RESEARCH PROTOCOL

Children with OCD:

Identifying Acceptable Support Strategies for Parents

(CO-ASSIST)

The University of Manchester

(INSERT NHS LOGOS)

Children with OCD: Identifying Acceptable Support Strategies for Parents (CO-ASSIST)

Study Title	**Children with OCD: Identifying Acceptable Support Strategies for Parents (CO-ASSIST)**
Short Title	Children with OCD: Identifying Support Strategies for Parents
Study Design	A mixed-method qualitative study involving three phases: Phase 1 will include -in-depth semi-structured remote telephone or videoconference interviews (and an optional journal) with parents/carers - videoconference focus groups (or individual telephone or videoconference interview) with professionals. Phase 2- 21/2 hour remote synthesis meeting (attended by the CO-ASSIST team & a 2 1/2 hour remote consensus workshop event attended by mixed stakeholders ..Phase 3 2-hour remote workshop will attended by mixed stakeholder events. These events are aimed at i) synthesising new and existing evidence to derive a roadmap of support resources and strategies, ii) identifying components of a future intervention and develop a protocol and outcome measures for its future development and testing.
Study Participants	-Parents/carers of children and young people aged 8-18 with OCD --Professionals involved in supporting children and families with OCD -Charity representatives or OCD researchers involved in service development for families with OCD
Planned Sample Size	**Phase 1** 25-30 patients/carers (interviews) 3-4 focus groups (of 6-8 people) with professionals who have experience of working with families with a child with a diagnosis of OCD (may include some individual interviews according to professional availability/preference) **Phase 2** 18-25 key stakeholders (including parents/carers, professionals, charity representatives and OCD researchers) **Phase 3** 10 key stakeholders (including parents/carers, professionals, charity representatives and OCD researchers) Total estimated aggregate sample across 3 phases N=95
Follow-up Duration	No follow up required
Planned Study Period	20 months: 01/04/2020 to 31/11/2021 (including 3 month extension to account for delays due to the pandemic)
Objectives	**Primary aim** To undertake development work to better support parents and carers of children and young people with OCD. **Objectives** To systematically review the evidence on interventions to support parents/carers of children with emotional disorders *(HRA approval not required)* To determine parent and professional (including professionals outside of the NHS) experiences, preferences and perspectives on support needs (*HRA approval required)* To undertake a mapping of local service provision *(HRA approval not required)* To identify key elements of potential support strategies and resources that are feasible and meet parental/carer needs *(HRA approval required)*
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1. PLAIN ENGLISH SUMMARY

Obsessive-compulsive disorder (OCD) frequently begins in children and young people. Parents/carers have to deal with the responsibility of helping their child to access treatment and manage their mental health problem. Parents/carers often find their support role difficult, leading them to become distressed and overwhelmed. Many parents/carers find that their lives become controlled by their child's symptoms, as they become drawn into helping with repetitive behaviours and rituals.

Consultation with UK OCD charities and parent/carers tell us that despite parents'/carers' important role, they are often given little or no support. There is currently little evidence on how parents/carers and professionals view parental/carer support needs, or the help they would find most useful.

This study will use qualitative methods to understand what support is needed, or the help that would be most useful and feasible. These findings will be combined with existing evidence and mixed stakeholder synthesis to identify workable ways of providing support that will meet the needs of parents/carers of young people with OCD.

2. BACKGROUND AND RATIONALE

Relatives of people with OCD report experiencing significant levels of burden (1) shown by some studies to be comparable to that experienced in families of people with psychosis (2). Obsessive-compulsive disorder (OCD) frequently begins in children and young people (3); therefore, its impact particularly affects the parents and carers of children and young people (CYP) with OCD. Parents'/carers' role as the primary provider of practical and emotional support to their children means that these individuals are likely to experience these burdens differently to other family member groups (4). Parents/carers have to deal with the responsibility of helping their child to access treatment and manage their mental health problem. This role is often difficult, leading to parents feeling distressed and overwhelmed. Many parents/carers find that their lives become controlled by their child's symptoms, as they become drawn into helping with repetitive behaviours and rituals (5). Access to NICE recommended treatments for OCD, remains a challenge for families living in the UK due to long waiting lists for Child and Adolescent Mental Health Services (CAMHS). For parents/carers of young people

experiencing OCD, these factors may ultimately mean that their caring role is challenging, long-term and disproportionate to their child's age (4).

This is of significant concern given parents'/carers' vital role in supporting their child with their mental health problem. Furthermore, parents'/carers' own health outcomes and that of their wider family are likely to be negatively affected by the strain of living with high levels of burden induced by OCD (6). Parents of CYP with OCD have been found to experience significantly higher levels of mental health symptoms compared with parents who have a child without mental health problems (7). These findings emphasise the need to support parents/carers, both to prevent the development of mental health problems and to prevent the deterioration of mental health problems in those who are already unwell. Supporting parents/carers to cope more adaptively with the demands of supporting a child with OCD may reduce their levels of distress (8). In the long term, this is likely to bring economic benefits through reducing the chances of parents/carers becoming users of the NHS themselves and by increasing their likelihood of continuing in employment. Remaining in work is a significant challenge for mothers of children with OCD in particular, resulting in them feeling socially isolated by their caring role (9).

While the understanding of the detrimental effect that caring for a family member with OCD has on the family has grown in recent decades (5, 10) there is currently little evidence on how parents/carers and professionals view parental/carer support needs, or the help they would find most useful. There is a critical need to ensure parents/carers receive adequate and timely support when caring for a child with OCD to ensure their own well-being and to improve outcomes for children growing up with the mental health problem (6).

To deliver effective and acceptable support, it is first necessary to develop a detailed understanding of parents'/carers' needs and the forms of support that they would find helpful and acceptable. To our knowledge, no qualitative study has sought to identify the support needs and preferences of parents/carers of children with OCD. A qualitative methodology will enable an in-depth exploration of this previously neglected area. This mixed-methods study aims to use qualitative methods, existing evidence and mixed stakeholder synthesis to identify acceptable and feasible strategies and resources that could ultimately improve parent/carer outcomes through rigorous research, development and implementation.

3 AIMS AND OBJECTIVES

3.1 Aim

To undertake development work to better support parents and carers of children and young people with OCD.

3.2 Objectives

- To systematically review the evidence on interventions to support parents/carers of children with emotional disorders.
- To determine parent and professional (including professionals outside of the NHS) experiences, preferences and perspectives on support needs.
- To undertake a mapping of local service provision.
- To identify key elements of potential support strategies and resources that are feasible and meet parental/carer needs.

3.3 Outcomes

- Roadmap of stakeholder identified strategies and resources scored according to key intervention design criteria(11)
- Evidence and stakeholder informed identification of key components of a future intervention and an outline for its testing in a subsequent study.
- Outputs that can enhance parent/carer, academic, professional and lay understanding of OCD.

6 STUDY DESIGN

The proposed work will comprise a mixed-methods study conducted in three phases.

6.1 Methods

6.1.1 PHASE 1

Systematic review

We will conduct a systematic review of interventions to support the psychological well-being, coping, and quality of life of parents and carers of children and young people with emotional disorders. This review will ensure that Phase 2 and 3 are informed by existing evidence.

Qualitative interviews with parents/carers (and optional journal)

The Research Associate (RA) will conduct and audio-record remote (telephone or videoconferencing) interviews with 25-30 parents/carers of children with OCD. Interviews will be guided by a) a semi-structured interview schedule and b) use of a journal as a prompt (where available) to explore the challenges faced and to reflect on what might have helped. Parents will be invited to complete an optional journal of the challenges and needs they may have experienced in a week leading up to the interview. The journal will provide further depth and richness to the qualitative interview data. A topic guide has been developed in conjunction with a parent/carer co-researcher (who has a child with OCD) and consultation with members of OCD UK to ensure it is acceptable and comprehensive. The guide has also been informed by our previous systematic review (12, 13) and the Theoretical Framework of Acceptability (13). The interview will:

- Explore experiences and perceptions of current services in terms of their provision of support for parents/carers supporting a child with OCD.
- Identify parents'/carers' support needs, barriers, and enablers to accessing support.
- Explore parents'/carers' preferences and priorities for the content, delivery, and format of interventions to support parents in their caring role.

Focus Groups (or qualitative interviews) with professionals

The RA and the parent co-researcher will facilitate 3-4 remote focus groups (of 6-8 people) with professionals (via approved videoconferencing software) who have experience of working with families with a child with a diagnosis of OCD. Focus groups will provide an efficient yet powerful tool to explore topics that have had little previous investigation and provide a group dialogue to determine both individual and professional community influences on implementation. Professional focus groups will commence three months after parent interviews, to enable parent/carer interviews to inform focus group questioning. The topic guide will be informed by the needs emerging from parent/carer interviews, our past (12) and current systematic review and the Theoretical Framework of Acceptability (13). The topic guide will be prepared in conjunction with our parent/carer co-researcher and reviewed by a clinician within our team who is experienced in supporting families affected by OCD. The guide will elicit health professional perspectives on:

- Perceptions of current services offered to families with a child who has OCD.
- The needs of parents/carers who support a child with OCD
- Organisational and individual level barriers and enablers to providing parental/carer support
- The content, delivery, and format of support that would be acceptable to parents/carers and professionals.

Additional one-to-one telephone/video will also be offered to professionals who cannot, or do not want to, attend a focus group.

Service mapping

During Phase 1, alongside interviews and focus groups, we will contact all recruitment sites in which we are collecting data to ask about the services they currently offer to families supporting a child or young person with OCD. HRA approval is not required for this aspect of the study as we will not seek any data on the individuals using these healthcare services - we are only interested in the provision currently offered (e.g. whether parents are offered any education about OCD). We will also supplement this information with data obtained during professional focus groups or through background questions obtained during Phase 1.

6.1.2 PHASE 2

Parents/carers, health professionals experienced in treating CYP with OCD, OCD researchers, professionals from education settings (e.g., pastoral leads), and charity representatives will take part in a 2 ½ hour remote stakeholder consensus workshop. The sample will comprise a mixed group of 18-25 stakeholders (with roughly equal proportions of parents/carers to professionals) to ensure an optimal meaningful discussion. Prior to the stakeholder consensus workshop the CO-ASSIST research team (including co-investigators, parent co-researcher and charity representatives will attend a 2 ½ hour event aimed at synthesising learning from phase 1 and existing evidence from our systematic review to identify potential strategies and resources to enhance parental/carer support in CYP OCD. These strategies and resources (identified during the synthesis event) will be sense-checked at the stakeholder workshop through discussion and voting to score and reach consensus on key intervention design criteria for each strategy/resource generated.

Our methodology for synthesis in Phases 2 and 3 of the study has been guided by PPI consultation, experience in synthesis methodology (14) and experts in intervention development. Phase 2 is aimed at synthesising existing and newly emerging evidence (from Phase 1) to identify the aspects of support that key groups (parents/carers, professionals and charities) want to include in a new support package.

6.1.3 PHASE 3

Phase 3 of the study, will comprise a 2-hour meeting with the research team and a mixed group of key stakeholders (n=10), including parents/carers, professionals, charity representatives, and OCD researchers. Through reviewing the outcomes of Phase 2, this panel will select potential support strategies and resources to be included in a complex intervention. These strategies will be located within a larger logic model designed to inform the future evaluation of our intervention.

The final design of Phase 2 and 3 will be informed by our findings from Phase 1 and feedback from piloting workshop events and feedback from PPI.

6.2 Data Collection

Following the recent introduction of additional research governance approvals due to COVID-19 the research team has taken the decision to use remote/digital data collection across all phases of the study (avoiding face-face methods) to mitigate risks relating to COVID-19. We have included the option of postal invites and parents may have the option of receiving a hard copy of the parent journal. No personal identifiable information will be contained within the contents of the journal. All paper-based data will be converted to an electronic copy as soon as it is received and the paper copies will be securely destroyed. We have also included the option of photographing and emailing paper journals to minimise the use of postal return methods.

The research team has successful experiences (pre- COVID 19) of remote data collection for similar project designs and feels there is currently no strong reason why the project cannot be conducted effectively via remote methods. Furthermore, we have sought advice from OCD-UK and the lead NHS Trust who have been supportive of a remote design for this project.

6.2.1 PHASE 1

Parent interviews (or individual professional interviews) may take place via phone or video conference according to parent preferences. Focus groups will be conducted via videoconferencing software. Audio recordings for Phase 1 will be made using a University of Manchester provided encrypted audio recorder, or via University approved software platforms Microsoft Teams or Zoom. Video conferencing software will only be used where required. Associated video files, which are automatically created during the recording process (within videoconferencing software) will be saved to a University encrypted laptop C drive and will be permanently deleted immediately after the interview has ended. Only audio-recordings will be transferred to a secure drive (once checked) and then deleted from the temporary storage as soon as possible. Interview data will be transcribed as soon as possible by a University-approved transcription company or an approved member of the research team. During the transcribing phase or as quickly as possible on receiving the transcript, any identifiable information will be replaced with non-identifiable generic terms or pseudonyms. All files containing data relating to each participant will be given a unique ID number to ensure confidentiality at all times (pseudonymisation). The key that links this ID number to participant's personal information will be stored separately, and only approved members of the research team will have access to this key.

6.2.2 PHASE 2 & 3

The remote workshops for Phase 2 and 3 will be implemented by a team of experts in both intervention design and remote workshops. The workshops will be supported by the infrastructure and expertise of The University of Manchester Medical Education Team, IT services, and our co-investigator Professor Karina Lovell (who has extensive experience in conducting remote clinical services and research). We will pilot remote workshops in advance and provide training for all facilitators. Parent participants who are not familiar with video conferencing or would like the opportunity to trial it before the event will be provided with the opportunity to participate in a training/familiarisation event. OCD UK and the parent co-researcher will contribute to piloting the remote event.

A remote design will enable stakeholders to review materials and submit their preferences and their reasoning through online methods, which will be supplemented with video conferencing events according to participants' preferences and availability at the time. Participants who are unable to login into the remote workshop on the day will be able to submit their votes electronically at a time that is convenient for them. Throughout the workshop events, there will be opportunities for parents/carers to hold some discussions separately from professionals (with the option of separate breakout spaces if required). The final design of

these phases will be informed by our findings from Phase 1 and feedback from piloting events and feedback from PPI.

6.2.3 Demographic data

All participants will be invited to answer some background questions (demographic details). It will be explained to the participant that this information will help inform understanding of the data and will be anonymised and grouped together with other parent/carer data and will only be used individually to provide context to individual quotes e.g. mother/father/carer . It will be made clear to the participant that they are free to decline any questions

A series of background questions have been designed for both parents and professional participants. For parent participants in Phase 1 this will be collected verbally, either at the beginning or end of the parent interview according to preferences. For all other participants, they will be invited to answer some background questions as part of the electronic consent process using secure Manchester University approved software. All participants invited to complete electronic consent and background questions will be sent an email explaining the process (Appendix 3).

6.3 Data Analysis

6.3.1 PHASE 1

Anonymised transcribed data will be imported into the qualitative Data Analysis Software NVivo-QSR 12 on secure University servers to facilitate the analytical process. The analysis will take place on the anonymised data set only, and members of the research team will undertake the analysis.

Framework Analysis (15) will be used to analyse the data, as its matrix-based format will facilitate the sharing of data as a team. Framework analysis will be used to inductively and deductively code data. Inductive and deductive coding will be conducted, using the Theoretical Framework of Acceptability (13) and key concepts identified through our previous and current systematic review on factors associated with relatives' burden (12) and current support strategies. Completed journals will also be incorporated into the data set alongside participant transcripts during the analysis process to provide a source of 'in the moment' data. Ideas and themes will be discussed with investigators, parent co-researcher and charity representatives and reviewed to ensure that all ideas are included and that findings are credible and confirmable. Gaining wider team perspectives in qualitative research has been identified as an important activity through which new interpretations and insights can be gleaned (16). Parents and professionals interviews will initially be analysed separately, but we will then synthesise the findings from these two stakeholder groups for similarities and differences related to acceptable support strategies. The results of the analysis will be used to inform the consensus work involving mixed stakeholder events which will take part over two separate events (Phase 2 and Phase 3).

6.3.2 PHASE 2

During the synthesis event attended by the CO-ASSIST team we will use a matrix to summarise Phase 1 data where the key findings are represented as columns and the different sources of data by rows. We envisage that multiple theories will inform our selection of strategies and resources. Strategies and resources identified during the synthesis will form the focus of the stakeholder consensus workshop. Resources and presentation materials for the consensus workshop will be reviewed and approved by sponsor and NHS REC/HRA prior to the event. We will set a priori criteria informed by the RAND/UCLA Appropriateness

Method (17) and APEASE (11) for group consensus and undertake anonymised electronic voting, recording if and where consensus is reached. By the end of phase 2, we will have generated a roadmap of potential professional and parent/carer-derived support strategies; each scored in terms of its importance, necessity, practicality and acceptability to its end users. We will keep any design work produced during the workshop to inform our intervention development. All workshop material, will be anonymised, and any potentially identifying details will be removed from any design work produced during the workshop.

6.3.3 PHASE 3

We will identify a theory of change underpinning the intervention and a logic model for ensuing research, detailing the inputs, processes and outputs needed for successful intervention delivery and evaluation. We will specify the details of the intervention using the Template for Intervention Description and Replication (TIDieR) checklist (18).

7 STUDY SETTING

The size of the population of parents with children and young people experiencing OCD and professionals involved in supporting these families is limited. To maximise the opportunity for eligible individuals to take part, we plan to use a variety of research sites, including NHS and third sector organisations.

Data will be collected remotely (via video conferencing or telephone interviews), electronically or via postal return.

8 SAMPLING AND RECRUITMENT

8.1 Inclusion criteria

Parents/carers of children or young people aged 8-18 who have a diagnosis of OCD. Parents of children who have recently (defined as within the last year) exceeded the age of 18 or who are not currently in their caregiver role, yet whose parenting/caring experience is still reflective of the needs of current parents/carers of CYP in this age range, will also be included

A parents'/carers' self-reported acknowledgement of their child's formal diagnosis of OCD is adequate to meet to the objective of this study, avoiding the need for more formal potentially intrusive methods involving a formal proxy diagnostic measures or access to medical notes. Interpreters will be available for participants who are unable to speak English.

Professionals who have experience of working with Children and Young People with OCD (including OCD focused research). The same inclusion criteria will apply to all phases of the study.

Parents taking part in Phase 2 or 3 will require access to a computer, tablet or smartphone to join Zoom or Microsoft Teams conferencing software which will be used to facilitate Phase 2 and 3 of the study. Both Zoom and Microsoft Teams are supported by the University of Manchester. We will support parents in accessing this software.

8.2 Exclusion criteria

Parents of children and young people with OCD or professional who support families with OCD, who live outside of the UK. There will be no other exclusion criteria, other than the parents not being able to give valid consent, but we will not include capacity assessments in the study design. The same exclusion criteria will apply to all phases of the study.

8.3 Sampling

Sampling will be purposive and include several recruitment pathways to ensure variability in the sample and maximum inclusivity.

8.3.1 Size of sample

For qualitative interview/focus group studies, sampling is ideally judged complete when theoretical saturation has been reached, i.e. when increasing the sample size no longer contributes to new evidence and the data collected can sufficiently address the research aim. In practice, it can be difficult to demonstrate this point and it cannot be precisely specified in advance as it depends on the variability in the sample and the properties of the data. On going analaysis will be used to determine theoretical saturation and inform our final sample size. However from previous experience we expect this to be achieved with a maximum of 25-30 interviews.

The total sample will comprise the aggregate total of parent and professional participants from each Phase 1, 2 and 3 of the overall study (N=70-95). Participants recruited to each phase will comprise different participants; however, there may be some overlap. Participants who express an interest in participating in more than one phase will be supported to do this.

- Phase 1: 25-30 parents and 25-30 professionals
- Phase 2: 18-25 key stakeholders
- Phase 3: 10 key stakeholders

8.3.2 Sampling technique

We aim to recruit different parents and professional participants for each phase from a variety of sites and recruitment pathways (including a variety of NHS, third-sector channels, and social media channels). This sampling technique will ensure a diverse range of views, to reduce research burden, and to mitigate against selection bias. However if a participant was keen to participate in multiple phases we would support this.

Professionals will be purposively sampled to include multidisciplinary health professionals and professionals from other sectors outside the NHS (e.g., pastoral leads in education settings, clinicians working in the private and third sector and charity representatives from OCD charities). This will ensure a holistic understanding of parental/carer needs and the approaches that might address them. Sampling of families will aim to provide a balance of those parenting/caring for a young person (12-18), and those parenting/caring for younger children (8-11) are included, as the needs of parents of teenagers markedly differ from those parenting younger children. Sampling will also aim to ensure diversity in terms of the gender of parents and children, as well as their ethnicity. As there may be variation among parents/carers needs, according to their level of engagement with services, the sample will include parents/carers who have received a diagnosis of OCD but are still on the waiting list awaiting treatment (e.g., after initial assessment); those currently receiving treatment, and those who are currently not receiving treatment.

