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Memory reshaping for depression: a randomised controlled feasibility trial of a novel blended digital therapy

Submission date
23/06/2025

Recruitment status
Recruiting

Registration date
26/06/2025

Overall study status
Ongoing

Last Edited
26/01/2026

Condition category
Mental and Behavioural Disorders

[X] 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 testing a new kind of digital therapy for people with major depression. The therapy is designed for those who find it hard to engage with current mental health treatments, such as talking therapies or medication. It uses simple, self-guided techniques that people can use in their daily lives, especially helpful for those who are sensitive to medication or prefer to work independently. The therapy focuses on reshaping personal memories that may contribute to low mood and self-worth. It combines two approaches—one that helps people recall positive experiences more flexibly, and another that helps reduce feelings of self-blame. These methods have shown promise in earlier studies, and this trial will test how well they work together when delivered through a mobile app.

Who can participate?
Adults who have been diagnosed with major depressive disorder may be eligible to take part. There are some criteria that need to be met, and some conditions that may exclude people from participating, such as recent changes in medication.

What does the study involve?
Participants will be randomly assigned to one of two groups: one group will use the new memory reshaping app (called MemReD), and the other will use a standard online cognitive behavioural therapy (CBT) programme. Both groups will follow their assigned programme for 8 weeks. The therapy is delivered remotely, so participants can take part from home using their smartphone or tablet.

What are the possible benefits and risks of participating?
Taking part may help improve symptoms of depression, especially for those who haven’t found other treatments helpful. The study also helps researchers develop better therapies for the future. As with any mental health treatment, there may be emotional discomfort when reflecting on personal experiences, but support is available throughout the study.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
February 2025 to October 2028

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof. Roland Zahn, roland.zahn@kcl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
355767

Protocol serial number
MR/Y008545/1

Study information

Scientific Title
Memory Reshaping for Depression: a randomised controlled feasibility trial of a novel blended digital therapy

Acronym
MemReD - Feasibility RCT

Study objectives
The primary objective of this study is to probe the feasibility of memory reshaping for depression (MemReD), a novel blended digital therapeutic which is based on two previous face-to-face interventions. This feasibility randomised controlled trial will compare the new programme against the gold standard self-guided therapy in the UK National Health Service: computerised cognitive behavioural therapy (online CBT).

Our secondary objective is to estimate standard deviations of the outcome measures allowing us to inform sample size requirements for future efficacy and safety trials.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/07/2025, London - South East Research Ethics Committee (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 207 104 8000; londonsoutheast.rec@hra.nhs.uk), ref: 25/LO/0445

Primary study design
Interventional

Study design
Feasibility randomized controlled trial using two parallel groups

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of major depressive disorder

Interventions
This is a single-blind (assessors blinded for observer-rated outcomes), controlled feasibility randomisation trial. Our Clinical Trials Unit will use minimisation for baseline Maudsley Staging Model treatment-resistance subscale scores for i) duration (acute (01), sub-acute (02), chronic (03)), ii) symptom severity (mild (01), moderate (02), severe without psychosis (03)), and iii) treatment failures (mild (01), moderate (02), severe (03)) (Fekadu et al., 2009) when randomising into 1) 8 weeks of standard online computerised CBT which we will give participants access to vs. 2) our blended digital therapy , the MemReD programme (5 weeks of Memory Flexibility Training, followed by 3 weeks of self-blame-related memory re-appraisal training).

MemReD arm: The novel psychological intervention consists of four live video-based sessions with our research assistant (one memory flexibility and three self-blame reappraisal sessions based on the protocols from our previously published pilot trials with an additional strategy added during our lived experience co-design stage (“Standing up for yourself”, see also above) and use of the MemReD app to work through the 10 steps of the self-guided MemFlex programme and to remind of psychological strategies for the blame rebalancing training, log their usefulness and monitor symptoms. The MemReD app also hosts general information about depression in the form of short videos which have been co-designed with the MemReD expert by lived experience user group.

Internet CBT arm: Participants will get access to the standard internet CBT programme used in NHS improved access to psychological treatment services (IAPT) which is a self-guided programme over 8 weeks which consists of video and text-based materials explaining the CBT-approach and allowing participants also to track their mood state using standard scales (PHQ-9 and GAD-7), similarly to the functionality within MemReD. There will be no sessions with a psychologist as this is not part of the standard internet CBT intervention. However, the research team will be available to participants with any queries or should they feel worse during this 8-week period for advice as in the MemReD arm.

Intervention Type
Mixed

Primary outcome(s)
Acceptability measured by loss-to-follow-up rates

Key secondary outcome(s)
Standardised follow-up assessments 10–11 weeks after the baseline visit will assess trial outcomes:
1. Adherence is measured using app engagement data automatically recorded in the app and a self-report questionnaire at follow-up.
2. Acceptability of the web-based app is also measured using the Technology Acceptance Model – Fast Form (TAM-FF) at follow-up.
3. Acceptability of the treatment programme is further measured using the Satisfaction with Therapy subscale (Oei & Green, 2008) at follow-up.
4. Costs are measured using a service use questionnaire developed at the IoPPN and follow-up.
5. Quality of life is measured using the EQ-5D-5L at baseline and follow-up.
6. Adverse event rates are measured using clinical monitoring and adverse event reporting forms at follow-up.
7. Recruitment rate is measured using trial screening logs monthly after baseline assessment.

The following clinical measures will be used for characterising participants and their symptoms prior and after the intervention, but not as outcome measures per se. Standard deviation estimates for computing effect size estimates on symptom measures to inform sample size calculations for larger subsequent trials will be derived from measures of depressive symptoms:
8. Depressive symptoms are measured using the Montgomery-Åsberg Depression Rating Scale (MADRS) at baseline and final visit. This could be used as the primary outcome in our future definitive trial.
9. Global clinical change is measured using the Clinical Global Impression change scale rated by participant and blinded observer at final visit.
10. Anxiety symptoms are measured using the Generalised Anxiety Disorder – 7 (GAD-7) scale at baseline and final visit.
11. Depressive symptoms are also measured using the Maudsley Modified PHQ-9 (MM-PHQ-9) at baseline and follow-up.
12. Self-esteem is measured using the Rosenberg Self-Esteem Scale at baseline and follow-up.
13. Self-blame is measured using the moral emotion addendum of the AMDP Psychopathology Interview at baseline and follow-up.
14. Psychosocial functioning is measured using the DSM-5 Social and Occupational Functioning Scale at baseline and follow-up.
15. Psychiatric status is measured using the Psychiatric Status Ranking scale at baseline and final follow-up.

Completion date
31/10/2028

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. PHQ-9 score≥10 (i.e. “caseness” definition in NHS psychological treatment services)
3. Diagnosis of MDD on SCID-I for DSM-5
4. Able to understand written materials, this is essential for the scientific quality of the study, because this intervention is text-based in large parts, which at this stage of the research we are only able to provide in English with translations into other languages planned should our project be successful and allow us to obtain further funding

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Previously tried computerised CBT
2. High suicide risk (MINI suicidality screen)
3. Current self-harm with injuries within the last 6 months (self-report)
4. Medication changed in the last 6 weeks including dose changes (self-report)
5. Ongoing psychotherapy (self-report)
6. Past violence in the last 6 months (self-report)
7. Current aggression (screening or pre-screening assessments)
8. Current psychotic symptoms (screening or pre-screening assessments)
9. History of schizophreniform symptoms (screening or pre-screening assessments using validated screening questions)
10. Bipolar disorder including otherwise specified (structured interview for DSM-5 or pre-screening assessment)
11. Current mixed episode (structured interview for DSM-5)
12. No personal smartphone or tablet with internet access

Date of first enrolment
22/01/2026

Date of final enrolment
30/05/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Psychiatry, Psychology & Neuroscience, King's College London
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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in anonymised format in a non-publicly available repository such as https://kcl.figshare.com/.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes