ISRCTN80309011 https://doi.org/10.1186/ISRCTN80309011

Brief use of the Unmind digital mental health platform

Submission date
19/01/2021

Recruitment status
No longer recruiting

Registration date
19/01/2021

Overall study status
Completed

Last Edited
04/03/2022

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
Mental ill-health affects hundreds of millions of employees worldwide, impacting individual quality of life and creating a significant economic burden for employers. However, many people struggle to access appropriate care in a timely manner. Recently, digital (online and smartphone-based) platforms have emerged as a means of providing mental health care that's widely accessible and affordable. Digital platforms can also enable employees to proactively look after their mental wellbeing, reducing their risk of developing problems in the future. Unfortunately, many digital mental health platforms have not been rigorously studied, and it remains unknown whether they are effective.

This study aims to conduct an initial test of Unmind -- a digital mental health platform for employees. Unmind provides employees with tools to help them maintain and improve their mental health and wellbeing, based on psychological techniques such as cognitive behavioural therapy (CBT) and mindfulness. The study will test three brief Unmind programmes that are designed to address stress, anxiety, and resilience, respectively. The programmes will be examined for recruitment, retention, engagement, acceptability, and preliminary indicators of potential effectiveness. If the programmes 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, who live in the UK and are in full- or part-time employment

What does the study involve?
Participants will be asked to complete a survey about their mental health and wellbeing, before being randomly allocated to one of the three Unmind programmes, or to a control group. Participants in the Unmind groups will be given free access to Unmind for two weeks and will have to complete their assigned programme on the platform. This will consist of seven sessions of approximately 10 minutes each, that can be accessed via the Unmind smartphone app or website. Participants in the control group will not have access to Unmind and won't need to complete a programme.

At the end of the two weeks, all participants will be asked to complete a second survey about their mental health and wellbeing, followed by a final survey a month later. This will enable the research team to compare how peoples' mental health scores might be changing over time between the four groups. Participants in one of the three Unmind groups will also be asked to provide feedback on their use of the Unmind platform.

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 mental health and wellbeing. Each participant will be required to answer questions about their 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 mental health. The psychological techniques taught by the Unmind programmes are not known to be associated with any adverse effects. However, in the event of a participant experiencing a high degree of distress the research team would follow good practice and ensure that the participant is referred on to an appropriate source of support.

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

When is the study starting and how long is it expected to run for?
August 2020 to March 2021.

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
6z3we

Study information

Scientific Title
Feasibility and preliminary efficacy of a digital intervention for common mental health problems in working adults: a multi-arm randomised pilot trial

Study objectives
The primary aim of this study is to test the feasibility and acceptability of three brief interventions featured on the Unmind digital mental health platform. As the present study is a pilot randomised controlled trial, 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 24/11/2020, University of Sussex Sciences & Technology Research Ethics Committee (Falmer, Brighton, BN1 9RH, UK; +44 (0)1273 877492; crecscitec@admin.susx.ac.uk), ref: ER /KC226/2

Study design
Parallel multi-arm external pilot randomized controlled trial

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
Common mental health problems in working adults

Interventions
This study will evaluate three individual self-guided programmes ('Series') that feature on the Unmind platform that address the management and/or prevention of common mental health problems. Participants will be randomised to one of the three intervention arms or to a no-intervention control group with an allocation ratio of 1:1:1:1. Randomisation will be implemented via the Qualtrics "randomizer" feature (https://www.qualtrics.com), which uses block randomisation to ensure balanced groups.

Unmind is a digital platform designed to be used by working adults to measure, manage and improve their mental health and wellbeing. It can be accessed via web, mobile or tablet (Android or iOS), and the Unmind smartphone app can be downloaded via the Apple or Google Play stores. The platform features a wide range of resources and content created by academics and clinicians with expertise in adult mental health, and rooted in evidence-based practices such as cognitive behavioural therapy (CBT; Beck, 1976), mindfulness meditation (MM; Kabat-Zinn, 1994), behavioural activation (BA; Jacobson, Martell, & Dimidjian, 2001), acceptance and commitment therapy (ACT; Hayes, Strosahl, & Wilson, 1999), and psychoeducation.

This study will focus on evaluating three individual Series that address the topics of stress, anxiety, and resilience, respectively. Series typically consist of between 5-7 sessions, each of approximately 10 minutes in duration, that are designed to be completed sequentially, and include a mix of audio and video content, infographics, and interaction with a chatbot. Each Series typically utilises one key therapeutic approach, such as CBT, MM or ACT. A brief description of the three intervention arms is included below:

1. Combatting Stress
This Series draws upon CBT and ACT techniques. Over the course of 7 sessions, it provides psychoeducation on stress and its physical manifestations, helps users to spot personal triggers, and explores different approaches to coping. It also introduces the idea of acceptance. Users are taught stress management techniques and are encouraged to practice between sessions.

2. Working With Worry
This Series is underpinned by a number of theoretical models of generalised anxiety disorder (GAD), although it is targeted at users who identify as worriers, rather than those meeting any predefined criteria for a diagnosis of GAD. Content spans 7 sessions and covers key elements of CBT, including tolerance of uncertainty, challenging worry beliefs, problem solving and working with imagery. It also encourages users to apply evidence-based techniques, including relaxation and attentional focus.

3. Building Resilience
This Series aims to help users apply evidence-based techniques to aid the cultivation of essential qualities of personal resilience, drawing upon CBT and ACT. Over the course of 7 sessions, learning covers topics such as honing strengths, facing challenges and tolerating discomfort. It also explores aspects such as styles of coping and realistic optimism. The Series encourages users to increase their self-awareness, and guides them to build a personal resilience plan.

Intervention Type
Behavioural

Primary outcome measure
Captured through a combination of objective adherence data (captured via the Unmind platform) and a feedback questionnaire delivered at post-intervention, and will include:
1. Feasibility: Recruitment, intervention uptake, adherence to instructions (the proportion of participants that engage with their assigned Unmind Series, without completing other platform content), and retention (at post-intervention and 1-month follow-up)
2. Acceptability: Intervention adherence (the proportion of participants completing all seven intervention sessions within the study period), participant satisfaction, reasons for discontinuing the intervention, and qualitative feedback
3. Engagement: Average intervention sessions completed, and three questions adapted from Sections A and B of the Mobile App Rating Scale (MARS; Stoyanov et al., 2015)
4. Transferability: One item adapted from Section E of the MARS
5. Relevance: One item assessing subjective relevance of the intervention
6. Adverse effects: One item adapted from recent guidelines on assessing adverse effects (Rozental et al., 2014), and the proportion of participants that deteriorate from pre- to post-intervention across all secondary outcome measures (for each intervention arm and relative to the no-intervention control)

Secondary outcome measures
Self-reported measures of common mental health problems (at baseline, post-intervention, and 1-month follow-up)
1. Stress, assessed using the Perceived Stress Scale (PSS; Cohen & Williamson, 1988) adapted for a two-week reporting period (see Baer, Carmody, & Hunsinger, 2012; Cavanagh et al., 2018)
2. Anxiety, assessed using the Generalized Anxiety Disorder-7 scale (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006)
3. Depression, assessed using the Patient Health Questionnaire-8 scale (PHQ-8; Kroenke, Spitzer, & Williams, 2001; Kroenke et al., 2009)

4. Resilience, assessed using the Brief Resilience Scale (BRS; Smith et al., 2008)
5. Mental wellbeing, assessed using the Unmind Index

Overall study start date
03/08/2020

Completion date
19/03/2021

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. Having an active account on the Prolific online participant recruitment platform (https://www.prolific.co)
5. Having access to an internet connection via a smartphone or desktop device
6. Being fluent in English

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Total final enrolment
400

Key exclusion criteria
Previous use of the Unmind platform

Date of first enrolment
25/01/2021

Date of final enrolment
28/01/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of Sussex
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Sponsor type
Industry

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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
01/12/2021

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) 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		03/03/2022	04/03/2022	Yes	No