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Child anxiety treatment in the context of COVID-19

Submission date
08/10/2020

Recruitment status
No longer recruiting

Registration date
23/10/2020

Overall study status
Completed

Last Edited
12/02/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anxiety problems are among the most common mental health concerns in children. We have treatments that work well for child anxiety problems but COVID-19 has brought challenges in how we deliver them. We don't know the best way to deliver treatment for child anxiety problems when there are social-distancing restrictions. To find out, we want to compare a new online treatment to the approach that is currently being used in clinics.

The aim of this study is to compare an online parent-led program with therapist support to treatment as usual:
Treatment A: The new online platform involves 7 online modules which are accompanied by 7 weekly telephone calls for the parent/carer with a clinician
Treatment B: Treatment as usual will be whatever a clinic currently offers to help children with anxiety problems.
Families will receive either Treatment A or Treatment B and this will be decided at random.

This research will help us to make future treatments as effective and as efficient as possible. We hope this will help give as many children as possible the best chance of support and recovery.

Who can participate?
Children referred to a CAMHS service aged 5-12 with anxiety as the primary presenting problem, and their parents/carers.

What does the study involve?
When a parent and their child agree to be participants in the study, they will be allocated to Treatment A or Treatment B and will receive this treatment from a therapist at the clinic they are attending.
We will ask parents and their child to fill out some online questionnaires about the child's anxiety, mood, behaviour. This will be done before starting treatment, and then at after 14 and 26 weeks after this. The parents will also be asked some questions about their general lifestyle to provide some general information about their family.
Parents will be asked to keep a diary about the health-related appointments they and their child attend.

The parent and their child's participation in the study is likely to last approximately 7 months in total.
We will ask some parents to take part in an additional interview after the treatment.

What are the possible benefits and risks of participating?
Possible Benefits
• We have good reason to think that most families who receive either therapy will benefit, but we don't know if one treatment will be better than the other or if they will be the same. That is why we are carrying out this research
• By taking part, you and your child will be helping us to try to find the best way to treat anxiety problems in children in the COVID-19 context and we will learn a lot from this for the future
Possible Risks
• You and your child will have to complete more questionnaires than you would normally do as part of your usual care
• Some of the questions will involve discussing thoughts and feelings that may be upsetting. The questions are similar to the ones that are used in usual clinical practice and we work with families to try make sure that the questions we ask are as acceptable as possible

Where is the study run from?
The University of Oxford (UK)

When is the study starting and how long is it expected to run for?
September 2020 to March 2023.

Who is funding the study?
This study is funded by the DHSC and UKRI COVID-19 Rapid Response Initiative.

Who is the main contact?
Lucy Taylor, lucy.taylor@psych.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
288074

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 288074, CPMS 46902

Study information

Scientific Title
Child Anxiety Treatment in the context of COVID-19 (Co-CAT): Enabling Child and Adolescent Mental Health Services (CAMHS) to provide efficient remote treatment for child anxiety problems

Acronym
Co-CAT

Study objectives
The primary objective of this study is to evaluate the parent-reported clinical effectiveness of a brief parent-led cognitive behavioural treatment (CBT) delivered by the OSI* platform with therapist support (OSI+therapist support) for the treatment of child anxiety compared to 'COVID-19 treatment as usual' (C-TAU) in CAMHS throughout the next phases of the COVID-19 pandemic.
*OSI is an online platform for sharing content and record keeping as part of a brief therapist-supported parent-led cognitive behavioural treatment (CBT).

Secondary objectives are:
- To further evaluate the clinical effectiveness of OSI+therapist support for the treatment of child anxiety compared to 'COVID-19 treatment as usual' (C-TAU) in CAMHS
- To evaluate the cost-effectiveness of OSI+therapist support for the treatment of child anxiety compared to 'COVID-19 treatment as usual' (C-TAU) in CAMHS
- To explore the trajectory of change reported within the OSI arm
- To understand therapist and parents' experiences of treating child anxiety in the COVID-19 context(across both arms)

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 04/09/2020, London - City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3 Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8214; cityandeast.rec@hra.nhs.uk), ref: 20/HRA/4431

Study design
Interventional multi-site two-arm parallel-group randomized controlled non-inferiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety problems in children aged 5-12

Interventions
Intervention(s)
Online psychological intervention for child anxiety with therapist support (OSI+therapist support). OSI is an online platform for sharing content and record keeping as part of a brief therapist-supported parent-led cognitive behavioural treatment (CBT). The seven modules are completed by the parent over seven weeks, supported by 7 weekly 20 minute telephone sessions between the parent/carer and a therapist and a review session 4 weeks after the final treatment session.

Comparator
Treatment as usual for children with anxiety in clinical Child and Adolescent Mental Health Services in the COVID-19 context (C-TAU). The exact nature of this will depend on what the usual treatments are within each service.

For both treatment arms (intervention and comparator), there is an online follow up assessment at 14 and 26 weeks after randomisation.

Therapists will introduce and provide access to information about the study to eligible families. Participants will be automatically randomised to receive either the OSI+therapist support intervention or the comparator after consenting online and completing some baseline measures online. Treatment allocation will be communicated to the participant and their therapist via email.

Intervention Type
Behavioural

Primary outcome(s)
Child Anxiety is measured using a parent self-report questionnaire (The Child Anxiety Impact Scale-parent report, CAIS-P) at baseline, 14 weeks, and 26 weeks.

Key secondary outcome(s))
Secondary Clinical Outcomes:
1. Child reported anxiety is measured using a child self-report questionnaire (CAIS-C, RCADS-C) at baseline, 14 weeks, and 26 weeks
2. Parent report on child’s anxiety symptoms is measured using a self-report questionnaire

(RCADS-P, SCAS-8P)
3. Parent report on overall functioning is measured using a self-report questionnaire (ORS) at baseline, 14 weeks, and 26 weeks
4. Parent report COVID-19 specific worries is measured using a self-report questionnaire (PAS) at baseline, 14 weeks, and 26 weeks
5. Parent report on common comorbid emotional and behavioural problems is measured using a self-report questionnaire (SDQ-P) at baseline, 14 weeks, and 26 weeks

Economic Outcomes:
6. Parent report on their quality of life is measured using a self-report questionnaire (EQ-5D-5L, parent-self report) at baseline, 14 weeks, and 26 weeks
7. Parent report on their child's quality of life is measured using a self-report questionnaire (CHU-9D proxy version) at baseline, 14 weeks, and 26 weeks
8. Parent report on their use of services is measured using a self-report questionnaire (CSRI) at baseline, 14 weeks, and 26 weeks
9. Time spent on treatment delivery is measured by a therapist completed log of time spent on treatment delivery for each participant

Exploratory Outcomes:
10. Child outcomes will be monitored during treatment for the OSI+therapist support arm using parent self-report questionnaires built into the system (OSI RCADS-P CAIS-P SCAS-8P ORS SRS GBOs), collected at the beginning of each module (module 1-7)

Completion date
31/03/2023

Eligibility

Key inclusion criteria
Child inclusion criteria:
1. Aged 5-12 years at intake
2. Primary problem is anxiety
3. Willing and able to assent

Parent/Carer inclusion criteria:
1. Has sufficient English language to complete measures/ access interventions
2. Family has access to the internet
3. Is willing and able to provide consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
12 years

Sex
All

Total final enrolment
444

Key exclusion criteria
Child exclusion criteria:
1. The child has co-morbid conditions that are likely to interfere with treatment delivery, (established autism spectrum condition/ learning disability, suicidal intent/ recurrent or potentially life-limiting self-harm)
2. The child is identified by social services due to child protection concerns

Parent/Carer exclusion criteria:
1. The parent has a significant intellectual impairment or severe mental health problem that is likely to interfere with treatment delivery
2. The parents are unable to access or understand the written English language materials necessary for the interventions

Date of first enrolment
02/11/2020

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Warneford Hospital
Oxford Health NHS Foundation Trust
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation (UKRI) COVID-19 Rapid Response Initiative

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/02/2024	12/02/2024	Yes	No
Protocol article		16/11/2022	18/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other files	Health Economics Analysis Plan version 1.0		03/11/2022	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.5	21/10/2022	01/11/2022	No	No
Statistical Analysis Plan	version 3.0	01/09/2022	04/10/2022	No	No
Statistical Analysis Plan	version 4.0	25/10/2022	01/11/2022	No	No