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Digital cognitive–behavioural therapy for insomnia compared with digital patient education about insomnia in individuals referred to secondary mental health services in Norway: protocol for a multicentre randomised controlled trial

Håvard Kallestad ,[1,2] Simen Saksvik,[2] Øystein Vedaa,[2,3] Knut Langsrud,[1,2] Gunnar Morken ,[1,2] Stian Lydersen,[4] Melanie R Simpson,[5] Signe Karen Dørheim,[6] Bjørn Holmøy,[7] Sara G Selvik,[8] Kristen Hagen,[2,9] Tore Charles Stiles,[10] Allison Harvey,[11] Lee Ritterband,[12] Børge Sivertsen,[2,3] Jan Scott [2,13]

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For numbered affiliations see end of article.

Correspondence to
Dr Håvard Kallestad;
havard.kallestad@ntnu.no

ABSTRACT

Introduction Insomnia is highly prevalent in outpatients receiving treatment for mental disorders. Cognitive–behavioural therapy for insomnia (CBT-I) is a recommended first-line intervention. However, access is limited and most patients with insomnia who are receiving mental healthcare services are treated using medication. This multicentre randomised controlled trial (RCT) examines additional benefits of a digital adaptation of CBT-I (dCBT-I), compared with an online control intervention of patient education about insomnia (PE), in individuals referred to secondary mental health clinics.

Methods and analysis A parallel group, superiority RCT with a target sample of 800 participants recruited from treatment waiting lists at Norwegian psychiatric services. Individuals awaiting treatment will receive an invitation to the RCT, with potential participants undertaking online screening and consent procedures. Eligible outpatients will be randomised to dCBT-I or PE in a 1:1 ratio. Assessments will be performed at baseline, 9 weeks after completion of baseline assessments (post-intervention assessment), 33 weeks after baseline (6 months after the post-intervention assessment) and 61 weeks after baseline (12 months after the post-intervention assessment). The primary outcome is between-group difference in insomnia severity 9 weeks after baseline. Secondary outcomes include between-group differences in levels of psychopathology, and measures of health and functioning 9 weeks after baseline. Additionally, we will test between-group differences at 6-month and 12-month follow-up, and examine any negative effects of the intervention, any changes in mental health resource use, and/or in functioning and prescription of medications across the duration of the study. Other exploratory analyses are planned.

Ethics and dissemination The study protocol has been approved by the Regional Committee for Medical and Health Research Ethics in Norway (Ref: 125068). Findings from the RCT will be disseminated via peer-reviewed publications, conference presentations, and advocacy and stakeholder groups. Exploratory analyses, including potential mediators and moderators, will be reported separately from main outcomes.

Trial registration number ClinicalTrials.gov Registry (NCT04621643); Pre-results.

Strengths and limitations of this study

- Use of an automated intervention in individuals awaiting assessment for face-to-face treatment for mental disorders could yield important information about how to stratify treatment interventions and offer insights into the role of sleep patterns in mental disorders.
- A large-scale multicentre trial, with broad eligibility criteria, undertaken in a public sector service, increases the likelihood that findings are generalisable to other clinical settings.
- Sample size allows for detection of medium-small effect sizes on secondary outcomes.
- Limitations include potential sampling biases, for example, recruitment via self-ratings of insomnia rather than clinical evaluation.
- The sample comprises non-urgent referrals to mental health services, so translation of the findings to acutely ill psychiatric populations may be limited.

BACKGROUND

Insomnia is characterised by subjectively reduced sleep quality, in the form of delayed sleep onset or frequent or prolonged awakenings at night, and is associated with reduced daytime functioning.[1 2] It is highly prevalent in individuals with mental disorders.[3] In a study of more than 2000 secondary psychiatric outpatient clinic attendees in Norway, about 70% reported a concurrent sleep disturbance regardless of primary diagnosis; and 40% reported severe sleep difficulties.[4] Traditionally, insomnia has been regarded as a secondary problem that often arises among those experiencing a primary mental disorder. Recently, this view has been challenged, and the current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) now advises clinicians to record 'insomnia disorder' as an independent comorbidity (rather than a secondary diagnosis).[1] This change is important for clinical practice as it has increased the prominence of insomnia as a separate condition in psychiatric populations and draws attention to the suboptimal outcomes of standard psychiatric treatments in individuals with co-occurring insomnia.[5 6] Further, it is increasingly clear that even when insomnia symptoms are a core symptom of the presenting syndrome, they may be more treatment refractory than other phenomena with 40%–70% of individuals who show improvement with antidepressant treatments continuing to report ongoing sleep difficulties.[7–11] Overall, clinicians and researchers now acknowledge the reciprocal relationship between sleep and mental disorders, such that they often perpetuate and exacerbate each other. This has raised awareness of the need to target interventions for insomnia, rather than assuming that it will simply be resolved following general psychiatric treatment.

While medications are employed for insomnia, there is reluctance to co-prescribe these medications with the complex regimes that are routinely used to treat mental disorders. Concerns range from their addictive potential, the risk of drug interactions especially with polypharmacy and their low level of medium-to-long-term effectiveness.[12] As such, there is a growing interest in the application of psychological interventions for insomnia, such as cognitive–behavioural therapy for insomnia (CBT-I) which has a more favourable risk-to-benefit ratio and is a recommended first-line treatment for insomnia.[13 14] Further, several review articles and meta-analyses that synthesise data from randomised controlled trials (RCTs) demonstrate that this intervention may also be effective in reducing sleep problems in individuals with comorbid physical and/or mental disorders.[15–19]

Taken together, it is clear that trials of CBT-I would be a useful addition to the knowledge base regarding sleep and mental disorders. However, there is a paucity of trained CBT-I therapists and insufficient numbers of expert practitioners are available within specialist mental health services. This undermines the feasibility and utility of conducting large-scale RCTs relying on face-to-face therapy as it would be difficult to translate the findings to day-to-day practice. Self-guided, fully automated digital CBT-I (dCBT-I) has been developed, tested and employed as a means of increasing access to the intervention to large, geographically spread populations. Automated dCBT-I has previously been shown to reduce insomnia severity among individuals with comorbid mental disorders in non-clinical populations,[20] to reduce depressive symptoms in individuals with subclinical depressive presentations,[21] and across different sociodemographic groups.[22] Also, it appears to reduce psychotic symptoms in non-clinical samples.[23] These findings are encouraging and indicate that self-guided dCBT-I could be beneficial even in secondary care settings, such as mental healthcare outpatient clinics. One small trial in older men who were receiving psychiatric treatment for depression found that automated dCBT-I was effective in reducing insomnia severity 9 weeks after baseline assessment, and suggests a larger, longer term trial is warranted.[24] Importantly, automated dCBT-I could be initiated immediately after an intake assessment (even if the individual is awaiting other interventions) and this strategy could potentially reduce the overall duration or intensity of specialist care.

Aims

The protocol outlines a two-arm, parallel-group, superiority RCT that examines the additional benefits of dCBT-I compared with a control intervention of digital patient education about insomnia (PE) offered over 9 weeks. This multicentre RCT will recruit adults who have been referred to public sector secondary psychiatric outpatient clinics in Norway who are awaiting treatment of a mental disorder.

The overarching aim of the trial is to test the effectiveness of dCBT-I in a clinical, transdiagnostic population of non-urgent referrals to adult psychiatric outpatient services. The primary endpoint is outcome 9 weeks after the baseline assessment. This endpoint was selected because it allows sufficient time to complete the intervention, and the average wait-time before routine treatments commence is currently estimated at about 12 weeks, that is, few patients will have initiated regular treatment by 9 weeks, allowing sufficient time for most participants to complete the key phase of the RCT prior to exposure to any specific psychiatric interventions that are proposed for the presenting condition. We will also assess outcomes 33 and 61 weeks after baseline assessments to test if there are any long-term gains or adverse effects associated with the experimental intervention.

