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An international study of therapist-supported online cognitive behavioural therapy for the reduction of repetitive negative thought (overthinking, rumination, worry) in adults: the Calming Minds study

Submission date
18/12/2025

Recruitment status
Recruiting

Registration date
06/01/2026

Overall study status
Ongoing

Last Edited
04/02/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Repetitive negative thought (including worry, overthinking, rumination) is known to exacerbate and prolong stress and low mood and increase the risk of developing clinical anxiety and depression. Reducing repetitive negative thought can benefit many people's wellbeing and mental health and improve the treatment and prevention of anxiety and depression. We have developed a version of cognitive behavioural therapy (CBT) that has been proven to effectively reduce repetitive negative thought in face-to-face and online treatment. However, CBT has many components, and we don't know which are the active ingredients. This study aims to help us understand how CBT reduces repetitive negative thought. If we can find out which components within CBT are the active ingredients that best reduce repetitive negative thought, we can further improve treatment to make it more powerful, simpler, and more available, and help more people reduce their repetitive negative thought, stress, low mood and anxiety. We are comparing 16 versions of CBT to see which one is most effective at reducing repetitive negative thought. Each of the 16 versions will be made up of different combinations of the key components of CBT, including some core common elements.

Who can participate?
Anyone aged 18+ years who has elevated levels of repetitive negative thought, has access to a suitable smartphone - Android version 8.0 or higher, or, Apple, iOS 16.4 or later. People will not be able to take part if any of the following applies to them as the study is unlikely to be suitable: severe post-traumatic stress disorder (PTSD), current alcohol or substance abuse/dependence; diagnosed with bipolar disorder or psychosis; having suicidal thoughts. People will also not be able to take part if you are currently receiving another form of psychotherapy or have been taking antidepressants or anti-anxiety medications at a stable dose for less than six weeks,

because this would prevent us from determining whether any change in repetitive negative thought is due to the CBT provided through the study. If people are unable to take part in the study for any of these reasons, they will be signposted to relevant advice or support.

What does the study involve?
Participants will receive one of 16 variants of online CBT with either a high or low level of information on each of the CBT components. They will have up to 16 weeks to complete 6 therapy sessions. They will also receive a minimum of three contact sessions with a Psychological Wellbeing Practitioner (PWP; UK)/coach (USA) during the treatment phase to support their completion of the online CBT. Participants will also complete questionnaires before the therapy, through the 16-week treatment period and at 16- & 52-weeks after they join the study.

What are the possible benefits and risks of participating?
Everyone who takes part in the study will receive free online CBT. The online CBT includes six online sessions and a minimum of three video/telephone sessions with a trained therapist, which people can find beneficial. Participants will receive information about support services that could be relevant to them. By taking part, participants will help to improve treatment for repetitive negative thought, which in turn will improve the well-being and mental health for many people, including those with, or at risk of, depression and anxiety. They may also learn about, understand, and better manage their own repetitive negative thought.
There is no known health risk with any of the questionnaires or therapy being used in this study. However, completing the questionnaires and the CBT can be time-consuming. Also, because some of the questionnaires ask about past and present negative emotions and experiences, and the CBT asks you to try new strategies, there is a small chance that this may produce mild and brief upset if you are reminded of an unpleasant event. However, this would typically be no more than usually experienced in daily life. One of the questionnaires asks about suicide, which can be a distressing thing to be asked about. The study therapists will be available to support you in the event of any distress, and if they have any concern,they may contact you to discuss and signpost or refer you to appropriate services as appropriate.

Where is the study run from?
The study is being run by University of Exeter in the UK and University of California, Los Angeles in the USA.

When is the study starting and how long is it expected to run for?
The study is starting in early 2026 and is expected to be recruiting participants until the end of 2027 with the final participants being followed up for 12 months after that. The overall end of the study and the results are anticipated for end of 2029.

Who is funding the study?
The study is funded by the Wellcome Trust (UK)

Who is the main contact?
Calming-minds@exeter.ac.uk

Contact information

Type(s)
Scientific

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356635

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Study information

Scientific Title
An international randomised factorial trial of therapist-supported online cognitive behavioural therapy for the reduction of repetitive negative thought (overthinking, rumination, worry) in adults: the Calming Minds study

Study objectives
The objective of this study is to delineate the causal mechanisms underpinning reduction in RNT, a characteristic of the most common mental health conditions. Our specific inter-related research questions are:
1. What are the causal mechanisms that underpin effective cognitive-behavioural interventions to reduce RNT?
2. What are the active ingredients within RNT-focused cognitive-behavioural therapy (RF-CBT) that effectively manipulate these mechanisms, and, thereby, reduce RNT?

Secondary objectives are to:
1. Examine potential moderators of treatment outcome by condition and to examine potential personalisation.
2. Examine the mechanism and factors related to implementation.
3. Development and examination of linguistic Natural Language Processing markers.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/12/2025, Yorkshire and The Humber – Leads East (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048138; leedseast.rec@hra.nhs.uk), ref: 25/YH /0227

Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Repetitive negative thought (overthinking, rumination, worry)

Interventions
If the participant has completed their baseline questionnaires and 60% of the mPath prompt questions within the specified time limits, they will proceed to be automatically randomised via the study database (REDCap).

They will be allocated to one of 16 variants of the online CBT. Each of the 16 versions will be made up of different combinations of the key components of CBT, including some core common elements.

The online CBT will consist of six sessions, completed online in a self-directed manner via the MyDataHelps platform. Participants will be given 16 weeks to complete these.

Participants will also have a minimum of three and a maximum of six phone/videocalls with a PWP (UK)/coach (US) throughout this period to support them in completing the online CBT.

Intervention Type
Behavioural

Primary outcome(s)
RNT as indexed by the Perseverative Thinking Questionnaire from baseline to post-treatment (16 weeks)

Key secondary outcome(s))
The following secondary outcomes will be measured using standardised validated measures at baseline, and post-
treatment at 16 weeks and 52 weeks post-randomisation via participant survey on REDCap:
1. Anxiety measured with General Anxiety Disorder-7 (GAD-7)
2. Depression measured with Patient Health Questionnaire-9 (PHQ-9)
3. Mental wellbeing measured with Warwick-Edinburgh Mental Wellbeing Scale Short-form (WEMWBS)
4. Levels of rumination measured with RRS-Brooding subscale
5. Levels of worry measured with Penn State Worry Questionnaire –short-form (PSWQ)
6. Social functioning measured with Work and Social Adjustment Scale (WSAS)

The following secondary outcome will only be measured at baseline and at 16 weeks post-randomisation (captured by the mPath app):
7. Repetitive negative thought (RNT) in everyday life measured with EMA (aggregate person-level ratings of RNT across 10 day period; variability of RNT; relationship of RNT to mood state & contextual events; automaticity of RNT, based on EMA items)

We will also assess incidence of major depressive episodes and generalized anxiety disorder across the 12-month follow-up using standardized structured online measures (adapted lifetime history of depression and anxiety disorders (LIDAS) for depression, adapted GAD for anxiety), enabling us to test which factors have long-term effects on RNT and on the prevention of first incidence or recurrence of episodes of depression and anxiety, providing direct data to inform transformation of early interventions.

Completion date
31/12/2029

Eligibility

Key inclusion criteria
Participants must satisfy ALL of the following criteria to be enrolled in the study, and will be excluded in sequence if an individual does not meet a criterion during screening (to minimise participant burden):
1. Lives in UK or USA
2. Aged 18 years and over
3. Access to a suitable smartphone/device to use the m-Path app and MyDataHelps intervention (i.e. MyDataHelps requires iOS 16.4 or later. iOS 16.4 is compatible with all iPhone models starting from the iPhone 8 and later. For Android devices, MyDataHelps requires Android version 8.0 or higher.)
4. Elevated RNT based on the following assessment scores – scoring in top quartile in one and in top tercile for the other based on prior studies:
4.1. RRS brooding score above 12 (top quartile) and PSWQ-short form score above 24 (top tercile) OR

4.2. RRS brooding score above 11 (top tercile) and PSQW-short form score above 26 (top quartile)

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
Participants who self-report meeting ANY of the following criteria at time of recruitment will be excluded from study participation:
1. Concurrent psychotherapy
2. Current self-reported diagnosis of any of the following conditions, including receiving or waiting for treatment:
2.1. Alcohol abuse/dependence
2.2. Substance abuse/dependence
3. Self-reported diagnosis of current or history of bipolar disorder or psychosis at any time
4. Taking antidepressants or anxiolytic medications at a stable dose for less than six weeks
5. Severe post-traumatic stress disorder (PTSD, assessed as a score of 17 or higher in total for the first six questions AND a score of 2 or higher on the seventh question of the adapted International Trauma Questionnaire; ITQ)
6. Suicidal thoughts* and self-harm assessed by a combination of PHQ-9 question 9 score of 1 or higher and a yes to question R1a and/or R1B, and a yes to either question R2 and/or R3 (detailed below):
R1a = In the last 2 weeks have you been experiencing regular thoughts about suicide?
R1b = In the last 2 weeks have you been experiencing regular thoughts about self-harm?
R2 = In the last 2 weeks have you had any intention to hurt or kill yourself?
R3 = In the last 2 weeks have you made any plans to harm yourself or end your life?

Date of first enrolment
01/02/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

United States of America

Study participating centre
University of Exeter
Mood Disorders Centre
Henry Wellcome Building
Stocker Road
Exeter
England
EX4 4QD

Study participating centre
University of California, Los Angeles
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Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	15/12/2025	14/01/2026	No	No
Study website			29/12/2025	No	No