of Mental Disorders (4th edition).¹⁹

Use of sleep medication was assessed at baseline and at 9-week follow-up by the sleep diary item “did you take any over-the-counter or prescription medication(s) to help you sleep?” (answered “yes” or “no”). Patients were coded as using sleep medication at either timepoint if they reported using sleeping medication for one or more days.

At baseline, participants self-reported demographic information and any ongoing medical or mental health condition (selecting items from a pre-specified list which included cardiac, endocrine, renal, respiratory, skin, joint, and other problems). The mental health conditions listed included anxiety, depression, post-traumatic stress disorder, alcohol or substance use disorders, eating disorder, attention-deficit hyperactivity disorder, psychosis, and personality disorders.

Participants were also asked to complete several other questionnaires at baseline at a 9-week follow-up: the 14-item Hospital Anxiety and Depression Scale (HADS), as a measure of general psychological distress (with higher scores indicative of greater psychological distress);²⁰ the 11-item Chalder Fatigue Questionnaire (CFQ),²¹ which measures physical and psychological fatigue (with higher scores indicating greater daytime functional impairment [ie, more fatigue]), with two additional items that address the duration and intensity of any complaints; and the 12-Item Short-Form Health Survey (SF-12),²² which assesses an individual’s perceived physical and mental health status, as a general measure of health-related quality of life (with lower scores indicative of worse physical or mental health).

From week 9 after randomisation, all participants received daily email reminders to complete the online follow-up questionnaire, including the ISI, BIS, HADS, CFQ, and SF-12, as well as 10 days of sleep diaries.

Adverse events were not assessed at week 9 post-randomisation. However, participants were generally encouraged to contact the trial team if they had questions or experienced any problems (related to their health or technical issues). CBT-I is generally regarded as an intervention with minimal adverse effects, and previous large-scale dCBT-I trials have reported no adverse events.^{7,8}

Outcomes

The primary outcome was change in ISI score from baseline to week 9 in the intention-to-treat population. The secondary outcome measures reported in this Article consisted of daily self-rating of sleep–wake patterns (reported using the consensus sleep diary), use of sleep medications, BIS score, HADS score, CFQ score, and SF-12 score. For all outcome variables, the observed scores at baseline and 9-week follow-up were modelled by a random intercept and a fixed slope, and the effect of the intervention was estimated by using the group variable (dCBT-I vs patient education) as a predictor of the slope. For CFQ, mean values were used, whereas for ISI, BIS, and HADS, a total score was calculated. For SF-12, we used the scoring procedure described by Ware and colleagues.²²

Future analyses, including of sick leave and health resource use, are also planned and will require 2-year post-randomisation follow-up, as described in the protocol.¹² These data will be available from the Norwegian national registers in the next few years.

Statistical analysis

Based on previously published RCTs of dCBT-I compared with patient education,^{5,6} a large effect size (Cohen’s $d > |0.8|$) was expected for the difference in the primary outcome measure (change in ISI score). With an anticipated attrition rate of 50% of the recruited sample,⁶ 486 participants (243 per group) would suffice to detect a moderate-to-large effect size at $p < 0.05$ and with 80% statistical power. However, to account for the

2-year follow-up analysis, we decided a priori to recruit a minimum sample size of 1500 to provide sufficient statistical power (80%) to detect significant differences ($p < 0.05$) in sick leave and health care use. As the recruitment process was automated and could not be viewed by investigators in real time (because of masking procedures), the researchers received updates on the recruited sample size every 2 months. Therefore, the final sample size exceeded the planned sample size.

All reported analyses were done on the intention-to-treat population, unless otherwise stated. Mplus version 8.2 was used to analyse the effect of the intervention, and SPSS version 25 for additional analyses (eg, analyses of baseline characteristics).

To examine the effects of dCBT-I on the primary and secondary outcomes, the observed scores were analysed by means of latent growth models in Mplus. The observed scores before and after the intervention were modelled by a random intercept and a fixed slope. The effect of the intervention was estimated by using the group variable (dCBT-I vs patient education) as a predictor of the slope. This procedure yields identical estimates for the intervention effect as a linear mixed model with random intercept. Between-group effect sizes (Cohen's d) were calculated by dividing the mean difference in estimated change in scores from baseline to 9-week follow-up assessment by the pooled SD at baseline. Robust maximum likelihood was used as the estimator, providing unbiased estimates under the assumption of data being missing at random,²³ which might be partly met through the inclusion of baseline scores to the model.

As some data for week 9 outcome ratings could have been missing not at random, the robustness of the results under the missing-at-random assumption were tested by sensitivity analyses in which the missing scores at follow-up were replaced by baseline values for that individual. We also conducted two additional, more rigorous, sensitivity analyses: one in which missing post-intervention scores were replaced by pre-intervention scores multiplied by 1.25 in the dCBT-I group and by 1.00 in the control group; and another in which missing post-intervention scores were replaced by pre-intervention scores multiplied by 1.25 in the dCBT-I group and by 0.75 in the control group. More extreme scenarios were considered to be very unrealistic.

The proportions of participants per group who met the ISI criteria for response and remission were compared using Pearson's χ^2 test and the Newcombe hybrid score CI.

Number-needed-to-treat (NNT) analyses (with 95% CIs) for dCBT-I compared with patient education were done for categorical outcomes (ie, the proportion of individuals per group who met ISI criteria for response and remission at follow-up).²⁴

When examining compliance, we did a complier-average causal effect (CACE) analysis, which is considered to be more rigorous than a per-protocol analysis. A mixture model was used in which the intervention effect was

allowed to vary across a non-complier class one and a complier class two. Individuals in the dCBT-I group were assigned values of 1 for class one and 0 for class two if they were non-compliers, and 0 for class one and 1 for class two if they were compliers. Individuals in the patient education group were assigned values of 1 for both class one and class two, to indicate that they were allowed to be a member of either class. As such, compliers and non-compliers with valid outcome data at week 9 were included in the CACE analysis ($n=1117$).

We also did exploratory subgroup analyses in which the multiple group feature in Mplus (type=mixture, knownclass) was used to examine treatment effect heterogeneity across subgroups defined by self-reported comorbidity rates or recruitment pathway (eg, via the media or a primary care facility). These subgroups were not pre-defined in the protocol. A Wald test was used to determine the joint significance of the treatment-by-subgroup interaction, and within-subgroup treatment effects are reported.

This trial is registered with ClinicalTrials.gov (NCT02558647) and is ongoing, with 2-year follow-up analyses planned.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Participants were recruited between Feb 26, 2016, and July 1, 2018. 5349 individuals started the online screening process, of which 1497 did not meet the eligibility criteria or declined to participate, and a further 2131 discontinued the automated screening process before randomisation (figure). Therefore, the trial sample included 1721 participants, with a mean age of 45 years (SD 14; range 18–90). 1167 (68%) participants were female and 1074 (62%) were married or cohabiting (with data missing for one participant). Of the 1701 participants with available data, 1123 (66%) self-reported sleep problems for 6 years or more. Baseline characteristics are shown in table 2.

584 (67%) of the 868 participants randomly allocated to the dCBT-I group and 534 (63%) of the 853 allocated to the patient education group completed the ISI (the primary outcome measure) at the 9-week follow-up. In the dCBT-I group, 748 (86%) participants completed the first core of the dCBT-I programme, and 402 (46%) completed all six during the intervention period (table 1). Attrition over time could not be measured in the patient education group because those individuals received access to all elements of the patient education intervention following randomisation. No adverse events were reported to the trial team.