The trial is designed to address the following hypotheses: compared with PE, the dCBT-I intervention will, at each follow-up point (9, 33 and 61 weeks after baseline assessment), be associated with:

1. Lower severity of self-reported symptoms of insomnia (primary outcome).
2. Lower levels of self-reported psychopathology and somatic symptoms.
3. Improved health and cognitive function.

4. Less health resource utilisation (operationalised as the number of treatment sessions received during the 12-month trial).
5. Lower prescriptions rates for hypnotic, sedative/anxiolytic and antidepressant medications.

Secondary aims

These include analyses to test if there are specific subgroups that are more likely to benefit from dCBT-I; if exposure to dCBT-I or PE is associated with increased or reduced willingness to participate in face-to-face interventions for mental disorders in the future (eg, individual treatment delivered by a therapist at a clinic or via telemedicine (if offered during COVID-19, safety protocols remain in place)); whether dCBT-I is associated with any negative effects; and/or whether dCBT-I is associated with any additional reduction in sick leave, improved work productivity and daily activities outside of work.

Exploratory and additional analyses: we will perform mediation analyses and plan to undertake cost–benefit analysis; longer term health and social outcomes (>12 months) will be assessed from objective data available via national registries. Also, participants recruited at the lead centre (St Olavs Hospital, Trondheim) will be invited to participate in an actigraphy study examining objective recordings of sleep before, during and after the intervention (target sample ~40).

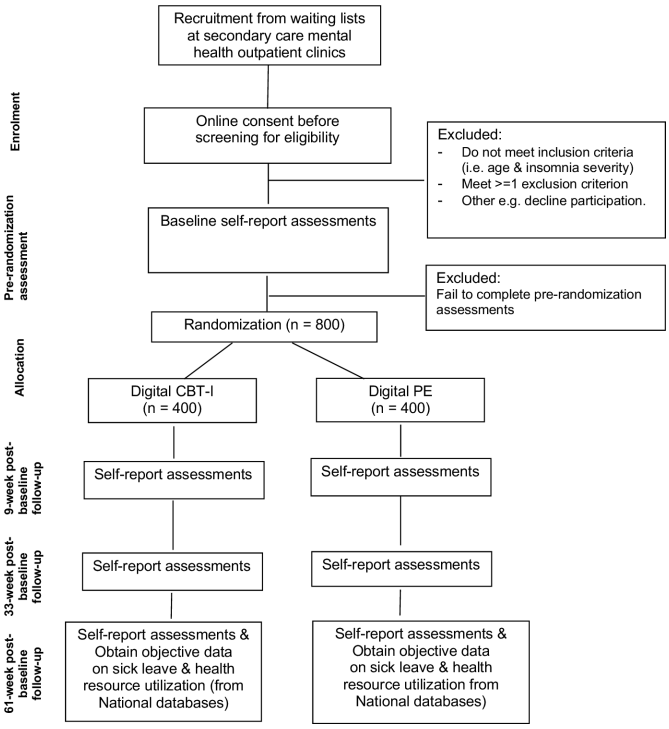

Figure 1 Flow chart of timeline for a randomised controlled trial of digital interventions for insomnia. CBT-I, cognitive–behavioural therapy for insomnia; PE, patient education about insomnia.

METHODS AND ANALYSIS

The protocol for the RCT follows the SPIRIT guidelines (Standard Protocol Items for Randomized Trials)[25] and figure 1 shows the flow chart for the recruitment and assessments. A completed SPIRIT checklist has been uploaded and a completed WHO Trial Registration Data Set can be found in online supplemental file 1.

Trial design

A multicentre, parallel-group, superiority RCT of individuals who meet established criteria for clinically significant insomnia according to self-report assessments undertaken with the internationally recognised standard rating. Trial participants will be randomised 1:1 to either dCBT-I or PE.

Recruitment

Recruitment will be undertaken at psychiatric outpatient clinics located in public healthcare organisations ('healthcare trusts') across rural and urban areas in Norway. Individuals referred for assessment for outpatient treatment of a mental disorder at the participating clinics will be sent an invitation to join the RCT. The invitation will be sent when the patient is registered on the waiting list for commencing mental health treatment (also see the online supplemental file 2 for additional details). This means that screening and randomisation can be completed, and digital interventions commenced before the individual attends their first scheduled treatment session.

Eligibility

Individuals with an interest in participating will be directed to a website that provides information about the RCT. They will then be offered the opportunity to participate in the consent procedure and complete an online screening assessment for eligibility. Individuals who give written informed consent and meet trial inclusion criteria will receive a telephone call from an investigator who will answer any questions, ensure that potential participants received all the relevant written documentation about the RCT and provide technical support regarding the digital intervention.

Inclusion criteria

1. Individuals aged ≥18 years.
2. Willing and able to provide written informed consent.
3. Insomnia Severity Index (ISI) >11 (this cut-off score is employed as we have previously used it to identify individuals experiencing clinically significant insomnia and/or those who may benefit from dCBT-I)[26]; also, it is the most sensitive to detect a diagnosis of insomnia disorder in a Norwegian sample.[27]

Exclusion criteria

1. Medical history contraindicating use of CBT-I, for example, (1) epilepsy plus self-report of ≥1 seizure within the preceding 12 months, or (2) recent cardiac surgery, or (3) currently in an attack phase of multiple sclerosis.
2. Individuals whose work schedule includes night shifts.

3. Pregnancy.
4. Inadequate opportunity to sleep or living circumstances that prevent modification of sleep pattern (eg, having an infant residing at home).
5. Currently receiving psychological treatment for insomnia.
6. Not registered at or under the care of any of the trial centres.

Interventions

Digital CBT-I

CBT-I[28] is a multicomponent intervention that includes the following: psychoeducation about sleep, sleep hygiene, sleep restriction therapy, stimulus control, and challenging dysfunctional beliefs and perceptions about sleep. This trial employs a dCBT-I programme named Sleep Healthy Using The internet (SHUTi),[20 29] which has been translated into Norwegian and employed in our previous RCTs.[30] SHUTi is fully automated and requires no contact with healthcare personnel and can be accessed on computers or handheld devices using a browser-based interface. The programme is interactive and comprises the same elements included in face-to-face CBT-I[28] (including tailoring of the programme to individual needs). The user is provided with access to new educational, behavioural or cognitive modules in the week after completing a previous module. Between modules, users enter self-monitoring information into a digital sleep diary.

Digital PE

The PE offers digital sleep hygiene information that can be accessed on computers or handheld devices and has been used in multiple RCTs of SHUTi for insomnia.[20 26 29 30] There is some content overlap with that included in the dCBT-I intervention, but it does not include any of the interactive features of the dCBT-I intervention and all the information is available to the user from the outset.

Randomisation

This RCT employs the same randomisation procedure as in a previous Norwegian trial of dCBT-I.[26] The automated procedure involves block randomisation with varying block sizes and cannot be influenced in any way by the researchers. Participants are blinded to their group allocation, but complete blinding is not possible as the participants may be able to discern whether they have received the active or control condition.

Withdrawal

Participants will be informed that they can withdraw from the trial at any time, without stating any reason and without any consequences whatsoever for their mental health treatment.

Crisis management procedure

All clinics have an emergency psychiatric service (24/7) for patients who require immediate assistance, experience crises, distressing increases in symptoms and/or marked deterioration in functioning. This service is responsible for all clinic attendees, including trial participants. If any trial participant uses the emergency service, the investigators will be informed and a decision made regarding continuation in the RCT and/or whether the crisis constitutes a trial-related adverse event.

Outcome assessments

The trial will adhere to the recommended standards for the research assessment of insomnia.[31] Self-report questionnaires will be completed online at baseline, post-assessment (9 weeks after baseline), 6 months after the post-assessment (33 weeks after baseline) and 12 months after the post-assessment (61 weeks after baseline). Table 1 summarises the type and timing of all assessments (also see the online supplemental file 3 for additional details). Individuals will receive an automated message prompting them to complete the relevant online assessments at each time point.

Demography and clinical characteristics

As shown in table 1, key demographic information will be recorded at baseline.

Self-reported clinical history will include information about sleep problems; medication use; previous medical, mental and physical disorders; treatments and admissions. Data will also be collected regarding type and number of physical disorders (from a list of 20 common medical conditions) and mental disorders (from a list of 9 common mental disorders).

Sleep measures

Primary outcome measure:

The ISI[32] is a 7-item questionnaire assessing the severity of insomnia symptoms the last 14 days.

Secondary outcome measures:

Other measures of sleep and chronotype

The Consensus Sleep Diary[33] assesses prospective daily sleep–wake patterns on at least 10 of 14 consecutive days.

The Reduced Morningness–Eveningness Questionnaire[34] measures chronotype, that is, time preference for daily activities, including bedtimes.

Bergen Insomnia Scale[35] assesses symptoms of insomnia based on the insomnia criteria in the DSM-IV.[36]

Level of psychopathology and functional impairment

The Outcome Questionnaire-45.2[37] assesses mental health status, including symptom distress, interpersonal relations and social role functioning.

The Hospital Anxiety and Depression Scale[38] assesses non-vegetative symptoms of anxiety and depression.

Nightmares and nocturnal mentation

Selected items from the Nightmare Frequency Questionnaire,[39] nightmare intensity[40] and nocturnal mentation[41] questionnaires will be used to assess frequency and intensity of nightmares and nocturnal mentation.

Table 1 Key measures and timing of assessment

	Screening and/or baseline	9-week follow-up	33-week follow-up	61-week follow-up
Demography and clinical characteristics				
Demographics (age, sex, ethnicity)	X			
Marital status	X		X	X
Number of children living at home	X		X	X
Years of education	X			
Employment status	X	X	X	X
Medication use	X	X	X	X
Duration of sleep problems	X			
Previous treatments for mental disorders	X			
Previous treatments for insomnia	X			
Previous psychiatric hospital admissions	X			
Physical health	X			
Mental health	X			
Sleep and circadian rhythms*				
Insomnia Severity Index	X	X	X	X
Brief Morningness–Eveningness Questionnaire	X		X	X
Consensus Sleep Diary	X	X	X	X
Bergen Insomnia Scale	X	X	X	X
Epworth Sleepiness Scale	X			
Level of psychopathology				
Outcome Questionnaire-45.2	X	X	X	X
Hospital Anxiety and Depression Scale	X	X	X	X
Nightmares and nocturnal mentation				
Nightmare Frequency Questionnaire	X	X	X	X
Nightmare intensity	X	X	X	X
Nocturnal mentation	X	X	X	X
Somatic symptoms and health				
Chalder Fatigue Questionnaire	X	X	X	X
EuroQol-5D	X	X	X	X
Body mass index	X	X	X	X
Alcohol Use Identification Test-Consumption	X	X	X	X
Headache Impact Test-6	X	X	X	X
Cognitive function				
Cognitive Complaints in Bipolar Disorder Rating Assessment	X	X	X	X
Intervention-related assessments				
Treatment expectations	X			
Self-efficacy for sleep-related behavioural change	X	X		
The Negative Effects Questionnaire		X		
Impact on future treatment		X		
Use of sleep strategies		X	X	X
Work capacity and resource use (registry data)				
Work Productivity and Impairment Scale	X	X	X	X
Health service utilisation and ICD-10 diagnoses	X			X
Prescribed medications	X			X

Continued

Table 1 Continued

	Screening and/or baseline	9-week follow-up	33-week follow-up	61-week follow-up
Number of hospital admissions (and reasons)				X
Resource use				X
Cause of death				X

*Actigraphy data will be collected at each time point for sample recruited via St Olavs University Hospital.
ICD-10, International Classification of Diseases, 10th Revision.