8.4 Recruitment

Recruitment pathways for each phase will be comparable; however, each phase will have its own set of study documentation (invitation letter, consent to contact form- paper and electronic, participant information sheet, participant ID, and consent form/process) designed according to each phase and participant group.

Potential recruitment pathways will include:

a) Relevant NHS sites and third sector organisations that have agreed to act as research sites will advertise the study through posters and online methods.
b) The study will be promoted through a project-specific website and social media accounts set up by the study team (through Twitter and social media). We will also advertise on the University of Manchester website/mail lists.
c) Research sites (i.e. a member of the clinical team or a member of the Trust's research delivery team acting under arrangement with the responsible care organisation) may introduce the study either in person (only if the family is attending the service for routine care), via telephone or letter (postal or email -including a consent to contact form). The consent to contact form has been designed both as a hard copy and as an electronic version to reduce postal returns. Research sites will be provided with all study documentation including invitation letters, participant information leaflets and SAE. All study documentation will also be accessible via the study website in pdf form to reduce paper methods.

Potential participants will be made aware of CO-ASSIST's independence from the research site, that participation is voluntary, and that they can withdraw from the study at any time without giving a reason and without their care or their child's care or legal rights being affected. The research sites will only be responsible for identifying and signposting potential participants to the CO-ASSIST research team or obtaining 'consent to contact' if they are interested in participating or finding out more about the study. The CO-ASSIST research team will be responsible for recruitment of participants, including obtaining informed consent. Participants will be offered as much time as is needed to consider participation. Interested parents will be contacted by the RA to explain the study, answer questions and go through the informed consent form.

We anticipate that our primary recruitment pathway will be through online advertisements by displaying or distributing study posters/flyers at research sites, which will include both NHS and third sector organisations. This method will require participants to actively 'opt in' by contacting the research team if they wish to take part or find out more about the study.

8.4.1 Sample identification

Study advertisements will include contact details so that interested individuals can 'opt-in' to the study by contacting the researcher. The direct care team may assist in the identification of potential participants by reviewing families' medical records. The members of the CO-ASSIST team will not have access to family records (for screening for potential participants) or any contact details prior to participants giving 'consent to contact'.

8.4.2 Consent

Informed consent must be obtained prior to a participant undergoing any activities that are specifically for the purposes of the study. Following careful consideration and consultation with senior management teams within

the University of Manchester and NHS Trusts, a combination of audio-recorded verbal consent and electronic consent has been selected, as the most effective methods to ensure both the ethical conduct and safeguarding during the pandemic.

All potential participants will be provided with a CO-ASSIST Information Sheet, which has been designed according to the different requirements of the participating parties, i.e. parents, professionals/providers and according to the different phases of the study. Phase 2 and 3 have the same Participant Information Sheet for both parents and professionals. In addition to providing the information sheet, the researcher will briefly summarise the study paying particular attention to the voluntary nature of participation; the purpose of the study; what it will involve; any risks or benefits, their rights to decline or withdraw at any point and what will happen to the information they give us.

All participants will be given a minimum of 24 hours to consider the CO-ASSIST relevant Participant Information Sheet, and whether they would like to take part in the study. The RA will ensure that they are completely satisfied that the person fully understands the study and has had the opportunity to ask questions and have them answered before they can be asked to provide informed consent. Where participants appear to struggle to understand any aspect of the study, the researcher will repeat the information, trying to make the information as clear as possible. Participants will be given further time to consider the study if they appear unsure of their involvement.

Parents participating in Phase 1 of the study will be required to provide audio-recorded verbal consent before taking part in a qualitative interview. The consent will be recorded using a University of Manchester provided encrypted audio recorder or approved University video conferencing software, and the sound file will be stored separately to the qualitative interview. The associated video files for both the verbal consent and the qualitative interview will be deleted as soon as possible after completion of the interview. The RA will use a Standard Operating Procedure (SOP) and an electronic Pro-forma during the process of collecting verbal consent. A reference copy (electronic or paper according to participant preferences) of the consent details for each phase will be made available to all participants.

Informed consent for professionals interested in taking part in any of the three Phases will be obtained online through a secure electronic consent form designed within a University of Manchester approved software tool . Informed consent for parents interested in participating in Phase 2 and 3 will also be obtained online in the same way. Each participant will be assigned a unique ID before the completion of the online consent form and guidelines will be emailed to all participants. When they visit the link the first box will say 'please enter your unique ID', otherwise access the form will not be permitted. The options of Yes and No will be listed next to each statement of the Consent Form so that if a participant does not wish to consent to any optional point, they can clearly state this. There is also a measure in place that if a participant does not consent to the non-optional points, then they would be taken to a page thanking them for their participation but confirming that they could not take part in the study.

