ISRCTN12117573 https://doi.org/10.1186/ISRCTN12117573

Online parent-led treatment for obsessive-compulsive disorder in preadolescent children

Submission date
24/11/2025

Recruitment status
Recruiting

Registration date
02/12/2025

Overall study status
Ongoing

Last Edited
18/12/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
Childhood Obsessive-Compulsive Disorder (OCD) is a serious mental health condition that often starts around the age of 10 years old and affects up to 3% of preadolescent children worldwide. Cognitive Behavioural Therapy (CBT), including Exposure and Response Prevention (ERP), is a current treatment that helps many preadolescent children with OCD; however, current treatments are often long (requiring more than 10 hours of specialist therapist support), which can limit access to care.

Online Support and Intervention (OSI) is a brief online, therapist-supported, parent-led CBT programme that has the potential to increase access to support for affected families. OSI only requires around 3 hours of direct therapist support and can be delivered by trained non-specialist therapists. OSI has been evaluated for childhood anxiety problems and is acceptable to families and therapists, effective, and likely to be cost-effective compared to usual treatment (mostly CBT) in services. OSI has been co-adapted for OCD by working with parents of children with OCD, children with OCD, and clinicians to ensure that the OSI-OCD is acceptable, relevant, and appropriate for families. This study will be a preliminary evaluation of OSI-OCD.

This project will test the feasibility of OSI adapted for parent/carers of preadolescent children (aged 5 – 12 years old) with OCD, and a future large Randomised Controlled Trial (RCT) to test whether OSI for OCD is non-inferior to (i.e., no worse than) usual treatment in services.

This feasibility RCT will establish the likely recruitment rates, the number of participants who complete treatment, the number of participants who take part in the research follow-ups, and help us to describe what 'usual treatment' looks like in routine clinical services, and identify suitable clinical, daily functioning, and cost-effectiveness measures. The study will also explore the clinical outcomes in the OSI group at 20- and 32-week follow-ups (i.e., whether OSI for OCD appears to help children overcome OCD), explore what key stakeholders (e.g., parents, children, therapists) think of the treatment and trial procedures, and describe any negative effects of the treatment.

A 'process evaluation' will be conducted, which is a way of taking a closer look at how an intervention is being carried out. This evaluation will explore how OSI for OCD can be

implemented into clinical services, how the treatment might bring about change for families, and factors affecting treatment delivery, engagement, and outcomes for OSI for OCD to inform the design of a future RCT and potential wider use of OSI for OCD.

Who can participate?
Children aged between 5 and 12 (inclusive) years who have OCD (confirmed by the research team) and their parent/carer(s) from approximately 6 mental health services that provide treatment on behalf of the National Health Service (NHS).

What does the study involve?
Eligible participants will be randomly assigned to one of two groups: one group will receive the new OSI for OCD treatment, and the other will receive the usual treatment for OCD. Measures will be collected at baseline, 20 weeks and 32 weeks post-randomisation. Additionally, parent-reported session-by-session measures will be collected for participants (i.e., parents and their children) randomised to OSI for OCD. Interviews with some parents, children, therapists, clinical supervisors, service leads and commissioners involved in the trial will help to inform the process evaluation.

What are the possible benefits and risks of participating?
Benefits:
Both treatments could be helpful for children with OCD, but it is unknown which treatment works best or if they work equally well. That's why this research is being done. By taking part, participants will be helping the research team understand whether this treatment is feasible and acceptable for helping children to overcome OCD, and their participation will contribute to improving treatment options for others in the future.

Risks:
The parent and their child will be asked to complete some additional questionnaires that they wouldn't normally do as part of usual care. These are to gather information about the child's difficulties and the impact these difficulties have on their life.

Some of the questions in the interviews or questionnaires may ask about difficult topics, such as the child's thoughts and feelings. While these questions are similar to those asked in clinical care, the research team understands they might be upsetting. The research team will monitor the parents' and children's responses during these assessments and, if signs of significant distress are noticed, the team will contact the parent to check in. If necessary, and with the parent's agreement (or sooner if there are concerns about safety), the team may contact the child's clinical team. If the parent or child feels uncomfortable or distressed at any point, they can contact their therapist or the research team, and support will be provided. They can also choose to stop answering questions or leave the study at any time without affecting the child's future care.

Taking part in the study will require the parent and child to spend extra time completing interviews and questionnaires and participating in treatment sessions. These additional tasks might take time away from other activities or routines, but the research team will work to make the process as convenient as possible.

The research team does not expect any harm or significant risks to come from taking part in the study. All research team members have undergone criminal record checks and have been approved by the University of Oxford to work with children. If at any point the parent feels that participating in the study is not right for them, they are free to withdraw with no negative impact on the child's care or treatment.

Where is the study run from?
This study is sponsored by the University of Oxford, and is being run by the Oxford Psychological Interventions for Children and adolescents (TOPIC) research group, based in Experimental Psychology, UK.

When is the study starting and how long is it expected to run for?
September 2025 to June 2027.

Who is funding the study?
The Medical Research Council (MRC).

Who is the main contact?
Dr Chloe Chessell (Chief Investigator), Postdoctoral Researcher and Fellow at The Oxford Psychological Interventions for Children and adolescents (TOPIC) research group, based in Experimental Psychology, chloe.chessell@psych.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Chloe Chessell

Contact details
Postdoctoral Researcher, University of Oxford. Life and Mind Building, South Parks Rd
Oxford
United Kingdom
OX1 3EL
-
chloe.chessell@psych.ox.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
354658

Central Portfolio Management System (CPMS)
69337

Medical Research Council (MRC) grant code
MR/Z503642/1

Study information

Scientific Title
Feasibility of a randomised controlled trial to compare an adapted online parent-led treatment to treatment as usual for preadolescent children with obsessive compulsive disorder (OCD)

Study objectives
a. Establish the feasibility of (a) the novel intervention and (b) a future definitive non-inferiority RCT comparing the clinical outcomes and cost-effectiveness of OSI for OCD to usual treatment
b. Conduct a process evaluation to explore (a) the implementation and acceptability, (b) mechanisms of impact, and (c) contextual factors that affect delivery, engagement, and outcomes for OSI for OCD to optimise the design of a future definitive non-inferiority trial RCT and subsequent wider implementation of OSI for OCD, if indicated.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/07/2025, East Midlands - Leicester Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 02071048181; leicestercentral.rec@hra.nhs.uk), ref: 25/EM/0159

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Personality disorder - OCD; Health Category: Mental health; Disease/Condition: Neurotic, stress-related and somatoform disorders

Interventions
Families taking part in the study will be randomly assigned to one of two groups: either the OSI for OCD intervention or treatment as usual (TAU) within mental health services that provide treatment on behalf of the NHS.

Stratified randomisation will be conducted using a web-based randomisation tool designed for clinical trials and research studies to ensure balance across key variables, including: Child’s age (e.g., ≤8 years; >8 years), Gender and OCD symptom severity (measured by baseline CY-BOCS scores). We will use a randomisation tool that operates through a secure online platform, accessible only to authorised study personnel.

Participants will be randomly assigned to either the OSI for OCD (n=24) or treatment as usual (TAU) arms (n=24), within one month of completing baseline assessments. Families allocated to the OSI for OCD treatment will be added to the online intervention platform by the research team, from which they can start their treatment, with therapist support. This includes completing 10 online modules, with 10 x 20-30 minute phone calls (including 8 therapist sessions, and 2 check-ins). For families in the OSI for OCD group, routine outcome measures (ROMs) that are collected as part of this treatment will also be available to the research team. OSI treatment lasts for approximately 4 months. Families assigned to TAU will receive their usual care, and information on the nature of this treatment will be collected from therapists and supervision logs.

Parents and children will be invited to complete post-treatment and follow-up questionnaires and interviews online at 20 and 32 weeks after randomisation. To address researcher bias, outcome assessors, who will conduct the diagnostic and clinical assessments, will be blinded to the treatment allocation of participants. This is to ensure that data collection for primary and secondary outcomes remains unbiased. Note. The research team will call all families to let them know the outcomes of the ADIS-C/P and CY-BOCS at 20 weeks and 32 weeks post randomisation. All families who complete these interviews will be provided with a letter summarising the outcomes following their final interview.

Trial therapists will be identified through the participating trial sites.

An embedded process evaluation will explore how to optimise the design of a future definitive non-inferiority trial RCT and subsequent wider implementation of OSI for OCD, if indicated. A subset of parents (~15) and children (~15) from the OSI for OCD treatment arm will be invited to take part in qualitative interviews. This may include those who completed the OSI for OCD treatment, as well as those who did not fully complete it, so we can understand a range of perspectives. We will also invite up to 15 therapists, clinical supervisors, clinical leads, and commissioners from the OSI for OCD arm. These interviews will explore (a) the implementation and acceptability; (b) mechanisms of impact; and (c) contextual factors that affect delivery, engagement, and outcomes, for OSI for OCD. These interviews will involve up to 15 parents and 15 children from the OSI for OCD group, as well up to 15 therapists, clinical supervisors, clinical leads and commissioners. The adequacy of the sample size will be continually reviewed, and recruitment will end when the sample holds sufficient information power to provide a rich insight into the research questions.

Interviews will be conducted by research team members online and will be recorded and transcribed for analysis. In addition to qualitative interviews, the process evaluation aims to collect data to assess the acceptability of the intervention and how the intervention was implemented, including therapist treatment logs, usage data from the OSI platform, and clinical outcome measures. This information will help determine whether OSI for OCD is a feasible and effective approach for supporting families of children with OCD.

Intervention Type
Other

Primary outcome(s)
1. Trial feasibility measured using willingness of participants (parents and their children) to be randomised at throughout study

2. OCD symptom severity measured using Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) (parent and child report) at baseline, 20 weeks post randomisation, and 32 weeks post randomisation

Key secondary outcome(s))

1. Anxiety disorders and OCD are measured using the Anxiety Disorder Interview Schedule (ADIS-C and ADIS-P) at screening, 20 weeks post-randomisation, and 32 weeks post-randomisation
2. OCD symptom severity is measured using the Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
3. OCD symptom severity is measured using the Obsessive Compulsive Inventory (OCI-CV-R) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
4. OCD symptom severity is measured using the Obsessional Compulsive Inventory (ChOCI-R-P) at baseline, at the start of each OSI-OCD module, and at 20 weeks and 32 weeks post-randomisation
5. Parental stress is measured using the Parental Stress Scale (PSS) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
6. Health-related quality of life for parents is measured using the EuroQol 5-Dimension 5-Level questionnaire (EQ-5D-5L) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
7. Health-related quality of life in children and young people is measured using the EuroQol 5-Dimension Youth 3-Level questionnaire (EQ-5D-Y-3L) and Child Health Utility 9D (CHU-9D) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
8. Health and social care resource use is measured using the Client Service Receipt Inventory (CSRI) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
9. Parents' beliefs about treatment credibility and expectations of improvement are measured using the Credibility and Expectation of Improvement Scale – Parent report (CEI) immediately post-randomisation and at 20 weeks post-randomisation
10. Therapists' beliefs about treatment credibility and expectations of improvement are measured using the Credibility and Expectation of Improvement Scale – Therapist report (CEI) immediately post-randomisation and at 20 weeks post-randomisation
11. Family accommodation of obsessive–compulsive symptoms is measured using the Family Accommodation Scale for Obsessive-Compulsive Disorder – Parent Report (FAS-PR) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
12. Parent-reported OCD-related interference is measured using the Children's Obsessive Compulsive Impact Scale – Revised, Parent version (COIS-R-P) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
13. Child-reported OCD-related interference is measured using the Children's Obsessive Compulsive Impact Scale – Revised, Child version (COIS-R-C) at baseline, 20 weeks post-randomisation, and 32 weeks post-randomisation
14. Parents' knowledge and confidence to help their child overcome OCD are measured using 3 items at the start of each OSI-OCD module and at 20 weeks and 32 weeks post-randomisation
15. Parents' perception of their child's learning and coping ability is measured using 2 items at the start of each OSI-OCD module and at 20 weeks and 32 weeks post-randomisation
16. Child anxiety and depression symptoms are measured using the Revised Child Anxiety and Depression Scale – Parent version (RCADS-P) with the full scale completed at the start of OSI-OCD modules 0, 8, and 9, and the OCD subscale completed at the start of modules 1–7
17. Child functioning and wellbeing are measured using the Outcome Rating Scale (ORS) at the start of each OSI-OCD module
18. Therapeutic alliance is measured using the Session Rating Scale (SRS) at the start of each OSI-OCD module
19. Progress towards individually agreed goals is measured using Goal-Based Outcomes (GBOs)

at the start of each OSI-OCD module
20. Overall clinical improvement is measured using the Clinical Global Impressions – Improvement scale (CGI-I) at 20 weeks post-randomisation and 32 weeks post-randomisation
21. Therapist treatment and supervision activity is measured using therapist treatment and supervision logs collected during OSI-OCD modules 0–9 and during treatment as usual
22. Treatment feasibility and acceptability are measured using qualitative interviews with parents, children, therapists, and stakeholders within four weeks after OSI-OCD treatment has finished
23. Feasibility parameters including willingness of therapists to recruit participants, number of eligible participants, follow-up rates, and questionnaire response rates are measured using trial records at end of study

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Child has been diagnosed with OCD on the basis of the ADIS-C or ADIS-P by the research team.
2. Parent/carer is willing and able to give informed consent for participation in the study on behalf of their child and themselves.
3. Child is willing and able to give informed assent for participation in the study.
4. Child aged 5–12 years.
5. Child has been referred to services that provide psychological support for child mental health problems on behalf of the NHS.
6. Child and parent/carer are able to understand, read, and communicate in English.
7. Parent/carer is willing and able to engage with the online intervention platform (OSI) if randomised to the OSI for OCD treatment arm.
8. Parent/carer is willing and able to complete required assessments.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
12 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. The child is currently receiving any other psychological intervention.
2. The child is receiving psychotropic medication and the dose has not been stable for at least two months.
3. The child has a confirmed or likely diagnosis of autism (indicated by a score > 15 on the Social Communication Questionnaire-lifetime version).
4. If the child has profound learning difficulties evidenced by attending a specialist school.
5. If there are risk and/or safeguarding concerns which are paramount and would interfere with treatment delivery, including suicidal intention, recurrent or potentially life-limiting self-harm, or if the child has a child protection plan/is on the child protection register/the research team consider the child to be suffering, or likely to suffer, significant harm.
6. Parent/carer or child is unable to understand, read, or communicate in English, which would prevent meaningful participation in the intervention or assessments.
7. The child is referred to a clinical team where the only usual treatment option is the University of Oxford's face-to-face/telephone version of brief therapist guided, parent-led CBT for OCD

Date of first enrolment
01/09/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Berkshire Healthcare NHS Foundation Trust
London House
London Road
Bracknell
England
RG12 2UT

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
England
RM13 8GQ

Study participating centre
Mersey Care NHS Foundation Trust
V7 Building
Kings Business Park
Kings Drive
Prescot
England
L34 1PJ

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital
77 London Road
Kettering
England
NN15 7PW

Study participating centre
Herefordshire and Worcestershire Health and Care NHS Trust
Unit 2 Kings Court
Charles Hastings Way
Worcester
England
WR5 1JR

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

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 and/or analysed during the current study will be stored in a publicly available repository.

Once analyses are complete and the linking document containing personal details is deleted, a sufficiently anonymised version of the data will be made available in a public repository, such as the UK Data Service. The data collected about participants (i.e., parents, their children, therapists and other stakeholders) will be preserved and made available in a form in which they cannot be identified. To ensure this, all data will be pseudonymised before archiving, and any direct identifiers (e.g., names, contact details) will be removed or stored separately. Data shared for future research or collaboration will be checked for potential identifiers before being made accessible.

IPD sharing plan summary
Stored in publicly available repository