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 on the SPIRIT (Standard Protocol Items for Randomized Trials) 2013 recommendations.

Methods and analysis: Mixed methods evaluation with a two-arm randomised waitlist control design of a six weeks dCBT-I+ER intervention through self-guided online platform and four videoconferencing therapy sessions. A process evaluation will examine fidelity of delivery and experiences of the intervention. Primary outcomes are the Insomnia Severity Index (ISI), the Patient Health Questionnaire (PHQ-9) and the Generalised Anxiety Disorder (GAD-7). 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 post-randomisation (T2). We will recruit 156 workers with sleep and emotion regulation 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 2.8_Aug21. Publication of results will inform the scientific, clinical, and business communities through peer-reviewed articles, webinars, conferences, and newsletters.

Trial registration: ISRCTN, ID: ISRCTN13596153. Registered on 08/06/2021.

Keywords: Sleep, Insomnia, Workplace, dCBT-I, Online, Emotion Regulation, Mental Health, Productivity

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Strengths and limitations of this study

- Novel hybrid digital cognitive behavioural therapy for insomnia and emotion regulation intervention in comparison to waitlist control (i.e. 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, its impact on mental health and productivity.
- Mixed methods evaluation of the intervention will provide insight into the application of 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 being 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 three months.[2, 3] Insomnia causes stress in social, occupational, educational domains other important areas of functioning for individuals and causes economic burden on health care systems.[4-6] Chronic insomnia symptoms affect around 30-48% of adults in the general population [7, 8] with a prevalence of 6% as insomnia diagnosis 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-pharmacologic treatment for insomnia as evidenced by European and American clinical practice guidelines,[11, 12] and is comprised of cognitive, behavioural, and educational elements. Previous meta-analyses show a moderate to large effect of CBT-I on most sleep parameters (e.g., sleep efficiency, 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 not cost-effective and can often be inaccessible. To overcome these barriers, digital CBT-I (dCBT-I) was introduced and allows cost-effective and scalable access to psychological therapy compared to standard face-to-face therapy [14] with moderate to large insomnia symptoms improvements and effect sizes in the range of those found for face-to-face interventions.[14, 15]

Indeed, recent cost benefit analysis assumed that 64% of CBT provided using a computer, is translated into significant cost savings of between £116 million and £136 million per annum in England compared to therapist face to face provision [16]. This may therefore suggest that dCBT-I could be equally cost effective enabling wider access to therapy for individuals with sleep problems.

Insomnia being one of the most prevalent occupational health risks impacting on workers' mental and physical wellbeing, a recent systematic review demonstrated that only a few studies have evaluated the effectiveness of CBT-I for employees in the workplace, and have found improvements in severity of insomnia and quality of sleep.[17] 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.[17] 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,[18] cardiovascular diseases [19] and diabetes.[20] 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, 21]

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.[22] 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 to a non-clinical control group.[23]

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.[24] 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-months follow-up period.[25]

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 of new treatment directions and have resulted in significantly better outcomes not only in sleep, but also mood, fatigue and pain-related outcomes.[26] 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 Cognitive Behavioural Therapy.[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.[27, 28]

The current study

This study will examine the efficacy of a new hybrid dCBT-I 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 on the primary outcomes of insomnia severity and symptoms of depression and anxiety.

Aim 2: Evaluate the effectiveness of the dCBT-I+ER intervention on the secondary outcomes of self-reported and objective sleep parameters.

Aim 3: Explore the effectiveness of the dCBT-I+ER intervention on the secondary outcomes of mental wellbeing, quality of life, work productivity, and job satisfaction.

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

Hypotheses

Hypothesis 1: Participants randomly allocated to receive dCBT-I+ER will demonstrate significantly greater improvements on the Insomnia Severity Index (ISI), the Patient Health Questionnaire- 9 (PHQ-9) and the General Anxiety Disorder-7 (GAD-7) compared to the waitlist control (WLC) participants at 8 weeks.

Hypothesis 2: Participants randomly allocated to receive to dCBT-I+ER will demonstrate significantly greater improvements on 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 the dCBT-I+ER on work productivity, job satisfaction, mental health wellbeing, 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 to a WLC group. We will recruit participants who self-report mild symptoms of insomnia on the ISI (>7) who also report subclinical to clinical depression or anxiety symptoms (see Eligibility Criteria below).

A randomised control trial (RCT) of CBT-I versus a WLC group will be conducted. The 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, 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 week 12 (follow-up). At week 8 all participants initially allocated to the WLC will be offered dCBT-I (see Fig. 1 for trial flowchart).

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.

Ethical approval has been granted from the University of Warwick Biomedical and Research Ethics Committee (BSREC 45/20-21 AM01) and the trial is registered at ISRCTN (ISRCTN13596153).

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 11,053 square miles with a population of 10,135,000 million.

Sample size

Based on the feasibility findings of Tang and colleagues [29] from which we model our current intervention, Tang and colleagues observed 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 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 in-person 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 [29] 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 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 $ICC=.03$ (to account for the multi-site individual-level clustering at randomisation), we anticipated needing a total sample of 130 participants, with 65 in the waitlist control 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 one 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 [30] through the '*clusterPower*' package.[31] To model for site variation, we use the *crtpwr.2mean* function, where we model site variation through an intraclass correlation coefficient.

Eligibility criteria

Inclusion criteria

- a) Able to give informed consent
- b) English-speaking.
- c) In employment (including being on furlough)
- d) Insomnia Severity Index score: $x > 7$
- e) General Anxiety Disorder-7 score: $x > 5$ or Patient Health Questionnaire-9 score: $x > 5$
- f) ≥ 18 years of age

Exclusion criteria

- a) Currently receiving treatment (psychological or pharmacological) for mental health problems (e.g. GP, private clinic, IAPT, specialist and community mental health services)
- b) Pregnant¹
- c) Current substance abuse/misuse problems, epilepsy, neurological conditions (e.g. Parkinson's or Alzheimer's), psychosis, bipolar disorder, or any other circadian rhythm and sleep disorders (e.g. sleep apnoea, periodic limb movement syndrome/restless leg syndrome, circadian rhythm disorders)²
- d) Retiring in the next 10 months
- e) Currently taking part in other psychological intervention trials
- f) In shift work³

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 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 (e.g., Twitter, LinkedIn, Facebook, Instagram), print (e.g., flyers in community and retail settings) and broadcast media (e.g. 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 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

¹ Sleep undergoes considerable changes during pregnancy, as the intervention uses sleep restriction this can be stressful for pregnant participants and their foetuses. Therefore, we are unable to include pregnant women in this study.

² Sleep restriction components of this intervention may adversely affect participants with these conditions.

³ Individuals in shift work will find that the sleep restriction in the intervention can become stressful and damaging, as the current intervention is not targeted for sleep disturbances caused by circadian misalignment due to shift work.

participants are asked to complete the pre-screen 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 Improving Access to Psychological Therapies (IAPT) services, whilst 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 trials based on the matching eligibility criteria. They will be provided with a study specific participant information leaflet (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 upon completion of baseline measures. We will use random length block between two and eight; blocking is conducted to minimise the risk of uneven groups. The randomisation will be conducted using '*blockrand*' package on R.[32] 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 (i.e. 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 (i.e. all non-identifiable data). Statistical analyses will be conducted by members of the research team (TM, KP), who will be blind to allocation and only have access to all non-identifiable research data.

Study procedure

<Insert Figure 1 here>

Digital Hybrid CBT intervention

The digital hybrid intervention will be delivered online on a learning management system platform. The self-guided programme is structured into six weekly sessions (see figure 2) with varying number of topics each week, lasting approximately 60

minutes 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 [29, 33] and the Integrative Training of Emotional Competencies designed to target cognitive-behavioural processes maintaining anxiety and depression.[34] The core components are behavioural (e.g. sleep restriction therapy, stimulus control therapy), cognitive (e.g. unhelpful thinking styles and cognitive distortions, cognitive reframing), educational (e.g. sleep science, sleep hygiene) and emotion regulation skills (e.g. relaxation, non-judgmental awareness, acceptance and commitment) 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 login on the platform and complete the topics. In addition, treatment adherence will be monitored by therapists documenting session attendance.

<Insert figure 2 here>

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 (NT). Therapists are psychologists with at least either a Master of Science or PhD 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, prevent confusion, demoralisation and unnecessary dropouts. Therapists received formal training, by attending a European Accreditation Council for Continuing Medical Education (EACCME) accredited course for CBT-I. In addition, they were trained in-house by NT (six sessions of 60min each), with further guidance on the application 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-minute session (see Table 1). This template ensures consistency across the therapists, as well as providing a space for the therapists to make any relevant notes, allowing continuity across sessions. Therapists also attend weekly group supervision sessions of 60-90 minutes with NT, to discuss any issues they may be encountering with cases and receive feedback from NT and the other therapists.

Table 1 Online therapy sessions content

Session 1	Session 2	Session 3	Session 4
Overview of the programme	Reviewing sleep diary	Reviewing sleep diary	Reviewing sleep diary
Psychoeducation (e.g. 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 (e.g. stimulus control, relaxation)	Psychoeducation and emotion regulation (e.g. worrying, rumination, cognitive restructuring)	Progress review and maintenance plan
Importance of keeping a sleep diary; reviewing 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			

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 time-points. If participants do not complete measures within 5 days, they will receive three further email reminders every five 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 co-primary outcomes. These are insomnia severity assessed by the Insomnia Severity Index (ISI),[35] anxiety symptoms, assessed by the General Anxiety Disorder-7 (GAD-7),[36] and depression symptoms, assessed by the Patient Health Questionnaire-9 (PHQ-9),[37]. These will be measured at baseline, 8 weeks, and 12 weeks post-randomisation, but used as primary outcomes at 8-weeks post randomisation only.

The ISI is a seven-item scale validated with reference to the diagnostic criteria for primary insomnia in the DSM-IV with items evaluated on a 5-point Likert scale (0= not at all, 4= extremely) and total score ranging 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.[38] The ISI has shown to have good psychometric properties [35] and to be valid even with non-clinical groups with a Cronbach $\alpha = 0.81 - 0.91$. [38, 39] In non-clinical samples, the ISI shows high internal consistency ($\alpha = 0.89$), 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 consisting 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.[36, 40] 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, whilst scores above 15 indicate severe symptoms and advises for active treatment.

The PHQ-9 assesses the severity of depression across the nine DSM-IV criteria for major depressive disorder on a 0-3 Likert scale. The scale has been validated for use in primary care.[41] The PHQ-9 has been shown to identify depression in at risk populations.[42, 43] A criterion score of ≥ 10 has been shown to have a 88% sensitivity and specificity for major depressive disorder.[44] 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 ($\alpha = 0.91$) [45] and a valid latent structure in nonclinical samples (CFI = 0.914- 0.983).[46]

Secondary outcomes

Work productivity - measured through the Work Productivity and Activity Impairment: General Health v2.0 (WPAI:GH).[47] 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 ($\alpha = 0.74$), with a high intraclass correlation coefficient ($r = 0.79 - 0.90$) in clinical populations.[48]

Job satisfaction - measured using the Indiana Job Satisfaction Scale (IJSS),[49] which is a brief job satisfaction questionnaire designed for use with individuals with a 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 ($\alpha = 0.90$) and test-retest reliability ($r = .75$).[49]

Well-being - measured using the Warwick-Edinburgh Mental Health Well-being Scale (WEMWBS).[50] The WEMWBS consists of 14-items and has been shown to have good internal consistency ($\alpha = 0.91$) and was shown to correlate highly with mental health measures, such as the GHQ-12 in clinical populations. [50] WEMWBS has shown high internal consistency with nonclinical populations ($\alpha = 0.94$; test-retest = 0.83).[51]

Quality of life- measured using the EuroQOL EQ-5D-5L questionnaire.[52] The EQ-5D-5L consists of six items, 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-5L has shown high internal consistency in clinical samples ($\alpha = 0.86$)[53] and in nonclinical populations ($\alpha = 0.84$).[54]

Sleep diary data- Participants will be asked to complete a sleep diary every day during the 8 weeks study period. The diary is a modified version from the Consensus Sleep Diary [55] (see Appendix 1). The questions include information about daily bedtime, waking and out-of-bed times, self-reported estimates of sleep onset latency (SOL), and total wake time after sleep onset (WASO). Items on the diary also include rated self-reported subjective sleep quality. The main outcomes are average SOL, total sleep time (TST), WASO and sleep efficiency (SE percentage = TST/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 morning) from the total time in bed (TIB). We will only use a one-week average as outcomes of sleep diary in subsequent analyses from baseline (pre-intervention) and week 8 (post-intervention).

Actigraphy- Continuous actigraphy monitoring will be conducted by a wristwatch-like device, the MotionWatch8 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 one week before the intervention, and one week after the intervention. Data will be downloaded and analysed using the MotionWare 1.3.17 software. The extracted outcomes will be the same as for sleep diaries (i.e. average SOL, TST, WASO and SE over the one week period).

Usage of online platform - We will examine the usage of the online platform (i.e. analytics), this will include the average duration of time spent on each topic and 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 baseline, post-intervention (week 8), and follow-up (week 12) (see Table 2 below). For each cohort, those initially randomised to the WLC arm, will be offered the dCBT-I at week 9 and therefore all follow-ups beyond that point will be part of a naturalistic follow-up. See Appendix 2 for data collections forms.

Table 2 Schedule of activities and assessments

	Study Period			
	Enrolment	Allocation	Post-allocation (week 8)	Follow-up (week 12)
Timepoint	T-1	T0	T1	T2
Enrolment:				
Expression of interest	X			
Pre-screen 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 ⁴		
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

Note: dCBT-I- digital cognitive behavioural therapy; ISI- Insomnia Severity Index; PHQ-9- Patient Health Questionnaire 9; GAD-7- General Anxiety Disorder 7; WPAI-GH- Work Productivity and Activity Impairment: General Health; IJSS- Indiana Job Satisfaction Scale; WEMWBS- Warwick-Edinburgh Mental Health Well-being Scale, EQ-5D-5L- Euro Quality of Life

Process evaluations

The aim of the process evaluation is to explore the hybrid digital CBT-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 the maximum number of 30 interviews suggested by Marshall and colleagues [56] before reaching data saturation), and consented to be contacted again for the qualitative interview. At the end of the 6-weeks 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-minutes 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 sleep restriction therapy (SRT), which is one of the behavioural component of CBT-I.[57] Participants will be fully instructed as to the rationale and potential side effects of the intervention at the outset during the informed consent

⁴ Although sleep diary data is collected throughout the 8 weeks 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.

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 wellbeing 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 (GCP) requirements for non-CTIMPs, we define AE and SAE in this study as follow-

Adverse Event (AE):

An AE is any untoward medical occurrence in a study participant, which does not necessarily have a causal relationship with the research. An adverse event 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 (SAE):

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 anomaly or birth defect; (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 numbers 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 CI (CM) within 24 hours of the research staff being aware of the event. The CI or a clinical delegate of the CI (LW, CT, NT) 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 intervention), 3) definite (clearly related to intervention), and if there is a link, then the CI will assess whether the event is 'expected'. If the event is both 'related' (i.e. if they resulted from administration of any of the research procedures) and 'unexpected' (i.e. 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 CI 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 (CB⁵, CK⁶). All study data will be stored separately to the trial management and logistic data and will be accessed by the research fellows (KP, TM) 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 the research fellows (KP, TM), 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: 04/2022). 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 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 sleep restriction therapy, 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 questionnaires 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 datasets. 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.

⁵ Casey Barnes- Project administrator

⁶ Charlotte Kershaw- Project manager

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 PI will authorise the data lock procedure, by submitting a formal request in writing to the executing team members (KP and TM). Study datasets 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 datasets will be available from the OSF repository, DOI-10.17605/OSF.IO/2G75Y.

Analysis plan

Statistical analyses

In accordance with Consolidated Standards of Reporting Trials (CONSORT) 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 chi-square 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 eight-weeks post-intervention. In each model, we will include as fixed effects randomisation allocation indicator (i.e. dCBT-I group or WLC), a cohort factor (to denote time in different cohort entries into the trial), an interaction term of cohort x 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 sleep efficiency, 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, hours of work).

Given the waitlist control design of the study, where all participants eventually receive dCBT-I, data collected beyond the eight weeks period will be analysed as exploratory analyses looking at the change score of the primary outcomes within individual 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 ($\alpha = 0.016$). The analyses will be conducted on the R statistical platform [30] using the lme4 package [58] through the lmer function.

Additional exploratory analyses will assess whether age and other demographic and covid-related factors (e.g. positive infection, bereavement due to covid, 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, though 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.

Dissemination

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 pre-register all publications stemming from the study at open access repositories (e.g. OSF preprints) and publish pre-prints. Please contact the corresponding author for requests to access the research data (conditional on journal policies and embargo periods).

Patient and Public Involvement

We have formed a group of four individuals with lived experience of mental health problems who are currently in 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 emotion regulation 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 18th June 2021 and is ongoing.

AUTHOR CONTRIBUTIONS

CM is principal investigator. CM, NT, LW, CT, KP, and TM were involved in the design of the study. NT and TM led the treatment development. NT facilitated the therapists training. TM drafted the manuscript and all authors revised and approved the final manuscript.

COMPETING INTERESTS

This was not an industry supported study. The online platform was developed by Volute under contractual agreement with University of Warwick. All authors declare no conflict of interest.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

All participants are required to read the information sheet and consent (see 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) and ethical approval from the University of Warwick Biomedical and Research Ethics Committee (BSREC 45/20-21) and the trial is registered at ISRCTN (ISRCTN13596153). 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.

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The study funders had no role in the study design, collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

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Figure Captions

Figure 1 Flow chart diagram showing summary of the trial design for the study

Figure 2 SLEEP intervention trajectory and summary of weekly topics

Pre-print