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Effects of a hybrid digital cognitive–behavioural therapy for insomnia and emotion regulation in the workplace (SLEEP): study protocol for a randomised waitlist control trial

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ABSTRACT

Introduction This trial tests the efficacy of implementing a hybrid digital cognitive–behavioural therapy for insomnia (dCBT-I) and emotion regulation (ER) in the workplace. The study protocol follows the SPIRIT (Standard Protocol Items: Recommendations for Intervention Trials) 2013 recommendations.

Methods and analysis This is a mixed methods evaluation with a two-arm randomised waitlist control design of a 6-week dCBT-I+ER intervention through self-guided online platform and four videoconferencing therapy sessions. A process evaluation will examine the fidelity of delivery and experiences of the intervention. The primary outcomes are the Insomnia Severity Index, the Patient Health Questionnaire-9 and the Generalised Anxiety Disorder-7. The secondary outcomes are job productivity, job satisfaction, well-being, quality of life, self-reported (sleep diary data) and objective (actigraphy) sleep parameters, and usage of online intervention platform. Assessments take place at baseline (T0), week 8 post-treatment (T1) and week 12 postrandomisation (T2). We will recruit 156 workers with sleep and ER problems ranging from subclinical to clinical levels not engaged in treatment at the time of the trial.

Ethics and dissemination Full approval was given by the University of Warwick Biomedical and Research Ethics Committee (BSREC 45/20-21). The current protocol version is 2.9_Dec21. Publication of results will inform the scientific, clinical and business communities through peer-reviewed articles, webinars, conferences and newsletters.

Trial registration number ISRCTN13596153.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study compares a novel hybrid digital cognitive–behavioural therapy for insomnia and emotion regulation intervention with waitlist control (ie, life as usual) in workers recruited from small, medium and large businesses in the Midlands region of the UK.

⇒ Evaluation of an early intervention of worker with mild to severe symptoms of insomnia and emotion regulation difficulties will contribute to the understanding of benefits of early interventions in the workplace and its impact on mental health and productivity.

⇒ Mixed methods evaluation of the intervention will provide insight into the application of the intervention and help us understand people's experiences of the intervention and what helped or hindered its use.

⇒ This pilot study will form the basis of what could become a larger nationwide service delivery programme of mental health interventions in the workplace.

BACKGROUND

Insomnia is a serious public health concern with substantial occupational health risks to the working population.[1] According to the Diagnostic Classification of Mental Disorders (DSM-5), insomnia is defined as dissatisfaction with sleep quantity or quality, which can be manifested as difficulty initiating sleep, maintaining asleep and/or waking up early in the morning with the inability to return to sleep, present for at least three nights per week over 3 months.[2 3] Insomnia causes stress in social, occupational and educational domains and other important areas of functioning for individuals and causes economic burden on healthcare systems.[4–6] Insomnia symptoms affect around 30%–48% of adults in the general population,[7 8] with chronic insomnia having a prevalence of 6% in primary care.[8]

Insomnia is linked to impaired work productivity.[1 9] Several studies show a link between poor sleep and various aspects of occupational functioning, such as absenteeism, reduced productivity and low work satisfaction.[4–6]

According to the RAND Europe report,[10] one in every three workers in the UK are affected by sleep problems to some level, and lack of sleep costs the UK economy around £36 billion every year due to loss of productivity in the workplace. This results in around 200 000 working days lost every year to insufficient or poor sleep, and it is estimated that the cost to industry will rise steadily to £44 billion by 2030 if nothing is done about it.

Cognitive–behavioural therapy for insomnia (CBT-I) is the first-line non-pharmacological treatment for insomnia, as evidenced by European and American clinical practice guidelines,[11 12] and comprised cognitive, behavioural and educational elements. Previous meta-analyses show a moderate to large effect of CBT-I on most sleep parameters (eg, sleep efficiency (SE), sleep onset latency (SOL), wake after sleep onset (WASO), sleep quality) in individuals with insomnia disorders with or without comorbid psychiatric conditions.[13] However, with the growing number of people with sleep problems, standard face-to-face CBT-I is no longer cost-effective and can often be inaccessible. To overcome these barriers, digital CBT-I (dCBT-I) was introduced which allows cost-effective and scalable access to psychological therapy compared with standard face-to-face therapy,[14] with moderate to large insomnia symptom improvements and effect sizes in the range of those found for face-to-face interventions.[14 15] A recent network meta-analysis shows that dCBT-I with therapist support improves sleep parameters with prolonged total sleep time (TST), shortened SOL, reduced WASO and enhanced SE compared with fully self-guided dCBT-I programmes.[16]

Indeed, recent cost–benefit analysis assumed that 64% of cognitive–behavioural therapy (CBT) provided using a computer is translated into significant cost savings of between £116 million and £136 million per annum in England compared with therapist face-to-face provision.[17] This may therefore suggest that dCBT-I could be equally cost-effective, enabling wider access to therapy for individuals with sleep problems.

Insomnia is one of the most prevalent occupational health risks impacting workers' mental and physical well-being, but a recent systematic review demonstrated that only a few studies so far have evaluated the effectiveness of CBT-I among employees in the workplace and have found improvements in severity of insomnia and quality of sleep.[18] Three of the studies also evaluated the impact of the intervention on work-related outcomes and found slight improvements in productivity and presenteeism, but not in absenteeism.[18] Further studies are needed to explore the impact of CBT-I on productivity, presenteeism and absenteeism.

Research shows that chronic insomnia is an independent risk factor for depression,[19] cardiovascular diseases[20] and diabetes.[21] Furthermore, according to a US national health survey consisting of 93 386 individuals, those with insomnia are five times more likely to present with anxiety and depression symptoms.[2 22]

The role of emotion regulation (ER) and its impact on sleep needs to be highlighted better. ER is conceptualised as the processes influencing which emotions we have, when we have them and how we express and experience them.[23] Dysfunctions to any of these domains cause emotional dysregulation, which is related to the majority of psychiatric disorders, notably depression and anxiety.[3] One study shows that self-reported rumination, worry and negative automatic thoughts maintained insomnia symptoms compared with a non-clinical control group.[24]

Further, a recent review indicates that insomnia may not just be a sleep disorder but identifies maladaptive ER as an important underlying mechanism for insomnia.[25] In fact, one longitudinal study shows that people with increasing ER difficulties had a higher risk of incidence or persistence of insomnia over an 18-month follow-up period.[26]

In summary, hybrid models addressing both insomnia and ER appear to be needed. In fact, hybrid treatment approaches in the management of mental health conditions such as chronic pain have been well received in the search for new treatment directions and have resulted in significantly better outcomes not only in sleep, but also mood, fatigue and pain-related outcomes.[27] In this study, we therefore adopt a hybrid transdiagnostic approach of dCBT-I targeting both ER and sleep problems with cognitive, behavioural and psychoeducation components, which is in line with the American Academy of Sleep Medicine clinical guidelines of treating insomnia with multicomponent CBT.[11]

Further, while most interventions for insomnia are focused on the treatment of those above clinical thresholds, there is a crucial need for early intervention and prevention of insomnia. This need has been further exacerbated during the COVID-19 pandemic due to social and physical isolation, financial insecurities and job loss, fatigue, loss of loved ones, and fear of infection, causing extensive sleep problems as well as stress, anxiety and depressive symptoms.[28 29]

The current study

This study will examine the efficacy of a new hybrid dCBT-I with therapist support for mild to severe insomnia and symptoms of depression and anxiety delivered to employees in the workplace. We refer to the intervention as dCBT-I+ER in the manuscript.

Study aims

- Aim 1: evaluate the effectiveness of the dCBT-I+ER intervention in the primary outcomes of insomnia severity and symptoms of depression and anxiety.
- Aim 2: evaluate the effectiveness of the dCBT-I+ER intervention in the secondary outcomes of self-reported and objective sleep parameters.
- Aim 3: explore the effectiveness of the dCBT-I+ER intervention in the secondary outcomes of mental well-being, quality of life, work productivity and job satisfaction.

- Aim 4: explore the long-term primary and secondary outcome measures in those who received the dCBT-I+ER intervention at 12 weeks.

Hypotheses

- Hypothesis 1: participants randomly allocated to receive dCBT-I+ER will demonstrate significantly greater improvements in the Insomnia Severity Index (ISI), the Patient Health Questionnaire-9 (PHQ-9) and the Generalised Anxiety Disorder-7 (GAD-7) compared with the waitlist control (WLC) participants at 8 weeks.
- Hypothesis 2: participants randomly allocated to receive dCBT-I+ER will demonstrate significantly greater improvements in objective and self-reported sleep parameters measured by actigraphy and self-reported sleep diary entries, respectively.

Aims 3 and 4 will be addressed as exploratory analyses looking at the impact of dCBT-I+ER on work productivity, job satisfaction, mental health well-being and quality of life, as well as the long-term impact on insomnia severity, depression and anxiety symptoms.

METHODS

Design

This study is a randomised waitlist control trial which will examine the efficacy of a hybrid dCBT-I compared with a WLC group. We will recruit participants who self-report mild symptoms of insomnia on the ISI (>7) and who also report subclinical to clinical depression or anxiety symptoms (see the Eligibility criteria section).

A randomised control trial of CBT-I versus WLC group will be conducted. dCBT-I will be delivered via a self-guided online platform accompanied by four videoconferencing therapy sessions with trained CBT-I therapists.

The study will be carried out entirely online. Participants will be administered screening, informed consent, assessments, and allocation to condition and intervention through web-based platforms. Online assessment of the primary and secondary dependent variables will take place at week 0 baseline (pre-intervention), at week 8 (post-intervention) and at week 12 (follow-up). At week 8, all participants initially allocated to WLC will be offered dCBT-I (see figure 1 for trial flow chart).

At the end of the intervention, we will randomly select 25 participants who complete the intervention and invite them to take part in qualitative process evaluation interviews.

Participants

Our objective is to recruit employees and self-employed workers from organisations across the Midlands Engine region. These are full-time or part-time paid workers working on-site or remotely, recruited either through our partner employers or directly from the community (via online advertising outlets). There are no eligibility constraints to industries or sectors. The Midlands Engine region is the central part of England covering 28 630 km^2, with a population of 10 135 000 million.

Sample size

Based on the feasibility findings of Tang and colleagues,[30] from which we model our current intervention, a very large effect size (hybrid CBT intervention vs self-help control) difference (Cohen's d=1.73; Hedges' g=1.73) in insomnia severity was observed, as measured with the ISI at 12 weeks post-treatment. These estimates, however, were based on a very small sample size of individuals with chronic pain and insomnia problems (n=25 at baseline, n=12 at post-treatment) with possible selective attrition bias, as well as individuals receiving the treatment programme as inperson intensive individual sessions. These findings therefore show that hybrid CBT does have a positive impact on sleep and other related outcomes in clinical populations.

The sample population in this study is likely to be a more heterogeneous group of employees with insomnia and mood symptoms. Further, we cannot directly translate the findings from the clinical population in Tang and colleagues' study[30] to a much diverse population in a different setting with symptoms ranging from subclinical to clinical levels. Therefore, we anticipate a smaller effect size and a larger sample variance. Based on the nature of this trial aiming to test the efficacy of a hybrid dCBT-I, we expect to find at least a moderate effect size (d=0.5) in insomnia severity measured by the ISI. Using standard significance level (significance level=0.05) with default statistical power (power=0.8) and a small interclass correlation coefficient (ICC=0.03) (to account for the multisite individual-level clustering at randomisation), we anticipated needing a total sample of 130 participants, with 65 in the WLC and 65 in the digital intervention, based on a 1:1 allocation ratio. In order to account for a 20% attrition rate after randomisation and until follow-up after 1 month, we inflated the sample size to 156 (76 in each arm) to ensure adequate power for calculations at every stage of data collection. The sample size calculations were conducted using R statistical software[31] through the 'clusterPower' package.[32] To model for site variation, we use the *crtpwr.2mean* function, where we model site variation through an intracluster correlation coefficient.

Eligibility criteria

Inclusion criteria

- Able to give informed consent.
- English-speaking.
- On employment (including being on furlough).
- ISI score>7.
- GAD-7 score ≥5 or PHQ-9 score ≥5.
- ≥18 years of age.

Exclusion criteria

- Currently receiving treatment (psychological or pharmacological) for mental health problems (eg, general

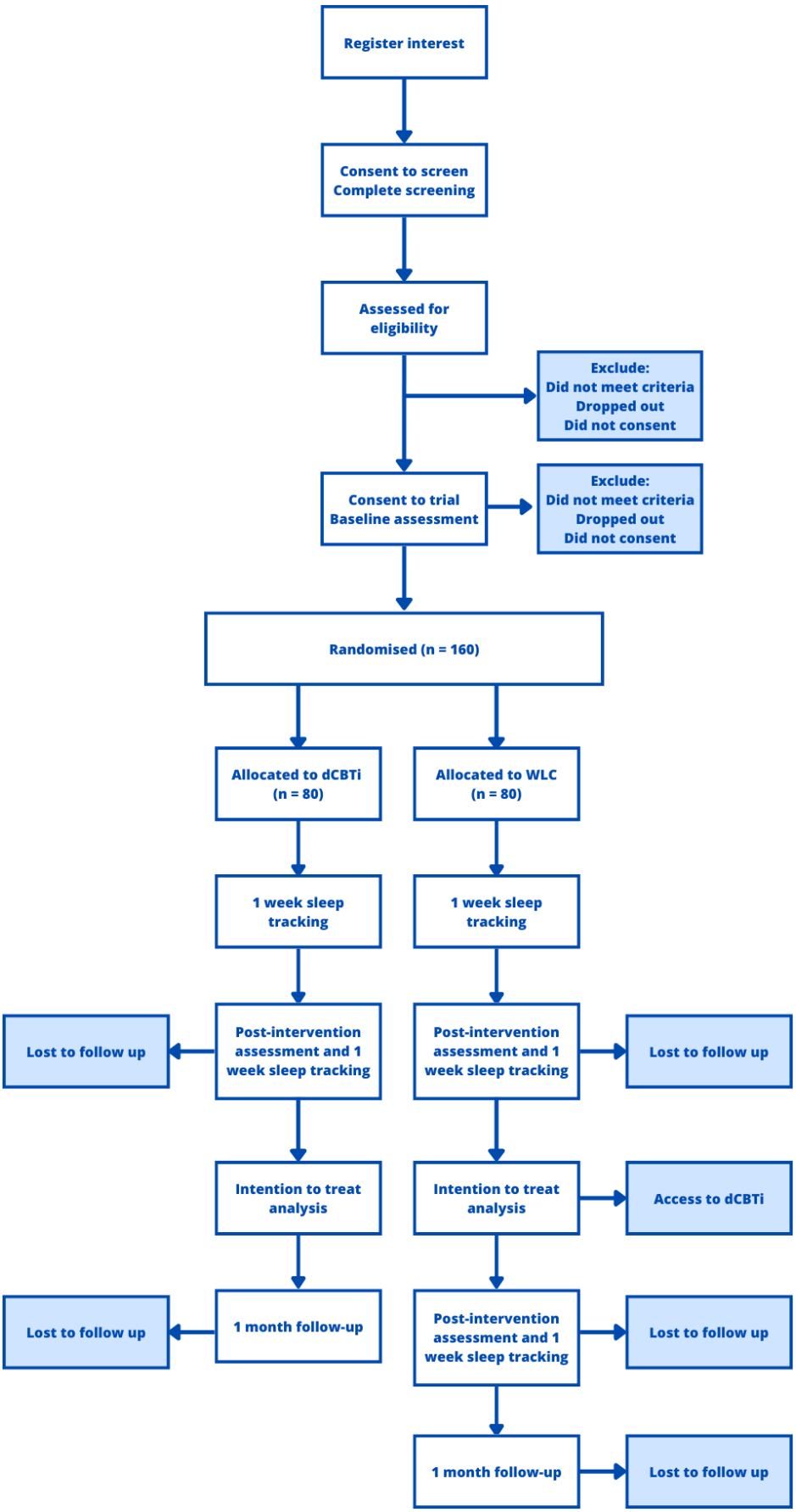

Figure 1 Flow chart diagram showing summary of the trial design of the study. dCBTI, digital cognitive–behavioural therapy for insomnia; WLC, waitlist control.

practitioner (GP), private clinic, Improving Access to Psychological Therapy (IAPT), specialist and community mental health services).
- Pregnant. Sleep undergoes considerable changes during pregnancy, and as the intervention uses sleep restriction this can be stressful for pregnant participants and their fetuses. Therefore, we are unable to include pregnant women in this study.
- Current substance abuse/misuse problems, epilepsy, neurological conditions (eg, Parkinson's or Alzheimer's), psychosis, bipolar disorder, or any other circadian rhythm and sleep disorders (eg, sleep apnoea, periodic limb movement syndrome/restless leg syndrome, circadian rhythm disorders). Sleep restriction components of this intervention may adversely affect participants with these conditions.
- Retiring in the next 10 months.
- Currently taking part in other psychological intervention trials.
- On shift work. Individuals on shift work will find that the sleep restriction in the intervention can become stressful and damaging, as the current intervention is not targeted to sleep disturbances caused by circadian misalignment due to shift work.

Recruitment procedures

This project, funded by the Midlands Engine, comprises the initial pilot study of three interventions (SLEEP: Supporting employees with insomnia and emotional regulation problems; REST: Reducing stress in the workplace; and MENTOR: Supporting employers and employees receiving treatment for mental health problems to remain engaged and productive work—known together as the INWORK study: INterventions to improve mental health in the WORKplace: a pilot study) to improve workforce mental health and productivity as part of the Mental Health and Productivity Pilot (MHPP) programme. Given the nature of the funding, we will recruit participants from across the Midlands through partnering with public and private sector organisations, as well as directly recruiting from across the Midlands region. The study will recruit through multiple channels. This will be via employers who have partnered up with the research team to act as gatekeepers for the study and advertise it in their organisations, as well as via direct recruitment by the research team through online (eg, Twitter, LinkedIn, Facebook, Instagram), print (eg, flyers in community and retail settings) and broadcast media (eg, local radio channel) advertisements. Individuals from the wider working community in the Midlands who are not employees of partners will be accessing the study of their own accord, without a gatekeeper.

Interested employees and self-employed workers will be able to sign up their voluntary interest in the study by completing a brief form on Qualtrics accessible through links on the advertising materials.

The research team will then contact interested employees by sending them the INWORK participant information leaflet (PIL), as the screening stage of all three trials is common. This trial uses a two-stage consent process, with an initial consent to the eligibility screening questionnaire, after which eligible prospective participants will be asked to consent to a trial. After reading through the INWORK PIL, interested participants are asked to complete the prescreen consent form and the eligibility screening questionnaire.

Employees and working individuals who score above the clinical threshold on any of the screening questionnaires (GAD-7, PHQ-9 and ISI) will be recommended to contact their GP and advised to contact IAPT services, while still being eligible for the study. This will be implemented as an automated page with advice and contact information and links displayed to qualifying participants. Participants will need to acknowledge reading the advice to continue.

Subsequently, those who are eligible will be invited to participate in either SLEEP, REST or MENTOR trial based on the matching eligibility criteria. They will be provided with a study-specific PIL (separate for each trial) and asked to complete a trial-specific consent form.

Randomisation and allocation concealment

Participants will be assigned to the dCBT-I or waitlist arm by simple randomisation with a 1:1 allocation ratio. Randomisation will be carried out and the allocation sequence generated automatically on completion of baseline measures. We will use random length block of between two and eight; blocking is conducted to minimise the risk of uneven groups. The randomisation will be conducted using 'blockrand' package on R.[33] For individuals recruited through the partnered employer pathway, we will stratify the randomisation process across sites based on employee size. Due to unknown size considerations, individuals through direct recruitment will not be stratified over sites. Randomisation will be conducted by a researcher independent of allocating participants and will be blinded to the subsequent allocations. Members of the research team will be unable to influence randomisation and will be concealed from future assignments.

Blinding

Self-reported questionnaire assessments will be completed entirely online by participants on the Qualtrics survey platform. Participants will be informed of their randomisation outcome (dCBT-I or WLC) via email by the trial management team (CB, CK), and so they will not be blind to treatment allocation (ie, single-blinded trial). The trial management team will not be blind since they will inform participants of group allocation and will have access to personal identifiable data, but not to the research data (ie, all non-identifiable data). Statistical analyses will be conducted by members of the research team (TRM, KP), who will be blind to allocation and only have access to all non-identifiable research data.

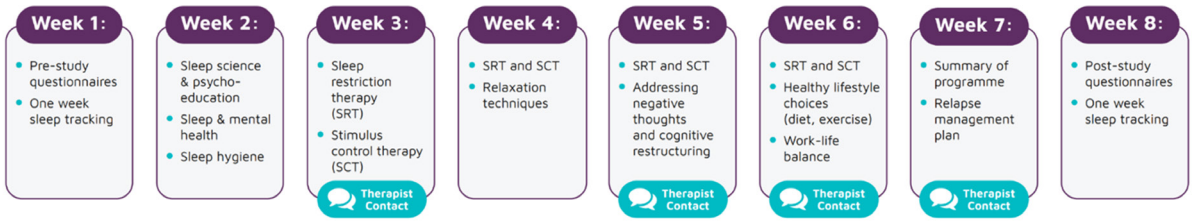

Figure 2 Sleep intervention trajectory and summary of weekly topics.

Study procedure

Digital hybrid CBT intervention

The digital hybrid intervention will be delivered online on a computer-based learning management system platform. The self-guided online program is structured into 6 weekly sessions (see figure 2) with varying number of topics each week, lasting approximately 60 min each. In addition, all participants will receive four videoconferencing therapy sessions by trained CBT-I therapists held over Microsoft Teams. The treatment content is based on the intervention protocol from a recently published intervention of CBT-I[30 34] and the Integrative Training of Emotional Competencies designed to target cognitive–behavioural processes maintaining anxiety and depression.[35] The core components are behavioural (eg, sleep restriction therapy (SRT), stimulus control therapy), cognitive (eg, unhelpful thinking styles and cognitive distortions, cognitive reframing), educational (eg, sleep science, sleep hygiene) and ER (eg, relaxation, non-judgemental awareness, acceptance and commitment) skills in the form of interactive psychoeducation, skills training, exercises and homework.

Participants will complete a daily sleep diary throughout the intervention, which is used during therapy sessions to provide tailored support in the sleep restriction element of the programme.

To promote adherence to intervention protocols, participants will be sent a weekly reminder email to log in on the platform and complete the topics. In addition, treatment adherence will be monitored by therapists documenting session attendance.

Participants can access the online program as well as attend the therapy appointments on their computer, tablets or phones.

Therapy sessions

The therapist sessions are delivered by five trained therapists under the direct supervision of an experienced clinical psychologist with expertise in insomnia and CBT-I (NKYT). Therapists are psychologists with at least either a Master's of Science or PhD degree in a relevant field with clinical experience. Therapy sessions are meant to be light-touch with greater similarity to coaching than actual therapy sessions. The idea of these therapist contacts is to provide human contact and prevent confusion, demoralisation and unnecessary dropouts. Therapists received formal training by attending a European Accreditation Council for Continuing Medical Education accredited course for CBT-I. In addition, they were trained in-house by NKYT (six sessions of 60 min each), with further guidance on the application of a patient-centred approach, and were provided with opportunities to role-play. To ensure treatment integrity, each therapist is provided with a session template detailing the checklist of topics to cover in each 45 min session (see table 1). This template ensures consistency across the therapists, as well as provides a space for the therapists to make any relevant notes, allowing continuity across sessions. Therapists also

Table 1 Online therapy session content

Session 1	Session 2	Session 3	Session 4
Overview of the programme.	Review of sleep diary.	Review of sleep diary.	Review of sleep diary.
Psychoeducation (eg, sleep and mental health, sleep hygiene).	Sleep efficiency calculation and troubleshooting sleep schedule.	Sleep efficiency calculation and troubleshooting sleep schedule.	Sleep efficiency calculation and troubleshooting sleep schedule.
Sleep restriction and stimulus control ground rules.	Psychoeducation and emotion regulation (eg, stimulus control, relaxation).	Psychoeducation and emotion regulation (eg, worrying an rumination, cognitive restructuring).	Progress review and maintenance plan.
Importance of keeping a sleep diary; review of sleep diary; sleep efficiency calculation and setting up new sleep schedule.	Q/A and troubleshooting.	Work–life balance and lifestyle changes with problem solving.	Relapse management.
Safety concerns and expectation management.		Q/A and troubleshooting.	Q/A and troubleshooting.
Lifestyle changes.			
Q/A and troubleshooting.			

Q/A, Question and answer.

attend weekly group supervision sessions of 60–90 min with NKYT to discuss any issues they may be encountering with cases and receive feedback from NKYT and the other therapists.

Measures

Participants will be prompted by email to complete all outcome measures on a secure online survey platform (Qualtrics). The order of the assessments will be consistent across all participants and all timepoints. If participants do not complete measures within 5 days, they will receive three further email reminders every 5 days of non-response. Every effort will be made to obtain outcome data from participants, even those who discontinue the intervention.

Primary outcomes

The trial has three coprimary outcomes. These are insomnia severity assessed by the ISI,[36] anxiety symptoms assessed by the GAD-7[37] and depression symptoms assessed by the PHQ-9.[38] These will be measured at baseline, 8 weeks and 12 weeks postrandomisation, but used as primary outcomes at 8 weeks postrandomisation only.

The ISI is a seven-item scale validated with reference to the diagnostic criteria for primary insomnia in the DSM-4, with items evaluated on a 5-point Likert scale (0=not at all, 4=extremely) and total score ranging from 0 to 28. A score of ≥15 identifies cases of clinical insomnia with 94% sensitivity and specificity. A change score of −8.4 is associated with moderate improvement in a clinical sample.[39] The ISI has shown to have good psychometric properties[36] and to be valid even with non-clinical groups, with a Cronbach α of 0.81–0.91.[39 40] In non-clinical samples, the ISI shows high internal consistency (α=0.89), with a single latent factor consistent with clinical populations (factor loadings 0.76–0.90).

The GAD-7 is commonly used in primary care and mental health settings as a screening tool and symptom severity measure for anxiety and consists of seven items ranging from 'not at all' (0) to 'nearly every day' (3). A score of 10 identifies cases of generalised anxiety disorder with 89% sensitivity and 82% specificity, with high test–retest reliability (ICC=0.83). Higher GAD-7 scores have been shown to correlate with disability and functional impairment.[37 41] A score of 5–9 indicates mild symptoms and suggests monitoring these individuals, 10–14 indicates moderate symptoms and describes a possible clinically significant condition, while scores above 15 indicate severe symptoms and advises active treatment.

The PHQ-9 assesses the severity of depression across the nine DSM-4 criteria for major depressive disorder on a 0–3 Likert scale. The scale has been validated for use in primary care.[42] The PHQ-9 has been shown to identify depression in at-risk populations.[43 44] A criterion score of ≥10 has been shown to have 88% sensitivity and specificity for major depressive disorder.[45] PHQ-9 scores of 5, 10, 15 and 20 represent mild, moderate, moderately severe and severe depression, respectively. The PHQ-9 has shown high internal consistency (α=0.91)[46] and a valid latent structure in non-clinical samples (Comparative Fit Index (CFI)=0.914–0.983).[47]

Secondary outcomes

Work productivity

Work productivity is measured through the Work Productivity and Activity Impairment: General Health V.2.0 (WPAI:GH).[48] The WPAI:GH yields four types of scores: 'Absenteeism', 'Presenteeism', 'Work productivity loss' and 'Activity Impairment'. The WPAI:GH has been shown to demonstrate good internal consistency (a=0.74), with a high intraclass correlation coefficient (r=0.79–0.90) in clinical populations.[49]

Job satisfaction

Job satisfaction is measured using the Indiana Job Satisfaction Scale (IJSS),[50] which is a brief job satisfaction questionnaire designed for use in individuals with severe mental illness. The IJSS consists of a 32-item self-report questionnaire divided into six subscales: 'General Satisfaction', 'Pay', 'Advancement and Security', 'Supervision', 'Coworkers' and 'How I feel about this job'. The IJSS shows high internal consistency (α=0.90) and test–retest reliability (r=0.75).[50]

Well-being

Well-being is measured using the Warwick-Edinburgh Mental Health Well-Being Scale (WEMWBS).[51] The WEMWBS consists of 14 items and has been shown to have good internal consistency (α=0.91) and to correlate highly with mental health measures, such as the General Health Questionnaire-12, in clinical populations.[51] The WEMWBS has shown high internal consistency with non-clinical populations (α=0.94; test–retest=0.83).[52]

Quality of life

Quality of life is measured using the European Quality Of Life-5 Dimensions (EQ-5D) questionnaire.[53] The EQ-5D consists of six items and five items of Likert scale responses to mobility, self-care, usual activities, pain/discomfort and anxiety/depression, with a sixth item of a rating of health on a visual analogue scale. The EQ-5D has shown high internal consistency in clinical samples (α=0.86)[54] and in non-clinical populations (α=0.84).[55]

Sleep diary data

Participants will be asked to complete a sleep diary every day during the 8-week study period. The diary is a modified version of the Consensus Sleep Diary[56] (see online supplemental appendix 1). The questions include information about daily bedtime, waking and out-of-bed times, self-reported estimates of SOL and total WASO. Items on the diary also include rated self-reported subjective sleep quality. The main outcomes are average SOL, TST, WASO and SE (SE percentage=total sleep time/time in bed). TST will be calculated by subtracting the total time spent awake after initial sleep onset (sum of SOL, WASO and time spent awake before getting out of the bed in the

Table 2 Schedule of activities and assessments

	Study period			
	Enrolment	**Allocation**	**Postallocation (week 8)**	**Follow-up (week 12)**
Timepoint	T1	T0	T1	T2
Enrolment				
Expression of interest	X			
Prescreen consent and eligibility screen	X			
Trial informed consent	X			
Allocation		X		
Interventions				
dCBT-I		<----------	---------->	
Waitlist control		<----------	---------->	
Sleep tracking		X	X	
Sleep diary		Every week from T0 to T1*		
Assessments				
Screening (ISI, PHQ-9, GAD-7)	X			
Demographics, COVID-19, WPAI-GH, IJSS, WEMWBS, medication checklist, ISI, GAD-7, PHQ-9, EQ-5D-5L		X	X	X

*Although sleep diary data are collected throughout the 8-week period, T0 and T1 weekly averages will be used in analyses, while the remaining data collected during the active treatment period of 6 weeks will be used in therapy sessions complementing sleep restriction and stimulus control therapies to provide individualised advice and guidance to participants.
dCBT-I, digital cognitive–behavioural therapy for Insomnia; EQ-5D, European Quality Of Life-5 Dimensions; GAD-7, generalised anxiety disorder-7; IJSS, indiana job satisfaction scale; ISI, insomnia severity index; PHQ-9, patient health questionnaire-9; WEMWBS, warwick-edinburgh mental health well-being scale; WPAI-GH, work productivity and activity impairment: general health.

morning) from the total time in bed (TIB). We will only use a 1-week average as outcomes of sleep diary in subsequent analyses from baseline (preintervention) and week 8 (postintervention).

Actigraphy

Continuous actigraphy monitoring will be conducted by a wristwatch-like device, the MotionWatch 8 supplied by CamNtech, providing objective detection and quantification of a person's movement to assess sleep patterns objectively. Participants will be asked to wear and use the sleep tracker for 1 week before the intervention and 1 week after the intervention. Data will be downloaded and analysed using the MotionWare V.1.3.17 software. The extracted outcomes will be the same as for sleep diaries (ie, average SOL, TST, WASO and SE over the 1-week period).

Usage of online platform

We will examine usage of the online platform (ie, analytics) and this will include the average duration of time spent on each topic and the number of topics completed in each week during the 6-week period. These will be used in exploratory analyses.

Assessment points

Assessments will take place at baseline, postintervention (week 8) and follow-up (week 12) (see table 2). For each cohort, those initially randomised to the WLC arm will be offered dCBT-I at week 9 and therefore all follow-ups beyond that point will be part of a naturalistic follow-up. See online supplemental appendix 2 for the data collection forms.

Process evaluations

The aim of the process evaluation is to explore the hybrid dCBT-I by examining implementation, mechanisms of impact and contextual factors that facilitate or impede intervention delivery. We will explore user perception and experience of the intervention, including reflections on implementing all aspects of the intervention programme, their perceptions of benefit, as well as any unexpected consequences and treatment fidelity. We will select 25 participants by random automatic selection who have completed the intervention (based on a maximum number of 30 interviews suggested by Marshall and colleagues[57] before reaching data saturation) and consented to be contacted again for the qualitative interview. At the end of the 6-week intervention period, interviews will be conducted online via Microsoft Teams by members of the University of Warwick research team, who are independent from the treatment delivery process of the selected individuals. The interviews will last around 45 min and will be conducted using a semi-structured, open-ended interview schedule. Interviews will be audio-recorded using OBS Studio and recordings

will be subsequently transcribed verbatim by a third-party university-approved vendor.

Assessment of safety

The likelihood of serious adverse events occurring during this trial is low. Previous studies have shown that daytime sleepiness, tiredness and vigilance impairment may increase during SRT, which is one of the behavioural component of CBT-I.[58] Participants will be fully instructed as to the rationale and potential side effects of the intervention at the outset during the informed consent process. In addition, participants will be advised to not drive or operate machinery if experiencing excessive daytime sleepiness. This element of the study will be overseen by a qualified clinical psychologist (NT) who is experienced and will be on hand throughout the trial to advise and supervise the intervention staff. Due to the online nature of the assessments and intervention, it is unlikely that the research team will become aware of all such events unless actively reported by the participants by email or during any of the four videoconferencing therapy sessions. Participants will therefore be offered different channels to communicate and will be encouraged to report any unwanted/unexpected effects (attributable or not to the treatment offered) to the research team as soon as they emerge. This is to ensure the health and well-being of the participants.

Adverse events (AE) and serious adverse events (SAE) during the study period that may or may not be due to the intervention will be recorded by the research team to check for any patterns or trends in events.

In line with the Good Clinical Practice requirements for research in human subjects other than clinical trials of investigational medicinal products (non-CTIMPs), we define AE and SAE in this study as follows:

Adverse event

An AE is any untoward medical occurrence in a study participant which does not necessarily have a causal relationship with the research. An AE can be any unfavourable and unintended symptom or disease that occurs during the time a participant is involved in the study, whether or not it is considered to be related to the intervention.

Serious adverse event

An AE is considered to be 'serious' if it fulfils one of the following criteria: (1) results in death; (2) is life-threatening; (3) requires or prolongs hospitalisation or prolongation of existing inpatients hospitalisation; (4) results in persistent or significant disability or incapacity; (5) consists of a congenital anomality or birth defect; and (6) is otherwise considered medically significant by the investigator.

Expected adverse event

- For SLEEP only: daytime sleepiness, tiredness and concentration difficulties.

Reporting processes

All therapists and researchers working in this study will be familiar with the processes and timescales of reporting AEs and SAEs. AE and SAE forms will be sent to the trial management team (CB, CK), who will log them in a central database for trial monitoring. All forms will be logged in a central database and reviewed by the trial management team monthly, with a cumulative review of all safety information by an independent trial monitoring committee (TMC). In addition, the trial management team will monitor and send the total number of SAEs per month to the TMC Chair in order to expedite a safety review if more SAEs are being seen than would be expected.

SAE forms will also be reported to the chief investigator (CM) within 24 hours of the research staff being aware of the event. The CI or a clinical delegate of the CI (LW, CT, NKYT) will then review the event to establish whether there is a causal link (relatedness): (1) not related (clearly not related to the intervention), (2) possible (may be related to the intervention) or (3) definite (clearly related to the intervention). If there is a link, the CI will assess whether the event is 'expected'. If the event is both 'related' (ie, if they resulted from administration of any of the research procedures) and 'unexpected' (ie, not listed in the protocol as expected occurrence), an expedited report (within 15 days) will be sent to the sponsor's representative by the trial management team. Any change of condition or other follow-up information will be sent to the chief investigator as soon as it is available or within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached.

Data management

The trial masterfile containing personally identifiable information will be stored separately to the study data along with any allocation information for unblinding; this will only be accessed by the trial management team (Casey Barnes, project administrator; Charlotte Kershaw, project manager). All study data will be stored separately to the trial management and logistic data and will be accessed by the research fellows (KP, TRM) and research assistants (ST, AHW). Due to the short duration of the trial and the low risks associated with the interventions, the trial does not have a data monitoring committee.

Research data will be deleted from the Qualtrics platform by one of the research fellows (KP, TRM), immediately after being transferred to the University of Warwick secure servers. We will also delete all personal data from the university servers immediately after the trial is completed (anticipated date: April 2022). The pseudo-anonymised study data will be deleted after 10 years.

At consenting to trial stage and through several other communications, participants are told they are free to withdraw anytime without giving a reason and that this will not impact them or their employment in any way. Given the intervention nature of the study, withdrawal

from treatment and withdrawal from the study are treated separately. If a participant chooses to withdraw, the trial management team will first enquire whether their wishes are in regard to the treatment element only (including attending therapy sessions, completing the sleep diary, completing online self-guided content and actigraphy) or the study altogether. We anticipate withdrawals due to burden caused by difficulties associated with the SRT, sleep monitoring tasks and attendance of therapy appointments during working hours. If participants wish to withdraw just from the treatment element, we will continue attempts to collect questionnaire measures, otherwise the trial management team will delete all research data collected until that point in time and their personal data from the separate identifiable data sets. The data will be deleted within 5 working days of the request and the participant will be informed of the confirmation of removal of data and withdrawal from the study.

Data lock will be conducted for each trial once the study is completed. We define completed as the closure of the follow-up measures. To confirm the data lock, the chief investigator will authorise the data lock procedure by submitting a formal request in writing to the executing team members (KP and TRM). The study data sets will be closed at the point where all reasonable attempts have been made to collect all outstanding data items/data queries and all study-specific parameters have been met.

Technical appendices, statistical codes and data sets will be available from the Open Society Foundations (OSF) repository (DOI-10.17605/OSF.IO/2G75Y).

Analysis plan

Statistical analyses

In accordance with the Consolidated Standards of Reporting Trials guidelines, we will record and report all participant flow. Descriptive statistics on recruitment, dropout and completeness of interventions will be provided. The main efficacy analysis will be via intention-to-treat (ITT) including all participants (regardless of group allocation), with no planned interim analysis for efficacy or futility. We will aim to obtain full follow-up data on every participant to allow full ITT analysis, but we will inevitably experience the problem of missing data due to withdrawal, loss to follow-up or non-response to some questionnaire items. Participants who withdrew consent or those with a protocol violation concerning eligibility will be excluded from the ITT analysis. Participants with missing baseline information will also be excluded from ITT analysis. Differences in baseline characteristics between those included in the analysis and those who drop out (but have not withdrawn consent) will be examined.

Independent samples t-tests and χ^2 tests will be used to examine between-group differences in baseline sociodemographic and characteristics. For variables showing between-group differences at baseline, the baseline value will be entered as a covariate in subsequent models.

To evaluate our intervention, we will use a mixed effects linear model to test the primary and secondary hypotheses modelling differences in scores between the control and intervention groups at 8 weeks postintervention. In each model, we will include as fixed effects randomisation allocation indicator (ie, dCBT-I group or WLC) a cohort factor (to denote time in different cohort entries into the trial), an interaction term of cohort × randomisation group and baseline ISI scores. Regarding the secondary hypothesis in relation to actigraphy and sleep diary data, we will analyse these using an analogous model as described above through parametrisation of SE, SOL, WASO, TST, TIB and sleep quality.

The models will include a random effect of participants and fixed effects of the secondary measures that are shown to be significantly correlated to our primary outcomes (IJSS, WEMWBS, WPAI:GH, COVID-19 questionnaire, EQ-5D-5L, medication), as well as a vector of control variables (including age, gender, ethnicity, income band and hours of work).

Given the waitlist control design of the study, where all participants eventually receive dCBT-I, data collected beyond the 8-week period will be analysed as exploratory analyses looking at the change score of the primary outcomes within individuals from baseline to week 8 and week 12.

Given the multiple number of primary outcome measures (ISI, PHQ-9, GAD-7), we will run our models adjusting for an inflated error rate by using a Bonferroni-corrected more conservative critical value. We will split the alpha over the three primary outcome measures to create a new alpha level (α=0.016). The analyses will be conducted on the R statistical platform[31] using the lme4 package[59] through the lmer function.

Additional exploratory analyses will assess whether age and other demographic and COVID-19-related factors (eg, positive infection, bereavement due to COVID-19, psychosocial factors such as furlough, relationship conflicts) mediate treatment-related effects on the primary and secondary outcomes. As part of our exploratory analyses, we will also look at the cost-effectiveness of the intervention.

Missing data will be reported (alongside reasons for missingness where available) and the missing data pattern will be explored by sensitivity analyses, although the mixed effects model implicitly will account for data missing at random.

Qualitative analysis

We will use a framework approach for qualitative data analysis supported by QSR NVivo (V.11), with the framework based on the main areas of implementation, mechanisms of impact and contextual factors, together with the more detailed issues that arise from these. We will analyse qualitative process data prior to knowing trial outcomes to avoid biased interpretation.

Ethics and dissemination

All participants are required to read the information sheet and consent (see online supplemental appendix 3) to participate in the study. This included consent for their anonymised data to be published. The study has been granted sponsorship (SOC.15/20-21; Mathew Gane at sponsorship@warwick.ac.uk). Ethical approval has been granted by the University of Warwick Biomedical and Research Ethics Committee (BSREC 45/20-21 AM04) and the trial is registered at the International Standard Randomised Controlled Trials Number registry (ISRCTN13596153). The current protocol version is '2.9_Dec21'. We will publish the results of this study in peer-reviewed journals, regardless of magnitude or direction of effect. Findings will also be presented at both national and international scientific meetings. The results will be made accessible online wherever possible, if permitted by journal policies. We also intend to preregister all publications stemming from the study at open access repositories (eg, OSF preprints) and publish preprints. Please contact the corresponding author for requests to access the research data (conditional on journal policies and embargo periods). Protocol modifications will be communicated to all members of the research team and submitted for approval to the relevant ethics committees prior to implementation, and the trial registry will be updated accordingly.

Patient and public involvement

We have formed a group of four individuals with lived experience of mental health problems who are currently on employment, and they will contribute during the trial by reviewing participant information sheets, consent form, intervention materials and questionnaire measures. They will advise on recruitment procedures and methods to engage prospective participants/retain enrolled participants.

End of trial

The end of the trial is defined as the date when the last participant completes their 1-month follow-up after randomisation. However, follow-up data collection will proceed beyond this date, in particular interviews with participants contributing to the process evaluation.

DISCUSSION

It is already established that dCBT-I is effective in reducing insomnia-related symptoms. What is yet to establish is whether improvement of insomnia with a hybrid dCBT-I addressing ER difficulties as well designed and tailored to a workplace setting is associated with improvement in work-related outcomes such as productivity.

TRIAL STATUS

Recruitment commenced on 18 June 2021 and is ongoing.

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Contributors CM is the principal investigator. CM, GD, SR, NKYT, LW, CT, KP and TRM were involved in the design of the study. NKYT and TRM led the treatment development. NKYT facilitated the therapists' training. TRM drafted the manuscript and all authors revised and approved the final manuscript.

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Competing interests None declared.

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