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Clinical trial of digitally enabled cognitive therapy for social anxiety disorder 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
Social anxiety disorder (SAD) is a common and distressing mental health problem that can persist for many years and hold people back in life. Cognitive therapy based on the Clark & Wells (1995) model helps people recover and rebuild their lives. Clinical trials have shown it is more effective than alternative treatments (Clark et al, 2003, 2006; Ingul, Aune, & Nordahl, 2013; Mörtberg, Clark, Sundin, & Åberg Wistedt, 2007; Stangier, Heidenreich, Peitz, Lauterbach, & Clark, 2003: Stangier, Schramm, Heidenreich, Berger, & Clark, 2011; Leichsenring et al., 2013; Nordahl et al., 2016). 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 SAD created an internet version. 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 at any time. A therapist supports them through the programme, but sessions are by video link or phone and much shorter than usual, as people have already learned many of the lessons of therapy from their online study.

Preliminary research shows many patients find the internet cognitive therapy acceptable (Clark, 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 Care and Clinical 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). NHS resources are limited and need to be spent wisely. NICE (2023b) therefore wishes to know how the internet therapy compares with clinic-based treatment when delivered by NHS staff to people with similarly disabling conditions.

This randomized controlled trial will answer NICE's question. People who are seeking treatment for SAD in six NHS Talking Therapy services and are willing to participate will receive internet

cognitive therapy or usual NHS treatment. Comparisons between the treatments will look at how many people recover, how their symptoms and quality of life change, 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 social anxiety 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 the iCT-SAD 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-SAD.

Participating therapists will be trained to guide and support patients during the iCT-SAD treatment programme. They will then treat patients with social anxiety 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-SAD.

What are the possible benefits and risks of participating?
All participants will receive a psychological treatment for their social anxiety disorder 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 social anxiety disorder can be challenging. Treatment encourages participants to reflect on their difficulties to understand how social anxiety 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 social anxiety disorder. 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)
352935

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 67316

Study information

Scientific Title
REal world internet COgnitiVE theRapy for Social Anxiety Disorder (RECOVER-SAD)

Acronym
RECOVER-SAD

Study objectives
Primary objective:
To compare the effectiveness of iCT-SAD to treatment as usual (TAU) in reducing self-reported social anxiety

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

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

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: REC ref: 25/LO/0574

Study design
Interventional multisite randomized controlled trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Social anxiety 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 social anxiety disorder. Cognitive therapy for social anxiety disorder based on the Clark & Wells model (1995) is recommended by NICE (2013) and international treatment guidance. It is usually delivered in one-to-one sessions.
A therapist-assisted internet-delivered version (iCT-SAD) 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 of iCT-SAD 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 individual patient and supports them through messages and video or phone calls. Treatment will be usually be delivered over a period of 3 to 5 months. 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, which usually involves one-to-one video or in-person sessions of an evidence-based psychological treatment for social anxiety disorder with a NHS CBT therapist.
Treatment will be usually be delivered over a period of 3 to 5 months. 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. Social anxiety symptoms measured with the Social Phobia Inventory (SPIN) 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 cut-offs on the Social Phobia Inventory (SPIN) and Patient Health Questionnaire (PHQ-9) completed at 22 weeks after randomisation, and actual end of treatment if different from 22 weeks.
2. 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.
3. Anxiety symptoms measured with the Generalised Anxiety Disorder Questionnaire (GAD-7) completed at baseline, 22 weeks, 44 weeks and 66 weeks, and actual end of treatment if different from 22 weeks.
4. 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.
5. 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
6. 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.
7. Therapist time involved in iCT-SAD and TAU as measured by number of sessions and their duration.
8. Cost effectiveness of iCT-SAD 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:
9. Treatment acceptability and patient satisfaction with treatment assessed with the NHS TT Patient Experience Questionnaire (PEQ), Acceptability Scale and interviews with some iCT-SAD patients at the end of treatment.
10. Credibility of treatment measured with the Borkovec and Nau Credibility scale after the second session with therapist.
11. Quality of therapeutic relationship as measured with the Working Alliance Scale completed by patients and therapists after the second session with therapist.
12. Changes in unhelpful cognitions, safety behaviours, and avoidance as measured by the Social Cognitions Questionnaire, Social Behaviour Questionnaire, Social Attitudes Questionnaire-short, Liebowitz Social Anxiety Scale, and Social Summary Scale at baseline, 22 weeks, 44 weeks, 66 weeks, and actual end of treatment if different from 22 weeks.
User experience with iCT-SAD:
13. Therapists' experience with delivering iCT-SAD assessed with the Therapist Experience Questionnaire and, for some, interview at end of study.
14. 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. Social Anxiety 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. Willingness to be allocated by chance to either iCT-SAD or NHS TT non-digital psychological treatment as usual (TAU)
4. Able to read and write in English
5. Access to the internet at home (or another safe location) and availability of tablet or laptop /computer, access to a mobile phone that can receive text messages

Clinicians:
1. High Intensity CBT therapist or Psychological Well-Being practitioner working within a participating NHS TT service
2. Trained in the delivery of iCT-SAD
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. Social Anxiety Inventory (SPIN) score below clinical caseness (< 19)
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
Littlemore
Oxford
United Kingdom
OX4 4XN

Study participating centre

Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
Beaconsfield Close
Hatfield
United Kingdom
AL10 8YE

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
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M25 3BL

Study participating centre
Homerton Healthcare NHS Foundation Trust
Homerton Row
London
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E9 6SR

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes