BMJ Open

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

Talar Rita Moukhtarian ,[1] Krishane Patel ,[2] Carla Toro,[2] Sean Russel,[3] Guy Daly,[4] Lukasz Walasek,[5] Nicole K Y Tang ,[5] Caroline Meyer[2]

To cite: Moukhtarian TR, Patel K, Toro C, *et al*. 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. *BMJ Open* 2022;**12**:e058062. doi:10.1136/bmjopen-2021-058062

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-058062).

Received 06 October 2021
Accepted 28 March 2022

Check for updates

© Author(s) (or their employer(s)) 2022. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

Correspondence to
Dr Talar Rita Moukhtarian; talar.moukhtarian@warwick.ac.uk

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]

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

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.

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

- 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

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

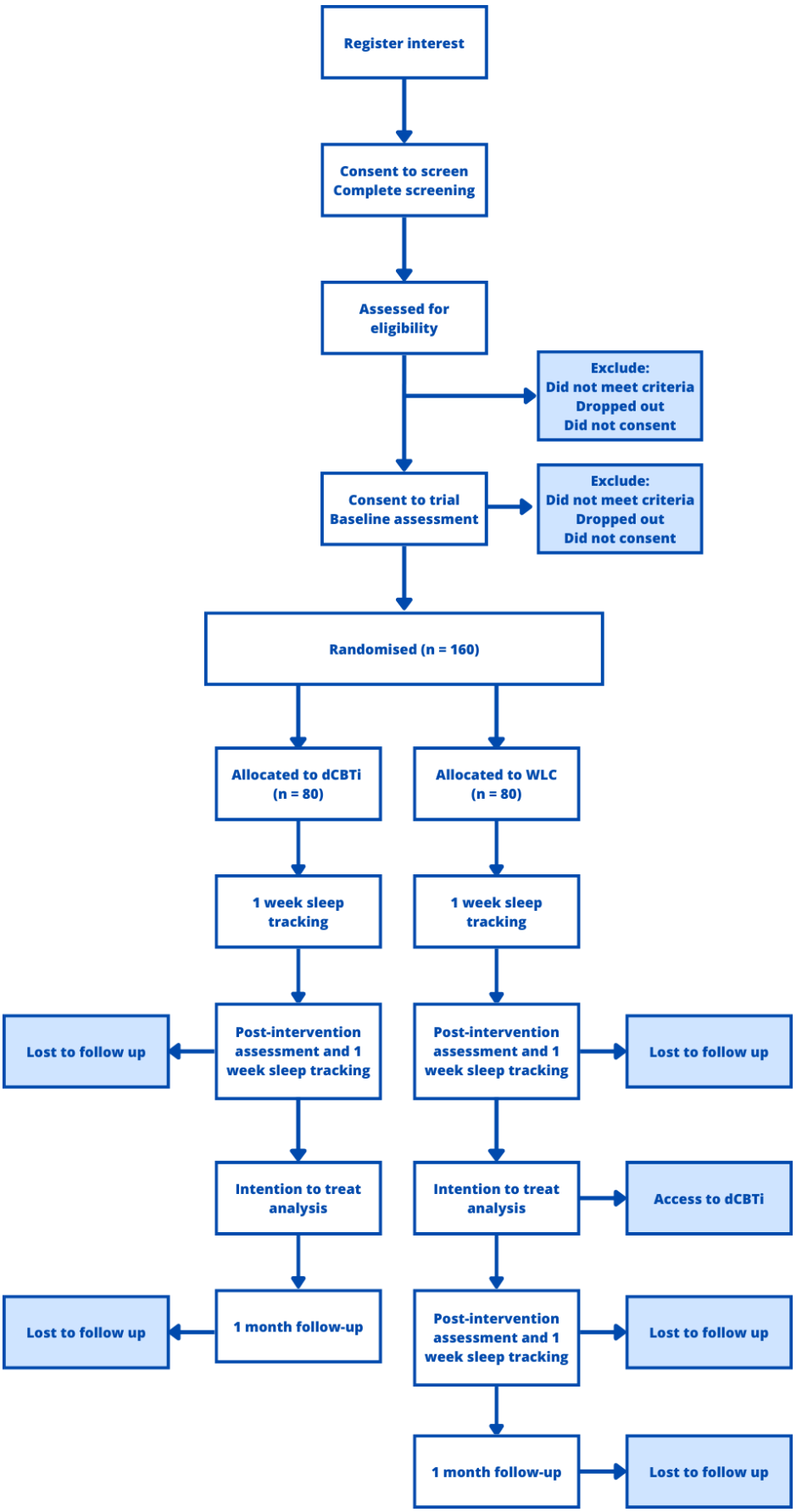


Figure 1 Flow chart diagram showing summary of the trial design of the study. dCBTI, digital cognitive–behavioural therapy for insomnia; WLC, waitlist control.

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

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.

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

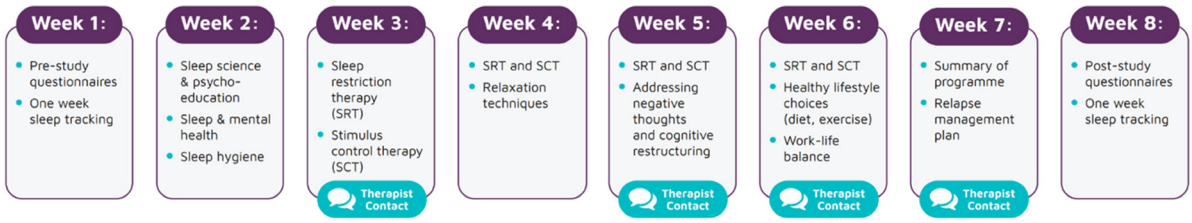


Figure 2 Sleep intervention trajectory and summary of weekly topics.

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.

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

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

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

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

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

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

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

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.

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

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.

Author affiliations
[1]Warwick Medical School, University of Warwick, Coventry, UK
[2]Warwick Manufacturing Group, University of Warwick, Coventry, UK
[3]Health and Life Science Centre, Coventry University, Coventry, UK
[4]The British University, Cairo, Egypt
[5]Department of Psychology, University of Warwick, Coventry, UK

Twitter Talar Rita Moukhtarian @TMoukhtarian

Acknowledgements We thank all our participants without whom this research will not be possible. We thank the patient and public advisory committee of the study for their invaluable feedback in the different stages of the study. We also thank the research assistants, therapists and project administrator team facilitating the smooth delivery of the trial.

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.

Funding This research is supported by Midlands Engine (R.ESWM.3932), UK as part of the Mental Health and Productivity Pilot programme (MHPP), which is collaborating across a range of diverse partners to provide an evidence-informed, cost-effective and sustainable resource that supports good mental health at work, reduces stigma and will ultimately increase productivity. 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.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs
Talar Rita Moukhtarian http://orcid.org/0000-0002-7404-8950
Krishane Patel http://orcid.org/0000-0001-9206-5642
Nicole K Y Tang http://orcid.org/0000-0001-7836-9965

REFERENCES

1 Yang B, Wang Y, Cui F, *et al*. Association between insomnia and job stress: a meta-analysis. *Sleep Breath* 2018;22:1221–31.
2 Morin CM, Benca R. Chronic insomnia. *Lancet* 2012;379:1129–41.
3 American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th. Arlington, VA: American Psychiatric Publishing, 2013.
4 Kucharczyk ER, Morgan K, Hall AP. The occupational impact of sleep quality and insomnia symptoms. *Sleep Med Rev* 2012;16:547–59.
5 Daley M, Morin CM, LeBlanc M, *et al*. Insomnia and its relationship to health-care utilization, work absenteeism, productivity and accidents. *Sleep Med* 2009;10:427–38.
6 Daley M, Morin CM, LeBlanc M, *et al*. The economic burden of insomnia: direct and indirect costs for individuals with insomnia syndrome, insomnia symptoms, and good sleepers. *Sleep* 2009;32:55–64.

