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Identifying child anxiety through schools - identification to intervention

Submission date
18/05/2021

Recruitment status
No longer recruiting

Registration date
27/05/2021

Overall study status
Completed

Last Edited
19/12/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Anxiety problems are common among children, but most children who experience difficulties with anxiety do not access support. Families face lots of hurdles accessing support: it can be hard to spot when a child is struggling with anxiety, it is hard to know who to ask for help, and professional support is often just not available. We want to find ways to remove these hurdles so that more children with anxiety difficulties receive effective support when they need it. We have worked with children, parents, teachers, and others to develop procedures for identifying and supporting children with anxiety problems through primary schools. In this study, we will try out these procedures in six primary schools (two Year 4 classes per school).

The main aim of this study is to find out whether there are any negative impacts or concerns about the study procedures, how many families take part, and if the questions we ask are relevant and meaningful for families. We will use these findings to help us decide if we should move on to a larger, randomised controlled study to evaluate these procedures for identification-to-intervention for child anxiety problems.

Who can participate?
Children (aged 8-9 years) in participating Year 4 classes, and their parents/carers and class teachers.

What does the study involve?
Children, parents/carers, and class teachers complete questionnaires at the start and the end of the study. After the initial questionnaires, families receive written feedback, including feedback on whether screening questionnaire responses indicate their child may be experiencing difficulties with anxiety or is unlikely to be experiencing difficulties with anxiety. Where responses indicate a child may be experiencing difficulties with anxiety, parents will have a feedback call with a study therapist, and they will be offered support through an online intervention called OSI (Online Support and Intervention for child anxiety). OSI will also be made available to all families, regardless of screening questionnaire responses.

What are the possible benefits and risks of participating?
The study team has reason to believe that most families who receive the intervention (OSI) will

benefit from it. Children, parents/carers, and school staff will need to spend time completing questionnaires. The questionnaires are widely used in research and other settings, but some questions do address thoughts and feelings that may be upsetting for some participants.

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

When is the study starting and how long is it expected to run for?
September 2020 to November 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
R71772/RE001, Grant Codes: RP-PG-0218-20010, CPMS 47903

Study information

Scientific Title
Identifying Child Anxiety Through Schools – identification to intervention (iCATS-i2i): Single-arm feasibility trial

Acronym
iCATS-i2i

Study objectives
1. To assess the feasibility of a subsequent cluster randomised controlled trial to evaluate procedures for identifying and supporting children (aged 8-9) with anxiety difficulties through primary schools.
2. To establish whether there are any negative impacts of study procedures, any concerns about the acceptability of the study procedures, estimated recruitment and retention rates, whether the proposed clinical and health economic measures capture all the relevant information and outcomes, and any changes needed to study procedures or outcome measures

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2020, Medical Sciences Interdivisional Research Ethics Committee (Research Services, University of Oxford, Wellington Square, Oxford, OX1 2JD, UK; +44 (0)1865 616577; ethics@medsci.ox.ac.uk), ref: R71772/RE001

Study design
Interventional non-randomized single-arm feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety disorders

Interventions
Children (aged 8-9 years) from six primary/junior schools (2 classes per school), their parent /carer and class teacher will complete questionnaire measures at baseline and 12-week follow-up.

Children who screen positive (score ≥3) on the parent-report child anxiety screening questionnaire completed at baseline will be the target population.

Parents receive written feedback on whether screening questionnaire responses indicate their child may be experiencing difficulties with anxiety (screen positive) or is unlikely to be experiencing difficulties with anxiety (screen negative). Where a child screens positive, parents also have a feedback telephone call with a Children's Wellbeing Practitioner (CWP), and are offered a brief, parent-led online intervention, (OSI: Online support and intervention for child anxiety). OSI will also be made available to all parents/carers who express an interest, regardless of screening outcomes.

OSI is an online version of an evidence-based parent-led Cognitive Behaviour Therapy (CBT) intervention for child anxiety. Parents work through seven online modules with inbuilt questionnaire measures. Each module is supported by a weekly short telephone session with a CWP, and a follow-up review 4 weeks after the intervention is complete. There is also an accompanying mobile game app for the child designed to help motivate the child to face their fears.

Intervention Type
Behavioural

Primary outcome(s)
1. Negative impacts and acceptability of study procedures measured using:
1.1. Monitoring participant reports throughout the study
1.2. A bespoke acceptability questionnaire (child-, parent-, and teacher-report) at baseline and 12 weeks
1.3. Qualitative interviews/discussion groups with children, parents/carers, and school staff throughout the study
1.4. The Study Steering Committee
2. Recruitment and retention rates measured using the number (%) of eligible participants who complete baseline and follow-up assessments, the number (%) of participants who screen positive (target population) who complete baseline and follow-up assessments, and the number (%) of participants who participate in OSI collected throughout the study
3. Relevance and acceptability of all clinical and health economic outcome measures measured using:
3.1. Proportion of missing data and patterns in missing responses/measures at baseline and 12 weeks
3.2. Descriptive statistics for each outcome measure at baseline and 12 weeks
3.3. Qualitative interviews/discussion groups with children, parents/carers, and school staff throughout the study

Key secondary outcome(s))
1. Clinical outcomes measured at baseline and 12-week follow-up:
1.1. Anxiety measured using the incidence of cases above/below cut-off (score ≥3) on the 2-item parent report child anxiety questionnaire
1.2. Child anxiety symptoms measured using the Brief Spence Children's Anxiety Scale (SCAS-8-child, parent, teacher report) and the Revised Children's Anxiety and Depression Scale-anxiety scale (RCADS-A-child and parent report)
1.3. Interference caused by child anxiety measured using brief child anxiety questionnaire (child, parent, teacher-report)
1.4. Child depressive symptoms measured using the RCADS-depression scale (child and parent report)
1.5. Child emotional and behavioural problems measured using the Strengths and Difficulties Questionnaire (SDQ-child and parent report)
2. Health economic outcomes measured at baseline and 12-week follow-up:
2.1. Child quality of life measured using Child Health Utility 9D-(child and parent report) and the EQ-5D-Y (child and parent report)
2.2. Parent/carer quality of life measured using EQ-5D-5L (parent self-report)
2.3. Individual resource use (e.g. service use, time off school and work) measured using a modified version of the Client Service Receipt Inventory (CSRI)-parent/ report
2.4. Time spent on intervention delivery measured using therapist and supervisor completed logs throughout
3. Acceptability measured using a bespoke questionnaire measure (child, parent and teacher report) at 12 weeks
4. Information on children's school attendance, punctuality, and learning will be collected from the child's school records at 12 weeks
5. Parents questionnaires used to guide the intervention, including measures of child anxiety symptoms (RCADS, SCAS-8), interference related to the child's anxiety (Child Anxiety Impact Scale), overall functioning (Outcome Rating Scale) progress towards meeting intervention goals (Goal Based Outcomes), and the therapeutic relationship (Session Rating Scale) at module 0-6 and follow-up review

Completion date
30/11/2021

Eligibility

Key inclusion criteria
Schools:
1. Primary or junior school in England with at least two Year 4 classes

Feasibility trial participants:
1. Children:
1.1. Aged 8-9 years
1.2. In a participating Year 4 class
1.3. Provides assent and their parent/carer does not opt-out
1.4. Sufficient English to give assent and complete questionnaires, with assistance if necessary
2. Parent/Carer of a child in a Year 4 participating class
2.1. Provides consent. Where a parent/carer has more than one eligible child, they will be invited to consent/participate for each child.
2.2. Sufficient English to give consent, and to complete questionnaires, with assistance if necessary.

3. Class teacher of participating child or nominated member of support staff who works regularly with the child

Target population:
1. Children who screen positive (score ≥3 on parent-report 2-item child anxiety questionnaire) at baseline, and their parent/carer

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 years

Upper age limit
9 years

Sex
All

Total final enrolment
275

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/11/2020

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
United Kingdom

England

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Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

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 data-sharing plans for the current study are unknown and will be made 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		13/12/2022	19/12/2022	Yes	No
Protocol article		10/08/2022	12/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (preprint)		30/06/2021	29/11/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes