ISRCTN13235264 https://doi.org/10.1186/ISRCTN13235264

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

Submission date 09/09/2020	**Recruitment status** No longer recruiting	☒ Prospectively registered
		☒ Protocol
Registration date 20/10/2020	**Overall study status** Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 26/05/2023	**Condition category** Mental and Behavioural Disorders	☐ 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.
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.

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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.

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Dr Rebecca Pedley
Rebecca.Pedley@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Rebecca Pedley

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
283830

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
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

Study type(s)
Other

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:
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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.

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Intervention Type
Other

Primary outcome(s)

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

Key secondary outcome(s))
There are no secondary outcome measures

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' 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

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

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?
Results article		03/05/2023	26/05/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.1	06/10/2020	23/10/2020	No	Yes
Participant information sheet	version V1.1	06/10/2020	17/03/2021	No	Yes
Participant information sheet	version 1.2	12/05/2021	24/06/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results	version 1.4		03/02/2022	No	Yes
Protocol file	version 1.5	02/08/2021	23/08/2022	No	No