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

7 Stewart R, Besset A, Bebbington P, *et al*. Insomnia comorbidity and impact and hypnotic use by age group in a national survey population aged 16 to 74 years. *Sleep* 2006;29:1391–7.
8 Ohayon MM. Epidemiology of insomnia: what we know and what we still need to learn. *Sleep Med Rev* 2002;6:97–111.
9 Espie CA, Kyle SD, Hames P, *et al*. The daytime impact of DSM-5 insomnia disorder: comparative analysis of insomnia subtypes from the great British sleep survey. *J Clin Psychiatry* 2012;73:e1478–84.
10 Hafner M*et al*. *Why sleep matters- the economic costs of insufficient sleep*. RAND Europe: United Kingdom, 2016.
11 Edinger JD, Arnedt JT, Bertisch SM, *et al*. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of sleep medicine clinical practice guideline. *J Clin Sleep Med* 2021;17:255–62.
12 Riemann D, Baglioni C, Bassetti C, *et al*. European guideline for the diagnosis and treatment of insomnia. *J Sleep Res* 2017;26:675–700.
13 Wu JQ, Appleman ER, Salazar RD, *et al*. Cognitive behavioral therapy for insomnia comorbid with psychiatric and medical conditions: a meta-analysis. *JAMA Intern Med* 2015;175:1461–72.
14 Zachariae R, Lyby MS, Ritterband LM, *et al*. Efficacy of internet-delivered cognitive-behavioral therapy for insomnia - A systematic review and meta-analysis of randomized controlled trials. *Sleep Med Rev* 2016;30:1–10.
15 Seyffert M, Lagisetty P, Landgraf J, *et al*. Internet-Delivered cognitive behavioral therapy to treat insomnia: a systematic review and meta-analysis. *PLoS One* 2016;11:e0149139.
16 Hasan F, Tu Y-K, Yang C-M, *et al*. Comparative efficacy of digital cognitive behavioral therapy for insomnia: a systematic review and network meta-analysis. *Sleep Med Rev* 2022;61:101567.
17 Health Do, ed. *Programme, I.A.t.P.T.I., Computerised cognitive behavioural therapy (cCBT) implementation guidance*, 2007.
18 Vega-Escaño J, Porcel-Gálvez AM, Diego-Cordero Rde, *et al*. Insomnia interventions in the workplace: a systematic review and meta-analysis. *Int J Environ Res Public Health* 2020;17:6401.
19 Baglioni C, Battagliese G, Feige B, *et al*. Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies. *J Affect Disord* 2011;135:10–19.
20 Vgontzas AN, Liao D, Bixler EO, *et al*. Insomnia with objective short sleep duration is associated with a high risk for hypertension. *Sleep* 2009;32:491–7.
21 Cappuccio FP, D'Elia L, Strazzullo P, *et al*. Quantity and quality of sleep and incidence of type 2 diabetes: a systematic review and meta-analysis. *Diabetes Care* 2010;33:414–20.
22 Pearson NJ, Johnson LL, Nahin RL. Insomnia, trouble sleeping, and complementary and alternative medicine: analysis of the 2002 National health interview survey data. *Arch Intern Med* 2006;166:1775–82.
23 Gross JJ. The emerging field of emotion regulation: an integrative review. *Review of General Psychology* 1998;2:271–99.
24 Gruber J, Eidelman P, Harvey AG. Transdiagnostic emotion regulation processes in bipolar disorder and insomnia. *Behav Res Ther* 2008;46:1096–100.
25 Van Someren EJW. Brain mechanisms of insomnia: new perspectives on causes and consequences. *Physiol Rev* 2021;101:995–1046.
26 Jansson-Fröjmark M, Norell-Clarke A, Linton SJ. The role of emotion dysregulation in insomnia: longitudinal findings from a large community sample. *Br J Health Psychol* 2016;21:93–113.
27 Tang NKY. Cognitive behavioural therapy in pain and psychological disorders: towards a hybrid future. *Prog Neuropsychopharmacol Biol Psychiatry* 2018;87:281–9.
28 Torales J, O'Higgins M, Castaldelli-Maia JM, *et al*. The outbreak of COVID-19 coronavirus and its impact on global mental health. *Int J Soc Psychiatry* 2020;66:317–20.
29 Cénat JM, Blais-Rochette C, Kokou-Kpolou CK, *et al*. Prevalence of symptoms of depression, anxiety, insomnia, posttraumatic stress disorder, and psychological distress among populations affected by the COVID-19 pandemic: a systematic review and meta-analysis. *Psychiatry Res* 2021;295:113599.
30 Tang NKY, Moore C, Parsons H, *et al*. Implementing a hybrid cognitive-behavioural therapy for pain-related insomnia in primary care: lessons learnt from a mixed-methods feasibility study. *BMJ Open* 2020;10:e034764.
31 Team, R.C. *R: A language and environment for statistical computing*. Vienna, Austria: R.F.f.S. Computing, 2020.
32 Kleinman K*et al*. ClusterPower: power calculations for cluster-randomized and cluster-randomized crossover trials 2017.
33 Snow G. Blockrand: randomization for block random clinical trials 2013.
34 Tang NKY, Goodchild CE, Salkovskis PM. Hybrid cognitive-behaviour therapy for individuals with insomnia and chronic pain: a pilot randomised controlled trial. *Behav Res Ther* 2012;50:814–21.
35 Berking M, Wupperman P, Reichardt A, *et al*. Emotion-regulation skills as a treatment target in psychotherapy. *Behav Res Ther* 2008;46:1230–7.
36 Bastien CH, Vallières A, Morin CM. Validation of the insomnia severity index as an outcome measure for insomnia research. *Sleep Med* 2001;2:297–307.
37 Spitzer RL, Kroenke K, Williams JBW, *et al*. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.
38 Spitzer RL*et al*. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. *Jama* 1999;282:1737–44.
39 Morin CM, Belleville G, Bélanger L, *et al*. The insomnia severity index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep* 2011;34:601–8.
40 Yu DSF. Insomnia severity index: psychometric properties with Chinese community-dwelling older people. *J Adv Nurs* 2010;66:2350–9.
41 Ruiz MA, Zamorano E, García-Campayo J, *et al*. Validity of the GAD-7 scale as an outcome measure of disability in patients with generalized anxiety disorders in primary care. *J Affect Disord* 2011;128:277–86.
42 Cameron IM, Crawford JR, Lawton K, *et al*. Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. *Br J Gen Pract* 2008;58:32–6.
43 Haddad M, Walters P, Phillips R, *et al*. Detecting depression in patients with coronary heart disease: a diagnostic evaluation of the PHQ-9 and HADS-D in primary care, findings from the UPBEAT-UK study. *PLoS One* 2013;8:e78493.
44 de Man-van Ginkel JM, Gooskens F, Schepers VPM, *et al*. Screening for poststroke depression using the patient health questionnaire. *Nurs Res* 2012;61:333–41.
45 Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;16:606–13.
46 Hansson M, Chotai J, Nordstöm A, *et al*. Comparison of two self-rating scales to detect depression: HADS and PHQ-9. *Br J Gen Pract* 2009;59:e283–8.
47 Doi S, Ito M, Takebayashi Y, *et al*. Factorial validity and invariance of the Patient Health Questionnaire (PHQ)-9 among clinical and non-clinical populations. *PLoS One* 2018;13:e0199235.
48 Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics* 1993;4:353–65.
49 Zhang W, Bansback N, Boonen A, *et al*. Validity of the work productivity and activity impairment questionnaire--general health version in patients with rheumatoid arthritis. *Arthritis Res Ther* 2010;12:R177–7.
50 Resnick SG, Bond GR. The Indiana job satisfaction scale: job satisfaction in vocational rehabilitation for people with severe mental illness. *Psychiatr Rehabil J* 2001;25:12–19.
51 Tennant R, Hiller L, Fishwick R, *et al*. The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes* 2007;5:1–13.
52 Dong A, Chen X, Zhu L, *et al*. Translation and validation of a Chinese version of the Warwick-Edinburgh mental well-being scale with undergraduate nursing trainees. *J Psychiatr Ment Health Nurs* 2016;23:554–60.
53 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
54 Bilbao A, García-Pérez L, Arenaza JC, *et al*. Psychometric properties of the EQ-5D-5L in patients with hip or knee osteoarthritis: reliability, validity and responsiveness. *Qual Life Res* 2018;27:2897–908.
55 Kim C, Ko H. The impact of self-compassion on mental health, sleep, quality of life and life satisfaction among older adults. *Geriatr Nurs* 2018;39:623–8.
56 Carney CE, Buysse DJ, Ancoli-Israel S, *et al*. The consensus sleep diary: standardizing prospective sleep self-monitoring. *Sleep* 2012;35:287–302.
57 Marshall B, Cardon P, Poddar A, *et al*. Does sample size matter in qualitative research?: a review of qualitative interviews in is research. *Journal of Computer Information Systems* 2013;54:11–22.
58 Kyle SD, Miller CB, Rogers Z, *et al*. Sleep restriction therapy for insomnia is associated with reduced objective total sleep time, increased daytime somnolence, and objectively impaired vigilance: implications for the clinical management of insomnia disorder. *Sleep* 2014;37:229–37.
59 Bates D, Mächler M, Bolker B, *et al*. Fitting Linear Mixed-Effects Models Using lme4. *J Stat Softw* 2015;67:1–48.

BMJ Open: first published as 10.1136/bmjopen-2021-058062 on 15 July 2022. Downloaded from http://bmjopen.bmj.com/ on August 3, 2022 by guest. Protected by copyright.

Sleep diary

ID number:

Guidance for filling out the diary

The SLEEP diary is a daily record of important sleep-related information to calculate your sleep efficiency and identify your sleep patterns and any other factors that can influence your sleep.

- To keep an accurate sleep diary, please fill it out **every day.**
- The sleep diary comprises of **7 morning diary** questions and **7 evening diary** questions.
- The morning diary should be completed within one hour of getting out of bed in the morning.
- The evening dairy should be completed just before going to bed.
- Question 8 in each of the morning and evening diaries is a space for you to write down anything you might think will be useful to remember that might have affected your sleep (e.g. having a cold, jet lag, sleepover at a relative or hotel).
- Completing the diary will take less than 5 minutes each day and it might be helpful to keep it on your bedside table as a reminder.
- Don't worry too much about giving exact answers, you are not expected to watch the clock excessively because of this. Just give your best estimate.
- For each week, fill in the date in the top left-hand box to indicate the start of that week (i.e. W/C: 05/07/21), and enter the day of the week in the top row of each column (i.e. Monday).

Week 1: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Tuesday							
1 At what time did you wake up this morning? *Final awakening*	7am							
2 At what time did you get out of bed? *What time did you get out of bed with no further attempt at sleeping? This may be different from your final awakening time you reported in question 1 (e.g. you may have woken up at 6:35 a.m. but did not get out of bed to start your day until 7:20 a.m.)*	7:20am							
3 At what time did you try to go to sleep last night? *Write the time that you got into bed (e.g. lights out)*	11pm							

Week 1: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
4 After settling down, how long do you think did it take you to fall asleep? (in minutes) *Beginning at the time you wrote in question 3, how long did it take you to fall asleep?* ***You are not expected to watch the clock excessively because of this. Just give your best estimate.***	25							
5 After falling asleep and until you woke up for the last time in the morning, for how long were you awake in bed in total? (in hours and/or minutes) *What was the total time you were awake between the time you first fell asleep and the time of your final awakening? For example, if you woke up 2 times during the night, for 20 min and 35 min, your answer will be 55 min.* ***You are not expected to watch the clock excessively because of this. Just give your best estimate.***	70 min							

Week 1: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
6 **Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken** *List the medication name, how much and when you took EACH different medication. If every night is the same, write "same" after the first day.*	Med.: Sleepwell Dose: 50mg Time taken: 11pm							
7 **How would you rate the quality of your sleep last night?** **1. Very poor** **2. Poor** **3. Fair** **4. Good** **5. Very good** *"Sleep Quality" is your sense of whether your sleep was good or poor.*	3							
8 **Notes** *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 1: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Monday							
1 **How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have today?**	2 drinks							
2 **How many units of alcohol did you have today?** *One unit of alcohol:*  *Half pint of "regular" beer, lager or cider*  *Half a small glass of wine*  *1 single measure of spirits*  *1 small glass of sherry*  *1 single measure of aperitifs*	0							

Week 1: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
3 **How many times did you nap or doze?** **In total, how long did you nap or doze?** *A nap is a time you decided to sleep during the day, whether in bed or not in bed. Estimate the total amount of time you spent napping or dozing, in hours and minutes. For instance, if you napped once, for 30 minutes, and dozed for 10 minutes, you would answer "40 minutes." If you did not nap or doze, enter 0 hours 0 minutes.*	2 times 1h 10min							
4 **How physically active were you today?** **0-10, 0 indicating not active at all, 10 indicating very active**	7							

Week 1: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
5 **How aware of your emotions have you been today?** **Rating scale with 0 (not at all aware of my emotions) – 10 (extremely aware of my emotions)?** *Have you noticed how you have felt during the day e.g. happy, anxious, sad, angry?*	5							
6 **How have you found managing your emotions today?** **Rating scale with 0 (extremely easy) – 10 (extremely difficult)** *Have you been able to control any strong or sudden changes in emotions?*	6							
7 **How would you rate your mood today?** **Rating scale with 0 (very bad) – 10 (very good)**	7							
8 **Notes** *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 2: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Tuesday							
1 At what time did you wake up this morning?	7am							
2 At what time did you get out of bed?	7:20am							
3 At what time did you try to go to sleep last night?	11pm							
4 After settling down, how long do you think did it take you to fall asleep? (in minutes)	25							
5 After falling asleep and until you woke up for the last time in the morning, for how long were you awake in bed in total? (in hours and/or minutes)	70 min							
6 Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken	Med.: Sleepwell Dose: 50mg Time taken: 11pm							

Week 2: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
7 How would you rate the quality of your sleep last night? **1. Very poor** **2. Poor** **3. Fair** **4. Good** **5. Very good**	3							
8 Notes *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 2: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Monday							
1 **How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have today?**	2 drinks							
2 **How many units of alcohol did you have today?**	0							
3 **How many times did you nap or doze?** **In total, how long did you nap or doze?**	2 times 1h 10min							
4 **How physically active were you today?** **0-10, 0 indicating not active at all, 10 indicating very active**	7							
5 **How aware of your emotions have you been today?** **Rating scale with 0 (not at all aware of my emotions) – 10 (extremely aware of my emotions)?**	5							

Week 2: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
6 **How have you found managing your emotions today?** **Rating scale with 0 (extremely easy) – 10 (extremely difficult)**	6							
7 **How would you rate your mood today?** **Rating scale with 0 (very bad) – 10 (very good)**	7							
8 **Notes** *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 3: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Tuesday							
1 At what time did you wake up this morning?	7am							
2 At what time did you get out of bed?	7:20am							
3 At what time did you try to go to sleep last night?	11pm							
4 After settling down, how long do you think did it take you to fall asleep? (in minutes)	25							
5 After falling asleep and until you woke up for the last time in the morning, for how long were you awake in bed in total? (in hours and/or minutes)	70 min							
6 Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken	Med.: Sleepwell Dose: 50mg Time taken: 11pm							

Week 3: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
7 How would you rate the quality of your sleep last night? **1. Very poor** **2. Poor** **3. Fair** **4. Good** **5. Very good**	3							
8 Notes *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 3: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Monday							
1 **How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have today?**	2 drinks							
2 **How many units of alcohol did you have today?**	0							
3 **How many times did you nap or doze?** **In total, how long did you nap or doze?**	2 times 1h 10min							
4 **How physically active were you today?** **0-10, 0 indicating not active at all, 10 indicating very active**	7							
5 **How aware of your emotions have you been today?** **Rating scale with 0 (not at all aware of my emotions) – 10 (extremely aware of my emotions)?**	5							

Week 3: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
6 **How have you found managing your emotions today?** **Rating scale with 0 (extremely easy) – 10 (extremely difficult)**	6							
7 **How would you rate your mood today?** **Rating scale with 0 (very bad) – 10 (very good)**	7							
8 **Notes** *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 4: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Tuesday							
1 At what time did you wake up this morning?	7am							
2 At what time did you get out of bed?	7:20am							
3 At what time did you try to go to sleep last night?	11pm							
4 After settling down, how long do you think did it take you to fall asleep? (in minutes)	25							
5 After falling asleep and until you woke up for the last time in the morning, for how long were you awake in bed in total? (in hours and/or minutes)	70 min							
6 Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken	Med.: Sleepwell Dose: 50mg Time taken: 11pm							

Week 4: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
7 How would you rate the quality of your sleep last night? **1. Very poor** **2. Poor** **3. Fair** **4. Good** **5. Very good**	3							
8 Notes *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 4: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Monday							
1 **How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have today?**	2 drinks							
2 **How many units of alcohol did you have today?**	0							
3 **How many times did you nap or doze?** **In total, how long did you nap or doze?**	2 times 1h 10min							
4 **How physically active were you today?** **0-10, 0 indicating not active at all, 10 indicating very active**	7							
5 **How aware of your emotions have you been today?** **Rating scale with 0 (not at all aware of my emotions) – 10 (extremely aware of my emotions)?**	5							

Week 4: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
6 **How have you found managing your emotions today?** **Rating scale with 0 (extremely easy) – 10 (extremely difficult)**	6							
7 **How would you rate your mood today?** **Rating scale with 0 (very bad) – 10 (very good)**	7							
8 **Notes** *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 5: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Tuesday							
1 **At what time did you wake up this morning?**	7am							
2 **At what time did you get out of bed?**	7:20am							
3 **At what time did you try to go to sleep last night?**	11pm							
4 **After settling down, how long do you think did it take you to fall asleep? (in minutes)**	25							
5 **After falling asleep and until you woke up for the last time in the morning, for how long were you awake in bed in total? (in hours and/or minutes)**	70 min							
6 **Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken**	Med.: Sleepwell Dose: 50mg Time taken: 11pm							

Week 5: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
7 How would you rate the quality of your sleep last night? **1. Very poor** **2. Poor** **3. Fair** **4. Good** **5. Very good**	3							
8 Notes *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 5: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Monday							
1 **How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have today?**	2 drinks							
2 **How many units of alcohol did you have today?**	0							
3 **How many times did you nap or doze?** **In total, how long did you nap or doze?**	2 times 1h 10min							
4 **How physically active were you today?** **0-10, 0 indicating not active at all, 10 indicating very active**	7							
5 **How aware of your emotions have you been today?** **Rating scale with 0 (not at all aware of my emotions) – 10 (extremely aware of my emotions)?**	5							

Week 5: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
6 **How have you found managing your emotions today?** **Rating scale with 0 (extremely easy) – 10 (extremely difficult)**	6							
7 **How would you rate your mood today?** **Rating scale with 0 (very bad) – 10 (very good)**	7							
8 **Notes** *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 6: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Tuesday							
1 **At what time did you wake up this morning?**	7am							
2 **At what time did you get out of bed?**	7:20am							
3 **At what time did you try to go to sleep last night?**	11pm							
4 **After settling down, how long do you think did it take you to fall asleep? (in minutes)**	25							
5 **After falling asleep and until you woke up for the last time in the morning, for how long were you awake in bed in total? (in hours and/or minutes)**	70 min							
6 **Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken**	Med.: Sleepwell Dose: 50mg Time taken: 11pm							

Week 6: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
7 How would you rate the quality of your sleep last night? **1. Very poor** **2. Poor** **3. Fair** **4. Good** **5. Very good**	3							
8 Notes *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 6: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Monday							
1 **How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have today?**	2 drinks							
2 **How many units of alcohol did you have today?**	0							
3 **How many times did you nap or doze?** **In total, how long did you nap or doze?**	2 times 1h 10min							
4 **How physically active were you today?** **0-10, 0 indicating not active at all, 10 indicating very active**	7							
5 **How aware of your emotions have you been today?** **Rating scale with 0 (not at all aware of my emotions) – 10 (extremely aware of my emotions)?**	5							

Week 6: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
6 **How have you found managing your emotions today?** **Rating scale with 0 (extremely easy) – 10 (extremely difficult)**	6							
7 **How would you rate your mood today?** **Rating scale with 0 (very bad) – 10 (very good)**	7							
8 **Notes** *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 7: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Tuesday							
1 **At what time did you wake up this morning?**	7am							
2 **At what time did you get out of bed?**	7:20am							
3 **At what time did you try to go to sleep last night?**	11pm							
4 **After settling down, how long do you think did it take you to fall asleep? (in minutes)**	25							
5 **After falling asleep and until you woke up for the last time in the morning, for how long were you awake in bed in total? (in hours and/or minutes)**	70 min							
6 **Did you take any over-the-counter or prescription medication(s) to help you sleep? If so, list medication(s), dose, and time taken**	Med.: Sleepwell Dose: 50mg Time taken: 11pm							

Week 7: Morning diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
7 How would you rate the quality of your sleep last night? **1. Very poor** **2. Poor** **3. Fair** **4. Good** **5. Very good**	3							
8 Notes *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

Week 7: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Enter the day of the week (Mon, Tues, Wed, etc.)	Monday							
1 **How many caffeinated drinks (coffee, tea, soda, energy drinks) did you have today?**	2 drinks							
2 **How many units of alcohol did you have today?**	0							
3 **How many times did you nap or doze?** **In total, how long did you nap or doze?**	2 times 1h 10min							
4 **How physically active were you today?** **0-10, 0 indicating not active at all, 10 indicating very active**	7							
5 **How aware of your emotions have you been today?** **Rating scale with 0 (not at all aware of my emotions) – 10 (extremely aware of my emotions)?**	5							

Week 7: Evening diary

W/C:	Example	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
6 **How have you found managing your emotions today?** **Rating scale with 0 (extremely easy) – 10 (extremely difficult)**	6							
7 **How would you rate your mood today?** **Rating scale with 0 (very bad) – 10 (very good)**	7							
8 **Notes** *If you have anything that you would like to say that is relevant to your sleep feel free to write it here.*	I have a cold							

SLEEP_Baseline

Start of Block: Consent

Study - **SLEEP**: Supporting empLoyEes with insomnia and Emotion regulation Problems **Investigator(s) -** Krishane Patel (University of Warwick), Talar Moukhtarian (University of Warwick), Carla Toro (University of Warwick), Laura Chandler (University of Warwick), Nicole Tang (University of Warwick), Steven Marwaha (University of Birmingham), Arianna Prudenzi (University of Birmingham), Feroz Jadhakhan (University of Birmingham), Lukasz Walasek (University of Warwick), Caroline Meyer (University of Warwick)

I confirm that I have read and understand the information sheet (SLEEP v1.7 7/07/21) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- ○ Yes (1)
- ○ No (2)

I confirm that I meet ALL the eligibility criteria of this study: English speaking; 18 years or above; Not retiring in the next 10 months; Currently not receiving treatment (psychological or medication) from mental health services; Currently not taking parting in other psychological intervention trials; Not pregnant; No current substance abuse/misuse problems; No diagnosis of epilepsy, neurological diseases, psychosis, bipolar disorder, or any other circadian rhythm and sleep disorders (e.g. sleep apnea); Not in shift work.

- ○ Yes (1)
- ○ No (2)

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my employment being affected.

- Yes (1)
- No (2)

I understand that data collected during the study, may be looked at by individuals from University of Warwick. I give permission for these individuals to have access to my data.

- Yes (1)
- No (2)

Would you like to be contacted to participate in a qualitative interview to understand how we can improve the intervention further

- Yes (1)
- No (2)

I am happy for my anonymised data to be used in future research.

- Yes (1)
- No (2)

I agree to take part in the above study.

- Yes (1)
- No (2)

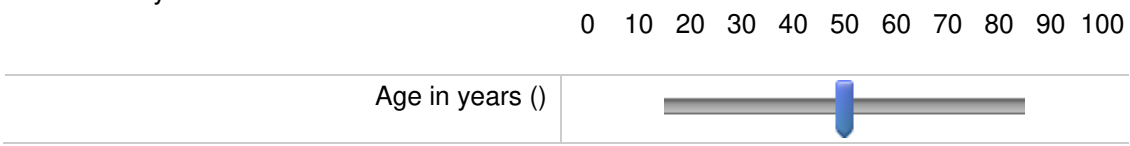
End of Block: Consent

Start of Block: Demographics

Thank you for consenting to take part in the SLEEP trial. This study will last for 8 weeks. You will have access to an online e-learning platform, and will receive four online therapy sessions. You will receive further information on how to access these in due course. For us to evaluate how well this intervention improves your sleep and wellbeing, we ask you next to complete a set of questionnaires. This will take approximately 45 minutes. Please read each question carefully before responding and feel free to take breaks where you need. If you do feel you need to take a break, please do not close the survey.
If you have any questions, please contact us at wmg-sleep@warwick.ac.uk

Page Break

How old are you?



JS

What gender do you identify as?

- Female (1)
- Male (2)
- Non-binary (3)
- Other (please specify) (4) _____
- Prefer not to specify (5)

JS

What is your ethnicity? (1 of 2)

- White... (1)
- Mixed / Multiple ethnic groups... (2)
- Asian or Asian British... (3)
- Black or Black British... (4)
- Mixed (5)
- Hispanic/Latino (6)
- Other (please specify) (7)

Page Break

Display This Question:

If What is your ethnicity? (1 of 2) = White...

What is your ethnicity? (2 of 2)

- English / Welsh / Scottish / Northern Irish / British (1)
- Irish (2)
- Gypsy or Irish Traveller (3)
- Any other White background (please describe if you wish) (4)

_____

Display This Question:

If What is your ethnicity? (1 of 2) = Mixed

What is your ethnicity? (2 of 2)

- White and Black Caribbean (1)
- White and Black African (2)
- White and Asian (3)
- Any other Mixed / Multiple ethnic background (please describe if you wish) (4)

_____

Display This Question:

If What is your ethnicity? (1 of 2) = Asian or Asian British...

What is your ethnicity? (2 of 2)

- ○ Indian (1)
- ○ Pakistani (5)
- ○ Bangladeshi (6)
- ○ Chinese (7)
- ○ Any other Asian background (please describe if you wish) (8)

_____

Display This Question:

If What is your ethnicity? (1 of 2) = Black or Black British...

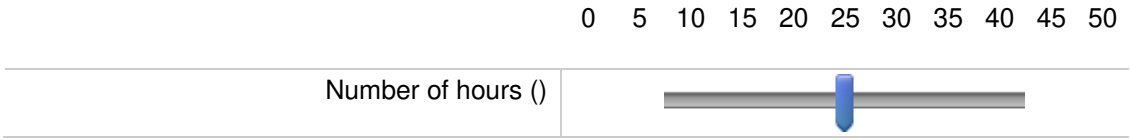
What is your ethnicity? (2 of 2)

- ○ African (1)
- ○ Caribbean (4)
- ○ Any other Black / African / Caribbean background (please describe if you wish) (5)

_____

Page Break

How many hours do you work per week?



Information about income is very important to understand. Would you please give your best guess?Please indicate the answer that includes your entire household income in (previous year) before taxes.

- ○ £10,000 to £29,999 (1)
- ○ £30,000 to £49,999 (2)
- ○ £50,000 to £69,999 (3)
- ○ £70,000 to £89,999 (4)
- ○ £90,000 to £109,999 (5)
- ○ £110,000 to £149,999 (6)
- ○ £150,000 or more (7)

JS

How would you describe your current relationship status?

- ○ Single (1)
- ○ Cohabiting (2)
- ○ Married (3)
- ○ Separated (4)
- ○ Divorced (5)
- ○ Widowed (6)
- ○ Other (please specify) (7) _____

Who do you live with?

- ○ I live by myself (1)
- ○ I live with flatmates (2)
- ○ I live with my partner (3)
- ○ I live with my parents/carers (4)
- ○ I live with other family members (6)

JS

What is your highest educational qualification?

- ○ No formal qualification (1)
- ○ Primary (2)
- ○ Secondary (e.g., GCSE, O-levels, GNVQ) (3)
- ○ Diploma (or professional qualification) (4)
- ○ Bachelor's degree (5)
- ○ Master's degree (6)
- ○ Doctorate degree (7)
- ○ Other (please specify) (8) _____

JS

In the last 8 weeks, to the best of your recollection, how much sick leave have you taken?

- ○ I have taken (1) _____
- ○ I have not taken any sick leave (2)
- ○ I would prefer not to answer this question (3)

Are you currently using any self-help resources?

This includes but is not limited to self help books, apps and websites

- ○ Yes (1)
- ○ No (2)

Since completing the screening questionnaire of this study, did you start receiving treatment from mental health services?

- ○ Yes (1)
- ○ No (2)

End of Block: Demographics

Start of Block: Contact

Page Break

As part of this study we need to request some further personal information for us to contact you during this study.

JS *

What is your phone number?

_____

What is your residential address?

_____

*

Please can you provide your postcode (Please type letters in capitals and include the space e.g CV32 7JA)

_____

End of Block: Contact

Start of Block: Availability

As part of the SLEEP intervention, you will receive four online therapy sessions with a trained therapist who will support you throughout the study. These sessions will last around 40 minutes and will be conducted online using Microsoft Teams. You will receive a link for these audio/video calls shortly. To help us organise these sessions and fit around your schedule, we would appreciate if you could answer the following questions to provide some information on your general availability.

What time and days would suit you best?

We understand that your availability may change during the study. This is to try and work around you as much as possible.

If you need to speak to someone then please contact us at: wmg-sleep@warwick.ac.uk

	AM (1)	PM (2)
Monday (1)	○	○
Tuesday (2)	○	○
Wednesday (3)	○	○
Thursday (4)	○	○
Friday (5)	○	○

End of Block: Availability

Start of Block: COVID_19

Page Break

As part of our research, we are interested in your experiences with COVID-19 and how this has impacted your life. Please read each question carefully and select the most appropriate response for you.

How worried are you about contracting COVID-19?

- ○ Not worried at all (1)
- ○ Slightly worried (2)
- ○ Moderately worried (3)
- ○ Very worried (4)
- ○ Extremely worried (5)

In which category are you considered to be in regard to COVID-19 according to the NHS and UK Government guidelines of England?

- ○ Clinically extremely vulnerable (1)
- ○ Clinically vulnerable (2)
- ○ Low risk (3)

Since the start of the pandemic, have you tested positive for COVID-19?

- ○ Yes (1)
- ○ No (2)

Display This Question:

If Since the start of the pandemic, have you tested positive for COVID-19? = Yes

Have you required hospitalised treatment for COVID-19?

- Yes (1)
- No (2)

Display This Question:

If Since the start of the pandemic, have you tested positive for COVID-19? = No

Do you suspect that you may have had COVID-19 due to presenting with symptoms? (temperature/fever, new persistent cough, loss of smell & taste)

- Definitely (1)
- Probably (2)
- Unsure (3)
- No (4)

Display This Question:

If Since the start of the pandemic, have you tested positive for COVID-19? = Yes

For some people, coronavirus can cause symptoms that last weeks or months after the infection has gone. This is sometimes called post-COVID-19 syndrome or "long COVID". Have you

experienced any of the following long COVID symptoms 12 weeks after initial infection? (Check all that apply)

- ☐ No (I feel fully recovered) (1)
- ☐ Extreme tiredness (fatigue) (2)
- ☐ Shortness of breath (3)
- ☐ Chest pain or tightness (4)
- ☐ Problems with memory and concentration ("brain fog") (5)
- ☐ Difficulty sleeping (insomnia) (6)
- ☐ Heart palpitations (7)
- ☐ Dizziness (8)
- ☐ Pins and needles (9)
- ☐ Joint pain (10)
- ☐ Depression and anxiety (11)
- ☐ Tinnitus, earaches (12)
- ☐ Feeling sick, diarrhoea, stomach aches, loss of appetite (13)
- ☐ A high temperature, cough, headaches, sore throat, changes to sense of smell or taste (14)
- ☐ Rashes (15)

Since the start of the pandemic, have any people you know tested positive for COVID-19? (Choose all that apply)

- ☐ Immediate family members (1)
- ☐ Extended family members (2)
- ☐ Neighbours (3)
- ☐ Friends (4)
- ☐ Colleagues (5)
- ☐ No one I know has tested positive (6)

Since the start of the pandemic, have you been asked to stop working temporarily under the government “furlough” scheme?

- ○ No (1)
- ○ Yes, I am currently on furlough (2)
- ○ Yes, I will soon be on furlough (3)
- ○ Yes, but have since returned to work (full time or part time) (4)

As a result of colleagues being placed on furlough, do you think your workload will/has:

- ○ Increase (d) (1)
- ○ Decrease (d) (2)
- ○ Stay (ed) the same (3)
- ○ Can't say yet (4)
- ○ N/A, as no one I work with has been furloughed (5)
- ○ N/A, as I am currently been furloughed (6)

Page Break

In light of the COVID-19 pandemic, what changes had been made within your organisation that have impacted you? (Tick all that apply)

- ☐ Hours of work (1)
- ☐ Pay cut (2)
- ☐ Working remotely (3)
- ☐ Not applicable (4)

Display This Question:

If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

Have you experienced any ongoing challenges in working remotely? (Tick all that apply)

- ☐ Technical difficulties (e.g. with internet, computers, access to workplace data storage) (1)
- ☐ Practical difficulties (no separate/private area from which to work) (2)
- ☐ Balancing work with caregiving/parenting responsibilities (3)
- ☐ Motivational difficulties (4)
- ☐ Other (please specify) (5)
- ☐ No challenges experienced (6)

Display This Question:

If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

How comfortable do you feel returning back to work and having the appropriate support from your organisation? (e.g. Covid-19 risk assessment)?

- Not comfortable at all (1)
- Slightly comfortable (2)
- Moderately comfortable (3)
- Very comfortable (4)
- Extremely comfortable (5)

Display This Question:

If In light of the COVID-19 pandemic, what changes had been made within your organisation that have... = Working remotely

How have these issues affected your ability to work?

- (Negative impact) -3 (1)
- -2 (2)
- -1 (3)
- 0 (4)
- 1 (5)
- 2 (6)
- (Positive Impact) 3 (7)

Have you experienced any of the following due to COVID-19? (Tick all that apply)
We understand this question may trigger distress and undesirable memories or thoughts. If so, please speak to a friend or family member or seek professional support (e.g. GP).

- ☐ Lost your job/unable to earn money (1)
- ☐ Another bill payer in your household lost their job or is/was unable to earn money (2)
- ☐ Unable to pay bills (3)
- ☐ Had difficulties accessing sufficient food (4)
- ☐ Evicted / lost accommodation (5)
- ☐ Had difficulties accessing required medication (6)
- ☐ Somebody close to you in hospital (7)
- ☐ Somebody close to you died (we are very sorry for your loss. We realise answering this question might make you uncomfortable or trigger unsettling feelings. If you feel you need to speak to someone or require support, please refer to this NHS resource) (8)
- ☐ Difficulties with family or social relationships (9)
- ☐ If you're a parent/carer, concerns about your child's/children's well-being and/or education (10)
- ☐ Having to change or delay major life plans or events (11)
- ☐ Not applicable (12)

How comfortable do you feel raising COVID-19 related issues with your organisation (e.g. line manager, human resources)?

- Not comfortable at all (1)
- Slightly comfortable (2)
- Moderately comfortable (3)
- Very comfortable (4)
- Extremely comfortable (5)

Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a research trial)

- Yes (1)
- No (2)

Display This Question:

If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

Have you experienced any of the following symptoms as a result of having the vaccine? (Tick all that apply)

- ☐ Headaches (1)
- ☐ Feeling tired (2)
- ☐ Feeling achy (3)
- ☐ Soreness, redness and swelling at the site of the vaccination (4)
- ☐ Mild or high fever (5)
- ☐ Feeling or being sick (6)
- ☐ Allergic reaction (7)
- ☐ I did not have any symptoms (8)

Display This Question:

If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

*

When did you receive your first dose? (please enter date as DD/MM/YYY)

_____

Display This Question:

If Have you had at least one dose of a COVID-19 vaccine (as part of the national roll-out or a resea... = Yes

Have you received a second dose of a COVID-19 vaccine?

- ○ Yes (1)
- ○ No (2)

Display This Question:

If Have you received a second dose of a COVID-19 vaccine? = Yes

*

When did you receive your second dose? (please enter date as DD/MM/YYY)

_____

What would you say is your one biggest concern or problem encountered, since the start of the pandemic?

_____

_____

_____

_____

_____

Page Break

Did you receive any help overcoming the concern/problem outlined above and if yes, what has been helpful or unhelpful? If no, what kind of help do you think you need right now?

_____

_____

_____

_____

_____

End of Block: COVID_19

Start of Block: WPAI_GH

The following questions ask about the effect of your health problems on your ability to work and perform regular activities. By health problems we mean any physical or emotional problem or symptom. Please fill in the blanks or indicate your response.

Are you currently employed (working for pay)?

- ○ Yes (1)
- ○ No (2)

Skip To: Q6.7 If Are you currently employed (working for pay)? = No

The next questions are about the **<u>past seven days</u>**, not including today.

*

During the past seven days, how many hours did you miss from work because of your health problems? Include hours you missed on sick days, times you went in late, left early, etc., because of your health problems. *Do not include time you missed to participate in this study.*

_____

*

During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?

_____

*

During the past seven days, how many hours did you actually work?

_____

During the past seven days, how much did your health problems affect your productivity while you were working? *Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If health problems affected your work only a little, choose a low number. Choose a high number if health problems affected your work a great deal.* Consider only how much health problems affected productivity while you were working.

No effect on my work

Completely prevented me from working

0 1 2 3 4 5 6 7 8 9 10

1 ()

During the past seven days, how much did your health problems affect your ability to do your regular daily activities, other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If health problems affected your activities only a little, choose a low number. Choose a high number if health problems affected your activities a great deal.

Consider only how much health problems affected your ability to do your regular daily activities, other than work at a job.

	No effect on my daily activities 0 1 2 3 4 5 6 7 8 9 10 Completely prevented me from doing my daily activities
1 ()	

End of Block: WPAI_GH

Start of Block: IJSS

As part of our research, we are interested in the amount of job satisfaction with respect to your current role. This questionnaire is a valid and reliable measure of job satisfaction. Please read each statement carefully and tell us how much you agree with each statement.

There are no incorrect answers and none of the information you provide will be shared with your employer.

I feel good about this job

- ○ Strongly agree (1)
- ○ Somewhat agree (2)
- ○ Somewhat disagree (3)
- ○ Strongly disagree (4)

This job is worthwhile

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

The working conditions are good

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I want to quit this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

This job is boring

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I am happy with the amount this job pays

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

The vacation time and other benefits on this job are okay

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I need more money than this job pays

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

This job does not provide the medical coverage I need

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)
- Not Applicable (5)

I have a fairly good chance for promotion in this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

This is a dead-end job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I feel that there is a good chance of my losing this job in the future

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My supervisor is fair

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My supervisor is hard to please

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My supervisor praises me when I do my job well

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My supervisor is difficult to get along with

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My supervisor recognizes my efforts

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My coworkers are easy to get along with

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My coworkers are lazy

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My coworkers are unpleasant

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My coworkers don't like me

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My coworkers help me to like this job more

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I have a coworker I can rely on

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I have a coworker I consider a friend

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I look forward to coming to work

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I often feel tense on the job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I don't know what's expected of me on this job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I feel physically worn out at the end of the day

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

Working makes me feel like I'm needed

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

My job keeps me busy

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I get to do a lot of different things on my job

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

I am satisfied with my schedule

- Strongly agree (1)
- Somewhat agree (2)
- Somewhat disagree (3)
- Strongly disagree (4)

End of Block: IJSS

Start of Block: WEMWBS

Page Break

Below are some statements about feelings and thoughts.
Please select the option that best describes your experience of each over the last 2 weeks

I've been feeling optimistic about the future

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been feeling useful

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been feeling relaxed

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been feeling interested in other people

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've had energy to spare

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been dealing with problems well

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been thinking clearly

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been feeling good about myself

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been feeling close to other people

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been feeling confident

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been able to make up my own mind about things

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been feeling loved

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been interested in new things

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

I've been feeling cheerful

- None of the time (1)
- Rarely (2)
- Some of the time (3)
- Often (4)
- All of the time (5)

End of Block: WEMWBS

Start of Block: Medication_checklist

We would like to know what medication (prescriptions and/or over the counter) you use, what dose and for what condition. Medications are tablets or capsules, but could also be (eye) drops, sprays, creams, drinks, inhaler puffs, suppositories etc. Prescription medications are ones that a

doctor prescribes. Over the counter medication are ones that you can purchase yourself without a prescription such as ibuprofen, vitamins, herbal remedies etc.

	Name of medication (1)	Dosage (mg/g/ml) (2)	How often do you take this medication (per day / week/ as needed) (3)	How much do you take per time (e.g. 2 tablets) (4)	What is this medication for? (5)	How long have you been using it for? (6)	Additional comments (7)
1. (1)							
2. (2)							
3 (6)							
4 (7)							
5 (8)							
6 (9)							
7 (10)							

End of Block: Medication_checklist

Start of Block: ISI

Page Break

For each question, please select the option that best describes your answer. Please rate the current (i.e. last 2 weeks) severity of your sleep problem(s).

Difficulty falling asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Difficulty staying asleep

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

Problems waking up too early in the morning

- None (1)
- Mild (2)
- Moderate (3)
- Severe (4)
- Very Severe (5)

How SATISFIED/DISSATISFIED are you with your current sleep pattern?

- Very Satisfied (1)
- Satisfied (2)
- Moderately Satisfied (3)
- Dissatisfied (4)
- Very Dissatisfied (5)

How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

- Not at all Noticeable (1)
- A little (2)
- Somewhat (3)
- Much (4)
- Very Much (5)

To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.)?

- ○ Not at all Interfering (1)
- ○ A little (2)
- ○ Somewhat (3)
- ○ Much (4)
- ○ Very Much Interfering (5)

How WORRIED/DISTRESSED are you about your current sleep problem?

- ○ Not at all Worried (1)
- ○ A little (2)
- ○ Somewhat (3)
- ○ Much (4)
- ○ Very Much Worried (5)

Copyright notice (C) Morin, C.M. (1993, 1996, 2000, 2006)

For any information on the use of the Insomnia Severity Index, please contact Mapi Research Trust, Lyon, France. Internet: https://eprovide.mapi-trust.org

End of Block: ISI

Start of Block: GAD7

Page Break

Over the next series of questions we will assess your mood and sleep. Please answer the questions as accurately as possible and remember there are no correct answers.

Over the last 2 weeks, how often have you been bothered by any of the following problems?

Feeling nervous, anxious or on edge?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Not being able to stop or control worrying?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Worrying too much about different things?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Trouble relaxing?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Being so restless that it is hard to sit still?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Becoming easily annoyed or irritable?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Feeling afraid as if something awful might happen?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

End of Block: GAD7

Start of Block: PHQ9

Page Break

Over the last two weeks, how often have you been bothered by any of the following problems?

Little interest or pleasure in doing things?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Feeling down, depressed, or hopeless?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Trouble falling or staying asleep, or sleeping too much?

- Not at all (1)
- Several days (2)
- More than half the days (3)
- Nearly everyday (4)

Feeling tired or having little energy?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Poor appetite or overeating?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Feeling bad about yourself - or that you are a failure or have let yourself or your family down?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Trouble concentrating on things, such as reading the newspaper or watching television?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

Thoughts that you would be better off dead, or of hurting yourself in some way?

- ○ Not at all (1)
- ○ Several days (2)
- ○ More than half the days (3)
- ○ Nearly everyday (4)

End of Block: PHQ9

Start of Block: disclaimer

The responses you provided indicate that you might be having difficulties with your mental health. This year has been really tough for many of us, especially when we are unable to do

the usual things that bring us joy like seeing friends and family. We strongly advise you to contact your GP or self-refer yourself to an NHS psychological therapies service (IAPT). To get in touch with IAPT please follow this link: https://www.nhs.uk/service-search/find-a-psychological-therapies-service/. The intervention programme should not be used as an alternative for seeking diagnosis and treatment from a professional. While you wait for an appointment, you can access expert advice and practical tips on the Every Mind Matters website. We have in addition put together resources below which you may find useful to look after your mental health. The Mind charity has produced information on how to take care of your wellbeing during the pandemic including advice for coping in the winter which you might find helpful. Mind Infoline: Call: 0300 123 3393
Email: info@mind.org.uk
Website: https://www.mind.org.uk/workplace/ Lines are open 9am to 6pm, Monday to Friday (except for bank holidays). Samaritans
Call: 116 123
Email: jo@samaritans.org Website: https://www.samaritans.org/
For a listening ear or just someone to talk to the Samaritans are open 24 hours a day. If you need mental health information and the above helplines are closed then please visit Mind's Mental health A-Z resource or contact NHS 111. NHS The NHS also has their own set of resources, this includes a website which provides access to other sources of information: https://www.england.nhs.uk/mental-health/resources/ If you have any questions or would like more information, please contact the research team at wmg-sleep@warwick.ac.uk Please confirm that you understand these requests. This does not impact your ability to take part in these studies in any way.

☐ I understand the request to contact my GP (4)

☐ I understand the request to contact IAPT (5)

End of Block: disclaimer

Participant Information Leaflet- Employer route

Study Title:	**SLEEP:** Supporting empLoyEes with insomnia and Emotion regulation Problems
Investigator(s):	Krishane Patel (University of Warwick), Talar Moukhtarian (University of Warwick), Carla Toro (University of Warwick), Laura Chandler (University of Warwick), Nicole Tang (University of Warwick), Feroz Jadhakhan (University of Birmingham), Arianna Prudenzi (University of Birmingham), Steven Marwaha (University of Birmingham), Lukasz Walasek (University of Warwick), Caroline Meyer (University of Warwick)

Introduction
You are invited to take part in a research study. Before you decide if you want to take part, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information (wmg-mhpp@warwick.ac.uk). Take the time to decide whether or not you wish to take part.

Who is organising and funding the study?
This project is funded by the Midlands Engine partnership which brings together public sector partners and businesses to generate added value for the whole of the Midlands, its communities and the wider UK. The design, implementation and management of this study is being conducted by the University of Warwick and the University of Birmingham. This study is sponsored by the University of Warwick.

What is the study about?
The **SLEEP** study aims to test the efficacy of a hybrid digital intervention designed to improve employee wellbeing, targeting sleep problems to stay engaged and productive in work. Mental health problems affect one in six workers each year and are the leading cause of sickness absence, where stress, anxiety and depression are responsible for approximately half of the working days lost (Deloitte, 2020). The study will assess the efficacy of a digital hybrid intervention, that is based on cognitive behavioural therapy (CBT) models for insomnia and emotion regulation skills to improve problems with insomnia and stress. CBT is a type of talking treatment, that combines cognitive therapy (examining the things you think) and behaviour therapy (examining the things you do) and focuses on how your thoughts, beliefs and attitudes affect your feelings and behaviour, and teaches you skills for dealing with different problems. For further information on CBT, you can refer to the NHS[1] and MIND[2] websites.

Why have I been chosen for this trial?
You registered your interest to take part in one of the pilot trials and completed screening questionnaires to check your eligibility against the study inclusion criteria. Based on the responses you provided, we are inviting you to take part in the **SLEEP** intervention of the Mental Health and Productivity Pilot (https://mhpp.me/).

What would taking part involve?
Participation in this study is voluntary and you can withdraw your involvement at any time, and this would not affect you or your employment. If you agree to take part in the **SLEEP** trial, please follow the link provided at the end of this form to consent to take part in the trial and complete the baseline measures of the study, which consists of a set of questionnaires on well-being, workplace productivity, job satisfaction, and health-related quality of life. In addition, you will be asked to provide some demographic information (i.e. employer name and address, gender identity, age, ethnicity, working hours, income band, education level, relationship status, number in household, number of absent days from work, what medications- prescription and over-the-counter you use) to understand the characteristics of our target sample and use that information to guide future larger-scale studies. At 8 weeks, you will be asked to complete the same questionnaire measures again. All questionnaire measures will be self-completed on an online platform called Qualtrics accessed through links sent to you by email.

You will then be randomly placed into either the **SLEEP** intervention group or a waitlist control group. Those in the intervention group will start with a 1-week sleep tracking facilitated by a sleep tracker provided by us. The sleep tracker is a compact and lightweight activity monitoring device that you need

[1] https://www.nhs.uk/conditions/cognitive-behavioural-therapy-cbt/
[2] https://www.mind.org.uk/information-support/drugs-and-treatments/cognitive-behavioural-therapy-cbt/about-cbt/

to wear on your wrist like a watch for the duration of that week, which tracks your sleep and physical movement. We will be sending out the sleep trackers along with a detailed instruction manual and a free-post envelop for you to return them after the tracking week. We will use data from the sleep tracker to assess your sleep quality. Following the sleep tracking week, you will be enrolled in the 6-week digital intervention consisting of an hour of weekly commitment, in addition to four 45-minute online sessions with trained specialists (see figure 2 below for interventions schedule). Before starting the intervention, you will be asked to note your preferences (e.g. day, am/pm) for the therapist sessions. The research team will do its best to accommodate you as much as possible. You will also be asked to fill in a paper-pencil sleep diary via a booklet sent by the research team. Data from the sleep diary will be used during the sessions with the therapists to understand your sleep patterns. You will then be sent another sleep tracker to complete a final 1-week of sleep tracking, and asked to return it, along with your sleep diary booklet in the provided free-post envelope.

Those in the waitlist control group will start with a 1-week sleep tracking facilitated by a sleep tracker provided by us. Following the sleep tracking week, you will be asked to continue life as usual for 6-week. You will then be asked to complete a final 1-week of sleep tracking. Subsequently, you will be offered the 6-week digital intervention as explained above, finished with another 1-week of sleep tracking. You will be provided with access to the online platform as well the therapy sessions.

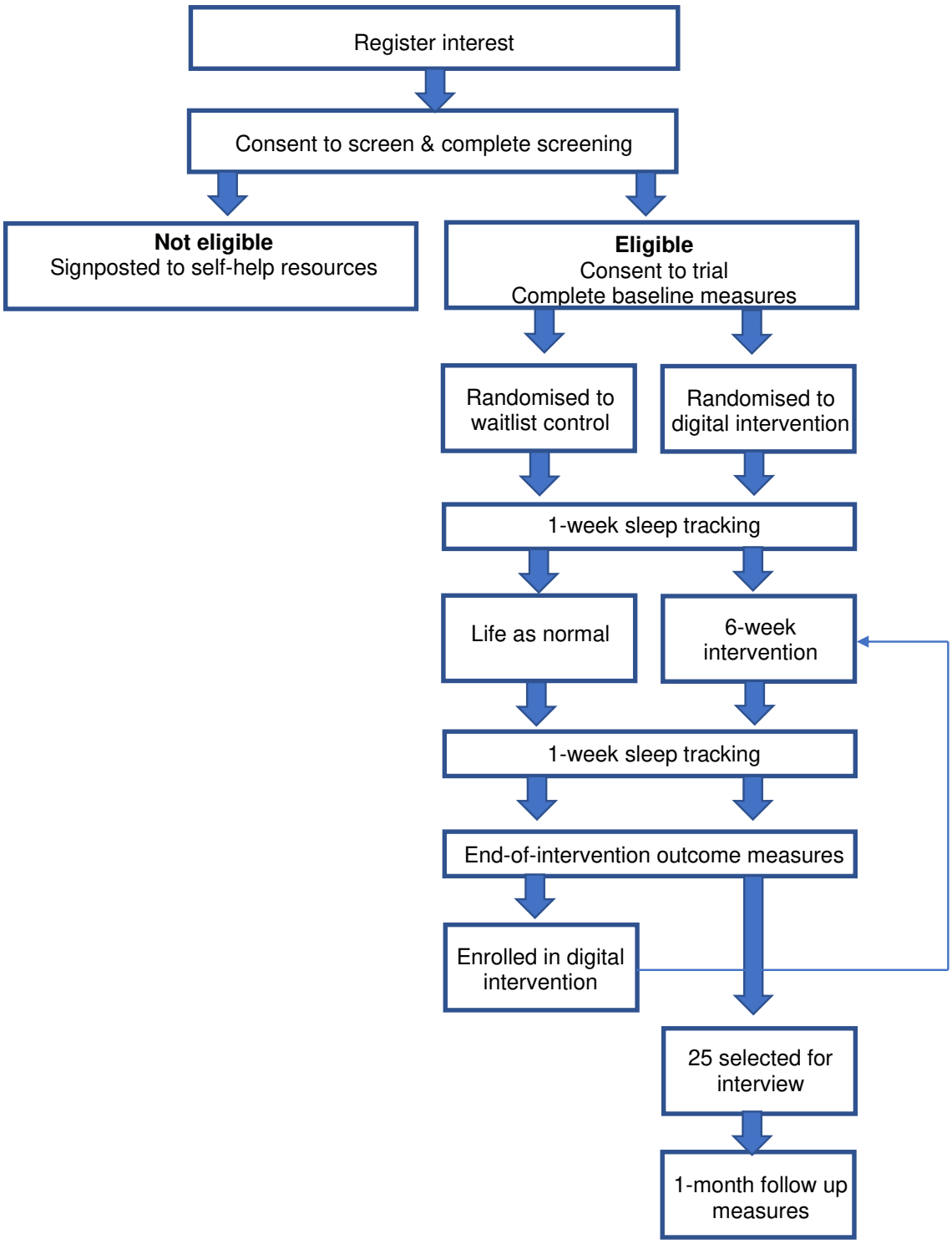
At the end of the digital intervention, we may ask you to take part in a qualitative feedback interview (if you consent to be interviewed) aiming to explore the effectiveness, acceptability, barriers, and facilitators of the intervention to inform future trials for subsequent evaluations. Interviews will be conducted online on Microsoft Teams or via telephone (participant's choice) by members of the research team, and audio-recorded using University of Warwick managed digital recording devices and then subsequently transcribed a third-party University approved transcription company. A confidentiality agreement will be in place for the transcription process to ensure confidentiality and anonymity.

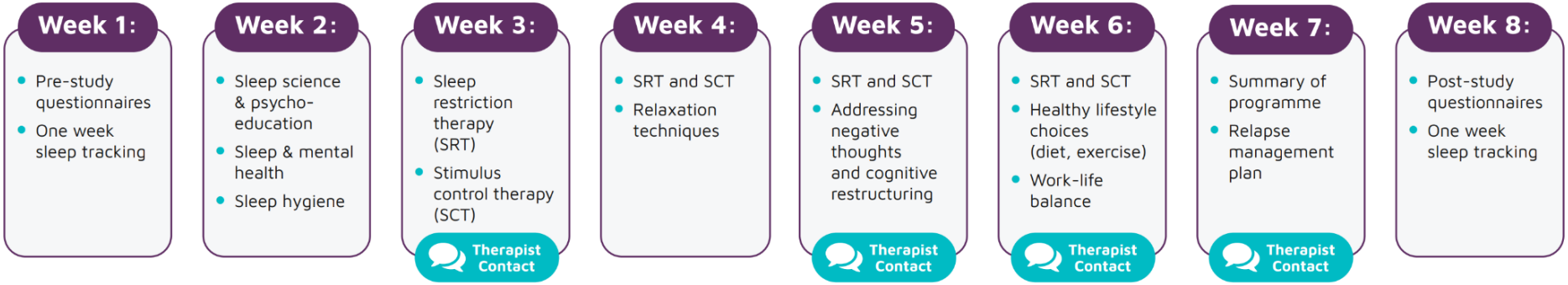
You will be contacted again after one month to complete the same questionnaire measures you completed at the start of the trial and at 8 weeks.

Overall, the study will last for 3 months if you are placed initially in the intervention group. If you are initially placed in the waitlist control group, you will be offered the intervention after an 8-week delay and be in the study for 5 months. For practical reasons, we will be running the trial in 3 separate cohorts, which participants will randomly be allocated to. This means eligible participants enrolled in the **SLEEP** study may have to wait for a short period (up to 13 weeks from consent to trial) as we pick a time slot for your start. For more information please see the study flow chart on the next page.

You will continue to have access to the platform until January 2022.

The digital intervention will include guidance through CBT for insomnia and emotional regulation skills training designed to alleviate stress.


Register interest
Consent to screen & complete screening
Not eligible
Signposted to self-help resources
Eligible
Consent to trial
Complete baseline measures
Randomised to waitlist control
Randomised to digital intervention
1-week sleep tracking
Life as normal
6-week intervention
1-week sleep tracking
End-of-intervention outcome measures
Enrolled in digital intervention
25 selected for interview
1-month follow up measures


Week 1:
Pre-study questionnaires
One week sleep tracking
Week 2:
Sleep science & psycho-education
Sleep & mental health
Sleep hygiene
Week 3:
Sleep restriction therapy (SRT)
Stimulus control therapy (SCT)
Therapist Contact
Week 4:
SRT and SCT
Relaxation techniques
Week 5:
SRT and SCT
Addressing negative thoughts and cognitive restructuring
Therapist Contact
Week 6:
SRT and SCT
Healthy lifestyle choices (diet, exercise)
Work-life balance
Therapist Contact
Week 7:
Summary of programme
Relapse management plan
Therapist Contact
Week 8:
Post-study questionnaires
One week sleep tracking

Do I have to take part?
Participation in this study is completely voluntary, and choosing not to take part will not affect you or your employment in any way. You can also choose to withdraw your participation at any time, without giving a reason by contacting the research team at wmg-mhpp@warwick.ac.uk. Further details about withdrawing from the study are provided at the end of this page.

What are the possible benefits of taking part in this study?
In this trial, we expect our digital intervention to reduce stress, improve sleep, and overall wellbeing to maintain and improve engagement and productivity at work. This will help businesses to get back on their feet in the current COVID-19 climate, helping businesses in the Midlands become more productive.

What are the possible disadvantages, side effects or risks, of taking part in this study?
We do not anticipate any major disadvantages, side effects or risks in taking part. The **SLEEP** intervention could involve "sleep restriction therapy" and/or sleep re-scheduling therapy, which may be associated with minor side effects such as daytime sleepiness. You will be fully instructed as to the rationale and potential side effects of the treatment at the outset. In addition, you will be advised to not drive or operate machinery if experiencing excessive daytime sleepiness.

Some participants will be randomly placed on the waitlist control group, in which case, the intervention will still be provided to them, but after a delay. You will be offered different channels to communicate with our research team 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.

The process evaluation interviews for **SLEEP**, which aim to explore the effectiveness, acceptability, barriers, and facilitators of the intervention might cause distress to some individuals. Should that occur, we will offer to pause and/or stop the interview and offer you appropriate support.

Due to the minimal direct contact the research team will have with participants, we advise and encourage you to report any event that you think may or may not be related to your being part of the study to the research team by email (wmg-mhpp@warwick.ac.uk) or to your therapist during the online sessions.

Expenses and payments
For each of the three assessment waves (i.e. upon completion of baseline questionnaires and return of sleep trackers with prepaid envelops, after intervention at 8 weeks and return of sleep trackers with prepaid envelops, and at 1-month follow-up), you will be provided with a £10 Amazon voucher as a gesture of good-will for your time and commitment to the study. Of those who have completed the intervention and have agreed to take part in the qualitative interview, we will randomly select 25 participants- those who complete the interview will also receive an additional £10 amazon voucher.

Will my taking part be kept confidential?
Your data will be kept confidential throughout the study. Research data will be de-identified as quickly as possible after data collection. Your study data will instead be associated with a unique participant ID number to complete all assessments and interventions. The key to identification will be stored separately and securely to the research data to safeguard your identity and access will be limited to the lead researcher (CT) and the project manager (CK), neither of whom will have any access to the study data. We are collecting your phone number and email address to contact you during the course of the study (e.g. sessions with therapist) and your postal address to send out the sleep tracker devices. Therapists will be taking notes during the sessions to refer to from week-to-week; these will be labelled with your unique study ID without any personal data that could reveal your identity such as name. Once your therapist sessions have ended, these notes will be securely destroyed. At the end of the intervention, you may be invited to take part in qualitative interviews (if you consent). The interviews will be audio recorded using University of Warwick manged digital recording devices for transcriptions, from which direct quotes may be included in the publication, however, these will not reveal any information that could identify enrolled employees (e.g. name). Personally identifiable data (e.g. name, email, postal address) collected in this study will be stored in password protected folders, kept separate from study data; all of which will be stored securely on the University of Warwick servers.

Your participation and individual data collected from the study will not be shared with your employer, nor are you under obligation to report your participation to your employer. It will also not be possible to identify you or infer your employment within an organisation from publications stemming from this study. Your employer has agreed to provide an allowing environment to employees wanting to take part in the trials. This may take the form of completing the trial "homework" during normal working hours, or

requesting computer access from your employer (subject to availability). We would like you to note that any resource request may identify you and therefore renders your participation not to be fully anonymous. Nevertheless, your employer has agreed that your participation will not affect you or your employment.

Participating businesses will only receive a summary report which will not include any identifiable information about enrolled employees. Additionally, no identifiable information (e.g., name) will be used for analysis or in publications emerging from this study.

What will happen to the data collected about me?
We will be using information from you in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation.

Data from the activity and sleep trackers (MotionWatch) will be stored locally on each device. Once you send the device back to the research team, your data will be deleted from the device immediately after being transferred to a password protected folder on the University of Warwick servers.

Data from the printed sleep diary booklet will be entered in a password protected excel file on the University of Warwick servers, and the physical booklets will be shredded immediately after.

Therapists' notes from the four sessions will be stored securely on the University of Warwick OneDrive, and only shared between therapists who are covering sessions for your main therapist. These notes will be securely destroyed after all four therapist sessions have ended.

We will examine individual usage of the digital intervention platform, this will include the number of logins, the frequency with which you use hyperlinks, how often you download any resources, submit assignments and any other additional requirements. The pseudo-anonymous intervention adherence data will be downloaded from the platform and transferred to a password protected folder on the University of Warwick servers.

The process evaluation interviews (conducted on a selected 25 participants only) will be done through a telephone or online through Microsoft Teams (participant's choice) and will be audio recorded using University of Warwick managed digital recording devices. The audio data will be transcribed then immediately deleted. The transcriptions will be kept in a password protected folder, with all personal identifiable information removed and pseudonyms used to protect participants' identity.

Study and personal data: Questionnaire data will be deleted from the Qualtrics platform, five days after being transferred to the University of Warwick servers. We will also delete all personal data from the University of Warwick servers immediately after the trial is completed (anticipated date: 12/2021), with the exception of consent forms, and contact details of any participants who consent to be contacted for future related research. The pseudo-anonymised study data will be deleted after 10 years from the University of Warwick servers.

Study data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

The anonymous data may be shared with the University of Birmingham for analysis purposes. Researchers from the University of Birmingham may conduct the process evaluations. For this process we will share your identifiable contact data, however, this will be minimised to ensure that only the data required to perform the process evaluations are shared and no additional data. Data sharing agreements and confidentiality clauses will be in place to ensure that you are treated with anonymity and confidentiality.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here: https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?
Participation is entirely voluntary; you have the right to withdraw at any time without giving a reason. If you wish to withdraw you will need to email the research team wmg-mhpp@warwick.ac.uk stating your intention to withdraw. In this event we will remove your study data and all identifiable data from the separate dataset.

What will happen to the results of the study?
The data collected will be analysed by researchers at the University of Warwick. The results are expected to be published in peer reviewed scientific journals and reported at national and international research meetings. Additionally, summary reports will be shared with all participating employers and our funders, the Midlands Engine. It will not be possible to identify you personally in these publications and reports.

Who has reviewed the study?
This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC). Ref: BSREC 45/20-21

Who should I contact if I want further information?
For more information contact the research team's Dr Krishane Patel or Dr Talar Moukhtarian at wmg-mhpp@warwick.ac.uk.

Who should I contact if I wish to make a complaint?
Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking the time to read this Participant Information Leaflet.

Participant Information Leaflet- Direct route

Study Title:	**SLEEP:** Supporting empLoyEes with insomnia and Emotion regulation Problems
Investigator(s):	Krishane Patel (University of Warwick), Talar Moukhtarian (University of Warwick), Carla Toro (University of Warwick), Laura Chandler (University of Warwick), Nicole Tang (University of Warwick), Feroz Jadhakhan (University of Birmingham), Arianna Prudenzi (University of Birmingham), Steven Marwaha (University of Birmingham), Lukasz Walasek (University of Warwick), Caroline Meyer (University of Warwick)

Introduction
You are invited to take part in a research study. Before you decide if you want to take part, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Please ask us if there is anything that is not clear or if you would like more information (wmg-mhpp@warwick.ac.uk). Take the time to decide whether or not you wish to take part.

Who is organising and funding the study?
This project is funded by the Midlands Engine partnership which brings together public sector partners and businesses to generate added value for the whole of the Midlands, its communities and the wider UK. The design, implementation and management of this study is being conducted by the University of Warwick and the University of Birmingham. This study is sponsored by the University of Warwick.

What is the study about?
The **SLEEP** study aims to test the efficacy of a hybrid digital intervention designed to improve employee wellbeing, targeting sleep problems to stay engaged and productive in work. Mental health problems affect one in six workers each year and are the leading cause of sickness absence, where stress, anxiety and depression are responsible for approximately half of the working days lost (Deloitte, 2020). The study will assess the efficacy of a digital hybrid intervention, that is based on cognitive behavioural therapy (CBT) models for insomnia and emotion regulation skills to improve problems with insomnia and stress. CBT is a type of talking treatment, that combines cognitive therapy (examining the things you think) and behaviour therapy (examining the things you do) and focuses on how your thoughts, beliefs and attitudes affect your feelings and behaviour, and teaches you skills for dealing with different problems. For further information on CBT, you can refer to the NHS[3] and MIND[4] websites.

Why have I been chosen for this trial?
You registered your interest to take part in one of the pilot trials and completed screening questionnaires to check your eligibility against the study inclusion criteria. Based on the responses you provided, we are inviting you to take part in the **SLEEP** intervention of the Mental Health and Productivity Pilot (https://mhpp.me/).

What would taking part involve?
Participation in this study is voluntary and you can withdraw your involvement at any time. If you agree to take part in the **SLEEP** trial, please follow the link provided at the end of this form to consent to take part in the trial and complete the baseline measures of the study, which consists of a set of questionnaires on well-being, workplace productivity, job satisfaction, and health-related quality of life. In addition, you will be asked to provide some demographic information (i.e. workplace address, gender identity, age, ethnicity, working hours, income band, education level, relationship status, number in household, number of absent days from work, what medications- prescription and over-the-counter you use) to understand the characteristics of our target sample and use that information to guide future larger-scale studies. At 8 weeks, you will be asked to complete the same questionnaire measures again. All questionnaire measures will be self-completed on an online platform called Qualtrics accessed through links sent to you by email.

[3] https://www.nhs.uk/conditions/cognitive-behavioural-therapy-cbt/
[4] https://www.mind.org.uk/information-support/drugs-and-treatments/cognitive-behavioural-therapy-cbt/about-cbt/

You will then be randomly placed into either the **SLEEP** intervention group or a waitlist control group. Those in the intervention group will start with a 1-week sleep tracking facilitated by a sleep tracker provided by us. The sleep tracker is a compact and lightweight activity monitoring device that you need to wear on your wrist like a watch for the duration of that week, which tracks your sleep and physical movement. We will be sending out the sleep trackers along with a detailed instruction manual and a free-post envelop for you to return them after the tracking week. We will use data from the sleep tracker to assess your sleep quality. Following the sleep tracking week, you will be enrolled in the 6-week digital intervention consisting of an hour of weekly commitment, in addition to four 45-minute online sessions with trained specialists (see figure 2 below for interventions schedule). Before starting the intervention, you will be asked to note your preferences (e.g. day, am/pm) for the therapist sessions. The research team will do its best to accommodate you as much as possible. You will also be asked to fill in a paper-pencil sleep diary via a booklet sent by the research team. Data from the sleep diary will be used during the sessions with the therapists to understand your sleep patterns. You will then be sent another sleep tracker to complete a final 1-week of sleep tracking, and asked to return it, along with your sleep diary booklet in the provided free-post envelope.

Those in the waitlist control group will start with a 1-week sleep tracking facilitated by a sleep tracker provided by us. Following the sleep tracking week, you will be asked to continue life as usual for 6-week. You will then be asked to complete a final 1-week of sleep tracking. Subsequently, you will be offered the 6-week digital intervention as explained above, finished with another 1-week of sleep tracking. You will be provided with access to the online platform as well the therapy sessions.

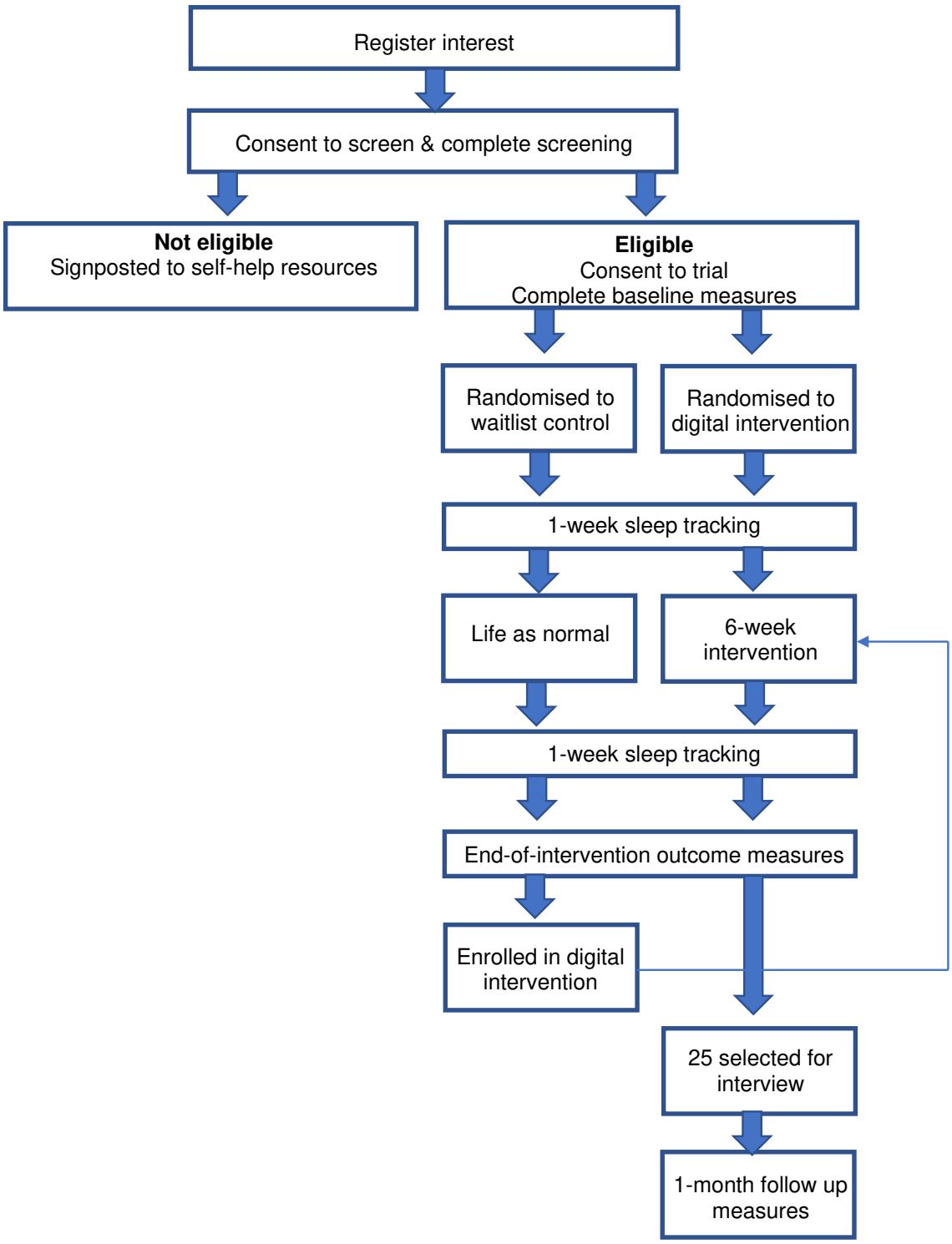
At the end of the digital intervention, we may ask you to take part in a qualitative feedback interview (if you consent to be interviewed) aiming to explore the effectiveness, acceptability, barriers, and facilitators of the intervention to inform future trials for subsequent evaluations. Interviews will be conducted online on Microsoft Teams or via telephone (participant's choice) by members of the research team, and audio-recorded using University of Warwick managed digital recording devices and then subsequently transcribed by a third-party University approved transcription company. A confidentiality agreement will be in place for the transcription process to ensure confidentiality and anonymity.

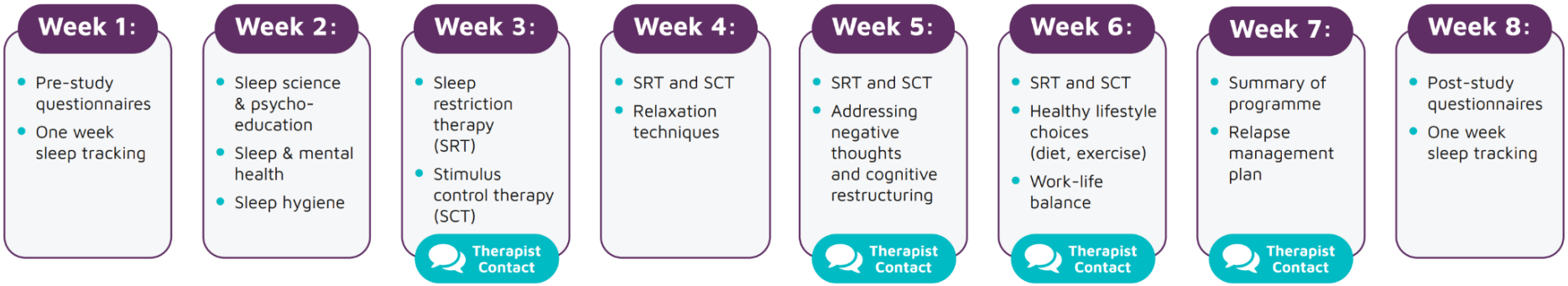
You will be contacted again after one month to complete the same questionnaire measures you completed at the start of the trial and at 8 weeks.