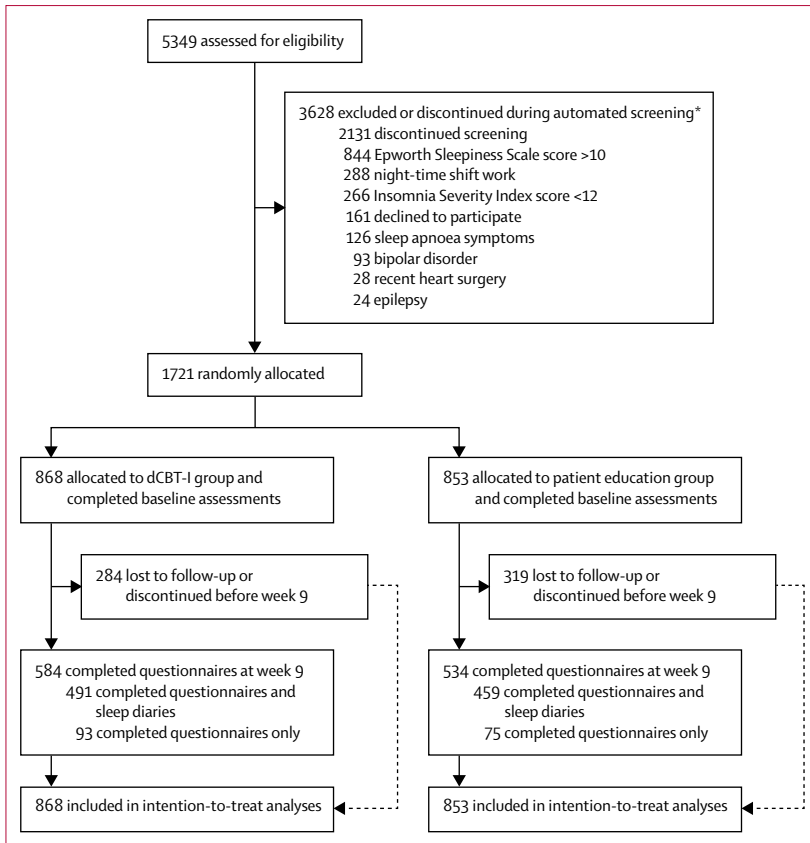


Figure: Trial profile
 *An individual could be deemed ineligible on the basis of more than one inclusion or exclusion criterion.
 dCBT-I=digital cognitive behavioural therapy for insomnia.

The latent growth model showed that participants in the dCBT-I group had a significantly greater reduction in ISI scores from baseline (mean score 19.2 [SD 3.9]) to 9-week follow-up (10.4 [6.2]) compared with those in the patient education group (from 19.6 [4.0] to 15.2 [5.3]; estimated mean difference -4.7 [95% CI -5.4 to -4.1]; Cohen's d -1.21; p<0.001; table 3).

At the 9-week follow-up, 337 (58%) of 584 participants in the dCBT-I group met the ISI criteria for response compared with 113 (21%) of 534 in the patient education group, representing a difference of 37 percentage points (95% CI 31-42; p<0.001) in proportion of responders. 219 (38%) participants in the dCBT-I group met the criteria for remission, compared with 41 (8%) in the patient education group (difference 30 percentage points [25-34]; p<0.001) in proportion of remitters. NNT analyses estimated that 2.7 (95% CI 2.4-3.2) individuals would need to receive dCBT-I for one additional individual to respond to the intervention compared with patient education, and that 3.2 (2.8-3.8) individuals would need to receive dCBT-I for one additional individual to achieve remission.

Significant group-by-time interaction effects indicated that participants in the dCBT-I group had larger

	dCBT-I (n=868)*	Patient education (n=853)
Age, years	44.2 (13.9)	44.8 (13.7)
Sex		
Female	596 (69%)	571 (67%)
Male	271 (31%)	282 (33%)
Missing data	1 (<1%)	0
Years in education	16.4 (3.0)	16.2 (2.9)
Employment status		
Full-time employment	427 (49%)	427 (50%)
Part-time employment	122 (14%)	120 (14%)
Unemployed	61 (7%)	46 (5%)
Retired	74 (9%)	74 (9%)
Student	69 (8%)	67 (8%)
Other	114 (13%)	119 (14%)
Missing data	1 (<1%)	0
Married or cohabiting with partner		
Yes	539 (62%)	535 (63%)
No	328 (38%)	318 (37%)
Missing data	1 (<1%)	0
Children living in household		
Yes	303 (35%)	317 (37%)
No	564 (65%)	535 (63%)
Missing data	1 (<1%)	1 (<1%)
Sleep problem duration		
<6 months	29 (3%)	19 (2%)
6-11 months	16 (2%)	17 (2%)
1-5 years	246 (28%)	251 (29%)
6-10 years	226 (26%)	216 (25%)
>10 years	343 (40%)	338 (40%)
Missing data	8 (1%)	12 (1%)
Checks email daily		
Yes	801 (92%)	781 (92%)
No	66 (8%)	72 (8%)
Missing data	1 (<1%)	0
Uses internet daily		
Yes	851 (98%)	837 (98%)
No	16 (2%)	15 (2%)
Missing data	1 (<1%)	1 (<1%)
Very comfortable with internet		
Yes	724 (83%)	708 (83%)
No	143 (16%)	145 (17%)
Missing data	1 (<1%)	0
Comorbidity		
Medical condition	102 (12%)	109 (13%)
Mental health condition	303 (35%)	286 (34%)
Medical and mental health condition	81 (9%)	118 (14%)
No comorbidity	380 (44%)	339 (40%)
Missing data	2 (<1%)	1 (<1%)

Data are mean (SD) or n (%). dCBT-I=digital cognitive behavioural therapy for insomnia. *One participant had missing data for all variables.

Table 2: Baseline characteristics

	dCBT-I		Patient education		Intervention effect		
	n	Value*	n	Value*	Estimate† (95% CI)	Cohen's d (95% CI)	p value
Insomnia measure							
Insomnia Severity Index score							
Baseline	867	19.2 (3.9)	853	19.6 (4.0)
Week 9	584	10.4 (6.2)	534	15.2 (5.3)	-4.7 (-5.4 to -4.1)	-1.21 (-1.38 to -1.05)	<0.001
Bergen Insomnia Scale score							
Baseline	867	27.9 (7.4)	853	28.0 (7.6)
Week 9	584	14.8 (9.8)	534	21.6 (9.4)	-7.1 (-8.1 to -6.0)	-0.94 (-1.08 to -0.80)	<0.001
Sleep diary measures							
Sleep onset latency (min)							
Baseline	868	55.0 (42.8)	853	55.7 (47.3)
Week 9	490	31.1 (34.5)	459	46.4 (42.0)	-15.6 (-20.0 to -11.1)	-0.35 (-0.45 to -0.24)	<0.001
Wake time after sleep onset (min)							
Baseline	868	45.5 (40.4)	853	44.6 (37.5)
Week 9	490	24.7 (27.1)	459	35.1 (34.6)	-12.3 (-16.2 to -8.4)	-0.32 (-0.42 to -0.22)	<0.001
Early morning awakening (min)							
Baseline	868	41.6 (34.0)	853	43.3 (39.2)
Week 9	490	18.9 (18.9)	459	33.0 (30.9)	-12.9 (-16.7 to -9.2)	-0.35 (-0.48 to -0.23)	<0.001
Time in bed (h)							
Baseline	868	8.3 (1.0)	853	8.2 (1.0)
Week 9	490	7.5 (1.1)	459	8.1 (1.0)	-0.6 (-0.7 to -0.5)	-0.60 (-0.72 to -0.47)	<0.001
Total sleep time (h)							
Baseline	868	5.9 (1.2)	853	5.9 (1.2)
Week 9	490	6.3 (1.1)	459	6.2 (1.2)	0.1 (0.0 to 0.2)	0.07 (-0.03 to 0.17)	0.154
Sleep efficiency (%)							
Baseline	868	71.9 (13.4)	853	71.5 (13.3)
Week 9	490	83.6 (10.5)	459	76.5 (13.2)	7.1 (5.7 to 8.5)	0.54 (0.43 to 0.64)	<0.001
Daytime function and mental health measures							
Psychological distress (HADS total score)							
Baseline	867	13.2 (6.9)	853	13.4 (7.2)
Week 9	584	10.2 (7.0)	534	11.5 (7.0)	-1.2 (-1.8 to -0.6)	-0.17 (-0.26 to -0.09)	<0.001
Chalder Fatigue Questionnaire score							
Baseline	867	20.8 (5.9)	853	20.9 (6.0)
Week 9	584	15.4 (7.2)	534	17.6 (6.4)	-2.4 (-3.1 to -1.6)	-0.40 (-0.53 to -0.27)	<0.001
SF-12 physical health score							
Baseline	867	41.7 (6.8)	853	41.8 (6.9)
Week 9	584	41.5 (6.6)	584	41.6 (6.6)	0.3 (-0.4 to 1.0)	0.05 (-0.06 to 0.15)	0.378
SF-12 mental health score							
Baseline	867	36.3 (11.4)	853	35.8 (11.3)
Week 9	584	42.9 (12.6)	584	39.2 (11.7)	3.2 (1.9 to 4.4)	0.28 (0.17 to 0.39)	<0.001
Use of over-the-counter or prescription medication(s) for sleep ("yes" or "no")							
Sleep medication use ("yes")							
Baseline	868	480 (55.3%)	853	514 (60.3%)
Week 9	490	191 (39.0%)	459	230 (50.1%)	0.49 (0.23 to 0.74)	..	0.007

dCBT-I=digital cognitive behavioural therapy for insomnia. HADS=Hospital Anxiety and Depression Scale. SF-12=12-Item Short-Form Health Survey. *Data are mean (SD) for continuous variables or n (%) for categorical variables. †For continuous variables, intervention effect is presented as the between-group difference in the mean change from baseline to week 9 (change in dCBT-I group minus change in patient education group); for categorical variables, intervention effect is presented as odds ratio in the dCBT-I group versus the patient education group.

