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Digital interventions for anxiety and stress in working adults

Submission date
08/10/2021

Recruitment status
No longer recruiting

Registration date
08/10/2021

Overall study status
Completed

Last Edited
18/05/2023

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
Work-related stress, anxiety and depression are common and now account for 55% of all working days lost to work-related ill health. Workplace stress and anxiety are associated with a greater risk for other common mental health problems, as well as poorer mental wellbeing, poorer physical health, reduced work performance and unemployment. There is a clear and urgent need for effective interventions.
Traditional face-to-face psychological interventions for stress and anxiety are effective, but are often associated with stigma, are expensive, and may not be widely available or flexible enough to accommodate everyone that may find them beneficial. Over the past decade, there has been an increase in the use of smartphone-based mental health applications (MHapps), with over 1000 now available. MHapps have the potential to provide accessible interventions on a large scale and at a low cost and have been shown to be effective in reducing stress and anxiety. However, only 2% of MHapps are currently supported by original research, and there is less clear evidence about their effects in a workplace setting.
This study aims to evaluate the potential impact of brief digital interventions for anxiety or stress featured on a digital workplace mental health platform (Unmind), in a real-world sample of working adults with access to the platform through their employer. Unmind provides employees with tools to help them track, maintain, and improve their mental health and wellbeing. The brief interventions evaluated in this study are based on psychological techniques including cognitive behavioural therapy (CBT) and mindfulness meditation (MM). The study is naturalistic in design, with participants able to choose from a selection of individual modules (known as 'Series') to engage with. Series are standalone interventions typically consisting of between 5-7 sessions of about 10 minutes in duration. Each Series evaluated in this study is designed to help users tackle feelings of anxiety or stress, and participants will also be able to engage with other content on the platform during the study. This will be the first evaluation of Unmind's effects on mental health outcomes in a real-world setting.

Who can participate?
This study is not recruiting public volunteers at this time. Current employees at the participating organisation with internet access and an interest in using Unmind to help tackle feelings of

anxiety or stress will be invited to participate. (Updated 22/10/2021, previously: All current employees at the participating organisation with internet access and an interest in using Unmind to help tackle feelings of anxiety or stress will be eligible to participate.)

What does the study involve?
First, participants will be asked to complete an online survey about their mental health and wellbeing. They will then be asked to select and complete one of 4 Series designed to help users tackle anxiety or stress over three weeks. Participants will also be able to use any additional content on the Unmind platform that they wish to during this period. At the end of this first 3-week period, participants will be asked to repeat most of the first online survey. Participants will then have a further 3 weeks to use any content on the platform that interests them. Participants can engage with the platform as much as they like, and at a time convenient to them. Finally, at the end of this second 3-week period, participants will be asked to complete a third and final survey. This will be similar to the first two assessments, with the addition of a short feedback questionnaire.

What are the possible benefits and risks of participating
Taking part will require participants to answer questions about their mental health and to use at least one intervention on the Unmind app designed to help tackle symptoms of anxiety and/or stress. 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. If participants are worried about anxiety or stress, their broader mental health, or they experience any kind of distress during the study, they will be strongly advised to visit their General Practitioner (GP) or call the Samaritans free helpline. Participants will also be provided with information about relevant resources available to them through their employment with the participating organisation.

Where is the study run from?
The study will be run entirely online, managed by the research team at Unmind Ltd (UK)

When is the study starting and how long is it expected to run for?
June 2021 to May 2022

Who is funding the study?
Unmind Ltd (UK)

Who is the main contact for the study?
Dr Rachael Taylor
research@unmind.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CS_01

Study information

Scientific Title
Digital interventions for anxiety and stress in working adults: protocol for a real world, single arm trial

Study objectives
The primary aim of this study is to evaluate the potential for impact of brief digital interventions for anxiety or stress featured on a digital mental health platform (Unmind). The researchers expect to see improvements in all primary and secondary outcome measures at the post-intervention time point relative to baseline and expect that these improvements are at least maintained at follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 08/10/2021, University of Sussex Sciences & Technology Research Ethics Committee (Falmer, Brighton, BN1 9RH, UK; +44 (0)1273 877492; crecscitec@admin.susx.ac.uk), ref: ER /KC226/5

Study design
Single-arm non-randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Feelings of stress and anxiety

Interventions
Unmind is a digital platform designed to help working adults measure, manage and improve their mental health and wellbeing. This study will evaluate the use of content on the Unmind platform designed to tackle symptoms of anxiety and stress. 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 BA (Jacobson et al., 2001), CBT; (Beck, 1976), ACT; (Hayes et al., 1999) and mindfulness meditation (Kabat-Zinn, 2004).

The content evaluated in this study will include 4 Series designed to help tackle anxiety and stress, listed below. Participants will also be encouraged to engage with any additional content on the Unmind platform during the study, recommendations for which will include the 'additional content' Series and tools listed below which are also designed to support users in managing specific anxiety symptoms and build resilience.

Mindfulness for Anxiety
This Series encompasses techniques from mindfulness and compassion-focused therapy and consists of 4 sessions, each lasting around 16 minutes. The Series is designed to help users change their relationship to anxiety, through applying self-compassion techniques and learning basic self-soothing.

Combatting Stress
This Series draws upon CBT and ACT techniques. Over the course of 7 sessions, each lasting approximately 8 minutes, it provides psychoeducation on stress and its physical manifestations. It also helps users to spot their own stress triggers, explores different approaches to stress management and introduces the principle of acceptance.

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 of approximately 12 minutes each and includes techniques designed to build tolerance of uncertainty, challenge worry beliefs, and bolster problem-solving skills.

Switching Off
This Series is designed to help users switch off from work, and detach from related rumination and worry. It consists of 7 sessions of approximately 11 minutes each and takes a CBT approach. The Series explores unhelpful beliefs, tackles perfectionism and incorporates practical problem-solving techniques to help increase resilience in the face of work-related stress.

Additional recommended content
The following Series designed to help users manage specific anxieties, burnout, difficult life events, and build resilience will also be recommended to participants as additional content they may find relevant and useful during the study. Series titles are 'Overcoming Burnout', 'Building Resilience', 'Tackling OCD', 'Social Anxiety', 'Tackling Panic', 'Health Anxiety', 'Mindfulness for Difficult Times'. Tool recommendations will also be made, including Tools in the 'Calm' category, which are brief audio sessions designed to help users manage anxiety and stress, the 'Transform' category, which are intended to help users overcome challenges, and the 'Mindfulness' category.

Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety measured using the Generalised Anxiety Disorder Scale at baseline, 3 weeks and 6 weeks
2. Stress measured using the Perceived Stress Scale at baseline, 3 weeks and 6 weeks

Key secondary outcome(s))
1. Wellbeing measured using the Unmind Index at baseline, 3 weeks and 6 weeks
2. Mood measured using the Patient Health Questionnaire (8 item version) at baseline, 3 weeks and 6 weeks
3. Self-efficacy measured using a single question adapted from the Mental Health Self Efficacy Scale at baseline, 3 weeks and 6 weeks
4. Acceptability measured as participant satisfaction, reasons for non-adherence, qualitative feedback and self-reported bad effects at 6 weeks. Reasons for non-engagement with the Unmind platform prior to the study will be collected at baseline.

Completion date
22/05/2022

Eligibility

Key inclusion criteria
1. Aged 16+ years
2. Eligible for access to the Unmind platform through their current employment with the participating organisation
3. Proficient in English
4. Internet access (desktop or mobile device)
5. A self-reported interest in using a brief digital intervention designed to help tackle symptoms of stress and anxiety

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
599

Key exclusion criteria
1. Current or previous participation in an Unmind study
2. Unwilling or unable to commit to participation for the full study duration (6 weeks)

Date of first enrolment
13/10/2021

Date of final enrolment
04/04/2022

Locations

Countries of recruitment
United Kingdom

England

Hong Kong

India

Study participating centre
Unmind Ltd
180 Borough High Street
London
United Kingdom
SE1 1LB

Sponsor information

Organisation
Unmind Ltd

Funder(s)

Funder type
Industry

Funder Name
Unmind Ltd

Results and Publications

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