

# Identifying acceptable support strategies for parents of children with obsessive-compulsive disorder

<b>Submission date</b> 09/09/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/05/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Current plain English summary as of 09/09/2021:

### Background and study aims

Obsessive-compulsive disorder (OCD) is a severe and debilitating emotional disorder that frequently begins in childhood. The effect of obsessions and compulsions are not only distressing for a child experiencing them but also for the child's parents/carers. Without adequate support, the role of caring for children and young people can pose a significant burden to parents/carers.

Supporting the family members of people with OCD is consistent with UK policy, which now recognises the vital role of unpaid carers and the need to ensure their wellbeing. Despite these policies, consultation with OCD charities and parent/carer groups indicate that relatives frequently receive little or no support in their parenting/caring role. This is of significant concern given parents'/carers' vital role in supporting their child with their mental health problem. Furthermore, parents'/carers' health outcomes and those of their wider family are likely to be negatively affected by the strain of living with high levels of burden induced by OCD. 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 aims to identify workable ways of providing the support that would meet the needs of parents/carers of children with OCD. This study has been initiated and designed through consultation with UK OCD charities and parents/carers and PPI involvement will continue throughout the research process, including the involvement of a parent co-researcher.

### Who can participate?

Parents /carers of children and young people with OCD, and professionals involved in supporting children and young people with OCD

### What does the study involve?

All research activities will be undertaken for each Phase of the study remotely (via telephone or video conferencing software) to mitigate any risks due to COVID-19. The study has three phases, which includes a different set of participants for each phase (though some overlap is possible).

### Phase 1

Parents/carers will participate in a one-to-one interview via telephone or video conferencing (and complete an optional one-week journal in advance of the interview). The journal and interview have been designed to explore parents/carers support needs and perceptions of current services. Professionals will participate in a remote focus group (of 6-8 people) designed to explore their perspectives on current services and the needs of parents/carers.

### Phase 2

The research team will invite 18-25 key stakeholders (parents/carers, charities, clinicians, OCD researchers) to attend a 2 ½ hour remote stakeholder consensus workshop to discuss, vote on and reach consensus on key intervention design criteria for each strategy/resource generated from learning from Phase 1.

### Phase 3

Participants will attend a 2-hour meeting to discuss the findings from phase 2 to inform the design of a potential intervention to support parents/carers of children with OCD.

What are the possible benefits and risks of participating?

The researchers do not perceive any risks of participating. While there are no direct benefits for participants, people often find that taking part in studies of this sort is useful because they have a chance to air their views, reflect on their experiences and contribute to service development.

Where is the study run from?

University of Manchester (UK)

When is the study starting and how long is it expected to run for

April 2020 to November 2021

Who is funding the study?

NIHR Research for Patient Benefit Programme (RfPB) (UK)

Who is the main contact?

Dr Rebecca Pedley

Rebecca.Pedley@manchester.ac.uk

Previous plain English summary:

Background and study aims

Obsessive-compulsive disorder (OCD) is a severe and debilitating emotional disorder that frequently begins in childhood. The effect of obsessions and compulsions are not only distressing for a child experiencing them but also for the child's parents/carers. Without adequate support, the role of caring for children and young people can pose a significant burden to parents/carers.

Supporting the family members of people with OCD is consistent with UK policy, which now recognises the vital role of unpaid carers and the need to ensure their wellbeing. Despite these policies, consultation with OCD charities and parent/carer groups indicate that relatives frequently receive little or no support in their parenting/caring role. This is of significant concern given parents'/carers' vital role in supporting their child with their mental health problem. Furthermore, parents'/carers' health outcomes and those of their wider family are likely to be negatively affected by the strain of living with high levels of burden induced by OCD. There is currently little evidence on how parents/carers and professionals view parental/carer support needs or the help they would find most useful.

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**Phase 2**

Participants will take part in a one-day remote workshop where evidence from Phase 1 will be discussed to identify strategies and resources to meet parents'/carers' needs.

**Phase 3**

Participants will attend a 2-hour meeting to discuss the findings from phase 2 to inform the design of a potential intervention to support parents/carers of children with OCD.

**What are the possible benefits and risks of participating?**

The researchers do not perceive any risks of participating. While there are no direct benefits for participants, people often find that taking part in studies of this sort is useful because they have a chance to air their views, reflect on their experiences and contribute to service development.

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Rebecca Pedley

**ORCID ID**

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**Contact details**

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**Type(s)**

Public

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

283830

**ClinicalTrials.gov number**

Nil known

## **Secondary identifying numbers**

IRAS 283830, CPMS 46195

# **Study information**

## **Scientific Title**

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

## **Acronym**

CO-ASSIST

## **Study objectives**

Consultation with UK OCD charities and parents/carers tells us that, despite their significant role in caring for children with OCD, they are often given little or no support. Furthermore, 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 aims to undertake development work to better support parents and carers of children and young people with obsessive compulsive disorder (OCD).

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approval 16/10/2020, West of Scotland REC 3, West of Scotland Research Ethics Service (Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0) 141 314 0211; WestofScotland.ResearchEthicsCommittee3@ggc.scot.nhs.uk), ref: 20/WS/0131

## **Study design**

Qualitative mixed-method multicenter study

## **Primary study design**

Observational

## **Secondary study design**

Qualitative mixed-method study

## **Study setting(s)**

Internet/virtual

## **Study type(s)**

Other

## **Participant information sheet**

Phase 1 parent/carer information leaflet is available in web format here. Information leaflets for later Phases of the study will be uploaded accordingly.

## **Health condition(s) or problem(s) studied**

Parents/carers of children and young people with obsessive-compulsive disorder (OCD)

## Interventions

Current interventions as of 09/09/2021:

This project aims to identify workable ways of providing support that would meet the needs of parents/carers of children with OCD. The study has three phases, which includes a different set of participants for each phase (though some overlap is possible).

Phase 1 will involve 25-30 parents/carers of children with OCD, participating in a one-to-one interview (and optional one-week journal in advance of the interview). Separately 3-4 focus groups (of 6-8) will be held with professionals who work with young people with OCD. The research team will use findings from the interview and focus groups to better understand parent /carer support needs.

Phase 2: The research team will invite 18-25 key stakeholders (parents/carers, charities, clinicians, OCD researchers) to attend a 2 ½ hour remote stakeholder consensus workshop. Prior to the stakeholder consensus workshop the CO-ASSIST research team (including co-investigators, parent co-researcher and charity representatives will synthesise 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 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.

Phase 3: a panel of ten parents/carers and professionals will attend a 2 hour online meeting to discuss findings from Phase 2 to inform the design of a potential intervention to support parents /carers of children with OCD.

This study was initiated and designed through consultation with UK OCD charities and parents /carers, and PPI involvement will continue throughout the research process.

Participants will be recruited from a range of NHS and third sector services and settings in the UK. All research activities will be undertaken remotely to mitigate risks associated with COVID-19.

Previous interventions:

This project aims to identify workable ways of providing support that would meet the needs of parents/carers of children with OCD. The study has three phases, which includes a different set of participants for each phase (though some overlap is possible).

Phase 1 will involve 25-30 parents/carers of children with OCD, participating in a one-to-one interview (and optional one-week journal in advance of the interview). Separately 3-4 focus groups (of 6-8) will be held with professionals who work with young people with OCD. The research team will use findings from the interview and focus groups to better understand parent /carer support needs.

Phase 2: the research team will invite 18-25 key stakeholders (parents/carers, charities, clinicians, OCD researchers) to attend a one-day event where evidence from Phase 1 will be discussed to identify strategies and resources to meet parents/carers needs.

Phase 3: a panel of ten parents/carers and professionals will attend a meeting to discuss findings from Phase 2 to inform the design of a potential intervention to support parents/carers of children with OCD.

This study was initiated and designed through consultation with UK OCD charities and parents /carers, and PPI involvement will continue throughout the research process.

Participants will be recruited from a range of NHS and third sector services and settings in the UK. All research activities will be undertaken remotely to mitigate risks associated with COVID-19.

## **Intervention Type**

Other

## **Primary outcome measure**

Phase 1:

1. Perspectives on parents/carers support needs, assessed using one-to-one qualitative interviews (and an optional 1-week journal) with parents/carers and focus groups with professionals in October 2020- April 2021
2. Current evidence on available support strategies determined using a systematic review in April 2021
3. Mapping of local service provision using data obtained from focus groups, demographic surveys and additional information obtained from Principle Investigators at Participating Centres in October 2020 - April 2021

Phase 2 & 3:

Evidence from Phase 1 will be used to inform synthesis events.

Synthesis events in Phase 2 and 3 will identify:

1. A roadmap of stakeholder identified strategies and resources scored according to key intervention design criteria (APEASE) in August 2021
2. Evidence and stakeholder informed identification of key components of a future intervention and an outline for its testing in a subsequent study in August 2021
3. Outputs that can enhance parent/carer, academic, professional and lay understanding of OCD in August 2021

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

01/04/2020

## **Completion date**

30/11/2021

# **Eligibility**

## **Key inclusion criteria**

Parents:

1. Parents/carers of children or young people (CYP) aged 8-18 who have a diagnosis of OCD
  - 1.1. A parents'/carers self-reported acknowledgement of their child's formal diagnosis of OCD is adequate to meet the inclusion criteria for the study
  - 1.2. Parents of children who have recently (defined as within the last year) exceeded the age of 18 or parents 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

1.3. A carer is defined as an adult who has parental responsibility for CYP with OCD

2. Interpreters will be available for participants who are unable to speak English

Professionals:

1. Professionals who have experience of working with Children and Young People with OCD (including OCD focused

(The same inclusion criteria apply to all phases of the study)

### **Participant type(s)**

Mixed

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

The target sample is approximately 95 participants, which will comprise the aggregate total of parent and professional participants from phase 1, 2 and 3 of the study. Participants recruited to each phase will comprise different participants; however, there may be some overlap. • Phase 1 will comprise 25-30 parents/carers & 25-30 professionals • Phase 2 will comprise 18-25 key stakeholders ( including parent/carers, charity representatives, clinicians, OCD researchers) • Phase 3 will comprise a mixed stakeholder panel of 10 key stakeholders including parent/carers, charity representatives, clinicians, OCD researchers

### **Total final enrolment**

45

### **Key exclusion criteria**

1. Parents of children and young people or professionals with OCD who live outside of the UK
2. Participants (for Phase 2 or 3) who do not have access to a computer, tablet or smartphone to join Zoom or Microsoft teams conferencing software
3. Professionals who have no experience in supporting families of children and young people with OCD

### **Date of first enrolment**

20/10/2020

### **Date of final enrolment**

03/11/2021

## **Locations**

### **Countries of recruitment**



England

United Kingdom

**Study participating centre**

**Greater Manchester Mental Health NHS Foundation Trust**

Prestwich Hospital

Bury New Road

Prestwich

Manchester

United Kingdom

M25 3BL

**Study participating centre**

**Pennine Care NHS Foundation Trust**

225 Old Street

Ashton-Under-Lyne

Manchester

United Kingdom

OL6 7SR

**Study participating centre**

**Manchester University NHS Trust**

Cobbett House

Oxford Road

Manchester

United Kingdom

M16 9HA

## **Sponsor information**

**Organisation**

University of Manchester

**Sponsor details**

Faculty of Biology, Medicine and Health

Faculty Research Governance Team

Carys Bannister Building

Rooms 5.011/5.012

Dover Street

Manchester

England

United Kingdom  
M139PL  
+44 (0)161 2755436  
fbmhethics@manchester.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.manchester.ac.uk/>

**ROR**

<https://ror.org/027m9bs27>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

1. Publication of an open-access journal article, co-authored by a parent/carer co-researcher
2. 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
3. The executive summary will be published online, shared via social media and sent directly to key charities and services

4. 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
5. Wide sharing through social media and relevant websites will enhance public awareness and understanding of OCD
6. The researchers will also send the lay summary to study participants and will ask related charities to disseminate these via their website and social media networks
7. Sharing the findings at the 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

## Intention to publish date

30/11/2023

## Individual participant data (IPD) sharing plan

The participant-level data generated and analysed during the current study will not be made publicly available due to potential breach of anonymity, but will be available from the study Chief Investigator Dr Rebecca Pedley (Rebecca.Pedley@manchester.ac.uk) on reasonable request.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version V1.1	06/10/2020	23/10/2020	No	Yes
<a href="#">Participant information sheet</a>	version V1.1	06/10/2020	17/03/2021	No	Yes
<a href="#">Participant information sheet</a>	version 1.2	12/05/2021	24/06/2021	No	Yes
<a href="#">Plain English results</a>	version 1.4		03/02/2022	No	Yes
<a href="#">Protocol file</a>	version 1.5	02/08/2021	23/08/2022	No	No
<a href="#">Results article</a>		03/05/2023	26/05/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No