9 ETHICAL AND REGULATORY CONSIDERATIONS

The potential for improving understanding of how best to support parents/carers is high, though we cannot claim there will be a direct benefit for participants in the present study. However, the study will provide the opportunity for individuals with parental responsibility of a child or young person with OCD to share their experiences and support needs and shape the development of future support interventions.

9.1 Assessment and management of risk

The main study burden is expected to be the use of the participant's time. As different participants will be invited to take part in each phase of the study, the burden incurred is expected to be kept to a minimum. The study across each phase has been developed in collaboration with five PPI representatives, a parent co-researcher and members of OCD UK to ensure the design is acceptable and comprehensible for parents. Our previous experiences of carrying out interviews with relatives of people with OCD tells us that many relatives appreciate the opportunity to talk about their experiences, as they often feel disregarded. In addition, all parent participants for each phase of the study will be compensated for their time with the payment of gift vouchers (phase 1, 3) or cash payments (Phase 2) (which has been calculated at a rate of £25 per hour).

It is possible that discussions of parent support needs in their role of caring for a child with OCD will bring some quite strong emotions to the surface. A distress protocol will be employed, where the participant appears to start showing signs of distress. To help manage the situation sensitively, the RA will signal to participants that they have control over what and how much they say, reminding participants that they can decline to answer any questions if they wish, take breaks or stop the interviews at any point.

9.2 Research Ethics Committee (REC) and other Regulatory review & reports

This study has been designed according to the UK Policy Framework for Health and Social Care (HRA, 2017). As the study requires access to parents/carers of children and young people with OCD who may be attending NHS sites before the before the start of the study, a favourable opinion will be sought from the UK Health Departments Research Ethics Service NHS REC and the HRA. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at sites. All correspondence with the REC will be retained, and the CI will notify REC of the end of the study. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

9.3 Peer review

In order to secure funding for this project, the application process involved 2 stages of scientific review conducted by the East Midlands Regional Assessment Committee of the NIHR Research for Patient Benefit Programme. The grant was also subject to an internal review which is a mandatory part of the University's submission process for RfPB.

9.4 Patient & Public Involvement

Consultation with the public (parents/carers) and people with lived experiences will occur at all stages of the research process. PPI has informed the proposed project from its conception. A focus on the support needs of parents/carers of children with OCD was derived from early consultation with OCD UK, a service user-led charity and 13 parents/carers of CYP with OCD from a support group. A key message was the high levels of distress experienced by parents/carers, including depression and anxiety, which they attributed to the strain of their caring role and the lack of support. Parents/carers wanted greater recognition of the impact of OCD on the family. They emphasised the need for strategies and resources that would address both their child's needs and the needs of the family who support them.

The design stage has also been informed by further consultation with five parents/carers of CYP with OCD who are members of an online national support group. Individuals with lived experience of OCD include a charity representative who will be consulted for the duration of the project. They will assist in recruitment, interpretation of data, attend programme meetings and synthesis events and advising on effective dissemination and.

A parent/carer (who has a child with OCD) will form part of the research team working as a co-researcher over the course of the project. Our team is experienced in working with service user-researchers and carer researchers and has the resources, skills and experience to ensure they will receive adequate support, mentorship and research skills training, including qualitative methods (19).

The parent co-researcher will assist an experienced researcher in conducting focus groups and undertake double coding of a sub-set of the qualitative dataset. The parent co-researcher will not be required to undertake any research activities alone or obtain informed consent and will always be supported by a member of the research team. To enhance the study design, we have worked with our parent/carer co-researcher and OCD UK to develop study materials, including the parent/carer journal crib sheet/template, interview schedules, participant information leaflets, and study advertisements. The parent/carer co-researcher charity members will also work with the team to develop dissemination materials, ensuring the parent/carer voice is effectively communicated through our summaries and podcast.

9.6 Data protection and patient confidentiality

All members of the research team and study site staff will be required to comply with the requirements of the Data Protection Act 2018 and General Data Protection Regulation (GDPR) with regards to the collection, storage, processing and disclosure of personal information and will uphold the regulations core principles. All personal data will be collected electronically and will be stored on password-protected secure University servers according to our Data Management Plan, which is subject to the University of Manchester Research Data Management Policy and GDPR.

All data will be transferred to a secure University server as soon as is practically possible, and all other sources of data will be safely destroyed. All data (except for the participants consent form) will be coded and depersonalised, where the participant's identifying information is replaced with a unique ID number (comprised of an unrelated sequence of characters). The identification key enabling pseudonymisation of the data will be stored in a password protected Excel spreadsheet, separately from all other data. Only the CI, Research Associate and co-investigators will have access to this key.

Data collected during the study may be looked at by individuals from The University of Manchester, NHS Trusts or regulatory authorities for monitoring and audit purposes. Otherwise, only approved members of the study team will have access to a participant's personal data. The University of Manchester Research Data Storage (RDS) will be used for longer-term secure storage. University secure drives are backed up regularly and can only be accessed by approved members of the research team.

Consent details (including audio recorded consent and Select Survey consent) will be archived as essential documents until relevant research data are destroyed. Audio-recordings will be kept until the data has been transcribed, checked for accuracy and the early stage of analysis has been completed, after which time audio-recordings will be safely destroyed. Items such as contact details of participants will be deleted as soon as they

are no longer needed. Contact details will be retained by the Chief Investigator until analysis is completed, to make it possible to send participants (who indicated in their consent form) a summary of the study findings. However, personal data will be securely destroyed following dissemination of the study findings. The study Chief Investigator -Dr Rebecca Pedley will act as the custodian for the data generated from this study.

10 DISSEMINATION POLICY

We will maximise the impacts of this study by producing outputs that:

a) Inform future intervention and service development through providing an evidence base of the strategies, resources and pathways that parents/carers and professionals perceive to meet parental/care need. Additionally, our consultation with OCD UK indicates that this work may help to support and inform their future funding bids (parent/carer benefit impact within 1-5 years – dependent on the strategies identified).
b) Directly lead to a subsequent funding application to test the intervention (parent/carer benefit within 2-5 years – dependent on the strategies selected and agreed by stakeholders).
c) Inform members of the public about the problems faced by parents/carers and their needs; enhancing their understanding of OCD; a concern highlighted within our previous studies [25]and parent/carer consultation (patient/family member benefit impact - immediate impact)

A-C will be achieved through:

- Publication of an open-access journal article, co-authored by our parent/carer co-researcher
- Production of an executive summary, providing the output of the synthesis day, summarising the identified strategies and resources that need development and testing, together with parent/carer/professional ratings of key intervention design criteria including acceptability and practicability. The executive summary will be published online, shared via social media and sent directly to key charities and services.
- Production of a lay summary and podcast, co-developed with our parent/carer co-researcher, outlining the problems faced by parents/carers supporting CYP with OCD, their unmet needs and identified support strategies. Wide sharing through social media and relevant websites will enhance public awareness and understanding of OCD. We will also send the lay summary to study participants and will ask related charities to disseminate these via their website and social media networks.
- Sharing our findings at our synthesis day (including online remote engagement), through the participation of parents/carers as well as those directly involved in delivering and influencing patient care and support, including clinicians and charities working nationally.

An impact and dissemination plan will be developed at the start of the project and will remain on the agenda for project meetings.

11 Project Timetable

This study will span 20 months (including a 3 month extension to compensate for delays due to the pandemic), commencing with PPI involvement and collaboration with potential research sites in order to finalise and optimise the research design. We are aiming to commence parent interviews as soon as possible after approvals are in place (ideally before the end of September 2020) and November/December 2020 for

professional focus groups (and interviews). Phase 1 will end in May 2021. Phase 2 and 3 will recruit in August – October 2021. The study will close to recruitment in October 2021. October and November 2021 will be spent disseminating a summary of the research findings and planning for the next application. The research team will write up the findings and publish these as the study progresses. The findings from each phase will inform the next phase of the study.

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11 APPENDICES

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
Draft for sponsor review	V.01	06.07.2020		
Second proof read of draft	V.02	14.07.2020	ESowden	Minor typographical changes
Final draft for submission to ethics	V1.0	18.08.2020	ESowden	Amendments made during sponsor review

A list of details of all protocol amendments will be detailed here here whenever a new version of the protocol is produced. Protocol amendments will be submitted to the Sponsor for approval prior to submission to the REC.