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Evaluating the efficacy of audio-based digital tools to improve sleep on the Unmind workplace wellbeing platform

Submission date
01/10/2024

Recruitment status
No longer recruiting

Registration date
11/10/2024

Overall study status
Completed

Last Edited
10/01/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Sleep plays a crucial role in many aspects of life, including mental and physical health, work productivity, relationship satisfaction, and overall quality of life. While the prevalence of chronic insomnia is estimated to be around 10%, insomnia symptoms are much more common and are estimated to be experienced by between 20 to 30% of the general adult population. Moreover, 25% of people sleep less than the age-specific recommendations. These are alarming figures, and it has been suggested that sleep loss is a silent public health epidemic with profound implications.

Given the widespread nature of sleep disturbances, novel and accessible treatments are needed. The NICE recommend using digital health interventions to increase access to care. Within NHS settings, the first line of treatment for clinical insomnia is Cognitive Behavioural Therapy for Insomnia (CBT-I), and research on digitally delivered versions of this form of therapy supports their use. However, another type of standalone, audio-based digital intervention has dramatically raised in popularity. These types of interventions (referred to as Sleep Tools here) are usually found in mental wellbeing apps or audio streaming platforms. These Sleep Tools include relaxing music and soundscapes, narrated stories, and mindfulness-inspired relaxation exercises – all designed to help people fall asleep, stay asleep or go back to sleep in the middle of the night. Despite the significant increase in popularity and use, very little research has been done to evaluate how well these Sleep Tools work. The current study aims to test how well different categories of sleep tools improve sleep and the effect on other areas of mental health, wellbeing, and work productivity.

To do this, this study will evaluate three categories of Sleep Tools featured on Unmind - a mental health platform accessible via the accompanying smartphone app. The categories of Sleep Tools that will be assessed in the study are "Sleep Sounds" (ambient music, nature sounds and coloured noise), "Bedtime Stories" (narrated stories, often including relaxation prompts and background music), and "Sleep Skills" (environmental, positive psychology, breathwork and mindfulness-inspired guided practices) which are all designed to facilitate improved sleep.

Who can participate?
Working adults (aged 18 - 67 years) with self-reported sleep disturbances who are fluent in English and currently live in the UK or USA

What does the study involve?
Participants will first be invited to complete a short screening survey to determine their eligibility for the study. Then, everyone who meets the requirements to participate will be invited to complete an online survey about their sleep, mental health and wellbeing, emotion regulation, and work productivity.
Participants will be randomly allocated to one of four groups. In groups 1 to 3, participants will be assigned to one Unmind Sleep tool category (Sleep Sounds, Bedtime stories or Sleep Skills). Participants in these groups will be asked to listen to one audio-based Unmind Sleep Tool from the category they were assigned each night for four weeks. They can choose to listen to the sleep tools just before sleep, while trying to fall asleep, or to go back to sleep if they wake up during the night. Participants in group 4 will be part of the control condition and will be asked to engage with a different feature of the Unmind platform called the Daily Boost. The Daily Boosts are short audio-based tracks that cover a wide variety of content, such as psychoeducation, relaxation, mindfulness and reflection prompts. Participants will be invited to listen to the Daily Boost every day, whenever they want (e.g. while commuting, during the daytime, in the evening), for four weeks.
At the end of the 4-week trial, all groups will be invited to re-take the same survey they took at the start of the study, with an additional feedback questionnaire to ask their opinion about the Unmind feature they were asked to use. The research team will then compare the answers from the first survey to the second to see if and how people's scores might have changed and compare these between the Unmind Sleep Tools groups and the control group.

What are the possible benefits and risks of participating?
All participants will receive monetary remuneration for completing the questionnaires. Participants allocated to the Unmind Sleep Tools may experience improvement in their sleep, and mental health or/and wellbeing. These audio-based exercises are minimally invasive, designed to promote relaxation, and are not associated with negative effects. While we don't expect participants in the control condition to experience improvements in their sleep, the Daily Boost is unlikely to cause any discomfort or negative effects. Moreover, participants in the control condition will be given full access to the Unmind Sleep tools after completing the study.
As part of the study, participants will be asked to answer questions about their sleep, mental health, wellbeing, and emotion regulation. This can cause discomfort in some people, and participants will be encouraged to seek appropriate support if they have any related concerns. The information sheet provided at the start of the study will include signposting details of who to contact in case of any concerns about their sleep or mental health.
Participants will be made clear that if they feel uncomfortable answering any questions, they can close the questionnaire and withdraw from the study immediately. They can also withdraw at any time after completing a questionnaire by contacting the research team.

Where is the study run from?
University of Sussex (UK). The study will be conducted entirely online.

When is the study starting and how long is expected to run for?
March 2024 to December 2024

Who is funding the study?
1. Unmind Ltd (UK)
2. Southeast Network for Social Sciences (part of the Economic and Social Research Council) (UK)

Who is the main contact?
1. Jessica Vazzaz (j.vazzaz@sussex.ac.uk)
2. Prof. Kate Cavanagh (kate.cavanagh@sussex.ac.uk)
3. Dr Marcos Economides (marcos.economides@unmind.com)

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Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Efficacy of digital tools to improve sleep quality in working adults with poor sleep: protocol for a multi-arm, randomised controlled trial

Acronym
USleep (Unmind Sleep)

Study objectives

The primary aim of the current study is to evaluate the efficacy of three categories of standalone, audio-based intervention (Sleep Tools) for poor sleep featured on the Unmind digital mental health platform.

Primary Hypothesis:
Hypothesis 1: Engagement with each category of audio-based intervention, compared to the active control, will significantly improve self-reported sleep disturbances (post-intervention).

Secondary Hypotheses:
Hypothesis 2: Engagement with each category of audio-based intervention, compared to the active control, will significantly improve mental wellbeing.

Hypothesis 3: Engagement with each category of audio-based intervention, compared to the active control, will significantly improve mental health (depression and anxiety).

Hypothesis 4: Engagement with each category of audio-based intervention, compared to the active control, will significantly reduce presenteeism (related to work productivity).

Exploratory Hypotheses:
Hypothesis 5: This study aims to assess the feasibility and acceptability of the active control condition via feedback questionnaire, adherence metrics and self-reported adverse effects. Moreover, credibility and expectations will be explored and compared to the experimental arms.

Hypothesis 6: Possible underlying mechanisms of action will be investigated by exploring pre-sleep arousal as a mediator and adaptive and maladaptive cognitive emotion regulation as moderators of intervention effects.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/09/2024, University of Sussex Sciences & Technology Research Ethics Committee (Falmer, Brighton, BN1 9RH, United Kingdom; + 44 (0)1273 877492; crecscitec@sussex.ac.uk), ref: ER/JV268/2

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Working adults experiencing poor sleep

Interventions
The study will be a multi-arm, parallel group, randomised controlled trial with pre- and post-intervention assessments.

The intervention will be delivered entirely online via Unmind, a digital mental health platform for working adults (https://unmind.com). Unmind can be accessed via web, mobile, or tablet (Android or iOS), and the app can be downloaded from the Apple or Google Play store. It features a wide range of resources and content created by academics and clinicians and is rooted in evidence-based practices.

This study will evaluate the effectiveness of three distinct categories of Unmind audio-based tracks designed for use before and/or during sleep (called Sleep Tools). For four weeks, participants will be randomly assigned to one of three sleep-related interventions or to an active control condition (the Daily Boost).

The three Sleep Tools categories are: 1) Sleep Sounds (SS; ambient music, coloured noise, and nature sounds, each of which is 30-60 minutes in duration), and 2) Bedtime Stories (BS; narrated stories, typically 15-40 minutes in duration, that include background music and/or sound cues) and 3) Sleep Skills (SK; behavioural, positive psychology, breathwork and mindfulness-inspired guided practices lasting between 10-15 minutes).

SSs do not include any voice narration, unlike BS and SK. The content of BS tends to focus on detailed sensory descriptions of visual scenes, e.g. vividly describing a painting or a natural landscape. They occasionally include short breathing prompts or deep breathing exercises, either at the start of each session or in between the descriptive storytelling, to aid relaxation. SK is a heterogenous category including guidance on creating a sleep-promoting environment, guided reflective practices combined with mindfulness techniques (such as breath focus), traditional body scans and progressive-muscle relaxation, practices to elicit positive emotions such as gratitude and self-compassion, and breathwork. As of February 2024, 60 Sleep Sounds, 18 Bedtime Stories and 8 Sleep Skills are featured on the Unmind platform.

The control condition will involve engagement with a separate feature of the Unmind platform called the Daily Boost (DB). Similarly to the experimental conditions, the DB are standalone, audio-based tracks. However, these are shorter than Sleep Tools, lasting between 1 and 2 minutes, and are not designed to be used before bedtime, even if they can be. The DB changes daily, and its content varies widely, including brief psychoeducation about different aspects of wellbeing, reflection prompts, brief mindfulness meditations and poetry.

Working adults with self-reported experience of poor sleep will be recruited via an online recruitment platform (Prolific). Participants will be randomised (via the Qualtrics “randomiser” feature) to one of the three intervention arms (SS, BS, SK) or to the control group (DB) with an allocation of 1:1:1:1. Randomisation will occur immediately after completing a baseline assessment. Subsequently, specific instructions on how to engage with the allocated feature during the study period (4 weeks) will be provided. Participants in the experimental conditions will be instructed to engage with one audio tool of their choosing (within the allocated category) per night. Similarly, participants in the control condition will be instructed to engage with the DB daily, but no indication regarding timing will be given. It will be made clear to all participants that it will be acceptable to occasionally fail to engage with the allocated feature throughout the 4-week study period. However, only participants who completed at least three sessions per week will be included in the per-protocol analysis.

After the 4-week study period, all participants will be invited to complete a post-intervention questionnaire.

Intervention Type
Behavioural

Primary outcome(s)

Sleep disturbances measured via standardised, self-reported PROMIS Sleep Disturbance Short Form 8a (SD-SF) at baseline (t0) and post-intervention (t1), 4 weeks after t0

Key secondary outcome(s))

1. Sleep-related impairment measured via standardised, self-reported PROMIS Sleep-Related Impairment Short Form 8a (SRI-SF) at baseline (t0) and post-intervention (t1), 4 weeks after t0
2. Sleep-disturbances related impact on occupational and overall functioning measured via standardised, self-reported Work Productivity and Activity Impairment (WPAI) at baseline (t0) and post-intervention (t1), 4 weeks after t0
3. Mental wellbeing measured via standardised, self-reported Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) at baseline (t0) and post-intervention (t1), 4 weeks after t0
4. Mental health outcomes measured via standardised, self-reported Patient Health Questionnaire-4 (PHQ-4) at baseline (t0) and post-intervention (t1), 4 weeks after t0
5. Cognitive and physiological pre-sleep arousal measured via standardised, self-reported Pre-Sleep Arousal Scale (PSAS) at baseline (t0) and post-intervention (t1), 4 weeks after t0
6. Cognitive emotion regulation strategies measured via standardised, self-reported Cognitive Emotion Regulation Questionnaire – 18 items version (CERQ-short) at baseline (t0) and post-intervention (t1), 4 weeks after t0

Feedback and adherence-related secondary outcomes will be captured through a combination of objective data (continually collected via the Unmind app) and feedback questionnaires delivered post-intervention (4 weeks after baseline) and will include:
1. Acceptability: intervention adherence (the proportion of participants completing, on average, at least three Sleep Tools per week, or 12 in total, where a playtime ≥5 minutes will be considered sufficient for completion), participant satisfaction, reasons for failing to adhere to the intervention, and qualitative feedback
2. Engagement: average number of Sleep Tools used (for each category), the average duration (in minutes) Sleep Tools are played (accounting for Tools that are stopped early), self-reported conditions that prompt Sleep Tool usage, self-reported patterns of Sleep Tool usage (e.g. frequency of use before bed versus after waking in the night), and one question adapted from Section B of the Mobile App Rating Scale
3. Transferability: one item adapted from Section E of the MARS.
4. Relevance: one item assessing the subjective relevance of the Sleep Tools.
5. Negative effects: the proportion of participants whose mental health (as measured by the Patient Health Questionnaire-4 [PHQ-4]) and sleep quality (as measured by the PROMIS Sleep Disturbance Short Form [SD-SF]) reliably deteriorates from t0 to t1 (based on a calculation of reliable change index for each measure) in the experimental arms compared to the control, one item capturing lasting bad effects

Participants allocated to the control conditions (DB) will also be instructed to complete a feedback questionnaire at t1, designed to assess the appropriateness of this novel active control condition. This questionnaire will be an adapted version of the feedback questionnaire for the experimental conditions and will include:
1. Acceptability: intervention adherence (the proportion of participants accessing, on average, at least 3 Daily Boosts per week, or 12 in total), participant satisfaction, reasons for failing to adhere to the intervention, and qualitative feedback.
2. Negative effects: the proportion of participants whose mental health (as measured by the Patient Health Questionnaire-4 [PHQ-4]) and sleep quality (as measured by the PROMIS Sleep Disturbance Short Form [SD-SF]) reliably deteriorates from t0 to t1 (based on a calculation of reliable change index for each measure) in the control condition compared to the experimental

arms, one item capturing lasting bad effects
3. Relevance: one item assessing the subjective relevance of the Daily Boost

Completion date
30/10/2024

Eligibility

Key inclusion criteria
1. Age 18 to 67 years old
2. Currently residing in the UK or USA
3. Self-identifying as being in full- or part-time employment
4. Self-reporting probable experience of poor sleep, defined as scoring ≥7 on the Jenkins Sleep Scale
5. Self-reporting an interest in improved sleep
6. Being fluent in English
7. Having access to the Internet at home via a smartphone, laptop, desktop computer, or tablet
8. Owning a smartphone (and/or tablet) and being willing to download and sign up to the Unmind app
9. Willing to be randomised
10. Having an active account on the Prolific online recruitment platform (https://www.prolific.co)

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
67 years

Sex
All

Total final enrolment
500

Key exclusion criteria
1. Undergoing treatment for a sleep disorder with a healthcare professional
2. Previous use of the Unmind platform
3. Current participation in a separate study involving use of the Unmind app

Date of first enrolment
22/10/2024

Date of final enrolment
27/11/2024

Locations

Countries of recruitment
United Kingdom

England

United States of America

Study participating centre
University of Sussex
School of Psychology
Falmer
Brighton
United Kingdom
BN1 9QH

Sponsor information

Organisation
Unmind Ltd

Funder(s)

Funder type
Industry

Funder Name
Unmind Ltd

Funder Name
Economic and Social Research Council

Alternative Name(s)
Economic and Social Research Council (ESRC), ESRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during the current study will be available upon request from Jessica Vazzaz (j.vazzaz@sussex.ac.uk) or Dr Marcos Economides (marcos.economides@unmind.com or research@unmind.com) after publication of findings. Data will be shared with other research teams for the purpose of contributing to systematic reviews and meta-analyses.
Participants will be explicitly asked in the main study consent form for future data use and sharing of their fully anonymised data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes