ISRCTN10554928 https://doi.org/10.1186/ISRCTN10554928

Clinical trial of digitally enabled cognitive therapy for PTSD in NHS Talking Therapies for anxiety and depression services

Submission date
29/10/2025

Recruitment status
Recruiting

Registration date
30/10/2025

Overall study status
Ongoing

Last Edited
30/10/2025

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

Posttraumatic Stress Disorder (PTSD) is a common and distressing mental health problem that can develop after extremely stressful events, may persist for many years and hold people back in life. Cognitive therapy based on Ehlers & Clark's (2000) model of PTSD helps people recover and rebuild their lives. Clinical trials have shown it is very effective and acceptable to patients and more effective than a range of other treatments (Ehlers et al., 2003, 2005, 2014, 2023). However, many people cannot access the treatment due to shortage of therapists or because they are unable to attend clinic-based therapy during working hours.

To overcome these problems, the group who developed cognitive therapy for PTSD created an internet version (iCT-PTSD). Instead of attending weekly 90-minute therapy sessions in a clinic, patients learn how to overcome their difficulties by working through an engaging and media-rich internet programme they can access from home (or another safe place) at any time. A therapist supports them through the programme. Sessions are by video link or phone and shorter than usual sessions, as people have already learned many of the lessons of therapy from their online study.

Previous research shows that many patients with PTSD find the internet cognitive therapy acceptable (Ehlers et al, 2023). So far, the reported outcomes are at least as good (often better) than those seen with traditionally delivered therapy in NHS services. These promising findings led the National Institute for Clinical and Care Excellence (NICE) to recommend the internet programme for use in the NHS while further data is being collected to unambiguously assess its value (NICE, 2023a). NICE (2023b) wishes to know how the internet therapy compares with clinic-based treatment when delivered by NHS staff to people with similarly disabling PTSD.

This randomised controlled clinical trial will answer NICE's question. People who are seeking treatment for PTSD in NHS Talking Therapies for anxiety and depression services in 4 NHS Trusts in England and are willing to participate will receive internet cognitive therapy (iCT-PTSD) or usual NHS treatment. Comparisons between the treatments will look at how their symptoms and quality of life change, how many people recover, the therapist time needed to deliver the treatments, cost-effectiveness, how satisfied patients and therapists are with the internet treatments and how they describe their experience.

Who can participate?
1. People with posttraumatic stress disorder who receive treatment at one of the participating NHS Talking Therapies (NHS TT) services and agree to participate in the study
2. About 20 therapists from participating NHS TT services who will deliver the internet-assisted treatment.

What does the study involve?
Participating patients will be allocated by chance to receive either either the iCT-PTSD treatment programme supported by a NHS TT therapist or treatment as usual (TAU) with an NHS TT therapist. It also involves completing questionnaires about their symptoms, thoughts, ways of coping, and quality of life at initial assessment and 22, 44 and 66 weeks after allocation (and at the end of treatment if this is later than 22 weeks). They also rate once how credible they find the treatment they receive, and how satisfied they are with the treatment and with working with their therapist. Some will be invited to attend an interview about their experience with iCT-PTSD.

Participating therapists will be trained to guide and support patients during the iCT-PTSD treatment programme. They will then treat patients with PTSD participating in the trial. At the end of the study they will complete a questionnaire on their experience with delivering the treatment. Some therapists will be invited to attend an interview about their experience with iCT-PTSD.

What are the possible benefits and risks of participating?
All participants will receive a psychological treatment for their PTSD that has been shown to be effective. The NHS therapists who deliver the treatments have received training and have regular supervision. As with any psychological treatment, it cannot be guaranteed that every participant will benefit.
Undertaking treatment for PTSD can be challenging. Treatment encourages participants to reflect on their difficulties to understand how PTSD works and supports them in tackling situations that they may have previously avoided.
While doing this may temporarily increase distress, facing these challenges is an important step towards overcoming PTSD. Treatment will be personalised for each patient.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
March 2024 to December 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Donna Winston, donna.winston@psy.ox.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
354700

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS ID 67297

Study information

Scientific Title
REal world internet COgnitiVE theRapy for PTSD (RECOVER-PTSD)

Acronym
RECOVER-PTSD

Study objectives
Primary objective:
To compare the effectiveness of digitally enabled cognitive therapy for PTSD (iCT-PTSD) to treatment as usual (TAU) in reducing PTSD symptoms

Secondary objectives:
1. To compare iCT-PTSD to TAU on the binary outcomes commonly reported by NHS TT services (reliable improvement and reliable recovery)
2. To compare the effectiveness of iCT-PTSD to TAU in reducing ICD-11 complex PTSD symptoms
3. To compare the effectiveness of iCT-PTSD to TAU in reducing symptoms of depression and general anxiety, reducing interference with life due to mental health problems, and in improving quality of life
4. To compare therapist time needed and cost-effectiveness of iCT-PTSD to TAU.

Process analyses:
1. To compare the credibility, working alliance, acceptability and treatment satisfaction of iCT-PTSD to TAU
2. To compare changes in unhelpful cognitions and safety behaviours of iCT-PTSD to TAU
3. To explore patient and therapist experience with iCT-PTSD

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/09/2025, London Bloomsbury Ethics Committee (85 Tottenham Ct Road, London, W1T 4TQ, United Kingdom; +44 (0)20 7104 8384; bloomsbury.rec@hra.nhs.uk), ref: 25/LO/0575

Study design
Interventional multisite randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Posttraumatic stress disorder

Interventions
Participants will be allocated by chance using an online randomisation system (SealedEnvelope) to one of two treatments.

- Half of the participants will receive a therapist-assisted internet version of cognitive therapy for PTSD. Cognitive therapy is a trauma-focused cognitive behavioural treatment for PTSD recommended by NICE (2018) and international treatment guidelines. It focuses on core factors maintaining PTSD according to Ehlers and Clark's (2000) model: Personal meanings of the trauma and its aftermath, disjointed trauma memories and unhelpful cognitive and behavioural coping strategies. It is usually delivered in one-to-one sessions. The therapist-assisted internet delivered version (iCT-PTSD) has been found to be efficacious and acceptable to patients. Patients are guided through the online treatment programme by a NHS CBT therapist. Patients work through the therapy modules on a secure website, as well as completing treatment-related tasks and activities as part of their daily routine. The therapist releases the modules that are relevant to the patient and supports them through messages and weekly video or phone calls. Treatment will be usually be delivered over a period of 3 to 5 months; the duration will depend on the number of traumas that will be addressed in therapy.
After treatment and discharge from the service, participants will complete follow-up questionnaires at 44 and 66 weeks after randomisation.

- The other half of participants will receive treatment as usual in NHS Talking Therapies services usually involves one-to-one video or in-person sessions of an evidence-based psychological treatment for PTSD with a NHS CBT therapist.
Treatment will be usually be delivered over a period of 3 to 5 months; the duration will depend on the number of traumas that will be addressed in therapy. After treatment and discharge from the service, participants will complete follow-up questionnaires at 44 and 66 weeks after randomisation.

Intervention Type
Behavioural

Primary outcome(s)
1. PTSD symptoms measured with the PCL Symptom Checklist for DSM-5 (PCL-5) completed at baseline, 22 weeks, 44 weeks and 66 weeks post-randomisation, and actual end of treatment if different from 22 weeks.

Key secondary outcome(s))
1.. Reliable improvement and reliable recovery as defined in NHS TT manual based on by cut-offs on the PTSD Symptom Checklist for DSM-5 (PCL-5) and Patient Health Questionnaire (PHQ-9) at 22 weeks after randomisation, and actual end of treatment if different from 22 weeks.
2. Complex PTSD symptoms measured with the International Trauma Questionnaire (ITQ) at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks.
3. Depression symptoms measured with the Patient Health Questionnaire (PHQ-9) completed at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks, and actual end of treatment if different from 22 weeks.
4. Anxiety symptoms measured with the Generalised Anxiety Disorder Questionnaire (GAD-7) completed at baseline, 22 weeks, 44 weeks, 66 weeks and actual end of treatment if different from 22 weeks.
5. Interference with life due to mental health difficulties as measured with the Work and Social Adjustment Scale (WSAS) completed at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks..
6. Changes in employment and benefits status measured by patient demographics questionnaire at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks.

7. Quality of life measured by the Recovering Quality of Life (ReQoL) at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks.
8. Therapist time involved in iCT-PTSD and TAU as measured by number of sessions and their duration.
9. Cost effectiveness of iCT-PTSD and TAU as measured by EuroQol EQ-5D-5L, Client Service Receipt Inventory, and iMTA Productivity Cost Questionnaire completed at baseline, 22 weeks, 44 weeks, 66 weeks, and actual end of treatment if different from 22 weeks.

Process measures:
10. Treatment acceptability and patient satisfaction with treatment assessed with the NHS TT Patient Experience Questionnaire (PEQ), Acceptability Scale and interviews with some iCT-PTSD patients at the end of treatment.
11. Credibility of treatment measured with the Borkovec and Nau Credibility scale after the second session with therapist.
12. Quality of therapeutic relationship as measured with the Working Alliance Scale completed by patients and therapists after the second session with therapist.
13. Appraisals of the trauma and its aftermath as measured with a short version of the Posttraumatic Cognitions Inventory (PTCIs) given at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks.
14. Qualities of trauma memories measured with a short version of the trauma memory questionnaire (TMQ) given at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks.
15. Responses to intrusive memories measured with the Response to Intrusions Questionnaire (RIQ) given at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks.
16. Safety behaviours measured with the Safety Behaviours Questonnaire (SBQ) given at baseline and at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks and actual end of treatment if different from 22 week
17. Dissociation measured with a short version of the Trait-State Dissociation Questionnaire (TDSQ) given at baseline at baseline, 22 weeks, 44 weeks and 66 weeks .
18. Patient activity on the online iCT-PTSD programme such as time spent on the programme and modules completed, recorded during treatment

User experience with iCT-PTSD:
1. Therapists' experience with delivering iCT-PTSD assessed with the Therapist Experience Questionnaire and, for some, interview at end of study.
2. Patients' experience assessed through ratings of helpfulness and free comments provided at the end of each module, and, for some, interview at end of study.

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Patients:
1. Post-Traumatic Stress Disorder is the main psychological problem, and the patient's priority to work on in therapy
2. Any gender, aged 18 years or above with no upper age limit
3. Access to an internet-enabled device at home or another safe location with a reliable internet connection; access to a mobile phone that can receive text messages

4. Able to speak, read and write English
5. Willingness to be allocated by chance to either iCT-PTSD or NHS TT non-digital psychological treatment as usual (TAU)

Clinicians:
1. High intensity CBT therapist working within a participating NHS TT service
2. Trained in the delivery of iCT-PTSD
3. Willing to participate
4. Clinical capacity and managerial approval to participate

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients:
1. PTSD Checklist 5 (PCL-5) score below clinical caseness (< 32)
2. Acute suicide risk
3. Substance dependence

Clinicians:
1. No exclusion criteria

Date of first enrolment
24/11/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Oxford Health NHS Foundation Trust
Littlemore Mental Health Centre
Sandford Road
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OX4 4XN

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current 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