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Brief use of the Unmind digital mental health platform to help tackle depressive symptoms

Submission date
21/09/2021

Recruitment status
No longer recruiting

Registration date
21/09/2021

Overall study status
Completed

Last Edited
19/06/2023

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
Depression is a common mental health disorder and evidence indicates that a considerable proportion of the general population (about 20-22%) experience subthreshold or mild to moderate symptoms. The implications of this are far-reaching and can include a poorer quality of life, and presenteeism and absenteeism in the workplace. Effective interventions such as psychological therapies can have limited accessibility and individuals are reportedly reluctant to engage due to associated stigma. In recent years, digital interventions (online or smartphone-based applications) designed to help people manage their mental health have become widely available and are less subject to problems of stigma, but unfortunately most have not been rigorously studied, meaning their effectiveness is unknown.
This study aims to conduct an initial test of interventions for low mood and depressive symptoms available on the Unmind platform. Unmind is a digital platform designed to help working adults measure, manage and improve their mental health and wellbeing. The study will test three brief interventions (called Series) based on psychological techniques including cognitive behavioural therapy and acceptance and commitment therapy. Each of the three Series will be tested for feasibility, acceptability and evidence of preliminary effectiveness in a group of working adults currently experiencing subthreshold or mild-moderate low mood and depressive symptoms. If the results show that the interventions are feasible, this will help to inform whether future studies should be conducted, and how such studies should be designed.

Who can participate?
Adults aged 18 years or over, living in the UK and in full- or part-time employment, who are interested in using digital interventions to help tackle low mood or depressive symptoms.

What does the study involve?
Participants will be asked to complete an online survey about their mental health and wellbeing, before being randomly allocated to one of four groups. Participants in the first three groups will then be given free access to the Unmind platform and will have 3 weeks to complete a short Series designed to help tackle low mood and depressive symptoms. At the end of the 3 weeks, access to Unmind will be removed and all participants will be asked to complete a second online

survey, similar to the first. Then, after a further 4 weeks have passed, all participants will be asked to complete a third and final online survey. Participants in the final (control) group will then also be given free access to the Unmind platform for 3 weeks.

What are the possible benefits and risks of participating
Participants will be asked questions about their mental health, and if they are in the first three study groups they will also be asked to use a brief intervention on the Unmind app designed to help tackle low mood. Some individuals may find this uncomfortable. Although the Unmind app is intended to be therapeutic, it's not a replacement for or a form of therapy. Nor is it intended to cure, treat, or diagnose medical conditions. Individual responses will not be monitored and therefore participants may wish to seek appropriate support if they are concerned about any aspect of their mental health. Participants will be signposted to support resources throughout the study and encouraged to contact their GP if needed.

Where is the study run from
This study is a collaboration between Unmind Ltd and the University of Sussex (UK)

When is the study starting and how long is it expected to run for
March 2021 to November 2021

Who is funding the study?
Unmind Ltd (UK)

Who is the main contact?
1. Dr Rachael Taylor, research@unmind.com
2. Prof. Kate Cavanagh, kate.cavanagh@sussex.ac.uk

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
S_02_pRCT

Study information

Scientific Title
Feasibility and preliminary efficacy of digital interventions for depressive symptoms in working adults: a multi-arm randomised pilot trial

Study objectives
The primary aim of this study is to assess the feasibility and acceptability of three brief interventions designed to help tackle low mood and depressive symptoms on the Unmind digital mental health and wellbeing platform. The present study is a pilot randomised trial and therefore will not be powered for formal hypothesis testing. The preliminary efficacy of each intervention will be reported as secondary outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2021, University of Sussex Sciences & Technology Research Ethics Committee (Falmer, Brighton, BN1 9RH, UK; +44 (0)1273 877492; crecscitec@admin.susx.ac.uk), ref: ER /KC226/4

Study design

Parallel multi-arm pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Low mood and depressive symptoms

Interventions
This study will evaluate three brief digital interventions for low mood and depressive symptoms on the Unmind digital mental health and wellbeing platform. Participants will be randomised 1:1:1:1 to an intervention arm or a waitlist control arm. Randomisation will be implemented by the Qualtrics "randomizer" feature (https://www.qualtrics.com), which uses block randomisation to ensure balanced groups. Unmind is a digital platform designed to help working adults measure, manage and improve their mental health and wellbeing. This study will evaluate three brief interventions (Series) on the Unmind platform intended to help users tackle low mood and depressive symptoms. Unmind can be accessed via the web on desktop, tablet or mobile devices. The mobile app can be downloaded from the Apple App or Google Play stores. Content on the platform is wide-ranging and includes a mood tracker (the 'Check-In'), an internally developed and validated measure of mental health and wellbeing (the 'Unmind Index'), a catalogue of standalone exercises designed to be used ad hoc ('Tools'), and more formal programmes designed to address specific areas of mental health and wellbeing, known as 'Series'. Unmind content is created by clinicians and academics with expertise in adult mental health, and is rooted in evidence-based practices including behavioural activation (BA) (Jacobson et al., 2001), cognitive behavioral therapy (CBT); (Beck, 1976), acceptance and commitment therapy (ACT) (Hayes et al., 1999), mindfulness meditation (Kabat-Zinn, 2004) and psychoeducation.

The Series assessed in this study are based on principles of BA, CBT and ACT for depression, and contain six to eight 10-20 minute sessions designed to be completed over a period of up to 3 weeks. The Series also include some additional activities or practices to be completed in between sessions, resources for which will be sent to users via email. The Series sessions include a combination of audio and video content, infographics, and chatbot interaction. Example screenshots from one of the Series included in this study are shown in Figure 1. Though rooted in evidence-based practices, the Series are not intended to be a substitute for professional treatment. A detailed description of each brief intervention included in this study is as follows:

Activate Your Mood (AYM)
AYM is a BA-based brief intervention for low mood and depressive symptoms consisting of eight

sessions of approximately 10 minutes each, and additional activities to be completed between specified sessions. This Series is designed to help the user understand the links between their behaviour and mood, and to increase their levels of activity, with the aim of improving mood. Users are encouraged to complete activities between sessions including a mood diary, activity monitoring and activity scheduling.

Mind Your Mood (MYM)
MYM is rooted in CBT for depression. The Series consists of six sessions of approximately 10 minutes each, and additional activities to be completed between sessions. MYM encourages the user to explore the cognitive component of low mood, understand the link between cognition and mood, and empowers them to spot and challenge negative thoughts. This Series includes advised activities between sessions, namely spotting and challenging negative thoughts and tackling rumination.

Finding Happiness (FH)
FH is an ACT-based brief intervention for low mood and depressive symptoms. The Series consists of seven sessions, each lasting 10-18 minutes. By looking at behaviour, clarifying values, and designing experiments, this Series helps users to expand their sense of meaning and purpose in the world, therefore improving their mood. Each session includes an experiential exercise (e.g. mindfulness) and users are encouraged to practice these between sessions.

Intervention Type
Behavioural

Primary outcome measure
Collected using a combination of objective adherence data obtained from the Unmind platform and self-report questionnaire data collected at the post intervention and follow up study assessments:
1. Feasibility: recruitment rate, intervention uptake (participants initiating their randomised brief intervention within the intervention period), and retention (study dropout)
2. Acceptability: intervention adherence (intervention completion rate, defined as the completion of all sessions of the allocated Series within the intervention period), activity adherence (the self-reported completion rate for all additional Series activities to be completed between sessions), participant satisfaction, reasons for non adherence, and qualitative feedback
3. Engagement: intervention sessions completed, self-reported additional (between session) activity completion, and three questions adapted from Sections A and B of the Mobile App Rating Scale (MARS)
4. Transferability: one question adapted from Section E of the MARS
5. Relevance: one question assessing subjective relevance of the brief intervention(s)
6. Negative effects: one question assessing bad effects, one question asking about lasting bad effects, and the proportion of participants that deteriorate from baseline to post intervention and follow up according to the PHQ-8 for each intervention arm and relative to the no-intervention control. Deterioration will be defined as an increase of >5 in PHQ-8 score from baseline

Secondary outcome measures
1. Mood measured using the Patient Health Questionnaire at baseline, post-intervention (3 weeks) and follow up (7 weeks).
2. Anxiety measured using the Generalised Anxiety Disorder Scale at baseline, 3 weeks and 7 weeks
3. Mental health and wellbeing measured using the Unmind Index at baseline, 3 weeks and 7

weeks
4. Mental wellbeing measured using the Short Warwick-Edinburgh Mental Wellbeing Scale at baseline, 3 weeks and 7 weeks
5. Health-related work productivity loss measured using the Work Productivity and Activity Impairment (WPAI) questionnaire at baseline, 3 weeks and 7 weeks

Overall study start date
30/03/2021

Completion date
22/11/2021

Eligibility

Key inclusion criteria
1. Aged 18+ years
2. Currently living in the UK
3. Fluent in English
4. Currently in full- or part-time employment
5. Internet access (desktop or mobile device)
6. Active account on the Prolific study recruitment website (https://www.prolific.co/)
7. Currently experiencing subthreshold or mild to moderate low mood and depressive symptoms according to the Patient Health Questionnaire 8 item version (PHQ-8; Kroenke et al., 2009), with a score between 5 and 14 at baseline
8. A self-reported interest in using a brief digital intervention designed to help tackle low mood and depressive symptoms
9. Willingness to download the Unmind app or engage with the platform via a desktop device and create an account using a personal email address.
10. Willingness to be randomised

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Self reported diagnosis of bipolar disorder, schizophrenia or other psychotic spectrum disorder, alcohol or substance use disorder, or neurocognitive disorder
2. Undergoing psychological therapy for low mood or depression with a health professional at screening

3. Previous use of the Unmind platform
4. Current or previous participation in another Unmind study
5. Participants will also be informed that they should not take part in this study should they be unwilling to commit to participation in the study period (3 weeks) and follow up (4 weeks)

Date of first enrolment
23/09/2021

Date of final enrolment
29/09/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

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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
1. The protocol has been uploaded as a private pre-registered project to the Open Science Framework (https://osf.io) but is not currently available to the public. It will be made available following the publication of the main trial findings.
2. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2022

Individual participant data (IPD) sharing plan
The datasets generated by this study will be indefinitely available upon request from Rachael Taylor (rachael.taylor@unmind.com) following the 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 and shared data will be fully anonymised. There are no other considerations or comments relating to this.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/06/2023	19/06/2023	Yes	No