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The effectiveness of a self-care smartphone app intervention in reducing symptoms of depression and anxiety

Submission date
28/03/2021

Recruitment status
No longer recruiting

Registration date
01/04/2021

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression and anxiety symptoms are common in university students and can have a serious impact on academic performance, quality of life and overall well-being. Many barriers to receiving help exist, including a perceived lack of need for help, a lack of time, stigma and long waiting lists for university wellbeing services. Digital interventions for mental health difficulties, such as mobile phone applications, offer a timely, private and effective intervention for students with symptoms of anxiety and depression. Despite numerous smartphone therapeutic interventions being available, the level of evidence is lacking. The aim of this study is to evaluate the effectiveness of a publicly available self-care smartphone application (My Online Therapy) in reducing symptoms of depression and anxiety in a student population.

Who can participate?
Adult students at UK universities who are currently experiencing feelings of depression and/or anxiety.

What does the study involve?
Participants will be randomly allocated to one of two groups. Those in the first group will be placed on a 'wait-list' for the duration of the study (8 weeks). Those in the second group will be given access to a self-care smartphone application (Mt Online Therapy) for the study period (8 weeks). At the start of the study and then each week for the study period (8 weeks), participants will complete a number of questionnaires to examine whether there are any changes in their mood and wellbeing.

What are the possible benefits and risks of participating?
There is a potential immediate benefit of reducing any feelings of depression and/or anxiety. It is also hoped that this work will inform our understanding of the use of digital interventions in the treatment of mental health issues. However, it is also possible that using the application will not improve mental wellbeing or reduce feelings of depression and/or anxiety.

Where is the study run from?
University College London (UCL) (UK)

When is the study starting and how long is it expected to run for?
November 2020 to April 2023

Who is funding the study?
University College London (UCL) (UK)

Who is the main contact?
Olivia McGowan
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Contact information

Type(s)
Scientific

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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
The effectiveness of a self-care smartphone application in reducing symptoms of depression and anxiety in a university student population: a randomized controlled trial

Study objectives
Use of a self-care smartphone application for 8-weeks will show a greater reduction in depression and anxiety symptoms compared to a 'wait-list' control condition for the same duration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/03/2021, University College London (UCL) Research Ethics Committee (Office of the Vice-Provost (Research), University College London, 2 Taviton St, London WC1E 6BT, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), Project ID: 1338/010

Study design
Single-centre interventional parallel 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
See additional files

Health condition(s) or problem(s) studied
Depression and anxiety

Interventions
The researchers will use a block randomisation method in which they will randomise blocks of 30 participants at a time to ensure equal numbers of participants in each group across the trial. Participants will be randomized to one of two groups:

Control group: Those in the control group will be placed on a 'wait-list' for the duration of the study period (8 weeks).

Intervention group: Those in the intervention group will be given access to My Online Therapy's self-care smartphone application, a publicly available that holds a library of short evidence-based audio therapy skills. Participants will have full access to the application throughout the 8-week trial period.

Intervention Type
Behavioural

Primary outcome measure
Measured via self-report questionnaires administered online:
1. Depression symptoms measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline and then weekly for 8 weeks
2. Anxiety symptoms measured using the Generalized Anxiety Disorder-7 (GAD-7) scale at baseline and then weekly for 8 weeks

Secondary outcome measures
Current secondary outcome measures as of 25/05/2021:
1. General mood measured by the Positive and Negative Affect Schedule (PANAS) at baseline and then weekly for 8 weeks
2. Self-compassion measured by the Self-Compassion Scale (SCS) at baseline and then weekly for 8 weeks
3. Mindfulness measured by the Mindfulness Attention Awareness Scale (MAAS) at baseline and then weekly for 8 weeks
4 Social connectedness measured by the Social Connectedness Scale at baseline and then weekly for 8 weeks
5. General well-being measured by the CORE Outcome Measure (CORE-OM) questionnaire at baseline and week 8
6. Quality of life measured by the 12-item Short-Form Health Survey (SF12) at baseline and week 8
7. Life satisfaction measured by the Satisfaction with Life Scale at baseline and week 8
8. Application usage measured by My Online Therapy's routinely collected frequency and duration of use data throughout the 8-week trial period

Previous secondary outcome measures:
1. General mood measured by the Positive and Negative Affect Schedule (PANAS) at baseline and then weekly for 8 weeks
2. Self-compassion measured by the Self-Compassion Scale (SCS) at baseline and then weekly for 8 weeks
3. Mindfulness measured by the Mindfulness Attention Awareness Scale (MAAS) at baseline and then weekly for 8 weeks

4 Social connectedness measured by the Social Connectedness Scale at baseline and then weekly for 8 weeks
5. General well-being measured by the CORE Outcome Measure (CORE-OM) questionnaire at baseline and week 8
6. Quality of life measured by the 12-item Short-Form Health Survey (SF12) at baseline and week 8
7. Application usage measured by My Online Therapy's routinely collected frequency and duration of use data throughout the 8-week trial period

Overall study start date
01/11/2020

Completion date
28/02/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 25/05/2021:
1. Aged 18 years or older
2. Current UK university student, including undergraduates and postgraduates
3. Has access to a smartphone with iOS or Android operating system
4. Self-reporting symptoms of depression and/or anxiety

Previous participant inclusion criteria:
1. Aged 18 years or older
2. Current student at University College London (UCL), including undergraduates and postgraduates
3. Has access to a smartphone with iOS or Android operating system
4. Self-reporting symptoms of depression and/or anxiety

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
230

Key exclusion criteria

1. Current psychiatric diagnosis
2. Current use of psychiatric medication
3. Any past or current major medical condition
4. Any previous negative experiences with psychological therapy

Date of first enrolment
12/04/2021

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
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Sponsor information

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Sponsor type

University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
University College London

Alternative Name(s)
University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
The current data-sharing plans for the study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/04/2021	No	Yes
Statistical Analysis Plan		30/08/2022	30/08/2022	No	No