

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/04/2021	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/11/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre
University College London
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Sponsor information

Organisation
University College London

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

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	Participant information sheet		06/04/2021	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		30/08/2022	30/08/2022	No	No