ISRCTN13596153 https://doi.org/10.1186/ISRCTN13596153

Supporting employees with insomnia and emotional regulation problems

Submission date
13/05/2021

Recruitment status
No longer recruiting

Registration date
08/06/2021

Overall study status
Completed

Last Edited
17/07/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 26/10/2021:

Background and study aims
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 about half of the working days lost. The high association between mental health conditions further exacerbates this problem, for instance 40-60% of insomnia sufferers also suffer from other mental health disorders, such as depression and anxiety. The estimated annual cost of poor mental health has increased 16% since 2017, and is now up to £45 billion.
The prevalence rates of mental health problems tend to increase substantially during large-scale disasters, such as traumatic events (e.g. mass shootings or terror attacks) or natural events (e.g. hurricanes or pandemics). In the context of the current COVID-19 pandemic, there has been an estimated increase of 500,000 cases of mental health problems due to factors such as income shocks, loneliness, and stress. It is estimated that about 41.8% of the UK population are at high risk of mental health problems due to their economic vulnerability and exposure to a negative economic shock as a result of the COVID-19 outbreak.
Various attempts have been made to intervene within the workplace to reduce mental health difficulties. However, these interventions are limited due to the quality of the screening tools used, accessibility and the lack of evidence-based approaches. Previous research shows that people with mental health difficulties find it problematic to find jobs or remain in work, and this is one reason why the associated financial costs of mental health are so high, and subsequently costly to society, employers and individuals. However, many employers are unaware of their role in supporting workers' mental health or unsure what to do to help.
This is the initial pilot study of an intervention to improve workforce mental health and productivity as part of the Mental Health and Productivity Pilot program (https://mhpp.me/).

Who can participate?
Employees and self-employed workers, aged 18 or over, in employment (including being on furlough) 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), who suffer from insomnia and anxiety but are not currently receiving treatment

What does the study involve?
SLEEP is a hybrid digital intervention consisting of cognitive behavioural therapy for insomnia and emotion regulation difficulties supplemented by online sessions with trained therapists, which aims to improve sleep problems and productivity across the Midlands. Participants are randomly allocated to the control group or the intervention group. The control group will receive the intervention after 8 weeks. Those in the intervention group will start with a 1-week sleep tracking facilitated by a sleep tracker. The sleep tracker is a compact and lightweight activity monitoring device that participants need to wear on their wrist like a watch for the duration of that week, which tracks their sleep and physical movement. The researchers will use data from the sleep tracker to assess participants' sleep quality. Following the sleep tracking week, participants 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. Participants will then be sent another sleep tracker to complete a final 1-week of sleep tracking. They will then be contacted after 1 month to complete the follow-up questionnaires. Those in the control group will start with a 1-week sleep tracking facilitated by a sleep tracker. Following the sleep tracking week, participants will be asked to continue life as usual for 6-week (i.e. they will not receive the 6-week digital intervention or provided with any other treatment). Participants will then be asked to complete a final 1-week of sleep tracking. Subsequently, participants will be offered the 6-week digital intervention, and finish with another 1-week of sleep tracking. Overall, the study will last for 3 months if participants are placed initially in the intervention group. If they are initially placed in the waitlist control group, they will be offered the intervention after an 8-week delay, and be in the study for 5 months. Upon completion of the 8-week study period, an evaluation of the 6-week intervention programme will be conducted using interviews to explore the effectiveness, acceptability, barriers, and facilitators of the intervention. This will be completed with a randomly selected 25 participants who have completed the intervention and consented to be contacted again for this part of the study.

What are the possible benefits and risks of participating?
While this study is part of a pilot project, the researchers expect to see an improvement in mental health symptoms of insomnia, depression and anxiety, as well as work productivity as a result of the intervention. The researchers do not anticipate any major disadvantages, side effects or risks in taking part. The digital intervention targeting sleep problems could involve established elements of "sleep restriction" and/or sleep re-scheduling therapy, which may be associated with minor side effects such as daytime sleepiness. Participants will be fully instructed as to the rationale and potential side effects of the intervention at the outset. 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 who is experienced and will be on hand throughout the trial to advise and supervise the intervention staff. Serious adverse events will be documented and reported. Additionally, the study questionnaire asks about self-harming and suicidal behaviour, which would require participants to disclose sensitive information. In addition, high scores on the questionnaires may indicate clinically significant conditions. This could highlight an undiagnosed severe mental-health condition for which the participant is not receiving care. To provide support and guidance to at-risk participants, individuals who report having suicidal and self-harming thoughts "several days, more than half the days, or nearly every day", as well as individuals with high scores on the questionnaires will be suggested to speak to their GP and provided with contact details for psychological therapies, whilst still being eligible to receive the interventions.

Where is the study run from?
University of Warwick (UK)

When is the study starting and how long is it expected to run for?
July 2020 to April 2022

Who is funding the study?
Midlands Engine (UK)

Who is the main contact?
Charlotte Kershaw, Charlotte.Kershaw@warwick.ac.uk
Dr Nicole Tang, N.Tang@warwick.ac.uk

Previous plain English summary:

Background and study aims
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 about half of the working days lost. The high association between mental health conditions further exacerbates this problem, for instance 40-60% of insomnia sufferers also suffer from other mental health disorders, such as depression and anxiety. The estimated annual cost of poor mental health has increased 16% since 2017, and is now up to £45 billion.
The prevalence rates of mental health problems tend to increase substantially during large-scale disasters, such as traumatic events (e.g. mass shootings or terror attacks) or natural events (e.g. hurricanes or pandemics). In the context of the current COVID-19 pandemic, there has been an estimated increase of 500,000 cases of mental health problems due to factors such as income shocks, loneliness, and stress. It is estimated that about 41.8% of the UK population are at high risk of mental health problems due to their economic vulnerability and exposure to a negative economic shock as a result of the COVID-19 outbreak.
Various attempts have been made to intervene within the workplace to reduce mental health difficulties. However, these interventions are limited due to the quality of the screening tools used, accessibility and the lack of evidence-based approaches. Previous research shows that people with mental health difficulties find it problematic to find jobs or remain in work, and this is one reason why the associated financial costs of mental health are so high, and subsequently costly to society, employers and individuals. However, many employers are unaware of their role in supporting workers' mental health or unsure what to do to help.
This is the initial pilot study of an intervention to improve workforce mental health and productivity as part of the Mental Health and Productivity Pilot program (https://mhpp.me/).

Who can participate?
Adults aged over 18, in employment (including being on furlough), who suffer from insomnia and anxiety but are not currently receiving treatment

What does the study involve?
SLEEP is a hybrid digital intervention consisting of cognitive behavioural therapy for insomnia and emotion regulation difficulties supplemented by online sessions with trained therapists, which aims to improve sleep problems and productivity across the Midlands. Participants are randomly allocated to the control group or the intervention group. The control group will receive the intervention after 8 weeks. Those in the intervention group will start with a 1-week sleep tracking facilitated by a sleep tracker. The sleep tracker is a compact and lightweight activity monitoring device that participants need to wear on their wrist like a watch for the duration of that week, which tracks their sleep and physical movement. The researchers will use data from the sleep tracker to assess participants' sleep quality. Following the sleep tracking

week, participants 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. Participants will then be sent another sleep tracker to complete a final 1-week of sleep tracking. They will then be contacted after 1 month to complete the follow-up questionnaires. Those in the control group will start with a 1-week sleep tracking facilitated by a sleep tracker. Following the sleep tracking week, participants will be asked to continue life as usual for 6-week (i.e. they will not receive the 6-week digital intervention or provided with any other treatment). Participants will then be asked to complete a final 1-week of sleep tracking. Subsequently, participants will be offered the 6-week digital intervention, and finish with another 1-week of sleep tracking. Overall, the study will last for 3 months if participants are placed initially in the intervention group. If they are initially placed in the waitlist control group, they will be offered the intervention after an 8-week delay, and be in the study for 5 months. Upon completion of the 8-week study period, an evaluation of the 6-week intervention programme will be conducted using interviews to explore the effectiveness, acceptability, barriers, and facilitators of the intervention. This will be completed with a randomly selected 25 participants who have completed the intervention and consented to be contacted again for this part of the study. Participants for the process evaluation will be sampled to account for sector, job role, seniority, age, and gender.

What are the possible benefits and risks of participating?
While this study is part of a pilot project, the researchers expect to see an improvement in mental health symptoms of insomnia, depression and anxiety, as well as work productivity as a result of the intervention. The researchers do not anticipate any major disadvantages, side effects or risks in taking part. The digital intervention targeting sleep problems could involve established elements of “sleep restriction” and/or sleep re-scheduling therapy, which may be associated with minor side effects such as daytime sleepiness. Participants will be fully instructed as to the rationale and potential side effects of the intervention at the outset. 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 who is experienced and will be on hand throughout the trial to advise and supervise the intervention staff. Serious adverse events will be documented and reported. Additionally, the study questionnaire asks about self-harming and suicidal behaviour, which would require participants to disclose sensitive information. In addition, high scores on the questionnaires may indicate clinically significant conditions. This could highlight an undiagnosed severe mental-health condition for which the participant is not receiving care. To provide support and guidance to at-risk participants, individuals who report having suicidal and self-harming thoughts “several days, more than half the days, or nearly every day”, as well as individuals with high scores on the questionnaires will be suggested to speak to their GP and provided with contact details for psychological therapies, whilst still being eligible to receive the interventions.

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Who is the main contact?
Charlotte Kershaw, Charlotte.Kershaw@warwick.ac.uk
Dr Nicole Tang, N.Tang@warwick.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number

BSREC 45/20-21

Study information

Scientific Title
Supporting employees with insomnia and emotional regulation problems: a multicentre interventional waitlist randomised-controlled trial

Acronym
SLEEP

Study objectives
The SLEEP intervention will reduce insomnia severity, anxiety and depression scores on the Insomnia Severity Index (ISI), General Anxiety Disorder-7 (GAD-7) and Patient Health Questionnaire-9 (PHQ-9) respectively compared to those initially assigned to the waitlist control group at 8 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/01/2021, Biomedical Sciences Research Ethics Committee (University of Warwick, Coventry, CV4 7AL, UK; +44 (0)24 765 73123; BSREC@warwick.ac.uk), ref: BSREC 45/20-21

Primary study design
Interventional

Study design
Multicentre interventional waitlist randomized-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Insomnia, anxiety and depression

Interventions
Participants are randomly allocated through blocked randomisation with stratification into the SLEEP intervention or a waitlist control group with a 1:1 allocation ratio. The researchers will stratify across different employer sites in the Midlands to ensure weighting approximate to staff size and representation of the larger population.

The SLEEP trial is a hybrid digital intervention of cognitive behaviour therapy for insomnia and emotion regulation for a duration of 6 weeks, that includes self-guided components on sleep psychoeducation, sleep monitoring, cognitive behavioural therapy, and guided sleep restriction therapy with a trained therapist.

Content for the self-guided intervention will be digitised and presented via an online platform, with each component being tailored to maximise the relevance of the treatment as a workplace intervention and the generalisability of the treatment across industries. The bulk of the

treatment content is a self-paced ‘homework’ that participants complete during the week, and supported by online therapists.

The core components of the SLEEP intervention will include:
1. Psychoeducation of sleep science
2. Stimulus control therapy
3. Sleep restriction therapy
4. Cognitive therapy for addressing insomnia-related cognitions and behaviour
5. Emotion regulation skills training (non-judgmental awareness, acceptance and tolerance, effective self-support, analysis and modification, physical activity)
6. Goal-setting (action planning, goal-setting)

Intervention Type
Behavioural

Primary outcome(s)
1. Insomnia measured using the Insomnia Severity Index at baseline, post-intervention (8 weeks) and follow-up (12 weeks)
2. Anxiety measured using the General Anxiety Disorder-7 at baseline, post-intervention (8 weeks) and follow-up (12 weeks)
3. Depression measured using the Patient Health Questionnaire-9 at baseline, post-intervention (8 weeks) and follow-up (12 weeks)

Key secondary outcome(s)
Current secondary outcome measures as of 26/10/2021:

1. Sleep quality parameters measured using Camntech MotionWatch actigraphy trackers and self-reported sleep diary data at week 1 (pre-intervention) and week 8 (post-intervention)
2. Work productivity measured using the Work Productivity and Activity Impairment: General Health v2.0 at baseline, post-intervention (8 weeks) and follow up (12 weeks)
3. Job satisfaction measured using the Indiana Job Satisfaction Scale at baseline, post-intervention (8 weeks) and follow up (12 weeks)
4. Well-being measured using the Warwick-Edinburgh Mental Health Well-being Scale at baseline, post-intervention (8 weeks) and follow up (12 weeks)
5. Quality of life measured using the EuroQOL EQ-5D-5L questionnaire at baseline, post-intervention (8 weeks) and follow up (12 weeks)
6. User experience behaviour of platform usage collected as the counts of activities completed on the platform as well as the average duration of time spent on each topic over the 8-week intervention period.

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Previous secondary outcome measures:

1. Sleep quality parameters measured using Camntech MotionWatch actigraphy trackers at week 1 (pre-intervention) and week 8 (post-intervention)
2. Job productivity measured using the Work Productivity and Activity Impairment: General Health v2.0 at baseline, post-intervention (8 weeks) and follow up (12 weeks)
3. Job satisfaction measured using the Indiana Job Satisfaction Scale at baseline, post-intervention (8 weeks) and follow up (12 weeks)
4. Well-being measured using the Warwick-Edinburgh Mental Health Well-being Scale at

baseline, post-intervention (8 weeks) and follow up (12 weeks)
5. Quality of life measured using the EuroQOL EQ-5D-5L questionnaire at baseline, post-intervention (8 weeks) and follow up (12 weeks)
6. User experience behaviour of platform usage collected as the number of log-ins and counts of activities completed on the platform over the 8-week intervention period. These will be downloaded by the research team directly from the platform at the end of each week.

Completion date
25/04/2022

Eligibility

Key inclusion criteria
1. Able to give informed consent
2. English-speaking
3. In employment (including being on furlough)
4. Insomnia Severity Index score: x >8
5. General Anxiety Disorder-7 score: x >5 or Patient Health Questionnaire-9 score: x >5
6. ≥18 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
159

Key exclusion criteria
1. Currently receiving treatment (psychological or pharmacological) from mental health services (e.g. GP, Improving Access to Psychological Therapies (IAPT), specialist and community mental health services)
2. Not pregnant
3. Current substance abuse/misuse problems, epilepsy, neurological conditions (e.g. Parkinson's or Alzheimer's), psychosis, bipolar disorder, or any other circadian rhythm and sleep disorders (e.g. sleep apnoea, periodic limb movement syndrome/restless leg syndrome, circadian rhythm disorders)

4. Retiring in the next 10 months
5. Currently taking part in other psychological intervention trials
6. In shift work

Date of first enrolment
11/06/2021

Date of final enrolment
30/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Wolverhampton NHS Trust
12, Corporate Services Centre
New Cross Hospital
Wolverhampton
England
WV10 0QP

Study participating centre
Leicester City Football Club
King Stadium
Filbert way
Leicester
England
LE2 7FL

Study participating centre
Conference Care
Hinckley
Leicestershire
England
LE10 3EY

Study participating centre
Pathfinder schools
Havelock Infant School

Desborough
Northamptonshire
England
NN14 2LU

Study participating centre
Birmingham City Council
-
Birmingham
England
B1 1BB

Study participating centre
Noble Events
-
Leicestershire
England
LE7 4UZ

Study participating centre
The University of Warwick
University Road
Coventry
England
CV4 7AL

Study participating centre
Jaguar Land Rover
Banbury Road
Abbey Road
Whitley
Coventry
England
CV4 7AL

Study participating centre
CCM Group
Nunn Brook Road
Huthwaite
England
NG17 2HU

Study participating centre
Mice and Dice
-
Newcastle-under-Lyme
England
ST5 2RP

Study participating centre
NTT
Darwin House
Lichfield South
Birmingham Road
Lichfield
England
WS14 0QP

Study participating centre
Herefordshire & Worcestershire Chamber of Commerce
Severn House
Prescott Drive
Worcester
England
WR4 9NE

Study participating centre
Micronclean
Skegness Roman Bank
Skegness
England
PE25 1SQ

Study participating centre
WJ North Ltd
7 Brock Way
Newcastle-under-Lyme
England
ST5 6AZ

Study participating centre
Colas Rail
Plant Depot
Mill Road
Rugby
England
CV21 1BE

Study participating centre
Perfect Home
Eagle Court 2
Hatchford Way
Sheldon
Birmingham
England
B26 3RZ

Study participating centre
Streets Heaver
-
Lincoln
England
LN6 3QN

Study participating centre
Capgemini UK
Stafford Park 11
Telford
England
TF3 3AY

Study participating centre
D2N2 Ltd
8 Experian Way
ng2 Business Park
Nottingham
England
NG2 1EP

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Other

Funder Name
Midlands Engine

Results and Publications

Individual participant data (IPD) sharing plan
Data stored in repository: https://www.doi.org/10.17605/OSF.IO/2G75Y

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results for randomised waitlist-controlled trial	17/02/2025	17/07/2026	Yes	No
Protocol article	study protocol for a randomised waitlist control trial	15/07/2022	16/08/2022	Yes	No
Protocol article	study protocol for a feasibility randomised waitlist-controlled trial	09/12/2022	04/07/2024	Yes	No
Basic results			26/05/2023	No	No
Other publications	Qualitative process evaluation	04/12/2025	17/07/2026	Yes	No
Participant information sheet	version V1.6		08/06/2021	No	Yes
Participant information sheet	version 1.7	08/07/2021	26/10/2021	No	Yes
Participant information sheet	IV version version 1.7	07/07/2021	26/10/2021	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes