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Evaluating use of audio tools for poor sleep on the Unmind mental health app

Submission date
13/10/2021

Recruitment status
No longer recruiting

Registration date
14/10/2021

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Sleep plays a vital role in maintaining physical and mental health. However, increased demands from work, higher perceived stress, and greater use of digital technology have led to an upwards trend in sleep disturbance. Insufficient sleep has major implications for the workplace, as it can contribute to decreased employee productivity at a high cost to employers.

Recently, smartphone apps have emerged as a way of increasing the reach of mental health and wellbeing interventions. Mobile apps are especially promising as a delivery mechanism for sleep interventions, as many people use their smartphones immediately before going to bed. To date, most evaluations of app-based sleep interventions have focused on formal treatment programs designed for clinical populations and specific disorders, such as cognitive behavioural therapy (CBT. for insomnia. Yet, there has been a dramatic increase in the demand, availability, and media coverage of standalone, audio-based tools designed for use by the general public before and during sleeping hours. Such tools are typically designed to aid relaxation, and often include content such as musical soundscapes, nature sounds, and/or narrated stories. Despite their popularity, very few studies have evaluated whether such tools are actually effective at improving sleep, and more studies are needed.

This study aims to conduct an initial test of two different types of sleep tools featured on Unmind -- a digital mental health app for employees. Unmind provides employees with tools and content to help them maintain and improve their mental health and wellbeing.
The two types of sleep tools being tested in this study are called “Nightwaves” (ambient music and nature sounds, each of which is 30-60 minutes in duration. and “Sleep Tales” (narrated stories, typically 15-40 minutes in duration, that include background music and/or sound cues, as well as some occasional breathing exercises). The two sleep tool categories will be examined for recruitment, retention, engagement, acceptability, and preliminary indicators of potential effectiveness. If the sleep tools are found to be feasible, this will help to inform whether further studies should be conducted, and how such studies should be designed.

Who can participate?
Adults aged 18 and above, fluent in English, who live in the UK and are in full- or part-time employment, and who are likely experiencing poor sleep.

What does the study involve?
Participants will first be invited to complete a screening survey to test whether they meet the requirements for taking part in the study. Everyone who is eligible to take part will be invited to complete an initial survey about their mental health and wellbeing (including aspects of their sleep, and ability to perform at work). Participants will then be randomly allocated to one of the two Unmind sleep tool categories, or to a wait-list control group. Participants in the Unmind groups will be given free access to the Unmind app for four weeks, and will be asked to complete one sleep tool of their choosing (from their assigned category. each night. Participants in the control group will not have access to the Unmind app straight away.

At the end of the four week period, all participants will be invited to retake the same survey about their mental health and wellbeing, so that the research team can compare how peoples' scores might have changed over the study period. Participants in one of the two Unmind groups will also be asked to provide feedback on their use of the sleep tools.

Finally, participants who were initially allocated to the control group will be given access to the Unmind app for a further four weeks, and will be free to use the sleep tools as little or as often as they like. They'll be invited to complete a third and final survey at the end of the second four-week period.

What are the possible benefits and risks of participating?
Participants will receive monetary compensation for taking part in the study, and some individuals may experience improvements in their sleep and mental health and/or wellbeing. The audio exercises that participants will be asked to use during the study are designed to aid relaxation and are not known to be associated with any negative effects. However, in the event of a participant experiencing a high degree of distress the research team would follow good practice and ensure that that individual is referred on to an appropriate source of support.

Each participant will be required to answer questions about their sleep and mental health, which may cause a degree of discomfort. Since individual responses will not be monitored, participants will be encouraged to seek appropriate support if they are worried about their sleep or mental health. Although participants will be given access to a sleep intervention, they will be asked not to change their normal sleeping routine, and not to engage with any new relaxation, meditation, or wellbeing apps (other than the study interventions. for the first 4 weeks of the study. This also applies to participants in the control group, who will have to wait 4 weeks to receive access to the Unmind app. The information sheet that participants receive will include details of who to contact in case of any concerns about their sleep or mental health, or in the event that they experience any distress or discomfort during the study.

Should participants feel uncomfortable answering any questions, they can opt to close the questionnaire and withdraw from the study. Participants can also withdraw any time after completing a questionnaire by contacting the research team.

Where is the study run from?
The study will be conducted online, and is a collaboration between the University of Sussex and Unmind Ltd (the creators of the digital mental health app being tested in this study. (UK).

When is the study starting and how long is it expected to run for?
February 2021 to April 2022.

Who is funding the study?
Unmind Ltd (UK)

Who is the main contact?
Professor Kate Cavanagh (kate.cavanagh@sussex.ac.uk)
Dr Marcos Economides (marcos.economides@unmind.com)

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Feasibility and preliminary efficacy of digital tools to improve sleep quality in working adults with poor sleep: protocol for a multi-arm randomised pilot trial

Study objectives
The primary aim of this study is to test the feasibility and acceptability of two brief interventions for poor sleep featured on the Unmind digital mental health platform. As the study is a pilot randomised controlled trial (RCT), it will not be powered for formal hypothesis testing. Preliminary intervention efficacy will be reported as secondary to the main feasibility results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/10/2021, University of Sussex Sciences & Technology Research Ethics Committee (Falmer, Brighton, BN1 9RH, UK; +44 (0)1273 877492; crecscitec@admin.susx.ac.uk), ref: ER /KC226/6

Study design
Interventional randomized controlled trial with nested pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions

This study will incorporate two nested trials. The primary study will be a multi-arm, parallel-group, external pilot RCT with pre- and post-intervention assessments. Participants will be randomised to one of two interventions featured on the Unmind platform (named Nightwaves and Sleep Tales), or to a wait-list control group, for a period of 4 weeks. The secondary study will be a non-randomized, naturalistic pilot study that will include participants randomized to the wait-list group in the primary study.

This study will evaluate two categories of standalone audio exercises designed to improve sleep featured on 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 via the Apple or Google Play stores. It features a wide range of resources and content created by academics and clinicians and is rooted in evidence-based practices.

Two specific categories of content will be evaluated in this study:
1. Nightwaves (NW; ambient music and nature sounds, each of which is 30-60 minutes in duration), and
2. Sleep Tales (ST; narrated stories, typically 15-40 minutes in duration, that include background music and/or sound cues).
Both categories are designed to be used prior to or immediately before bed, as an aid to falling asleep, or as an aid to get back to sleep after waking. The content of STs 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. NWs on the other hand do not include any voice narration. As of October 2021, there are 49 NWs and 9 STs featured on the Unmind app.

The primary study will recruit working adults with probable experience of poor sleep from an online recruitment platform (Prolific). Participants will be randomized (via the Qualtrics "randomizer" feature. to one of the two intervention arms (NW or ST. or to a wait-list (WL. control group with an allocation ratio of 1:1:1, immediately after completing a baseline assessment, for a period of 4 weeks. During this period, participants randomised to an intervention arm will be instructed to engage with one audio tool of their choosing per night (from their assigned intervention category. for the duration of the study (with an average of 3 sessions per week being the minimum threshold for inclusion in a per protocol analysis). Note that these instructions will serve as guidance only, and it will be made clear to participants that it will be acceptable to miss occasional nights throughout the 4-week study period.

For the secondary study, participants will be instructed to freely engage with any Sleep Tools of their choosing (from either NW or ST. as often as they would like (or not at all) for an equivalent 4-week period.

Intervention Type
Behavioural

Primary outcome measure
Primary outcomes will be captured through a combination of objective adherence data (captured continuously via the Unmind app. and a feedback questionnaire delivered post-intervention (4 weeks after baseline), and will be reported for each intervention arm separately (unless otherwise indicated). Outcomes will be equivalent for both the primary and secondary studies, and will include:
1. Feasibility: Recruitment, intervention uptake, and retention at post-intervention.

2. Acceptability: Intervention adherence (the proportion of participants completing, on average, at least 3 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.
3. Engagement: Average number of Sleep Tools used (for NW and ST, and combined across both), 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 (MARS).
4. Transferability: One item adapted from Section E of the MARS.
5. Relevance: One item assessing subjective relevance of the Sleep Tools
6. 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 baseline to post-intervention (based on a calculation of reliable change index for each measure. in NW and ST relative to the wait-list group; one item capturing lasting bad effects.

Secondary outcome measures
The following standardised, self-report measures will be completed at baseline (t0. and post-intervention (t1, 4 weeks after t0. for the primary trial, and post-intervention (4 weeks after t1. for the secondary trial (with the exception of the Single Item Sleep Quality Scale [SQS], which will be completed at screening instead of t0):
1. PROMIS Sleep Disturbance Short Form 8a (SD-SF)
2. PROMIS Sleep Related Impairment Short Form 8a (SRI-SF)
3. Single Item Sleep Quality Scale (SQS)
4. Work Productivity and Activity Impairment (WPAI)
5. Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)
6. Unmind Index (Overall Score only)
7. Patient Health Questionnaire-4 (PHQ-4)

Overall study start date
01/02/2021

Completion date
20/12/2021

Eligibility

Key inclusion criteria
1. Being at least 18 years old
2. Currently residing in the UK
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 (JSS)
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)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2000 at screening stage, with the aim of enrolling 300 eligible participants to the primary study

Total final enrolment
301

Key exclusion criteria
1. Undergoing treatment for a sleep disorder with a health 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
15/10/2021

Date of final enrolment
21/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sussex
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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Unmind Ltd

Results and Publications

Publication and dissemination plan
Planned publication in an open-access, peer-reviewed journal.

Intention to publish date
01/09/2022

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Dr Marcos Economides (marcos.economides@unmind.com, or research@unmind.com. following publication of the main trial findings. Data will be shared with other research teams for the purpose of contributing to systematic reviews and meta-analyses. Participant consent has been sought for this. Shared data will be fully anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/03/2023	17/11/2023	Yes	No