Protocol for a feasibility randomised controlled trial of Online Support and Intervention for Obsessive Compulsive Disorder (OSI-OCD) compared to usual treatment for preadolescent children in routine child mental health services.

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Abstract

Background: Obsessive Compulsive Disorder (OCD) affects up to 3% of preadolescent children, is highly impairing, and often follows a chronic course without appropriate treatment. Cognitive Behavioural Therapy (CBT) is an effective treatment for preadolescent children with OCD, however access to treatment is limited by existing treatments that require lengthy specialist therapist support. Online Support and Intervention for Obsessive Compulsive Disorder (OSI-OCD) is a brief online therapist guided, parent-led CBT intervention that only requires ~4-hours of therapist support and has been designed to be delivered by non-specialist therapists. This paper reports the protocol for a feasibility randomised controlled trial (RCT) that aims to explore the feasibility of (i) OSI-OCD and (ii) a future definitive trial comparing OSI-OCD to usual treatment in routine child mental health services.

Methods: This study is a multi-site, parallel-group, feasibility RCT with a nested mixed-methods process evaluation, with pre-defined progression criteria. Forty-eight parents and their children (aged 5-to-12-years old) will be recruited from at least six routine child mental health services in England. Parents/children will be randomised in a 1:1 ratio to receive OSI-OCD (10 online parent-led modules, and 10 therapist support calls, delivered over a 4-month period) or usual treatment for OCD in their service. Feasibility parameters, including clinical, functional, and health economic measures, will be collected and analysed at baseline, 20-weeks, and 32-weeks post-randomisation. Qualitative interviews will be conducted with a subset of key stakeholders and analysed using Framework Analysis to understand (i) the implementation and acceptability of OSI-OCD and the overall trial procedures, (ii) potential mechanisms of impact, and (iii) contextual factors that may influence the delivery, engagement, and outcomes of OSI-OCD.

Discussion: This study will determine whether OSI-OCD and a future definitive trial of OSI-OCD compared to usual treatment for OCD in routine child mental health services is feasible. Study outputs will inform necessary adaptations to study design and procedures to maximise the likelihood of a successful definitive trial, if indicated. This has the potential to ultimately substantially increase access to CBT for preadolescent children with OCD.

Trial Registration: Registered retrospectively on the ISRCTN Registry (ISRCTN12117577 https://www.isrctn.com/ISRCTN12117573, 02/12/2025).

Keywords: childhood; OCD; CBT; protocol; feasibility randomised controlled trial.

Background

Childhood Obsessive Compulsive Disorder (OCD) often onsets around 10 years of age (1,2), affects up to 3% of preadolescent children (3), and is associated with significantly impaired functioning (4), including poor school attendance (5), parental absenteeism from work (6), and substantial societal economic burden (6). Critically, experiencing OCD at a younger age (7) and for a longer duration predicts disorder persistence (7–9) – highlighting the need for early access to evidence-based treatment for preadolescent children with OCD specifically.

Cognitive Behavioural Therapy (CBT) including Exposure and Response Prevention (ERP) is the recommended evidence-based psychological treatment for preadolescent children with OCD e.g., (10–12). However, access to CBT including ERP is limited by existing treatments that are lengthy (>10 hours of therapist support (13,14), and a scarcity of sufficiently trained therapists to deliver such interventions (15). For instance, in the UK, child and adolescent mental health services have waitlists for up to two years (16) and families often report significant delays to accessing evidence-based treatment for their children with OCD (17,18).

Brief therapist guided, parent-led CBT for OCD has the potential to considerably increase access to CBT for preadolescent children with OCD and has shown promising initial clinical outcomes. Specifically, this treatment involves parents learning CBT including ERP techniques (with a focus on helping children to learn new information about their obsessions/their meaning, and their ability to cope in feared situations without performing compulsions) with the support of a non-specialist therapist. Parents receive written materials to read ahead of 4 x 1-hour appointments and 2-4 x 30-minute telephone appointments (equating to up to 6-

hours of non-specialist therapist support). An initial evaluation of this treatment showed that 7 out of 10 children treated (70%) were treatment 'responders' (≥ 35% reduction on Children's Yale-Brown Obsessive Compulsive Scale scores) and/or 'remitters' (no longer meeting diagnostic criteria for OCD) one-week post-treatment, and 60% of children at a one-month follow-up (19). Critically, this treatment appeared to be acceptable to parents (19), although some families found it challenging to attend and implement the treatment alongside busy family life (20). This treatment therefore represents a means whereby non-specialist workforces could be capitalised on to increase access to evidence-based treatments for affected families; however, it will be essential to optimise the treatment delivery to better fit within busy family lives.

Recent UK government initiatives have aimed to substantially increase the workforce of non-specialist low-intensity therapists who are well positioned to deliver brief therapist guided, parent-led CBT for preadolescent children with OCD. These initiatives include the training of Children's Wellbeing Practitioners and Educational Mental Health Practitioners (21) as well as Senior Wellbeing Practitioners (22) all of whom are trained to deliver 'low-intensity' interventions (i.e., brief interventions of up to 6-hours of therapist support and involve structured self-help materials as a core component, (23)) for children with common mental health problems. Moreover, CWPs and EMHPs are already trained to deliver brief therapist guided, parent-led CBT for anxiety problems (21) and are often working in services that need to respond to children's mental health needs that are beyond their initial remit (including the treatment of OCD; (24,25)) and SWPs are trained to deliver low-intensity CBT interventions for OCD specifically (22). However, given that the current demand for mental health services is likely to continue to outweigh the available support (24), it

is essential that brief therapist guided, parent-led CBT for OCD is also optimised to maximise service efficiency.

To increase the flexibility and efficiencies of brief therapist guided, parent-led CBT for OCD for both families and services, an online version of this treatment has been developed called Online Support and Intervention for Obsessive Compulsive Disorder (OSI-OCD). OSI-OCD was codesigned with children with lived experience of OCD, parents/carers of affected children, and a range of therapists (including CWPs, EMHPs, and SWPs). The treatment is based on (i) the 'offline' version of this treatment (described above, (19)) and (ii) OSI for anxiety problems, which has been shown to be clinically effective, likely to be cost-effective, and acceptable to parents, children, and therapists when delivered in routine services (26), and is now being more widely implemented across NHS services (27). OSI-OCD only requires ~4 hours of non-specialist therapist support and offers substantial flexibility for parents and services via brief telephone appointments (20-30 minutes) and online features (i.e., audio/video options, in-built routine outcome monitoring systems etc.). The intervention therefore has the potential to substantially increase access to CBT for preadolescent children with OCD via delivery by a range of therapists (including non-specialist therapists), as part of UK government workforce expansion programmes (21,22).

This paper reports the protocol for a feasibility Randomised Controlled Trial (RCT) of OSI-OCD compared to usual treatment (i.e., the standard of care) for preadolescent children (age 5-to-12-years old) with OCD in at least 6 NHS routine clinical services in England. The primary outcomes are to establish the feasibility of (i) OSI-OCD, and (ii) a future definitive RCT assessing clinical and cost-effectiveness of OSI-OCD compared to usual treatment. Key assessments will be conducted at baseline, 20-

week and 32-week post-randomisation. An embedded process evaluation will also be conducted to explore (i) the implementation and acceptability of OSI-OCD and the overall trial procedures, (ii) potential mechanisms of impact, and (iii) contextual factors that affect delivery, engagement, and outcomes of OSI-OCD to optimise the design of a future definitive RCT and subsequent wider implementation of OSI-OCD if indicated (28).

Methods

Aims of the study

The aims of this feasibility RCT are to:

1. Establish likely recruitment rates.
2. Establish treatment completion and adherence rates.
3. Establish retention to 20-week and 32-week post-randomisation assessments.
4. Identify ‘usual treatment’ in routine clinical services.
5. Identify appropriate clinical, functional, and health economic measures.
6. Explore the clinical outcomes for both treatment arms at 20-weeks and 32-weeks post-randomisation.
7. Describe any negative impacts of the OSI-OCD treatment.
8. Conduct a process evaluation to explore (i) the implementation and acceptability of the OSI-OCD treatment and overall trial procedures, including any implementation barriers that need to be addressed to facilitate future widespread implementation of OSI-OCD, if indicated, (ii) potential mechanisms of impact of OSI-OCD, and (iii) contextual factors that may influence the delivery, engagement, and outcomes of OSI-OCD.

A feasibility RCT is warranted to determine whether the planned trial procedures will be sufficient to conduct a definitive trial in routine child mental health services and to establish whether OSI-OCD warrants formal evaluation. The progression criteria for a future definitive trial are outlined in Table 1. Progression criteria will be evaluated using a traffic light system, and all criteria will be required to be rated as 'green' or 'amber' to provide sufficient confidence that a future definitive trial is viable:

- 'Green': A definitive trial is viable, without substantial changes to the OSI-OCD treatment and/or trial procedures.
- 'Amber': A definitive trial is viable, subject to further development of the OSI-OCD treatment and/or trial procedures.
- 'Red': A definitive trial may not be viable.

[Insert Table 1 here]

Trial design

This study is a multi-site, parallel-group, feasibility RCT with a nested process evaluation. Participants (i.e., parent(s)/carer(s), hereon referred to as parents, and their children) will be randomised in a 1:1 ratio (minimised by child age, gender, and OCD symptom severity) to OSI-OCD or usual treatment.

Trial setting

Services that provide psychological support for children's mental health problems on behalf of the NHS will be recruited. It is anticipated that at least 6 trial sites in England will be recruited. Trial sites will be selected based on their geographic diversity, regional ethnic diversity, and deprivation levels in the region to help maximise the likelihood of a diverse range of participants in the trial.

Participants

Forty-eight parents and their children will be randomised to receive either OSI-OCD or usual treatment. This sample size aligns with other feasibility studies in this area (29,30) and will provide sufficient data to evaluate the specified feasibility parameters and inform the design of a subsequent trial.

Inclusion criteria for parents and their children

- Child is aged 5 – 12 years old (inclusive) at the point of randomisation.
- Child has been referred to a service that provides psychological support for children's mental health problems on behalf of the NHS.
- Child has been diagnosed with OCD by the research team based on the ADIS-C or ADIS-P.
- Child and parent can understand, read, and communicate in English.
- Parent is willing and able to give informed consent for participation in the study for themselves and their child.
- Child is willing and able to give informed assent for participation in the study.
- Parent is willing and able to engage with OSI-OCD if randomised to this treatment arm.
- Parent is willing and able to complete required assessments.

Note. At least one parent is required to participate in the study and agree to complete the relevant measures. More than one parent per family is also able to participate in the study if they consent to do so.

Exclusion criteria for parents and their children

Parents and their children are not eligible for the study if one or more of the exclusion criteria are met:

- Child is currently receiving any other psychological intervention. (Note, children who are receiving Emotional Literacy Support Assistant (ELSA) support will not be excluded from the trial as this is not a formal psychological intervention).
- Child is receiving psychotropic medication, and the dose has not been stable for 2 months at the point of consent.
- Child has a confirmed or likely autism diagnosis (indicated by a score of ≥15 on the Social Communication Questionnaire-Lifetime Version, SCQ-LV, (31)). Note. If a child is on a waitlist for an autism assessment but scores <15 on the SCQ-LV, then the parent/child are still eligible to participate. If a child scores ≥15 on the SCQ-LV but likely autism has been ruled out by a mental health professional, then the parent/child are still eligible to participate).
- Child has profound learning difficulties evidenced by attending a specialist school.
- There are risk and/or safeguarding concerns which are paramount and would interfere with treatment delivery, including suicidal ideation, recurrent or potentially life-limiting self-harm, child protection plan, child protection register, or the research team consider the child to be suffering or likely to suffer significant harm.
- Parent or child is unable to understand, read, or communicate in English, which would prevent meaningful participation in the intervention or assessments.

<u>Inclusion criteria for trial therapists</u>

As this is a pragmatic feasibility RCT, trial therapists can include:

- Any clinical team member working in the mental health service who usually supports and/or delivers treatment for families of children with OCD.
- Any clinical team member who can deliver both OSI-OCD and usual treatment.

Exclusion criteria for trial therapists

- The only usual treatment that the trial therapist can deliver is Chessell et al.'s (19) brief therapist guided, parent-led CBT for OCD treatment protocol.

Inclusion criteria for stakeholder feedback interviews

- Trial therapist who delivered OSI-OCD to at least one family.
- Clinical supervisors who supervised trial therapists delivering OSI-OCD as part of the trial.
- Service leads or commissioners linked to an NHS service that delivered OSI-OCD to participating families.

There are no exclusion criteria for stakeholder feedback interviews.

Procedure

This protocol is written in line with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement 2025 ((32) see Additional File 1) and CONSORT extension checklist ((33) see Additional File 2). Figure 1 shows the SPIRIT participant timeline and Figure 2 provides an overview of study procedures.

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		Study Period							
		Enrolment		**Allocation**	**Post-randomisation**				
		Screening	Baseline	Allocation	Immediate post-randomisation	OSI-OCD or TAU*	Qualitative interviews**	20-week post-randomisation	32-week post randomisation/ close out
Timepoint		Month 0-2	Month 0-3	Month 0-3	Month 0-3	Month 3-7	Month 7-8	Month 8	Month 11
Enrolment (main trial)	Informed consent/assent	X							
	Demographic information	X							
	SCQ-LV	X							
	ADIS-P/ADIS-C	X						X	X
Assessments	CY-BOCS		X					X	X
	ChOCI-R-P		X			X		X	X
	FAS-PR		X					X	X
	COIS-R-P		X					X	X
	PSS		X					X	X
	EQ-5D-5L		X					X	X
	EQ-5D-Y-3L		X					X	X

	CHU-9D		X					X	X
	CSRI		X					X	X
	OCI-CV-R		X					X	X
	COIS-R-C		X					X	X
Allocation	Allocation			X					
Post-randomisation assessments	CEI-P/T				X			X	
	Therapist demographics				X				
	RCADS-P (OSI-OCD Modules 0, 8 and 9)/ RCADS-P OCD subscale (OSI-OCD Modules 1-7).					X			
	ORS					X			
	GBOs					X			
	3 items assessing parents' knowledge and confidence to help their child to overcome OCD					X		X	X
	2 items assessing parents' perception of how much their child has learned new information about their fears and their ability to cope in feared situations					X		X	X
	CGI-I							X	X

	Parent's experiences feedback form							X	X
	Feedback on measures questionnaire							X	
	Therapist treatment and supervision logs					X			
	AEs/SAEs Reporting					X		X	X
Enrolment (qualitative interviews)	Informed consent						X		
	Qualitative interviews						X		

Figure 1. SPIRIT participant timeline.

