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The effect of Online Social anxiety Cognitive therapy for Adolescents (OSCA) compared to treatment as usual for social anxiety disorder in adolescents

Submission date
06/01/2025

Recruitment status
Recruiting

Registration date
08/01/2025

Overall study status
Ongoing

Last Edited
24/06/2025

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
This study will compare the clinical and cost-effectiveness of internet-delivered therapist-assisted Cognitive Behaviour Therapy (CBT) for adolescent social anxiety, called OSCA (Online Social anxiety Cognitive therapy for Adolescents), to standard treatment. The standard treatment is another form of CBT, called Graded CBT, typically delivered face-to-face.

Who can participate?
Young people aged 11-18 years referred for treatment of social anxiety in an NHS-commissioned service

What does the study involve?
Participants will be randomly allocated to receive one of these treatments. Participants will have 6 study-related assessments: at baseline, 6, 16, 26, and 40 weeks (and 66 weeks if further funding permits) post-randomisation, as well as routine assessments throughout treatment. These will include standard outcome measures used in NHS treatment, and additional assessments of social anxiety symptoms and processes, functioning, and health econometrics. Acceptability of OSCA will be assessed through clinician interviews and clinician and family programme usage data. A subsample of clinicians will be interviewed to understand their experience of delivering OSCA. The study team will examine whether any observed benefits of OSCA are associated with the process measures targeted in the treatment.

What are the possible benefits and risks of participating?
Whichever treatment young people receive as part of their involvement in the study will be an evidence-based therapy. They may enjoy the flexibility of digital therapy if they receive OSCA. Participants may learn about social anxiety through participation in the study. Young people and their families will take part in more thorough assessments throughout which will be used to guide their treatment and they will be invited back for assessments over a longer period after treatment than would be typical as part of routine care, meaning their progress can be checked.

Other young people with social anxiety may benefit from your participation, through building knowledge about how to improve treatment.

Participants are not expected to experience any harm as a result of taking part in this study. All researchers involved are experienced and have been approved to work with children and vulnerable adults. Some of the questionnaires may ask things which young people and their families find upsetting. These measures are similar to the ones that are used in usual treatment. Young people and their families can always decide what they would like to discuss in assessment and therapy sessions. Young people and families will be completing more measures than in usual treatment, which they may find frustrating or tiring, but they will be reimbursed for their time.

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

When is the study starting and how long is it expected to run for?
January 2024 to December 2027

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
go.osca@psy.ox.ac.uk

Contact information

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
339554

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 61644

Study information

Scientific Title
Go-OSCA trial: examining the efficacy of online social anxiety cognitive therapy for adolescents (OSCA) compared to treatment as usual for social anxiety disorder in adolescents

Acronym
GO-OSCA

Study objectives
1. Is OSCA superior to standard care (Graded CBT) delivered by routinely trained clinicians working in NHS-commissioned services in terms of social anxiety symptoms, as well as broader anxiety and depression symptoms and functioning?
2. Is OSCA cost-efficient compared to standard care (Graded CBT)?
3. Are any observed benefits of OSCA compared to standard care associated with changes in social anxiety process measures targeted in OSCA?
4. We will explore acceptability of OSCA to clinicians.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/09/2024, London - Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0) 207 104 8150, 207 104 8243; riverside.rec@hra.nhs.uk), ref: 24/LO/0641

Study design
Parallel-assignment randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual, Other therapist office, Telephone, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Social anxiety disorder (SAD) in young people aged 11-18 years

Interventions
This interventional study is a parallel RCT in adolescents with SAD. Participants will be randomised to receive either OSCA or General CBT, with a randomisation ratio of 1:1 and stratification based on the key baseline feature that is likely to be associated with outcome (i.e., social anxiety symptom severity assessed by the LSAS-CA-SR).

OSCA is a therapist-assisted internet-delivered version of Cognitive Therapy for adolescents with SAD, designed with input from young people with lived experience. During the 14weeks of treatment, young people allocated to OSCA have short weekly phone or video (via MS Teams) calls with their therapist to review progress, assign new modules, deepen learning, and plan behavioural experiments. Most of the calls are around 20 minutes. Messaging within the programme and via SMS provides summaries of calls, encouragement and support.

Graded CBT is the therapy given as standard in the NHS to adolescents with SAD and other common anxiety problems. Treatment will follow a standard procedure in the participating services: it will be delivered face-to-face or via video call (MS Teams) and comprise a total of seven sessions (4 weekly, 2 fortnightly, and 1 at a month). As recommended by each participating service, clinicians will use worksheets that are freely available on the Internet or developed by their service to support the treatment.

Intervention Type
Behavioural

Primary outcome measure
Self-reported social anxiety symptoms as measured by the Liebowitz Social Anxiety Scale for children and adolescents (self-report version; LSAS-CA), at baseline, 16-, 26-, and 40-weeks post-randomisation.

Secondary outcome measures

The following secondary outcome measures will be assessed at baseline, 16-, 26-, and 40-weeks post-randomisation:
1. Parent and self-reported general anxiety and depression symptoms as measured by the Revised Child Anxiety and Depression Scale (RCADS)
2. Anxiety-related impairment as measured by the Child Anxiety Impact Scale
3. To assess cost-effectiveness, the self-reported CHU-9D, parent-reported EQ-5D-5L, and parent /carer-report Client Service Receipt Inventory (CSRI) will be completed

Overall study start date
01/01/2024

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Clinicians:
1. Working within a participating NHS-commissioned service
2. Willing to participate
3. Clinical capacity and managerial approval to participate

Young people:
1. Aged 11-18 years at assessment
2. A DSM-5 diagnosis of social anxiety disorder (American Psychiatric Association, 2013) that has been identified as the primary presenting disorder based on clinical assessment. SAD will be deemed primary if participants meet diagnostic criteria for SAD and this is the difficulty that they associate with most impairment (of any comorbid conditions) and for which they are seeking treatment.
3. Agreement not to start medication during the trial. If on a psychotropic medication at eligibility assessment then this has been stable for 8 weeks and there is an agreement to remain on a stable dose throughout the trial.
4. Agreement not to start another psychological therapy during the trial
5. Able to speak, read and write in English to a level that allows them to access treatment content and measures
6. Willingness to be randomised to either treatment
7. Willing to assent/consent to participate

Parents/Carers:
1. Over 18 years of age
2. Able and willing to provide written informed consent for their child’s participation in the study.
3. Willing and able to participate.

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
220

Key exclusion criteria
Current participant exclusion criteria as of 24/06/2025:
Clinicians
No further exclusion criteria

Young people
1. Diagnosed with a learning disability (i.e., IQ<70). Neither treatment has been sufficiently evaluated with this population
2. Autism has been diagnosed or is suspected (which we operationalise based on clinical assessment and in line with standard local procedures) and one or both of the treatments offered in this trial is considered to require adaptation to accommodate the young person's autistic traits
3. Another condition is primary. Anxiety is a common feature of conditions that neither broad-based CBT or OSCA were designed to treat (e.g., eating disorder, trauma-related disorders, dissociative disorders, psychosis, somatic symptom and related disorders, gender dysphoria, and autism/ADHD where there are significant unmet social/environmental needs). Where these other conditions are primary, they will require priority assessment and treatment and the individual will not be eligible for inclusion in this study.
4. At high risk of significant harm to self, to other, or from others to the point where managing risk needs to be the primary focus of any intervention
5. Currently receiving a psychological intervention or have received previous treatment with cognitive therapy or Graded CBT for social anxiety
6. There are clear environmental risks that need to be urgently addressed and if addressed are likely to relieve symptoms (e.g., severe and ongoing bullying, subject to current abuse or neglect, ongoing trauma)

Parents/Carers
No further exclusion criteria

Previous participant exclusion criteria:
Clinicians
a. No further exclusion criteria.

Young people
a. Diagnosed with a learning disability (i.e., IQ<70). Neither treatment has been sufficiently evaluated with this population.
b. Autism has been diagnosed or is suspected (the potential participant has been referred for ASD assessment).
c. Another condition is primary. Anxiety is a common feature of conditions that neither broad-based CBT or OSCA were designed to treat (e.g., eating disorder, trauma-related disorders, dissociative disorders, psychosis, somatic symptom and related disorders, gender dysphoria, and

autism/ADHD where there are significant unmet social/environmental needs). Where these other conditions are primary, they will require priority assessment and treatment and the individual will not be eligible for inclusion in this study.
d. At high risk of significant harm to self, to other, or from others to the point where managing risk needs to be the primary focus of any intervention.
e. Currently receiving a psychological intervention or have received previous treatment with cognitive therapy or Graded CBT for social anxiety.
f. There are clear environmental risks that need to be urgently addressed and if addressed are likely to relieve symptoms (e.g., severe and ongoing bullying, subject to current abuse or neglect, ongoing trauma).

Parents/Carers
a. No further exclusion criteria.

Date of first enrolment
13/01/2025

Date of final enrolment
10/01/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology University of Reading
University of Reading
Harry Pitt Building
Earley Gate
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Study participating centre
The Andy Research Clinic In Oxford
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Sponsor type
University/education

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Funder(s)

Funder type
Government

Funder Name
Medical Research Council

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Results and Publications

Publication and dissemination plan
The results of the trial will be published in peer-reviewed international journals within 2 years after the completion of the study. In line with open access policies, the main publications will be made open access.

Intention to publish date
31/12/2029

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