Measures of somatic symptoms and health

The Chalder Fatigue Scale[42] assesses levels of daytime physical and psychological fatigue.

EuroQol-5D[43] assesses general health state and allows measurement of quality-adjusted life years in individuals presenting with a range of physical and mental disorders.

Alcohol Use Disorders Identification Test-Consumption assesses the frequency and amount of alcohol use.

Headache Impact Test-6[44] assesses the intensity and consequences of headaches the last month.

Work performance

Work Productivity and Impairment Questionnaire General Health[45] assesses work performance and impairment in daily living.

Cognitive function

The Cognitive Complaints in Bipolar Disorder Rating Assessment assesses subjective cognitive function.

Intervention-related assessments

Expectations: one item assessing to what extent the patient thinks a digital sleep intervention can work for them (1=not at all, 9=perfectly).

Self-efficacy: at baseline, a questionnaire assessing self-efficacy related to making behavioural changes.

The Negative Effects Questionnaire[46] assesses negative effects of digital interventions.

Impact on future treatment: two items assess if exposure to digital interventions has impacted on willingness to participate in face-to-face therapy for mental disorders, and/or sleep problems.

The use of sleep strategies assesses how often individuals use different therapeutic techniques for sleep and their perception of its utility.

Resource use and national registries

Using objective data available from national registries, we will collate information on participants to allow to explore group differences before and/or after randomisation: (a) reasons for referral; (b) diagnoses; (c) substance use, person injury, incident leading to any hospital admission; (d) appointments, treatments and admissions at mental healthcare clinics; (e) dose, timing and type of prescribed medications and changes recorded during the RCT; (f) costs of treatment offered by the public services; (g) sick leave or in receipt of disability benefits; (h) if any deaths occur during the course of the study, we will record the cause (as recorded on the death certificate).

Subgroup data collection of objective sleep and circadian assessments

About 40 participants recruited at St Olavs Hospital will be invited to undertake concurrent actigraphy monitoring of sleep–wake patterns.[47]

Sample size

The primary outcome is difference in ISI scores at 9 weeks post-baseline. Published RCTs of CBT-I or dCBT-I report an effect size (ES) (Cohen's d) between 0.8 and 2.0 for these interventions compared with control conditions for community samples or clinical trials in populations with insomnia. However, we anticipate digital interventions may not have such a large effect in a transdiagnostic psychiatric outpatient population,[24] so we have estimated the RCT sample size based on a Cohen's d=0.5. Additionally, we wanted the sample size to provide adequate statistical power to detect small-to-moderate ES (Cohen's d=0.3–0.5) on the secondary outcomes (levels of psychopathology, etc). Lastly, other RCTs of CBT-I report sample attrition rates of between 12% and 50%.[20 21] As the planned RCT involves limited contact between investigators and participants and has a 12-month follow-up, we have assumed a study dropout rate of about 50%. Therefore, we aim to recruit 800 participants, to enable us to retain 400 patients (200 in each treatment arm) at the end of the RCT. For a two-sample t-test with alpha=0.05, this sample size gives a power of 99.9%, 93.7% and 84.9% of detecting a difference of Cohen's d=0.50, 0.40 and 0.30, respectively.

We did not undertake any statistical power calculations related to the analysis of service utilisation, medication use, etc, as assessed in the national registers, or cost–benefit analysis. Missing data are unlikely to be an issue when examining the national registers.

Statistical analytical plan

Descriptive statistics

Summary descriptions of demographic and clinical characteristics will be presented for each group. Categorical and binary variables will be presented as counts and percentages, continuous variables will be presented as means and SDs, or medians and IQRs, as appropriate.

Analysis of primary and secondary outcomes

The key outputs will be intention-to-treat analyses, that is, everyone who is randomised will be analysed. Per-protocol analyses will be reported for individuals who complete ≥4 dCBT-I modules. There will be no planned interim analyses during the inclusion period, though we will publish findings from self-reported data prior to the registry data.

We plan to use linear mixed model analysis to examine the difference between the two randomised groups on the primary and secondary outcomes with continuous variables. The model will include time, group, time–group interaction and baseline covariates. For binary secondary outcomes, logistic mixed model analysis will be used. Linear mixed models (logistic mixed models) provide unbiased (approximately unbiased) results when the data are missing at random (MAR). Model assumptions will be reviewed and if the assumptions are not met, this will be handled using bootstrapping, logarithmic transformations, or analysed using non-parametric testing as appropriate. We will assess the influences of deviations from MAR in sensitivity analyses as described below.

Mediation and moderator analysis

In order to identify if changes in insomnia symptoms, levels of psychopathology or cognitive function are important mediators of the effect of the digital treatment, we will perform mediation analyses assessing following the conceptual principles described by Kraemer *et al*.[48]

Sensitivity analysis

To investigate the influence of deviations from the MAR assumption, we will use a pattern-mixture models to simulate a range of situations where the data for both primary and selected secondary outcome variables are missing not at random.

Ethics and dissemination

The protocol has been approved by the Regional Committee for Medical and Health Research Ethics in Norway, REK Sør-Øst B (Ref: 125068). The RCT follows the guidance and principles outlined in the Revised Declaration of Geneva.[49] All eligible participants will be required to give online written informed consent before study entry (please see online supplemental file 4 for a copy). Participants will be provided with written and printable information regarding the RCT, which will also be repeated in a telephone call with an investigator. Both the written and oral pieces of information emphasise that participation is voluntary, that individuals will receive the same standard of care and treatment at the mental health clinic regardless of their participation, that they may withdraw from the trial at any time without any consequences for their clinical care and that they do not need to give a reason for withdrawal.

Self-report data will be de-identified and stored in encrypted and password-protected databases that are compliant with the General Data Protection Regulation. Data from national registries will be downloaded and incorporated into the files and anonymised.

The findings from the RCT will be disseminated via conference presentations and peer-reviewed scientific publications. The first academic publication will report any between-group differences on self-reported outcomes. Subsequent academic publications will report findings related to data extracted from the national registries, health economic analyses, and mediation and moderation analyses. The investigators will adhere to international guidelines regarding multi-authorship of manuscripts.

Patient and public involvement

The service user group for mental healthcare at the Central Norwegian Health Trust were consulted regarding the study outline and provided feedback on the aims of the trial and the assessments included in the protocol.

Study monitoring

A Data and Safety Monitoring Committee will meet weekly initially (during the start-up phase), and then monthly to oversee study progress, technical issues, status at the included sites and any reports of severe side effects. Other meetings can be convened if a specific problem or serious and untoward incident is reported. The committee comprises the project leader, project coordinator and the investigators involved in overseeing recruitment and eligibility. Clinical representatives from participating healthcare hospital trusts, statistical advisors, administrative leaders and other representatives will be co-opted as needed. The trial sponsor and the included healthcare trusts routinely and randomly audit one or more ongoing projects each year. The audit process ensures that trial protocols are followed, and ethical standards upheld. If any important protocol amendments are necessary, these will first be evaluated by the ethics committee and published on relevant study websites.

DISCUSSION

The utility of dCBT-I, and its impact on insomnia, psychopathology, cognitive functioning, and general health in routine clinical settings are not yet established. Given the bidirectional relationship between sleep and mental disorders, interventions that are effective in reducing insomnia severity may also have benefits for comorbid psychiatric conditions.[50–52] For instance, one meta-analysis of CBT-I for insomnia in individuals with physical and mental disorders reported small-to-moderate ES on comorbid symptoms with larger effects for psychiatric symptoms,[19] while another meta-analysis demonstrated small-to-medium ES for the effect of CBT-I on depressive symptoms.[53] It is possible that improvement in sleep early in the treatment process could lead to earlier response and/or improved outcomes of the presenting mental disorder. While findings of CBT-I research are encouraging, it

is noteworthy that many RCTs do not have adequate statistical power to enable detection of effects on a broader range of symptoms and phenomena (beyond sleep), while others have been conducted in convenience or non-clinical samples. This means the effects of CBT-I on sleep in many mental health treatment settings are unclear. The current RCT aims to address some of these knowledge gaps, the sample size is calculated to allow detection of small-medium ES on these secondary outcomes, and the trial is conducted in a transdiagnostic clinical sample.

There are scientific limitations associated with conducting an RCT in heterogeneous clinical samples attending different outpatient settings. First, diagnoses will be recorded by the clinicians at the clinics and not by the investigators, and there may be between-clinic differences in how some diagnoses are recorded. Also, there may be variability between clinics and between diagnostic subgroups regarding the waiting-time for a first treatment session. While most patients are likely to complete the course of dCBT-I before routine psychiatric outpatient treatment commences, others may experience an overlap between interventions. Thus, the trial may be a test of the effectiveness of dCBT-I when offered at an early stage of psychiatric treatment rather than prior to the introduction of routine care. Moreover, secondary psychiatric services and healthcare policies are continuously evolving, and it is conceivable that outpatient assessment and treatment protocols might change after the RCT has begun. Finally, there are 20 outpatient clinics that have agreed to recruit participants to the trial, but most have not been able to do any piloting of the protocol (partly due to COVID-19, etc). We do not know how much recruitment will differ between urban and rural areas in Norway, and/or if additional clinics will need to be added (eg, if recruitment is behind expected rates). This precludes using randomisation sequences that are stratified according to clinic. Despite these limitations, we believe the results of this trial will be important in moving the field forwards in its understanding of the feasibility and utility of fully automated dCBT-I in clinical samples of psychiatric outpatients with a wide range of mental disorders, and how treatment of insomnia can affect other important clinical and social outcomes.

Author affiliations
[1]Department of Mental Health Care, St Olavs Hospital University Hospital in Trondheim, Trondheim, Norway
[2]Department of Mental Health, Norwegian University of Science and Technology, Trondheim, Norway
[3]Department of Public Mental Health, Norwegian Institute of Public Health, Bergen, Norway
[4]Department of Mental Health Care, Norwegian University of Science and Technology, Trondheim, Norway
[5]Department of Public Health and Nursing, Norwegian University of Science and Technology, Trondheim, Norway
[6]Department of Mental Health Care, Stavanger University Hospital, Stavanger, Norway
[7]Department of Follo, Akershus University Hospital, Lorenskog, Norway
[8]Department of Mental Health Care, Namsos Hospital, Namsos, Norway
[9]Department of Mental Health, Molde Hospital, Molde, Norway
[10]Department of Psychology, Norwegian University of Science and Technology, Trondheim, Norway
[11]Department of Psychology, University of California Berkeley, Berkeley, California, USA
[12]Department of Psychiatry and Neurobehavioral Sciences, University of Virginia, Charlottesville, Virginia, USA
[13]Institute of Neuroscience, Newcastle University, Newcastle, UK

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Contributors Study design was undertaken by the research team: HK, SS, ØV, KL, GM, SL, MRS, SKD, BH, SGS, KH, TCS, AH, LR, BS and JS. HK conceived of the study and produced the first draft of the protocol paper with additional input from SS, ØV and JS. SL and MRS wrote the statistical analytical plan. All authors contributed to the drafting of the submitted version of the study protocol and all authors approved the final version of the manuscript.

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Competing interests LR reports financial or business interests in BeHealth Solutions and Pear Therapeutics, two companies that develop and disseminate digital therapeutics (including licensing the therapy 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. LR is also a consultant to Mahana Therapeutics, a separate digital therapeutic company not affiliated with this research. The terms of these arrangements have been reviewed and approved by the University of Virginia in accordance with its policies. All other authors declare no competing interests.

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ORCID iDs
Håvard Kallestad http://orcid.org/0000-0002-9173-942X
Gunnar Morken http://orcid.org/0000-0003-1972-5901
Jan Scott http://orcid.org/0000-0002-7203-8601

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