

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

<b>Submission date</b> 28/03/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/04/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/11/2023	<b>Condition category</b> 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  
olivia.mcgowan.20@ucl.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr James Bisby

**ORCID ID**  
<https://orcid.org/0000-0002-5334-3969>

**Contact details**  
UCL Division of Psychiatry  
Maple House  
149 Tottenham Court Road  
London  
United Kingdom  
W1T 7NF  
+44 (0)20 7679 7798  
j.bisby@ucl.ac.uk

**Type(s)**  
Public

**Contact name**  
Miss Olivia McGowan

**Contact details**  
UCL Division of Psychiatry  
6th Floor  
Maple House  
149 Tottenham Court Road  
London  
United Kingdom  
W1T 7NF  
+44 (0)207 679 7798  
olivia.mcgowan.20@ucl.ac.uk

# 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

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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**

6th Floor

Maple House

149 Tottenham Court Road

London

United Kingdom

W1T 7NF

## **Sponsor information**

**Organisation**

University College London

**Sponsor details**

UCL Division of Psychiatry

6th Floor

Maple House

149 Tottenham Court Road

London

England

United Kingdom

W1T 7NF

+44 (0)20 7679 2000

researchservices@ucl.ac.uk

**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?
<a href="#">Participant information sheet</a>			06/04/2021	No	Yes
<a href="#">Statistical Analysis Plan</a>		30/08/2022	30/08/2022	No	No