Table 3: Results from intention-to-treat latent growth model for primary and secondary outcomes

improvements than those in the patient education group for most secondary measures (table 3). For example, participants in the dCBT-I group were significantly less

likely than those in the control group to be using sleep medications at follow-up, with the reduction in prevalence of sleep medication use from baseline to follow-up

estimated to be around 16 percentage points for dCBT-I and 10 percentage points for patient education (odds ratio 0.49 [95% CI 0.23 to 0.74]; $p < 0.001$). Compared with the participants in the patient education group, the dCBT-I group showed a significantly greater reduction in fatigue on the basis of CFQ scores (Cohen's $d = 0.40$ [95% CI -0.53 to -0.27]; $p < 0.001$). There were no differences between the groups in terms of total sleep time or perceived physical health (SF-12 physical health score).

The complier-average causal effect estimation for the ISI score resulted in a slightly larger effect size (Cohen's $d = 1.78$ [-1.97 to -1.59]; $p < 0.001$) than that found in the intention-to-treat analysis.

Sensitivity analyses of primary and secondary outcomes with last observation carried forward produced decreased between-group effect sizes, although the differences found to be significant in the main analyses remained so in the sensitivity analyses (appendix pp 3–5). When missing post-intervention scores on the ISI were replaced by pre-intervention scores multiplied by 1.25 in the dCBT-I group and by 1.0 or 0.75 in the patient education group, the analysis yielded effect sizes (Cohen's d) of -0.51 (-0.67 to -0.35 ; $p < 0.001$) and -0.03 (-0.18 to 0.13 ; $p = 0.73$), respectively.

The treatment-by-subgroup effect was not statistically significant for comorbidity ($p_{\text{interaction}} = 0.69$) or recruitment source ($p_{\text{interaction}} = 0.74$) suggesting that the intervention was equally effective across corresponding subgroups (appendix pp 7–8). Given the exploratory nature of these analyses, the results should be interpreted with caution.

Discussion

This study is one of the largest RCTs to date to examine the efficacy of fully automated dCBT-I in a community-based sample of adults with high levels of insomnia. It is also the largest RCT to evaluate efficacy with the recommended standard outcomes for insomnia (ie, changes in ISI ratings and sleep-wake patterns as assessed using sleep diaries).⁹ At the 9-week follow-up assessment, 38% of participants in the dCBT-I group met the ISI criteria for remission (< 8 points), compared with only 8% of those in the patient education group. A similar pattern was observed for the proportion of participants with a response on the ISI, which is especially noteworthy given that a greater reduction in the prevalence of sleep medication use was seen in the dCBT-I group than in the patient education group from baseline to week 9. Overall, the dCBT-I group achieved significantly better insomnia outcomes while reducing their reliance on sleep medication. Importantly, dCBT-I also reduced daytime fatigue and led to improvements in other key markers of health and wellbeing, including psychological distress and perceived mental health.

Overall, our findings support those obtained in previous high-quality trials on the effects of fully automated dCBT-I for individuals with insomnia.^{5–8} The between-group effect size on ISI score was -1.21 in favour of dCBT-I.

On this basis, dCBT-I compares favourably to standalone self-help interventions that have fewer interactive and tailored elements than SHUTi, and the effect size is well within the range of that typically found with face-to-face therapies and the most successful therapist-guided dCBT-I interventions.^{25,26} To date, as no robust RCTs comparing fully automated interventions with guided or face-to-face therapies have been published, it is not possible to draw firm conclusions about the superiority of one such intervention over the other. Our trial showed NNTs of around three for response or remission based on the ISI. This finding is consistent with findings from smaller-scale dCBT-I trials reported in a meta-analysis,²⁶ but is particularly important because the NNT with hypnotics can be more than ten²⁷ (and use of these medications is not recommended in the long term²).

This study is the first large-scale, fully automated dCBT-I trial to report significant changes in the use of sleep medication during the course of therapy. These findings contrast with those of another RCT ($n = 303$) of fully automated dCBT-I compared with patient education, which showed no group-by-time interaction effect on medication use.⁵ This difference might be due to the greater sample size and statistical power in our trial, as well as differences in the operationalisation of medication use. However, another RCT ($n = 148$) showed that therapist guided dCBT-I was associated with less use of sleep medication up to 3 years after the intervention, compared to an active control group.²⁸

More research is needed on the possible negative effects of dCBT, the key moderators and mediators of any therapeutic effects, and early dropout or disengagement. In addition, it will be useful to explore how dCBT-I can be integrated into stepped or accelerated care models, especially in the primary health system. Although rapid implementation of new evidence-based innovations is important, it is also important to monitor the degree to which their efficacy (as shown in RCTs) transfers to clinical contexts.

Several limitations of this trial should be noted. First, of the more than 5000 potential participants who initiated the online screening test, more than 2000 discontinued for unknown reasons before reaching the randomisation process. In addition, 65% of participants completed the questionnaires and 55% completed the sleep diaries at the post-intervention assessment, making the representativeness of the sample unclear. However, these completion rates are well within an acceptable range, although lower than that typically achieved in well conducted face-to-face trials of CBT for insomnia, such as Edinger and colleagues' study.²⁹

Participants were also self-identified, which might restrict the generalisability of the results. The female preponderance (68%) suggests a skewed distribution; however, a higher prevalence of insomnia is typically reported in women, and women tend to seek treatment for

See Online for appendix

insomnia more often than men. In addition, the average time in education was somewhat higher (equivalent to a completed Bachelor's degree) than that in the general Norwegian population (in which 34% have a higher education degree).

This report covers only the short-term effects of dCBT-I (according to the a priori analysis plan),¹² resulting in uncertainty regarding the durability of the effects.

Furthermore, in this trial, other sleep difficulties were not assessed (with the exception of symptoms of sleep apnoea, which was an exclusion criterion). Thus, there is a risk that some cases might have been misidentified as insomnia (eg, restless legs). We reported participants' medication use as measured with a single, non-specific question from the sleep diary, without distinguishing between medication type or dose. It is also unclear whether nights without sleep medication in the diary reflect a discontinuation of sleep medication.

Another limitation is that only self-report data were used in the current trial. However, all variables were based on standardised questionnaires, and many of the targeted outcomes (eg, insomnia and psychological distress) are subjective by their very nature. Nevertheless, future trials should include objective measures of the effects of dCBT-I, including the effects on sleep and medication use.

Regarding intervention use, slightly less than 50% of individuals allocated to dCBT-I completed all six core elements of the intervention, which compares favourably with rates of about 18–48% in other large-scale dCBT-I trials.^{7,8} A previous trial investigating use of the SHUTi programme in an adult sample found that 60% of participants completed all six cores of the programme.⁵ As a practical comparison, in the USA, about 40% of patients with chronic conditions collect their prescribed medication and take it correctly.³⁰

Our findings provide scientific support that a self-guided dCBT-I programme made widely accessible could be effective in reducing both night-time and daytime impairments associated with the insomnia disorder, while also reducing the likelihood of sleep medication use in adults with high levels of insomnia. Although the findings support a widespread dissemination of dCBT-I, it is still unclear how to optimally disseminate and target such interventions.

Contributors

ØV, HK, and BS conceived the study. All authors contributed to study design. ØV produced the first draft of the manuscript with specific input from HK, JS, and BS. ORFS did all analyses masked to group allocation. All authors assisted in drafting of the final, submitted version of manuscript and all authors have approved this version.

Declaration of interests

FPT and LMR report financial or business interests in BeHealth Solutions and Pear Therapeutics, two companies that develop and disseminate digital therapeutics (including by licensing the therapeutic developed) based in part on early versions of the software from the University of Virginia, which is used in the research reported in this Article. These companies had no role in preparing this manuscript. LMR is also a consultant to Mahana Therapeutics, a separate digital therapeutic

company not affiliated with this research. Some of the research in this Article was done while FPT was a faculty member at the University of Virginia. The terms of these arrangements have been reviewed and approved by the University of Virginia (for FPT and LMR) in accordance with its policies. All other authors declare no competing interests.

Data sharing

De-identified data that underlie the results reported in this Article will be available to researchers from accredited research institutions. Access to data will be limited to investigators who provide a methodologically sound proposal and will be limited to a specified time period (commencing about 3 months after publication of this Article and ending after 5 years). To ensure compliance with the General Data Protection Regulation, data processing must be covered by the European Commission's standard contractual clauses for the transfer of personal data, which must be signed by the data requesters. Proposals and requests for data access should be directed to the corresponding author. User-friendly output from the trial will be disseminated to patient advocacy and other relevant organisations.

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