Note**.** SCQ-LV = Social Communication Questionnaire, Lifetime Version; ADIS-P/ADIS-C = Anxiety Disorders Interview Schedule, Parent Version/Child Version; CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; ChOCI-R-P = Children's Obsessional Compulsive Inventory-Revised, Parent Version; FAS-PR = Family Accommodation Scale, Parent Report; COIS-R-P = Child Obsessive-Compulsive Impact Scale-Revised, Parent Version; PSS = Parental Stress Scale; EQ-5D-5L = EuroQol 5-Dimension 5-Level Questionnaire; EQ-5D-Y-3L = EuroQol 5-Dimension Youth 3-Level Questionnaire; CHU-9D = Child Health Utility 9D; CSRI = Client Service Receipt Inventory; OCI-CV-R = Obsessive-Compulsive Inventory-Child Version-Revised; COIS-R-C = Child Obsessive-Compulsive Impact Scale-Revised, Child Version; RCADS-P = Revised Child Anxiety and Depression Scale, Parent Version; ORS = Outcome Rating Scale; GBOs = Goal-Based Outcomes; CGI-I = Clinical Global Impression – Improvement Scale; AEs/SAEs = Adverse Events/Serious Adverse Events; OSI-OCD = Online Support and Intervention for Obsessive-Compulsive Disorder; TAU = Treatment as Usual. *Assessment measures were only collected for the OSI-OCD treatment arm except for therapist treatment and supervision logs and AEs/SAEs which were collected for both treatment arms; **Qualitative interviews were only conducted for participants in the OSI-OCD treatment arm.

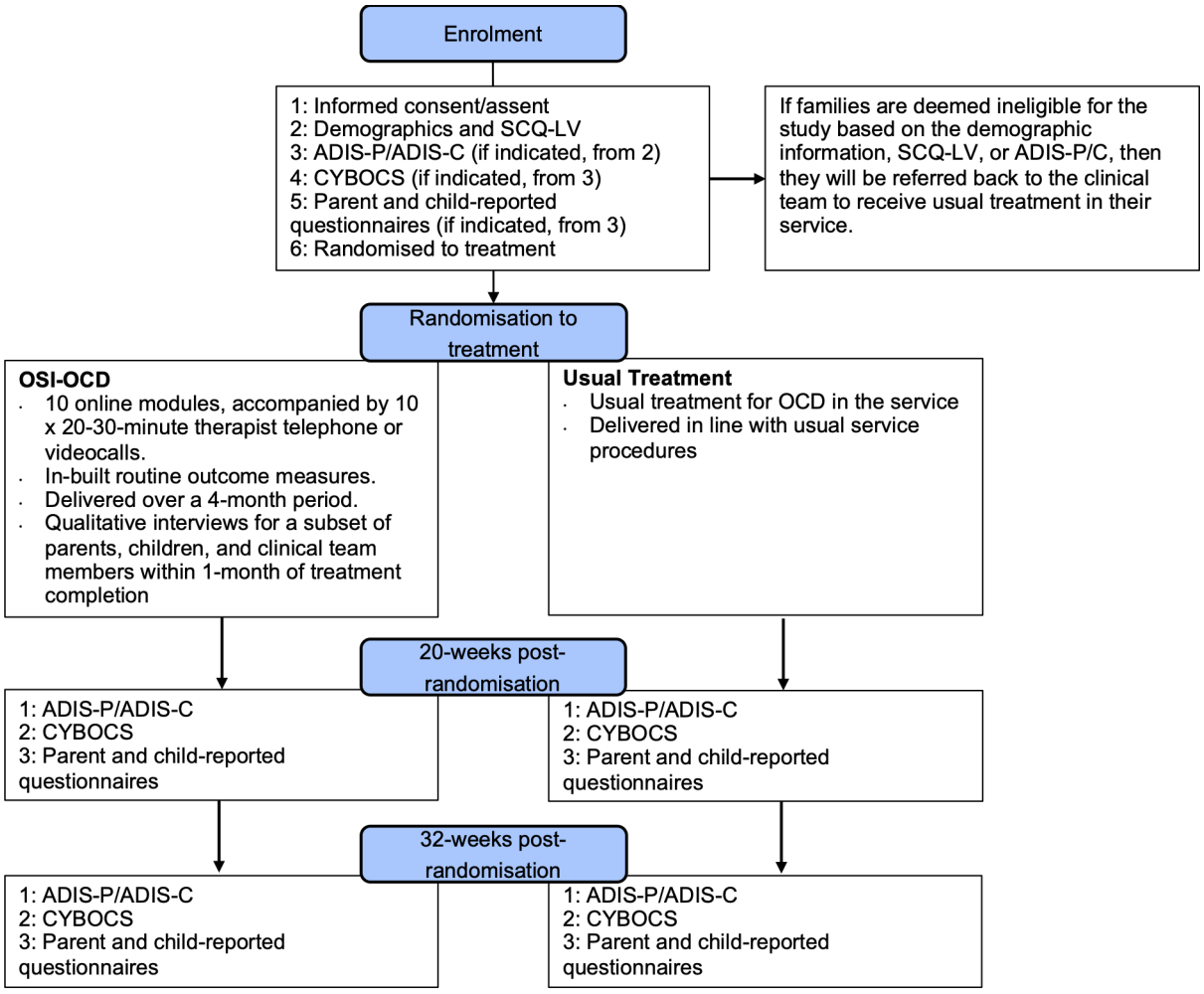


Figure 2. Overview of study procedures.

Note. ADIS-C/P = Anxiety Disorders Interview Schedule, Child/Parent Version; CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; SCQ-LV = Social Communication Questionnaire, Lifetime Version; OSI-OCD = Online Support and Intervention for Obsessive-Compulsive Disorder.

Recruitment

Clinical teams will identify potentially eligible parents/children via their usual assessment procedures (including advertising their services' offer via schools) and invite parents/children to receive further information about the study (i.e., information sheets and consent forms) via REDCap (a secure web-based system). Potentially eligible parents/children will then be able to access and complete consent and assent forms via REDCap if they wish to participate. Information sheets contain the

contact details of the research team so that parents/children can ask any questions prior to completing consent/assent forms. Reasons for declining to participate in the trial will be recorded for each site.

Randomisation and blinding

Parents/children will be randomised using a 1:1 ratio, minimised by child age (5 – 6 years, 7 – 8 years, 9 – 10 years, 11 – 12 years), gender (male, female), and OCD symptom severity (CY-BOCS score ≤24, CY-BOCS score ≥25) using QMinimum to reduce imbalances between the treatment groups on key characteristics. QMinimum will only be accessed/operated by necessary study team members. Distribution of families across both treatment arms will be closely monitored. If randomisation via QMinimum fails, measures will be taken to prioritise a 1:1 ratio across both treatment arms. Specifically, families will be directly allocated to a treatment condition to restore a 1:1 ratio where necessary and once restored, simple 1:1 randomisation using a randomised list generated by a statistician will be implemented. It will not be possible to blind parents/children and trial therapists to the treatment allocation. Outcome assessors (i.e., research assistants) and data analysts will be blind to treatment allocation.

Intervention

OSI-OCD is a brief online therapist guided, parent-led CBT intervention that was co-designed with children with lived experience of OCD, parents/carers of affected children, and therapists with a range of professional qualifications. Parents are provided with a link to a website containing 10 online modules (https://osiocd.osianxiety.ac.uk). Each online module consists of in-built Routine Outcome Measure (ROMs), treatment content (including interactive treatment

worksheets), an optional end-of-module quiz, and optional module feedback. Core treatment content includes: psychoeducation on OCD (including the OCD maintenance cycle), setting 'SMART' (Specific, Measurable, Achievable, Realistic, Time limited) goals, identification of the meaning of the child's obsessions and what the child needs to learn about the meaning of their obsessions to overcome OCD, ERP tasks with a focus on helping children to learn new information about the meaning of their obsessions and the ability to cope in feared situations without performing their compulsions, problem solving techniques, and relapse prevention. Parents work through the online modules and implement the treatment techniques before receiving a 20-to-30-minute telephone/videocall with the therapist. OSI-OCD is delivered over a 4-month period whereby Modules 0 – 5 (and accompanying therapist call) are completed weekly, Modules 6 – 8 (and accompanying therapist call) are completed every other week, and Module 9 (and accompanying therapist call) is completed one month after Module 8. Therapists have access to a therapist version of the website (https://osiocdclinician.osianxiety.ac.uk) where they can see parents' progress through the modules, answers to any interactive questions, and ROMs data (see 'measures and assessment' for further information). Therapists' role during the brief telephone/videocalls is to use the therapist manual to review how parents found the module content and to collaboratively problem solve any difficulties the parent experienced implementing the treatment techniques. Families who are randomised to OSI-OCD will be offered an optional £30 voucher to support the costs of internet for the treatment.

Usual treatment

Usual treatment refers to the standard of care that is provided for preadolescent children with OCD in the participating service. It is anticipated that the 'usual

treatment' will vary across and within services, therefore trial therapists will be asked to provide details of the usual treatment for each participating family via therapist treatment and supervision logs.

Training, supervision, and intervention fidelity

Trial therapists will receive one full day online training in OSI-OCD delivered by the study authors. Trial therapists with active OSI-OCD cases only will be asked to attend OSI-OCD skills sessions at regular intervals throughout the treatment including at Module 1 (SMART goals), Module 3 (ERP tasks with a focus on learning), Module 6 (to review progress), Module 8 (to review progress), and Module 9 (to review treatment outcomes). However, trial therapists will be able to attend OSI-OCD skills sessions whenever helpful. OSI-OCD skills sessions will be run twice weekly for one hour by a non-specialist therapist with experience in delivering brief online parent-led CBT interventions (CCh) and a clinical psychologist with expertise in OCD assessment/treatment (AF). Trial therapists will be instructed to receive their usual clinical supervision for both OSI-OCD cases and usual treatment cases. Treatment fidelity will not be explicitly monitored; however, therapists will be asked to complete therapist treatment and supervision logs which will provide an indication of fidelity to the recommended treatment schedule/timings of the OSI-OCD arm (see 'measures and assessment' for further information).

Measures and assessment

The measures and assessments used throughout this trial are outlined below. Whilst children need to assent to take part in the trial, all child-reported measures will be optional so that this is not a barrier to participation. Where child-reported measures have not been validated for younger children, the delivery of these measures will be

adapted (for example, research assistants will use developmentally appropriate language during diagnostic interviews and parents will be encouraged to support their children to answer the optional child-reported questionnaires).

Eligibility assessments

Potentially eligible families who consent/assent to the trial will be asked to complete the following screening measures. Families will have up to 1-month to complete the measures.

Demographic information. Parents will report (i) their child's date of birth, gender, ethnicity, previous and/or current psychological treatment/medication, school type/education provision, co-occurring conditions, and (ii) their gender, ethnicity, relationship to the child, household circumstances and income, education status, and employment status. Demographic information will be screened by the research team to ensure that the eligibility criteria for the trial are met and to describe the sample.

Social Communication Questionnaire-Lifetime Version (SCQ; (31)). The SCQ-Lifetime Version is a 40-item parent-reported screening tool for children aged 4-years and above to assess social communication behaviours that may be associated with autism. The SCQ has good psychometric properties, including internal consistency and validity as an autism screening measure, however its diagnostic accuracy varies across settings and populations (34). If a child scores ≥15 on the SCQ then they will not be eligible to participate in the study (unless likely autism has been ruled out by a mental health professional). This is because OSI-OCD has not currently been adapted for autistic children/children who are likely to be autistic. If a child scores <15 on the SCQ, then families will be invited to complete a mental health diagnostic interview.

Anxiety Disorder Interview Schedule – Parent and Child Report (ADIS-P/C; (35)). The ADIS-P/C is a parent-reported or child-reported a semi-structured, clinician administered diagnostic interview used to assess DSM-IV OCD, anxiety disorders, mood disorders, and behavioural problems in children aged 7-to-17-years-old. The ADIS-P/C will be adjusted to align with DSM-5 criteria for the purposes of this study. Clinical Severity Ratings (CSRs) will be allocated where diagnostic criteria are met (i.e., CSR ≥4). Children will be required to meet diagnostic criteria for OCD based on child or parent report to be eligible for the study. Assessments will be conducted by trained assessors (graduate level research assistants within the research team, who are blind to treatment allocation) and will be supervised by experienced ADIS assessors/supervisors (who may not be blind to treatment allocation). Any discrepancies between assessors and supervisors will be resolved by a further blind supervisor. The ADIS-C/P has good test re-test reliability (36), concurrent validity (37), and is sensitive to treatment change (38). Percentage agreement and inter-rater reliability for CSRs will be reported. The ADIS-P/C is also completed at 20-weeks and 32-weeks post-randomisation.

Outcome measures

Eligible participants will complete the following measures at baseline (which they have up to 1 month to complete), 20-weeks post-randomisation, and 32-weeks post-randomisation (unless otherwise indicated). Participants will be given a £20 voucher for the completion of measures at 20-weeks, and a further £20 voucher for completion of measures at 32-weeks to promote retention. Families who have dropped out of treatment will still be invited to participate in the 20-week and 32-week assessments in line with the original protocol timelines.

Children's Yale Brown Obsessive Compulsive Scale (CY-BOCS, (39)). The CY-BOCS is the proposed primary outcome measure for a definitive trial. It is a semi-structured, clinician administered 'gold standard' assessment of OCD symptom severity in children aged 6-to-17-years-old and is completed jointly by the parent and child. Obsession and compulsion severity are each measured on five scales: (1) time, (2) interference, (3) distress, (4) resistance, and (5) control. Each of the ten scales are rated out of 4 by the clinician, providing a total out of 40 (whereby higher scores indicate greater OCD severity). Assessments will be conducted by trained assessors (graduate level research assistants within the research team, who are blind to treatment allocation) and will be supervised by experienced CY-BOCS assessors/supervisors (who may not be blind to treatment allocation). Any discrepancies between assessors and supervisors will be resolved by a further blind supervisor. The CY-BOCS has good test re-test reliability (40), convergent validity (39), and is sensitive to treatment change (39). Percentage agreement and inter-rater reliability for total CY-BOCS scores will be reported.

Clinical Global Impressions – Improvement (CGI-I, (41)). The CGI-I is a therapist-rated measure assessing overall treatment response from 1 ('very much improved') to 7 ('very much worse') that will be completed at 20-weeks and 32-weeks post-randomisation. CGI-I ratings will be informed by the 20-week and 32-week post-randomisation ADIS-P/C and CY-BOCS assessments and will be double-rated by blind assessors (graduate level research assistants) and supervisors (who may not be blind to treatment allocation). Any discrepancies between assessors and supervisors will be resolved by a further blind supervisor.

Obsessive Compulsive Inventory – Child Version – Revised (OCI-CV-R; (42)). The OCI-CV-R is a child-reported 18-item measure of OCD symptom severity amongst

children aged 7-to-17-years old. Items are rated from 0 (‘never’) to 2 (‘always’) over the past month producing a total score out of 36 (with higher scores indicating greater symptom severity). The OCI-CV-R has good psychometric properties (42). The OCI-CV has been recommended for use by international consensus guidelines (43); however, does not have a parent-reported version. Thus, parent-report of children’s OCD symptoms will be captured by the ChOCI-R-P.

Children’s Obsessive Compulsive Inventory – Revised – Parent Report (ChOCI-R-P, (44)). The ChOCI-R-P is a parent-reported 32-item questionnaire measuring the presence and severity of OCD symptoms amongst children aged 7-to-17-years-old. Twenty items assess symptom presence and are rated from 0 (‘not a lot’) to 2 (‘a lot’) (providing a total symptom score out of 40). Twelve items assess symptom severity from 0 to 4 (providing a total impairment score out of 48). Higher scores indicate greater OCD symptoms/severity. The ChOCI-R-P has good international consistency and convergent validity with the CY-BOCS (44) and is sensitive to treatment change (45).

Family Accommodation Scale – Parent Report (FAS-PR, (46)). The FAS-PR is a parent-reported 12-item measure of the frequency and severity of parental accommodation of OCD amongst children aged 7-to-17-years old. Items are rated from 0 (‘never’) to 4 (‘always’) over the past month producing a total score out of 48 (with higher scores indicating greater parental accommodation of OCD). The FAS-PR has good psychometric properties (46).

Child Obsessive Compulsive Impact Scale – Revised – Parent and Child Version (COIS-R-P/COIS-R-C, (47)). The COIS-R-P/COIS-R-C is a parent-reported or child-reported 33-item measure of OCD-related functional impairment amongst children

aged 5-to-17-years-old. Items are rated from 0 (‘not at all’) to 3 (‘very much’) over the past month and has good psychometric properties (47). Due to the focus on preadolescent children in this trial, items relating to ‘boyfriend/girlfriend’ and ‘going on a date’ were removed, resulting in a possible total score out of 93 (with higher scores indicating greater functional impairment).

Parenting Stress Scale (PSS, (48)). The PSS is a parent-reported 18-item measure of positive and negative stress associated with parenting over the past month and has been validated for parents of children aged up to 18-years-old. Items are rated from 1 (‘strongly disagree’) to 5 (‘strongly agree’) producing a total out of 90 (with higher scores indicating greater parenting stress). The PSS has good psychometric properties (48).

Health economic measures

Eligible participants will complete the following measures at baseline, 20-weeks post-randomisation, and 32-weeks post-randomisation (unless otherwise indicated):

EuroQol-5 Dimension 5-Level Instrument (EQ-5D-5L, (49)). The EQ-5D-5L is an adult self-reported, preference-based measure of health-related quality of life across five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Parents rate each dimension from ‘no problems’ to ‘extreme problems’ to reflect their health on the day the measure is completed, with higher scores indicating better health. The EQ-5D-5L has good psychometric properties (50).

EuroQol-5 Dimension 3-Level Instrument (EQ-5D-Y-3L, (51)). The EQ-5D-Y-3L is a preference-based measure of children’s health-related quality of life across the same five domains as the adult version, but using a more child-friendly wording: mobility

(walking about); looking after myself; doing usual activities (for example, going to school, hobbies, sports, playing, doing things with family or friends); having pain or discomfort; and feeling worried, sad or unhappy. We us the proxy version of this instrument, namely parents rate each dimension from ‘no problems’ to ‘a lot of problems’ to reflect their child’s health on the day the measure is completed, with higher scores indicating better health. The EQ-5D-Y-3L has good psychometric properties (51).

Child Health Utility 9D (CHU-9D, (52)). The CHU-9D is a paediatric, preference-base measure of children’s health-related quality of life across nine domains (i.e., worry, sadness, pain, tiredness, annoyance, schoolwork, sleep, ability to engage in daily routines, and ability to join in activities), each of which is rated on an ordered 5-point scale, with higher scores indicating better health-related quality of life. We the proxy version of this instrument, i.e. parent’s report on child. The CHU-9D has good psychometric properties (53).

Client Services Receipt Inventory (CSRI; (54)). An adapted version of the CSRI will be used to collect information on primary and secondary health care use, social care utilisation, medicine use, travel time to access those services, for both the child and the parent. Information on child absence from school and parent absence from work (as applicable) due to the child’s OCD will also be collected. The CSRI is completed by the parent.

Therapist demographic characteristics; therapist treatment and supervision logs. Trial therapists will be asked to complete a demographic survey collecting data relating to therapist gender, ethnicity, role, region of England that the service is based, type of service, experience working with children with OCD, training in

psychological treatments, and working hours (full/part time) to describe the sample. Treating therapists across both treatment arms will be asked to complete treatment and supervision logs to track adherence to OSI-OCD and to describe usual treatment in services to support the planning of a definitive trial.

Treatment credibility

Therapist and parent treatment credibility will be assessed using the *Credibility and Expectation of Improvement Scale – Parent / Therapist Report (CEI-P/CEI-T; (55)).* The CEI-P/T is a 3-item measure assessing parents'/therapists' perceptions of the credibility of the allocated treatment and expectations of treatment benefit. The measure has good psychometric properties (55). The CEI-P/T will be administered after randomisation, and an adapted version will be completed at 20-weeks post-randomisation.

Treatment measures

In-built ROMs will be collected at each OSI-OCD module and will align with CYP IAPT recommended measures where possible (56), including: (1) *ChOCI-R-P* ((44) described above, completed at every OSI-OCD module), (2) *Revised Children's Anxiety and Depression Scale-Parent Report (RCAD-P; (57))*: a parent-reported 47-item measure of children's (aged 8-to-18-years-old) anxiety and low mood symptoms which are rated from 0 ('never') to 3 ('always') producing a total raw score out of 141 (with higher scores indicating greater symptom severity). The RCADS-P has good psychometric properties (57). The full RCADS-P is completed at Module 0, 8, and 9. The RCADS-OCD parent-reported subscale is completed at Modules 1 – 7. (3) *Outcome Rating Scale (ORS, (58))*: the ORS is a parent-reported measure assessing children's (aged 6-to-12-years-old) functioning including individual

wellbeing, interpersonal relationships, social functioning, and overall functioning along four 10cm scales (which higher scores indicating greater functioning). The ORS has good psychometric properties (58) and is completed at every OSI-OCD module. (4) *Goal Based Outcomes (GBOs; (59)).* Parents set up to 3 GBOs for their child to work towards during Module 1 of OSI-OCD. Parent-reported progress towards GBOs are rated at Module 1 and each subsequent OSI-OCD module from 0 ('no progress') to 10 ('goal fully achieved'). GBOs are widely used in child mental health services (56). (5) *Items assessing parents' knowledge and confidence to help their child to overcome OCD(19).* Parents complete three items at each OSI-OCD module, each on a 5-point scale, to assess their knowledge and confidence to help their child to overcome OCD (see Additional File 4). Items were devised by Chessell et al. (19) and no psychometric data is available. (6) *Items assessing children's learning about their fears and their ability to cope in feared situations (19).* Parents complete two items at each OSI-OCD module, each on a 5-point scale, to assess their perception of whether their child has learned new information about their obsessions/the meaning of their obsessions and their ability to cope in feared situations without performing compulsions (see Additional File 5). Items were devised by Chessell et al. (19) and no psychometric data is available. (7) *Session Rating Scale (SRS, (60)).* The SRS is a parent-reported measure of the therapeutic alliance after each OSI-OCD therapist call that measures: relationship with the therapist, goals and topics, therapeutic approach, and an overall rating along four 10cm scales (with higher scores indicating a stronger therapeutic alliance). The SRS has well established psychometric properties (60). (8) *Module feedback (61).* Each OSI-OCD module has 12 parent-reported items capturing parents' feedback on the module. Ten items are rated on a 5-point Likert scale from 'strongly disagree' to

'strongly agree' and 2 free-text items capture anything the parent found difficult about the module and would like to discuss with the therapist. Items were adapted from Hill et al. (61) to ensure there were specific to this version of OSI (see Additional File 6l).

Adverse events

Adverse events (i.e., clinically significant events that may affect participants' wellbeing resulting from the trial) and serious adverse events (i.e., any untoward medical concern) reported by parents/therapists will be logged on REDCap throughout the trial. Serious/adverse events will also be systematically captured at 20-weeks and 32-weeks post-randomisation via a parent experience feedback form (see Additional File 7) that captures any positive experiences and difficulties/challenges that families have faced because of participating in the trial. Serious/adverse events will be assessed by the study PI (who is not blinded to treatment allocation) and Trial Steering Committee (TSC) (who are blinded to treatment allocation) to determine the severity of the event (mild, moderate, severe) and whether the event is related to the trial using a 6-point scale (ranging from definitely related to definitely not related).

Feedback questionnaire

Parents in both treatment arms will be asked to complete six questions at the 20-week post-randomisation assessment measuring the applicability of the study questions to their child, whether any of the questions were difficult to understand/too burdensome, and any suggested improvements for the questionnaires used in the study (see Additional File 8). Parents' responses will be used to help refine the assessment procedures for a future definitive trial.

Post-trial care

Participation in the trial does not affect post-trial care. If families would like to obtain further treatment beyond the trial, then they will be referred to their clinical team who can advise on whether further care can be provided within the service and/or facilitate onward referrals.

Process evaluation

An embedded mixed-methods process evaluation will be conducted in line with the MRC guidelines to explore the (i) implementation and acceptability of OSI-OCD and the overall trial procedures, (ii) potential mechanisms of impact, and (iii) contextual factors related to delivery, engagement, and outcomes of OSI-OCD and to optimise the design of a future definitive RCT and subsequent wider implementation of OSI-OCD, if indicated (28). A sub-sample of parents (n=~15) and children (n=~15) who received OSI-OCD and treating therapists, clinical supervisors, service leads and commissioners attached to participating services (n=~15) will take part in semi-structured qualitative interviews. A purposive sampling approach will be used to invite participants who vary according to key characteristics (e.g., age, gender, ethnicity, caregiving role, caregiver education, OCD symptom subtype, treatment outcome, and therapists' role/experience of delivering OCD treatments, service context/locality). 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 (62). Relevant quantitative data will also be analysed (see data analysis section below).

Data storage and management

Personal information will be collected and stored on REDCap. The REDCap study database has been set up with appropriate measures to reduce the risk of data

errors (i.e., range checks for data values). Regular downloads of data stored within REDCap will be conducted throughout the trial, with copies stored securely on the University of Oxford SharePoint for monitoring and subsequent data analysis. OSI-OCD treatment data will be stored on OSI-OCD and will be regularly downloaded and saved on the University of Oxford SharePoint. OSI-OCD is hosted and maintained by an external provider with appropriate security measures who will only have access to treatment data held within OSI-OCD. Only necessary study team members with appropriate approvals will have access to the study data during and beyond the study. At the end of the trial, all study data will be stored on the University of Oxford SharePoint for three years and then deleted. Once main trial analyses are complete, a sufficiently anonymised version of the main study databases (including qualitative interviews, where possible) will be made available in a public repository. Where participants agree to be contacted for future research, the linking document containing personal details/contact information, will be permanently deleted after the youngest participant reaches 18-years-of-age. Where participants do not agree to be contacted for future research, the linking document containing personal details/contact information will be deleted 3 years after the end of the study.

Data analysis

A detailed statistical analysis plan will be registered on the Open Science Framework prior to data analysis being conducted. To establish recruitment rates, treatment completion and adherence rates, retention to 20-week and 32-week post-randomisation assessments, and to identify ‘usual treatment’ (i.e., study aims 1-4) a CONSORT diagram and table will be used outlining the number and percentage of participants at each timepoint. Moreover, the total number of families recruited and the average recruitment rate per month will be reported. For the OSI-OCD arm, the

number and percentage of families who complete the core OSI-OCD modules (i.e., Modules 0 – 4) will also be reported. Usual treatment will be described using information from the therapist treatment and supervision logs. To determine the appropriateness of the proposed clinical, functional, and health economic measures (i.e., study aim 5), descriptive statistics (i.e., means, standard deviations, range, completion rates) will be reported for all outcomes, for each treatment arm, at each timepoint. Those, together with the results from the qualitative interviews, will inform the choice of the primary economic outcome (e.g. CHU9D versus EQ-5D-Y-3L) for a future definitive trial, if indicated. To explore the clinical outcomes of both treatment arms (i.e., study aim 6), descriptive statistics (i.e., means, standard deviations) and within-group effect sizes (i.e., Cohen's d, 95% confidence intervals) will be calculated for the CY-BOCS (i.e., the proposed primary outcome measure for a future definitive trial) from baseline to 20-weeks post-randomisation, and baseline to 32-weeks post-randomisation per treatment arm. The number/percentage of children who meet international consensus criteria for 'response' (i.e., ≥35% reduction in CY-BOCS scores, plus CGI-I of 'very much' or 'much improved' for at least one week) and/or 'remission' (i.e., no longer meeting diagnostic criteria for OCD for at least one week) will also be reported at 20-weeks and 32-weeks post-randomisation per treatment arm (63). Based on previous research (19), a large within-group effect size on the OSI-OCD treatment arm would be anticipated to warrant a future definitive trial. The standard deviation of the CY-BOCS scores (if selected as the primary outcome for a definitive trial) at post-randomisation will be used to inform the sample size of a future definitive RCT. If the CY-BOCS is not deemed an appropriate primary outcome measure, then a future sample size will be determined from other appropriate measures collected in the trial. Whilst the progression criteria for OSI-OCD outcomes

is based on the above criteria, to further understand the OSI-OCD treatment outcome data, exploratory analyses (i.e., descriptive statistics and within group effect sizes) will also be conducted for families who have completed the 'core' OSI-OCD modules (i.e., Modules 0 – 4), and for families who have completed the full treatment (i.e., Module 0 – 9). Intent-to-treat analyses will be conducted (regardless of treatment compliance); per-protocol analyses will also be conducted; however, ITT analyses will be prioritised. Adverse events for each treatment arm will be described/reported (i.e., study aim 7). A mixed-methods process evaluation will be conducted to explore (i) the acceptability of OSI-OCD and the overall trial procedures and (ii) any implementation barriers that need to be addressed to facilitate future widespread implementation of OSI-OCD, if indicated (i.e., study aim 8). Quantitative data will include: (i) rates of response of clinical, functional, and health economic measures, (ii) descriptive analyses (i.e., means, standard deviations, percentages) of parents' engagement with OSI-OCD (i.e., number of module pages viewed, time spent on the module, optional interactive questions/quiz questions completed, module feedback responses), (iii) descriptive analyses (i.e., means, standard deviations) of parents' OSI-OCD SRS scores and (iv) descriptive analyses (i.e., medians, interquartile ranges) of parents' and therapists' credibility of OSI-OCD at 20-weeks post-randomisation. Qualitative interviews will be analysed using Framework Analysis (64), guided by the Consolidated Framework for Implementation Research (CFIR) framework (65) and will explore the implementation and acceptability, potential mechanisms of impact, and contextual factors affecting OSI-OCD engagement/outcomes in line with the MRC guidance (28) from the perspectives of parents, children, and clinical team members.

Trial monitoring

The research team will monitor the progress of the trial on an ongoing basis. Reasons for treatment and/or trial discontinuation will be logged by the research team. Any deviations to the protocol will also be logged. An independent TSC has been established, including an independent chair, two independent academic advisors, and two patient and public involvement representatives. The TSC will meet four times across the course of the trial, including to review the study protocol/ethical documents, recruitment rates at two timepoints, and to facilitate interpretation of the study results.

Discussion

The aim of this study is to conduct a feasibility RCT exploring the feasibility of (i) OSI-OCD (a brief online therapist guided, parent-led CBT treatment for preadolescent children with OCD), and (ii) a future definitive trial of OSI-OCD compared to usual treatment in routine child mental health services. The feasibility RCT will take place in at least 6 NHS services and treatment will be delivered by a range of therapists (including non-specialist therapists). Study outputs will provide sufficient information to determine if a large definitive RCT is feasible and will inform necessary adaptations to the study design/procedures to maximise the likelihood of a successful definitive trial. Given that the evidence-base for OSI-OCD is in its infancy, autistic children with OCD are not included in the current trial as previous research and NICE guidelines suggest that specific treatment adaptations are required for autistic children (66,67). It will therefore be essential to consider the needs of autistic children in future iterations of this treatment, if indicated. This work therefore has potential to help ultimately substantially increase access to CBT for preadolescent children with OCD and their families.

Trial status

The study is ongoing. Recruitment of participants started in September 2025 (first participant consented 29/10/2025) and will continue until 31/10/2026. The trial was registered retrospectively on the ISRCTN Registry (ISRCTN12117577. 02/12/2025).

List of abbreviations

ADIS-P/ADIS-C = Anxiety Disorders Interview Schedule, Parent Version/Child-Version;

AEs/SAEs = Adverse Events/Serious Adverse Events;

CBT = Cognitive Behavioural Therapy;

CGI-I = Clinical Global Impression – Improvement Scale;

ChOCI-R-P = Children's Obsessional Compulsive Inventory-Revised, Parent-Version;

CHU-9D = Child Health Utility 9D;

COIS-R-C = Child Obsessive-Compulsive Impact Scale-Revised, Child Version;

COIS-R-P = Child Obsessive-Compulsive Impact Scale-Revised, Parent Version;

CONSORT = Consolidated Standards of Reporting Trials;

CSR = Clinician Severity Rating;

CSRI = Client Service Receipt Inventory;

CWP = Children's Wellbeing Practitioner;

CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale;

ELSA = Emotional Literacy Support Assistant;

EMHP = Education Mental Health Practitioner;

EQ-5D-5L = EuroQol 5-Dimension 5-Level Questionnaire;

EQ-5D-Y-3L = EuroQol 5-Dimension Youth 3-Level Questionnaire;

ERP = Exposure and Response Prevention;

FAS-PR = Family Accommodation Scale, Parent Report;

GBOs = Goal-Based Outcomes;

NHS = National Health Service;

NICE = National Institute for Health and Care Excellence;

OCD = Obsessive-Compulsive Disorder;

OCI-CV-R = Obsessive-Compulsive Inventory-Child Version-Revised;

ORS = Outcome Rating Scale;

OSI-OCD = Online Support and Intervention for Obsessive-Compulsive Disorder;

PSS = Parental Stress Scale;

RCADS-P = Revised Child Anxiety and Depression Scale, Parent Version;

RCT = Randomised Controlled Trial;

ROMS = Routine Outcome Measures;

SCQ-LV = Social Communication Questionnaire, Lifetime Version;

SPIRIT = Standard Protocol Items: Recommendations for Interventional Trials;

SWP = Senior Wellbeing Practitioner;

TAU = Treatment as Usual;

UK = United Kingdom.

Declarations

Ethical approval and consent to participate

Ethical approval for this study protocol has been obtained from the University of Oxford (PID: 18803) and Leicestershire NHS Research Ethics Committee and Health Research Authority (REC Reference: 25/EM/0159). Any amendments to the protocol will be conducted in accordance with the University of Oxford/NHS/HRA guidelines,

including notifying trial sites. The current version of the ethically approved protocol is Version 2.1 (07/10/2026). Parents will be required to provide informed consent for themselves and their child to participant. Children will be required to provide assent.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

CCr is a developer of the OSI platform. Oxford University have a license agreement in place with Koa Health for the distribution and received consultancy fees and royalties. CCr does not receive any personal income from this. No other conflicts of interest are declared.

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Authors' contributions

All authors(s) have read and approved the final manuscript.

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Dissemination policy

The results of the trial will be published in a peer-reviewed journal article, presented at conferences, and disseminated (via plain English summaries) to participants and participating NHS services.

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Table 1. Progression criteria for a future definitive trial

Aims	Measure/method of assessment	Criteria for progression
Establish likely recruitment rates.	Decline logs to establish reasons for decline prior to consent and between consent and randomisation.	Green: ≥80% of eligible participants agree to randomisation. Amber: 70-79% of eligible participants agree to randomisation. Red: <70% of eligible participants agree to randomisation.
Establish treatment completion and adherence rates.	Number/percentage of families withdrawing during treatment as measured by therapist treatment logs.	Green: ≤20% drop-out in both treatment arms. ≥80% of participants allocated to OSI-OCD complete the 'core' modules (i.e., Modules 0-4). Amber: 21-30% drop-out in both treatment arms. 70-79% of participants allocated to OSI-OCD complete the 'core' modules. Red: >30% drop-out in both treatment arms. <70% of participants allocated to OSI-OCD complete the 'core' modules.
Establish retention to 20-week and 32-week post-randomisation assessments.	Number/percentage of families who complete post-randomisation assessments.	Green: ≥80% of participants complete 20-week and 32-week post-randomisation assessments. Amber: 70-79% of participants complete 20-week and 32-week post-randomisation assessments. Red: <70% of participants complete post-randomisation assessments.
Identify 'usual treatment' in routine clinical services.	Therapist treatment and supervision logs.	Not applicable.

Identify appropriate clinical, functional, and health economic measures.	Number/percentage of families who complete post-randomisation clinical, functional, and health economic assessments. Feedback on measures collected at 20-weeks, and via qualitative interviews.	Green: ≥80% of participants complete 20-week and 32-week post-randomisation assessments for the proposed primary outcome measure (i.e., CY-BOCS). Amber: 70-79% of participants complete 20-week and 32-week post-randomisation assessments for the proposed primary outcome measure. Red: <70% of participants complete post-randomisation assessments for the proposed primary outcome measure.
Explore the clinical outcomes for the OSI-OCD treatment arm at 20-weeks and 32-weeks post-randomisation.	Within-group effect sizes on the CY-BOCS from pre-treatment to 20-weeks post-randomisation, and from pre-treatment to 32-weeks post-randomisation.	Green: Large within-group effect-size at both timepoints (d=≥0.8). Amber: Medium within-group effect size at both timepoints (d=0.5 - 0.8). Red: Small within-group effect size at both timepoints (d=<0.5).
Describe any negative impacts of the OSI-OCD treatment.	Adverse event logs. Qualitative interviews with parents, children, and clinical team members.	Green: No serious negative impacts of the treatment are identified (e.g., no reports that the treatment procedures are life threatening, directly results in persistent/significant disability/incapacity, inpatient hospitalisation, or death as classified by the TSC). Amber: Potentially serious negative impacts of the treatment are identified. Red: Serious negative impacts of the treatment are identified.
Explore the acceptability of the OSI-OCD treatment and overall trial procedures; identified implementation barriers that need to be addressed to facilitate future widespread implementation of OSI-OCD, if indicated.	Treatment completion rates; post-randomisation assessment completion rates; CEI-P/T scores at 20-weeks post-randomisation; therapist treatment and supervision logs; adverse events; parent experience feedback form collected at 20-weeks and 32-weeks post-randomisation; feedback on measures collected at 20-weeks post-randomisation. OSI-OCD	Green: • No significant concerns are raised about the treatment/trial procedures (i.e., any concerns raised are not classed as a significant concern by the TSC). • Mean module feedback scores on each OSI-OCD module are ≥ 4 (i.e., agree or strongly agree). • Mean SRS scores for each OSI-OCD module are ≥36 • Parents/therapists' median scores on items assessing credibility of OSI-OCD are ≥7 (on a scale of 1 – 10, with

	engagement and usage data. Qualitative interviews with parents, children, and clinical team members.	higher scores indicating greater credibility) at 20-weeks post-randomisation. • Acceptability barriers are identified and classed as 'addressable' (from 0 - not at all addressable to 4 - extremely addressable*, e.g., parent-reported treatment measures are too burdensome, which can be addressed by using briefer versions of treatment measures). • Implementation barriers are identified and classed as 'changeable' (from 0 – not at all changeable to 4 – extremely changeable e.g., therapists' lack confidence to use OSI-OCD, which can be addressed through further training and supervision). Amber: • Potentially significant concerns are raised about the treatment/trial procedures (i.e., any concerns are classed as addressable by the TSC) • Mean module feedback scores on each OSI-OCD module are ≥ 3 (i.e., neutral or above) • Mean SRS scores for at least 5 OSI-OCD modules are ≥36 • Parents/therapists' median scores on items assessing credibility of OSI-OCD are ≥6 (on a scale of 1 – 10, with higher scores indicating greater credibility) at 20-weeks post-randomisation. • Acceptability barriers are identified and scored as ≥ 2 on an 'importance' scale and ≥1 on an 'addressability' scale. • Identified implementation barriers are scored as ≥ 2 on an 'importance' scale. Red: • Significant concerns are raised about the treatment/trial procedures (i.e., any concerns are classed as not addressable by the TSC)

			• Mean module feedback scores on each OSI-OCD module are < 3 • Mean SRS scores for 5 or more OSI-OCD modules are <36 • Parents/therapists' median scores on items assessing credibility of OSI-OCD are <6 (on a scale of 1 – 10, with higher scores indicating greater credibility) at 20-weeks post-randomisation.

Note. * 'Addressability' scale is adapted/based on Green and Aarons' (68) 'changeability' scale. OSI-OCD = Online Support and Intervention for Obsessive Compulsive Disorder; CY-BOCS = Children's Yale Brown Obsessive Compulsive Scale; SRS = Session Rating Scale; CEI-P/T = Credibility and Expectation of Improvement Scale – Parent/Therapist; TSC = Trial Steering Committee.

Additional Files

Additional File 1. SPIRIT Checklist

Additional File 2. CONSORT Extension Checklist

Additional File 3. TiDIER Checklist

Additional File 4. Items assessing knowledge and confidence

Additional File 5. Items assessing learning

Additional File 6. OSI-OCD Module Feedback

Additional File 7. Parent Experience Feedback Form

Additional File 8. Feedback Questionnaire