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Identifying child anxiety through schools

Submission date
08/12/2021

Recruitment status
No longer recruiting

Registration date
04/01/2022

Overall study status
Completed

Last Edited
18/01/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Anxiety problems are common among primary-school aged children, but very few children who experience problems with anxiety receive professional support. We have worked with children, parents/carers, school staff and others to develop a new way of identifying and supporting children with anxiety problems through primary schools. We now want to compare this new approach to existing, usual school practice. In this study, we will compare children's outcomes in schools that do and do not receive our procedures for identification-to-intervention.

Who can participate?
Children in year 4 (aged 8-9) in participating classes in participating schools

What does the study involve?
Children, parents/carers and class teachers will be invited to complete initial questionnaires, and we will also collect information about children from school records. Schools will then be randomly allocated to either 'feedback and intervention' or 'usual school practice'.

Families in schools allocated to 'feedback and intervention' group will receive feedback on whether responses to a short initial questionnaire completed by parents suggest their child may be or is unlikely to be experiencing difficulties with anxiety. Where responses suggest a child may be experiencing difficulties with anxiety, parents will be offered a brief, therapist supported online intervention. The intervention will also be made available to all participating families in these schools, regardless of initial questionnaire responses.

Families in schools allocated to usual school practice' will continue to receive any usual support available in their school and elsewhere, and at the end of study (2 years later) they will be offered written (PDF) versions of the intervention.

Children, parents/carers and class teachers in all schools will be asked to complete questionnaires again after4 months, 12 months and 24 months.

What are the possible benefits and risks of participating?
Families who take part will all be offered either a brief online and telephone support intervention as part of the study, or a written (PDF) version of the online intervention at the end of the study.

Participants will need to spend some time completing questionnaires. Although we work hard to try to make sure the questions are as acceptable as possible, some questions address thoughts and feelings that some participants may find upsetting.

Where is the study run from?
Oxford Health NHS Foundation Trust/ University of Oxford (UK)

When is the study starting and how long is it expected to run for?
August 2021 to November 2024

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

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

Study website
https://osiresearch.org.uk/icats/

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CUREC Ref: R66068. CPMS 50940

Study information

Scientific Title
Identifying Child Anxiety Through Schools – identification to intervention (iCATSi2i): a cluster randomised controlled trial

Acronym
iCATSi2i

Study objectives
Primary objective:
To compare outcomes for children (aged 8-9) who screen positive at baseline in schools allocated to 'feedback and intervention' versus 'usual school practice'

Secondary objectives:
1. To estimate the cost-effectiveness of 'feedback and intervention', extrapolating results beyond the end of the trial duration
2. To evaluate experiences of procedures for identification-feedback-intervention to inform an integrated process evaluation
3. To compare outcomes for the total population of Year 4 children (aged 8-9) in participating classes in schools allocated to 'feedback and intervention' versus 'usual school practice'

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/10/2021, 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: R66068/RE001

Study design
Interventional cluster randomized controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
https://osiresearch.org.uk/icats/family-info/

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

Interventions
Current intervention as of 11/04/2022:
Children in Year 4 (aged 8-9 years) in participating classes and their parent/carer and class teacher will be invited to take part. Assessments will be completed at baseline (before randomisation), and 4 months, 12 months and 24 months post-randomisation. Our target

population is children who screen positive (score above the cut-off on the 2-item parent-report child anxiety questionnaire) at baseline, but we will also follow-up all recruited children (total population).

The trial will include an internal pilot. We will recruit schools in two cohorts one year apart (pilot phase: 30 schools; phase 2: 50 schools). The decision to continue beyond the pilot phase will be taken by the funder, with advice from the independent programme steering committee.

After baseline assessments are complete in a cohort of schools, schools will be randomised by an independent statistician to either 'feedback and intervention' or 'usual school practice' in a 1:1 ratio stratified according to school demographic information. The statistician will pass the allocation to the study team who will notify schools and families.

'Feedback and intervention' arm:
i) Feedback
Parents/carers who complete the baseline2-item child anxietyquestionnaire will receive a written feedback letter that informs them whether their responses indicate their child may be experiencing difficulties with anxiety or is unlikely to be experiencing difficulties with anxiety. The letter also provides information about the intervention programme.Where a child 'screens positive', the parent/carer has a shortfeedback callwith a studyWellbeing Practitioner orClinicalPsychologist, and is offered the intervention programme. Where a child 'screens negative', the feedback letter will invite parents/carers to contact the research team if they may be interested in takingpart inthe interventionand/or would like to discuss this option.

The intervention programme will also be made available for all families in the 'Feedback and intervention' arm, including those where parents/carers did not give initial opt-in consent /complete baseline measures.

ii) Lesson on recognising and managing anxiety and resources for school staff
The research team and/or school staff will deliver a whole-class lesson on recognising and managing anxiety, and we will share information about the intervention and skills and strategies parents learn in the intervention with school staff.

iii) Online Support and Intervention for child anxiety (OSI)
Parents/carers work through seven online modules. Each module is supported by a short weekly telephone session with a therapist, and a follow-up telephone review about 4 weeks later. There is also an accompanying app for the child that is a game for mobilephones/tablets.

Schools will continue to provide any usual support, and families will be free to continue to seek and/or receive any other additional support from school and/or other service providers throughout the trial.

Usual school practice arm:
Schools will continue to provide any usual support, and families will be free to continue to seek and/or receive any other additional support from school and/or other service providers throughout the trial.After the 24-month assessment, families will be offered a written (PDF) version of the content of the online intervention.

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Previous intervention:
Children in Year 4 (aged 8-9 years) in participating classes and their parent/carer and class teacher will be invited to take part. Assessments will be completed at baseline (before

randomisation), and 6-months, 12 months and 24-months post-randomisation. Our target population is children who screen positive (score above the cut-off on the 2-item parent-report child anxiety questionnaire) at baseline, but we will also follow-up all recruited children (total population).

The trial will include an internal pilot. We will recruit schools in two cohorts one year apart (pilot phase: 30 schools; phase 2: 50 schools). The decision to continue beyond the pilot phase will be taken by the funder, with advice from the independent programme steering committee.

After baseline assessments are complete in a cohort of schools, schools will be randomised by an independent statistician to either 'feedback and intervention' or 'usual school practice' in a 1:1 ratio stratified according to school demographic information. The statistician will pass the allocation to the study team who will notify schools and families.

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Intervention Type
Behavioural

Primary outcome measure

Absence/presence of child anxiety problems 12 months post-randomisation in the target population determined by score below/above the cut-off on the 2-item parent-report child anxiety questionnaire

Secondary outcome measures

Current secondary outcome measures as of 11/04/2022:
1. Secondary clinical outcomes measured in the target population and total population at baseline, 4 months, 12 months, 24 months post-randomisation:
1.1 Child anxiety measured using the brief Spence Children's Anxiety Scale (SCAS-8), together with an impact supplement (child-report, parent -report, and teacher-report), and the Revised Children's Anxiety and Depression Scale (RCADS)-Anxiety Scale (child-report and parent-report)
1.2 Child depression symptoms measured using the Revised Children's Anxiety and Depression Scale (RCADS)-Depression Scale (child-report and parent-report)
1.3 Child emotional and behavioural problem symptoms measured using the Strengths and Difficulties Questionnaire (SDQ) (child-report and parent -report)
2. Health economic outcomes measured in the target population and total population at baseline, 4 months, 12 months, 24 months post-randomisation:
2.1 Child quality of life measured using Child Health Utility 9D-(child-report and parent/carer report on child) and EQ-5D-Y (child-report and parent/carer report on child)
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/carer report
2.4 Time spent on intervention delivery measured using therapist, supervisor and school staff completed logs throughout
3. Education related outcomes in the target population and total population collected from school records and (if approved) from the National Pupil Database, including:
3.1 School attendance and punctuality up to the end of Year 6 (age 11)
3.2 Academic attainment up to the end of Year 6 (age 11)
4. Participant experiences and process evaluation outcomes
4.1 Experiences of procedures for identification, feedback and intervention and process evaluation outcomes will be assessed via qualitative interviews with children, parents/carers, school staff, other stakeholders and members of the research team involved in delivering the intervention, during and after the intervention delivery period.
4.2 Experiences of study procedures measured by a bespoke child, parent, and teacher-report acceptability-questionnaire at baseline, 4 months, 12 months, 24 months post-randomisation

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Previous secondary outcome measures :
1. Secondary clinical outcomes measured in the target population and total population at baseline, 6-months, 12-months, 24-months post-randomisation:
1.1 Child anxiety measured using the brief Spence Children's Anxiety Scale (SCAS-8), together with an impact supplement (child-report, parent -report, and teacher-report), and the Revised Children's Anxiety and Depression Scale (RCADS)-Anxiety Scale (child-report and parent-report)
1.2 Child depression symptoms measured using the Revised Children's Anxiety and Depression Scale (RCADS)-Depression Scale (child-report and parent-report)
1.3 Child emotional and behavioural problem symptoms measured using the Strengths and Difficulties Questionnaire (SDQ) (child-report and parent -report)

2. Health economic outcomes measured in the target population and total population at baseline, 6-months, 12-months, 24-months post-randomisation:

2.1 Child quality of life measured using Child Health Utility 9D-(child-report and parent/carer report on child) and EQ-5D-Y (child-report and parent/carer report on child)
2.2 Parent/carer quality of life measured using EQ-5D-5L (parent self-report)
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2.4 Time spent on intervention delivery measured using therapist, supervisor and school staff completed logs throughout

3. Education related outcomes in the target population and total population collected from school records and (if approved) from the National Pupil Database, including:
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4.1 Experiences of procedures for identification, feedback and intervention and process evaluation outcomes will be assessed via qualitative interviews with children, parents/carers, school staff, other stakeholders and members of the research team involved in delivering the intervention, during and after the intervention delivery period.
4.2 Experiences of study procedures measured by a bespoke child, parent, and teacher-report acceptability-questionnaire at baseline, 6-months, 12-months, 24-months post-randomisation

Overall study start date
01/07/2021

Completion date
30/11/2024

Eligibility

Key inclusion criteria
Schools:
1. Mainstream primary/junior in England with at least 2classeswith Year 4 pupils
2. A minimum of 40 Year4pupils on school roll

Classes:
1. Where schools have two or three Year 4classes, all Year 4 classes will take part
2. Where schools have more thanthreeYear 4classes, three classes will be randomly selected to take part

Total population:
1. Children
1.1 ChildisinYear 4 inaparticipatingclass
1.2 Child’s parent/carer has not opted out

2. Parents/carers
2.1 Parent/carer ofachildin Year 4inaparticipating class.Families will be asked to nominate one parent/carertocompleteparent-reportmeasures.

3. Teachers
3.1 Baseline: class teacher ormember ofsupport staff who works regularlywithchildren inaparticipating class

3.2 Follow-up: participating child's current class teacher/member of support staff who works regularly with them

Target population:
1. Children: Child screens positive (scores above the cut-off) on the2-itemparent-report child anxiety questionnaire at baseline
2. Parents/carers: Parent/carer of a child who screens positive (score above the cut-off) on the2-itemparent-report child anxiety questionnaire at baseline
3. Teachers: Class teacher ormember ofsupport staff who works regularlywitha child who screens positive (scores above the cut-off) on the2-itemparent-report child anxiety questionnaire at baseline

Intervention (OSI) participants:
1. Parent/carer of a child in a school randomised to 'Feedback and Intervention'
2. Child screened positive (scored above the cut-off on 2-item parent-report child anxiety questionnaire) at baseline and/or the parent/carerdecides to take up theinterventionoffer
3. Where more than one child in a household or family takes part in the trial, the parent/carer will be offered the intervention for one child only.

Qualitative interviews:
1. Children: Childisin Year 4 in aparticipating class in a school allocated to 'feedback and intervention' and parent/carer provides consent
2. Parents/carers: Parent/carer of child inYear 4 in aparticipating classin a school allocated to 'feedback and intervention'
3. School staff: Member of staff inaparticipating schoolin a school allocated to 'feedback and intervention'
4. Other key stakeholders: Governor in participating school or representative of another key stakeholder organisation who has a professional role within or related to a participating school, for example a mental health service provider, local authority, local policy maker organisations (e.g.local public health team)
5. Members of the research team involved in delivering the intervention: Children's Wellbeing Practitioner or Clinical Psychologist who deliveredand/or supervised the delivery of OSI as part of the trial

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Schools: 80; Target population: 398 children and their parent/carers and class teachers; Total population: 4471 children, 1987 parents/carers, 552 teachers

Key exclusion criteria
Schools: Schools witha current "Mental Health Support Team"(as part of the DfE/NHS England initiative)
Children:Childrenwhodo not have sufficient English language or comprehension skills to answer

questions, even with support,will not complete measures themselves
Parents/carers:Parentswhodo not have sufficient English language or comprehension skills to answer questions and/or take part in the intervention, even with support,will not take part

Date of first enrolment
05/01/2022

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warneford Hosptial
Oxford Health NHS Foundation Trust & University of Oxford
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Sponsor type
University/education

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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health Research (NIHR)

Results and Publications

Publication and dissemination plan
The study protocol will be published in due course.

Outcomes will be published in high-quality publications and through additional routes to reach academic, educational, clinical, policymaker and public audiences.

All publications will be open access.

Intention to publish date
30/06/2025

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?
Protocol article		22/10/2022	24/10/2022	Yes	No
Statistical Analysis Plan		17/01/2024	18/01/2024	No	No