Overall, the study will last for 3 months if you are placed initially in the intervention group. If you are initially placed in the waitlist control group, you will be offered the intervention after an 8-week delay, and be in the study for 5 months. For practical reasons, we will be running the trial in 3 separate cohorts, which participants will randomly be allocated to. This means eligible participants enrolled in the **SLEEP** study may have to wait for a short period (up to 13 weeks from consent to trial) as we pick a time slot for your start. For more information please see the study flow chart on the next page.

You will continue to have access to the platform until January 2022.

The digital intervention will include guidance through CBT for insomnia and emotional regulation skills training designed to alleviate stress.


Register interest
Consent to screen & complete screening
Not eligible
Signposted to self-help resources
Eligible
Consent to trial
Complete baseline measures
Randomised to waitlist control
Randomised to digital intervention
1-week sleep tracking
Life as normal
6-week intervention
1-week sleep tracking
End-of-intervention outcome measures
Enrolled in digital intervention
25 selected for interview
1-month follow up measures


Week 1:
Pre-study questionnaires
One week sleep tracking
Week 2:
Sleep science & psycho-education
Sleep & mental health
Sleep hygiene
Week 3:
Sleep restriction therapy (SRT)
Stimulus control therapy (SCT)
Therapist Contact
Week 4:
SRT and SCT
Relaxation techniques
Week 5:
SRT and SCT
Addressing negative thoughts and cognitive restructuring
Therapist Contact
Week 6:
SRT and SCT
Healthy lifestyle choices (diet, exercise)
Work-life balance
Therapist Contact
Week 7:
Summary of programme
Relapse management plan
Therapist Contact
Week 8:
Post-study questionnaires
One week sleep tracking

Do I have to take part?
Participation in this study is completely voluntary. You can also choose to withdraw your participation at any time, without giving a reason by contacting the research team at wmg-mhpp@warwick.ac.uk. Further details about withdrawing from the study are provided at the end of this page.

What are the possible benefits of taking part in this study?
In this trial, we expect our digital intervention to reduce stress, improve sleep, and overall wellbeing to maintain and improve engagement and productivity at work. This will help businesses to get back on their feet in the current COVID-19 climate, helping businesses in the Midlands become more productive.

What are the possible disadvantages, side effects or risks, of taking part in this study?
We do not anticipate any major disadvantages, side effects or risks in taking part. The **SLEEP** intervention could involve "sleep restriction therapy" and/or sleep re-scheduling therapy, which may be associated with minor side effects such as daytime sleepiness. You will be fully instructed as to the rationale and potential side effects of the treatment at the outset. In addition, you will be advised to not drive or operate machinery if experiencing excessive daytime sleepiness.

Some participants will be randomly placed on the waitlist control group, in which case, the intervention will still be provided to them, but after a delay. You will be offered different channels to communicate with our research team 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.

The process evaluation interviews for **SLEEP**, which aim to explore the effectiveness, acceptability, barriers, and facilitators of the intervention might cause distress to some individuals. Should that occur, we will offer to pause and/or stop the interview and offer you appropriate support.

Due to the minimal direct contact the research team will have with participants, we advise and encourage you to report any event that you think may or may not be related to your being part of the study to the research team by email (wmg-mhpp@warwick.ac.uk) or to your therapist during the online sessions.

Expenses and payments
For each of the three assessment waves (i.e. upon completion of baseline questionnaires and return of sleep trackers with prepaid envelops, after intervention at 8 weeks and return of sleep trackers with prepaid envelops, and at 1-month follow-up), you will be provided with a £10 Amazon voucher as a gesture of good-will for your time and commitment to the study. Of those who have completed the intervention and have agreed to take part in the qualitative interview, we will randomly select 25 participants- those who complete the interview will also receive an additional £10 amazon voucher.

Will my taking part be kept confidential?
Your data will be kept confidential throughout the study. Research data will be de-identified as quickly as possible after data collection. Your study data will instead be associated with a unique participant ID number to complete all assessments and interventions. The key to identification will be stored separately and securely to the research data to safeguard your identity and access will be limited to the lead researcher (CT) and the project manager (CK), neither of whom will have any access to the study data. We are collecting your phone number and email address to contact you during the course of the study (e.g. sessions with therapist) and your postal address to send out the sleep tracker devices. Therapists will be taking notes during the sessions to refer to from week-to-week; these will be labelled with your unique study ID without any personal data that could reveal you such as name. Once your therapist sessions have ended, these notes will be securely destroyed. At the end of the intervention, you may be invited to take part in qualitative interviews (if you consent). The interviews will be audio recorded using University of Warwick manged digital recording devices for transcriptions, from which direct quotes may be included in the publication, however, these will not reveal any information that could identify enrolled employees (e.g. name). Personally identifiable data (e.g. name, email, postal address) collected in this study will be stored in password protected folders, kept separate from study data; all of which will be stored securely on the University of Warwick servers.

Your participation and individual data collected from the study will not be shared with your employer, nor are you under obligation to report your participation to your employer. It will also not be possible to identify you or infer your employment within an organisation from publications stemming from this study.

Your employer is under no obligation to support you in taking part in this trial.

Participating businesses will only receive a summary report which will not include any identifiable information about enrolled employees. Additionally, no identifiable information (e.g., name) will be used for analysis or in publications emerging from this study.

What will happen to the data collected about me?
We will be using information from you in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation.

Data from the activity and sleep trackers (MotionWatch) will be stored locally on each device. Once you send the device back to the research team, your data will be deleted from the device immediately after being transferred to a password protected folder on the University of Warwick servers.

Data from the printed sleep diary booklet will be entered in a password protected excel file on the University of Warwick servers, and the physical booklets will be shredded immediately after.

Therapists' notes from the four sessions will be stored securely on the University of Warwick OneDrive, and only shared between therapists who are covering sessions for your main therapist. These notes will be securely destroyed after all four sessions have ended.

We will examine individual usage of the digital intervention platform, this will include the number of logins, the frequency with which you use hyperlinks, how often you download any resources, submit assignments and any other additional requirements. The pseudo-anonymous intervention adherence data will be downloaded from the platform and transferred to a password protected folder on the University of Warwick servers.

The process evaluation interviews (conducted on a selected 25 participants only) will be done through a telephone or online through Microsoft Teams (participant's choice) and will be audio recorded using University of Warwick managed digital recording devices. The audio data will be transcribed then immediately deleted. The transcriptions will be kept in a password protected folder, with all personal identifiable information removed and pseudonyms used to protect participants' identity.

Study and personal data: Questionnaire data will be deleted from the Qualtrics platform, five days after being transferred to the University of Warwick servers. We will also delete all personal data from the University of Warwick servers immediately after the trial is completed (anticipated date: 12/2021), with the exception of consent forms, and contact details of any participants who consent to be contacted for future related research. The pseudo-anonymised study data will be deleted after 10 years from the University of Warwick servers.

Anonymised study data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

The anonymous data may be shared with the University of Birmingham for analysis purposes. Researchers from the University of Birmingham may conduct the process evaluations. For this process we will share your identifiable contact data, however, this will be minimised to ensure that only the data required to perform the process evaluations are shared and no additional data. Data sharing agreements and confidentiality clauses will be in place to ensure that you are treated with anonymity and confidentiality.

For further information, please refer to the University of Warwick Research Privacy Notice which is available here: https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?
Participation is entirely voluntary; you have the right to withdraw at any time without giving a reason. If you wish to withdraw you will need to email the research team wmg-mhpp@warwick.ac.uk stating your

intention to withdraw. In this event we will remove your study data and all identifiable data from the separate dataset.

What will happen to the results of the study?
The data collected will be analysed by researchers at the University of Warwick. The results are expected to be published in peer reviewed scientific journals and reported at national and international research meetings. Additionally, summary reports will be shared with all participating employers and our funders, the Midlands Engine. It will not be possible to identify you personally in these publications and reports.

Who has reviewed the study?
This study has been reviewed and given favourable opinion by the University of Warwick's Biomedical & Scientific Research Ethics Committee (BSREC). Ref: BSREC 45/20-21

Who should I contact if I want further information?
For more information contact the research team's Dr Krishane Patel or Dr Talar Moukhtarian at wmg-mhpp@warwick.ac.uk.

Who should I contact if I wish to make a complaint?
Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance
Research & Impact Services
University House
University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: DPO@warwick.ac.uk.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Thank you for taking the time to read this Participant Information Leaflet.

Consent form (Employer route)

Participant Identification Number for this study:

Study Title:	**SLEEP**: Supporting empLoyEes with insomnia and Emotion regulation Problems
Investigator(s):	Krishane Patel (University of Warwick), Talar Moukhtarian (University of Warwick), Carla Toro (University of Warwick), Laura Chandler (University of Warwick), Nicole Tang (University of Warwick), Steven Marwaha (University of Birmingham), Arianna Prudenzi (University of Birmingham), Feroz Jadhakhan (University of Birmingham), Lukasz Walasek (University of Warwick), Caroline Meyer (University of Warwick)

Please initial all boxes

1. I confirm that I have read and understand the information sheet (SLEEP v1.7 08/07/21) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I confirm that I meet ALL the eligibility criteria of this study: English speaking; 18 years or above, not retiring in the next 10 months, currently not receiving treatment (psychological or medication) from mental health services, currently not taking parting in other psychological intervention trials, not pregnant; no current substance abuse/misuse problems; no diagnosis of epilepsy, neurological diseases, psychosis, bipolar disorder, or any other circadian rhythm and sleep disorders (e.g. sleep apnea); not in shift work. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my employment being affected. ☐

4. I understand that data collected during the study, may be looked at by individuals from Universities of Warwick. I give permission for these individuals to have access to my data. ☐

	YES	NO
5. Would you like to be contacted to participate in a qualitative interview to understand how we can improve the intervention further (tick as appropriate).	☐	☐

6. I am happy for my anonymised data to be used in future research. ☐

7. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Consent form (direct recruitment)

Participant Identification Number for this study:

Study Title: **SLEEP**: Supporting empLoyEes with insomnia and Emotion regulation Problems

Investigator(s): Krishane Patel (University of Warwick), Talar Moukhtarian (University of Warwick), Carla Toro (University of Warwick), Laura Chandler (University of Warwick), Nicole Tang (University of Warwick), Steven Marwaha (University of Birmingham), Arianna Prudenzi (University of Birmingham), Feroz Jadhakhan (University of Birmingham), Lukasz Walasek (University of Warwick), Caroline Meyer (University of Warwick)

Please initial all boxes

1. I confirm that I have read and understand the information sheet (SLEEP v1.7_IV 07/07/21) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I confirm that I meet ALL the eligibility criteria of this study: English speaking; 18 years or above, not retiring in the next 10 months, currently not receiving treatment (psychological or medication) from mental health services, currently not taking parting in other psychological intervention trials, not pregnant; no current substance abuse/misuse problems; no diagnosis of epilepsy, neurological diseases, psychosis, bipolar disorder, or any other circadian rhythm and sleep disorders (e.g. sleep apnea); not in shift work. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐

4. I understand that I am not employed by an organisation/company that has formally agreed to support my participation in SLEEP, and that my employer is not obliged to support me in taking part. ☐

5. I understand that data collected during the study, may be looked at by individuals from Universities of Warwick. I give permission for these individuals to have access to my data. ☐

	YES	NO
6. Would you like to be contacted to participate in a qualitative interview to understand how we can improve the intervention further (tick as appropriate).	☐	☐

7. I am happy for my anonymised data to be used in future research. ☐

8. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature