ISRCTN13546434 https://doi.org/10.1186/ISRCTN13546434

# Helping people manage anxiety and depression using mindfulness and emotional awareness through smartphone-based support

**Submission date**
29/09/2025

**Recruitment status**
No longer recruiting

**Registration date**
29/09/2025

**Overall study status**
Completed

**Last Edited**
29/09/2025

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
This study is part of a larger research project that aims to understand what helps people stick to and achieve their goals in everyday life. Researchers test a strategy that may improve motivation and goal-setting. They also use a mobile phone app to track behaviour and wellbeing throughout the day. The purpose is to make sure the process works well and feels acceptable to participants before launching a larger study.

Who can participate?
Participants must be aged 18 years or older, live in the UK, be able to read and understand English, and own a personal mobile phone with Android or iOS. People with a current mental health diagnosis or who are receiving psychotherapy are not eligible to take part.

What does the study involve?
Participants begin by completing questionnaires about their wellbeing, behaviour, and background. They then learn a strategy to help with goal-setting, either through a short session with a researcher or a step-by-step guide. For 28 days, they use a mobile app to answer short questionnaires six times a day. Each questionnaire takes less than a minute. Participants receive reminders to use the strategy and provide feedback on how it works for them. The app also collects passive data such as movement and location to help researchers understand daily activity patterns. No travel is required, but participants need reliable internet or mobile data.

What are the possible benefits and risks of participating?
Participants may benefit from learning a strategy that improves motivation and behaviour. At the end of the study, they receive a personalised report showing what helps or hinders their goal pursuit. All participants are entered into a prize draw for a £50 voucher. Those who complete at least 80 percent of the app questionnaires receive £20. The main risk is the time commitment, as participants complete six short questionnaires each day for 28 days. They may also become more aware of their feelings and behaviour, which could feel uncomfortable. Data is collected online, but steps are taken to keep it secure and confidential.

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

When is the study starting and how long is it expected to run for?
November 2023 to February 2025.

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

Who is the main contact?
Dr Ciaran O'Driscoll , c.odriscoll@ucl.ac.uk

# Contact information

### Type(s)
Public, Scientific, Principal investigator

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
158328

# Study information

### Scientific Title
Mindfulness and mentalization smartphone-based Ecological Momentary Interventions for common mental health problems: a pilot randomized controlled trial

### Acronym

EE EMI UCL

## Study objectives
The primary aims of this study are to examine:
1. The impact of perceived expressed emotion (EE) on mood and behaviour in people experiencing clinically significant depressive or anxious symptomatology, i.e. a clinical sample.
2. Whether implementing an ecological momentary intervention (EMI) to support mentalisation mitigates the impact of perceived EE on mood and behaviour over time in a clinical sample compared to an active control condition.
3. Examine the acceptability and feasibility of delivering a mentalisation EMI in a clinical sample.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 17/11/2023, University College London (UCL) Research Ethics Department (Gower Street, London, WC1E 6AE, United Kingdom; +44 (0) 20 7679 2000; ethics@ucl.ac.uk), ref: 26261/001

## Study design
Parallel-group pilot randomized controlled trial with 1:1 allocation ratio and exploratory framework

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Depression, anxiety

## Interventions
All participants download the m-path app. They then complete identical ecological momentary assessments (EMA) four times daily for 28 days, scheduled around individual sleep-wake times. Each assessment measures mood, stress, perceived expressed emotion (criticism, hostility, overinvolvement), warmth, and interpersonal behaviours. Participants receive video training on app use.

Participants are randomly allocated to fully automated mindfulness-based or mentalization-based ecological momentary interventions via computer-generated randomisation.

Intervention phase begins after 20 timepoints of baseline EMA, continuing for 21 days. The EMI is activate when any EE item ratings (criticism, hostility, overinvolvement or support) deviate >1 standard deviation from their rolling average. Interventions are delivered automatically via the mPath app.

Mentalization-EMI arm: This micro-intervention was a structured reflection exercise on self and others' mental states with a free-text response option to aid reflection. The first step encourages self-focused mentalizing, asking the client to reflect on their own perspective and understanding of a situation. Then other-focused mentalizing is encouraged, specifically asking

the client to imagine the mental states (drives, motivations) and the intentions behind the other person's actions. The final step encourages self-focused mentalizing with a future orientation, asking the client to reflect on alternative responses and their own intentions for future behaviour.

Mindfulness arm: This micro intervention employs a three-step mindfulness breathing exercise. The first step encourages internal awareness. The second step present-moment awareness and acceptance of one's current mental state, with an emphasis on physical sensations. The final step, integration of multiple physical aspects of self-experience (whole body awareness).

Participants are blind to the alternative intervention options. Outcomes are self-assessed through questionnaires after four weeks.

### Intervention Type
Behavioural

### Primary outcome(s)
1. Recruitment rate evaluated by tracking the number of individuals screened, the number meeting eligibility criteria, and the percentage of eligible participants who subsequently consented and were randomised to a study arm.
2. Retention rates defined as the percentage of randomised participants who completed the final study assessment at 4-week.
3. Adherence rates operationalised as the percentage of participants who engaged with at least 60% of the EMAs over the 4-week intervention period.
4. Engagement with the intervention content measured by the average number of mindfulness or mentalizing exercises completed per participant throughout the intervention period, as recorded by the application.
5. Acceptability post intervention measures using a post-intervention questionnaire. This assessment aims to understand participants' perceptions of the intervention's usability, utility, and overall experience. In addition to quantitative ratings, participants provide open-ended questions to offer qualitative feedback on their overall experience, including perceived benefits, challenges, suggestions for improvement, and any other relevant comments regarding the intervention and the delivery method.

### Key secondary outcome(s))
At baseline and post intervention (4 weeks):
1. Depression (PHQ-9)
2. Anxiety (GAD-7)

### Completion date
15/02/2025

## Eligibility

### Key inclusion criteria
1. Aged 18 years or above
2. Currently experiencing symptoms of anxiety and/or depression (scoring in clinical range, a ‘caseness’ threshold score of >9 on the PHQ-9, or >7 on the GAD-7)
3. Able to access and use a personal smartphone

4. Had daily contact with a partner, family member(s) or friend
5. Were able to read and write in English
6. Were registered with a GP in the UK.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
84

### Key exclusion criteria
1. Currently receiving psychological therapy
2. Taking medication for their mental health
3. Expressing any suicidal ideation or thoughts of self-harm at the point of screening (i.e. scored >0 on question nine of the PHQ-9)

### Date of first enrolment
03/03/2024

### Date of final enrolment
12/01/2025

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**University College London**
Research Department of Clinical, Educational and Health Psychology
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**
This is a retrospective registration -this study was pre-registered: as predicted (#158328). All data and code has been saved on the Open Science Framework https://osf.io/chfy2/

**IPD sharing plan summary**
Stored in publicly available repository