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Minimising young children's anxiety through schools

Submission date	Recruitment status	[X] Prospectively registered
12/01/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
14/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/02/2026	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and aims

Anxiety disorders are common and create a substantial personal and societal burden. Intervening before anxiety problems become ingrained and have an ongoing impact on children's lives would benefit families and wider society. Elevated anxiety symptoms, inhibited temperament and high parental anxiety are risk factors for later anxiety disorders in children. There is emerging evidence that prevention can be effective in each of these contexts. The reach of prevention could be substantially improved by delivering an online intervention through schools to parents of children who have one or more of these risks. Furthermore, identifying moderators and mediators of child outcomes will establish who to target and how to optimise prevention.

The main aims of this study are to establish if a supported online intervention for parents of at-risk children (4-7 years) reduces the frequency of anxiety disorders 1 year later, and to identify who benefits most and how to maximise outcomes.

Who can participate?

Parents/carers of children (aged 4-7) in reception, year 1 and year 2 classes in participating schools will be invited to take part in screening. Parents/carers of children who screen positive on the basis of child anxiety symptoms, behavioural inhibition and/or parent anxiety symptoms will be eligible.

What does the study involve?

Parents/carers of children in participating classes will be invited to complete screening questionnaires. Following screening, the research team will contact parents/carers to let them know the outcome of the screening and whether they are eligible or not.

Parents/carers who agree to take part will be asked to complete some more questionnaires. Half of the participating schools will be allocated to the intervention group, and half to the usual school practice group. Participating parents/carers of children in schools allocated to the intervention group will receive a therapist-supported online programme. Parents/carers of children in schools in the usual school practice group will continue to receive any usual support available at their school, and at the end of the project will receive PDF versions of the online

programme.
Parents/carers in both groups will be asked to complete questionnaires again after 6 weeks and 12 weeks, and to complete questionnaires and take part in an interview after 12 months.

What are the possible benefits and risks of participating?
The researchers have good reason to think that most families who receive the therapist supported online programme or the PDF version of the programme at the end of the project will benefit.
Parents/carers will need to spend time completing questionnaires and an interview. The researchers work with families to try to make sure the questions we ask are as acceptable as possible, but the questions 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?
May 2020 to November 2023

Who is funding the study?
Kavli Trust (Norway)

Who is the main contact?
Tessa Reardon
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Contact information

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Scientific

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Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Minimising Young Children's Anxiety Through Schools (MY-CATS): a cluster randomised controlled trial

Acronym
MY-CATS

Study objectives
Current hypothesis as of 29/11/2021:
Study hypothesis: Fewer children have an anxiety disorder in the intervention arm compared to the usual school practice arm at 12 months post-randomisation.

Primary objective: To compare diagnostic outcomes 12 months post-randomisation for children who screen as positive on one or more risk factors in schools allocated to the intervention versus usual school practice.

Secondary objectives:
1. To compare anxiety symptoms, related interference, externalising symptoms and additional

intervention targets 12 weeks and 12 months post-randomisation for children who screen-positive on one or more risk factor in schools allocated to intervention compared to usual school practice
2. To identify moderators (including number of risks) and mediators of the primary outcome
3. To evaluate experiences of systematic screening
4. To evaluate experiences of the supported parent-led online intervention
5. To estimate the cost-effectiveness of the intervention compared to usual school practice, 12 months post-randomisation

_____

Previous hypothesis:
Primary objective: To compare diagnostic outcomes 12 months post-randomisation for children who screen-positive on one or more risk factors in schools allocated to the intervention versus usual school practice.

Study hypothesis: Fewer children have an anxiety disorder in the intervention arm compared to the usual school practice arm at 12 months post-randomisation.

Secondary objectives:
1. To compare anxiety symptoms, related interference and externalising symptoms 12 weeks and 12 months post-randomisation for children who screen-positive on one or more risk factor in schools allocated to intervention compared to usual school practice
2. To identify moderators (including number of risks) and mediators of the primary outcome
3. To evaluate experiences of systematic screening
4. To evaluate experiences of the supported parent-led online intervention
5. To estimate the cost-effectiveness of the intervention compared to usual school practice, 12 months post-randomisation and model potential cost-effectiveness in the future

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/01/2021, 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: R62531/RE001

Study design
Interventional cluster randomized controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions

Schools will be randomised to the intervention or usual school practice arm in a 1:1 ratio stratified according to school-demographic information. An independent statistician will conduct randomisation via a computer-generated algorithm. Schools will be randomised on block, after screening, participant enrolment and baseline assessments have been completed in a cohort of schools. The statistician will pass the allocation to the Trial Manager who will assign schools to arms.

Assessment points for both arms will be: screening, baseline, 6 weeks, 12 weeks and 12-months post-randomisation.

Intervention arm: Parents/carers of children identified as 'at risk' for developing anxiety problems in schools randomised to the intervention arm will work through OSI (Online Support and Intervention for Child Anxiety). OSI is an online version of an evidence-based parent-guided Cognitive Behaviour Therapy (CBT) intervention for child anxiety, and the content has been adapted for parents of children aged 4-7 years who are at risk of anxiety disorders. Parents work through seven online modules (one module per week), with each supported by a brief (15 – 20 minute) telephone session with a Children's Wellbeing Practitioner, 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.

Usual school practice arm: Parents/carers of children identified as 'at risk' for developing anxiety problems in schools randomised to the usual school practice arm will continue to receive any usual support available in their school. At the end of the trial (after 12-month follow-up), parents /carers will receive PDF versions of the online intervention.

Intervention Type
Behavioural

Primary outcome(s)
Absence/presence of an anxiety disorder measured using Anxiety Disorder Interview Schedule-Child Version-Parent Interview (ADIS-P) at 12-months post-randomisation

Key secondary outcome(s))
Current secondary outcome measures as of 21/12/2022:
1. Secondary clinical outcomes measured at baseline, 12 weeks and 12 months post-randomisation:
1.1. Child anxiety symptoms measured using the Preschool Anxiety Scale -parent/carer report
1.2. Inference caused by child anxiety measured using the Child Anxiety Life Interference Scale-Preschool version-parent/carer report
1.3. Child externalising symptoms measured using the Strengths and Difficulties Questionnaire-Externalising Scale-parent/carer report
2. Moderators of primary outcome measured at screening and baseline:
2.1. Child age, child gender, child ethnicity, parent gender, parent ethnicity, and family socioeconomic status measured using parent/carer-report bespoke socio-demographic questionnaire
2.2. Risk factors (child anxiety symptoms, behavioural inhibition, parent anxiety symptoms) and number/combination of risk factors measured using Preschool Anxiety Scale-parent/carer report, Approach subscale of the Short Temperament Scale for Children-parent/carer report, Generalised Anxiety Disorder-7 (GAD-7) Scale-parent self-report
3. Mediators of primary outcome measured at baseline, 12 weeks and 12 months post-randomisation:

3.1. Risk factors (child anxiety symptoms, behavioural inhibition, parent anxiety symptoms) measured using the Preschool Anxiety Scale-parent/carer report, Approach subscale of the Short Temperament Scale for Children-parent/carer report, Generalised Anxiety Disorder-7 (GAD-7) Scale
3.2. Additional intervention targets, including:
3.2.1. Parent overprotection measured using the Parental Overprotection Scale-parent/carer report
3.2.2. Parenting self-efficacy measured using the Parenting Sense of Competence Scale-self-efficacy subscale-parent/carer report
3.2.3. Child behavioural avoidance measured using the Child Avoidance Measure-parent/carer report
3.2.4. Child coping efficacy measured using an adapted version of the Coping Questionnaire-parent/carer report
3.2.5. Child intolerance of uncertainty measured using the Responses to Uncertainty and Low Environmental Structure questionnaire-parent/carer report
4. Experiences of screening and intervention assessed using one-to-one qualitative interviews with parents/carers, children, and school staff throughout the project and a bespoke parent-report acceptability questionnaire at 12 months
5. Economic outcomes measured at baseline, 12 weeks and 12 months post-randomisation:
5.1. Child quality of life measured using Child Health Utility 9D-(parent/carer report on the child) (removed 15/04/2021): and EQ-5D-Y-proxy version (parent/carer report on the child)
5.2. Parent/carer quality of life measured using EQ-5D-5L (self-report)
5.3. 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
5.4. Time spent on intervention delivery measured using therapist and supervisor completed logs throughout

Previous secondary outcome measures:
1. Secondary clinical outcomes measured at baseline, 12 weeks and 12 months post-randomisation:
1.1. Child anxiety symptoms measured using the Preschool Anxiety Scale -parent/carer report
1.2. Inference caused by child anxiety measured using the Child Anxiety Life Interference Scale-Preschool version-parent/carer report
1.3. Child externalising symptoms measured using the Strengths and Difficulties Questionnaire-Externalising Scale-parent/carer report
2. Moderators of primary outcome measured at screening and baseline:
2.1. Child age, child gender, child ethnicity, parent gender, parent ethnicity, and family socioeconomic status measured using parent/carer-report bespoke socio-demographic questionnaire
2.2. Risk factors (child anxiety symptoms, behavioural inhibition, parent anxiety symptoms) and number/combination of risk factors measured using Preschool Anxiety Scale-parent/carer report, Approach subscale of the Short Temperament Scale for Children-parent/carer report, Generalised Anxiety Disorder-7 (GAD-7) Scale-parent self-report
3. Mediators of primary outcome measured at baseline, 6-weeks, 12-weeks and 12-months post randomisation:
3.1. Risk factors (child anxiety symptoms, behavioural inhibition, parent anxiety symptoms) measured using Preschool Anxiety Scale-parent/carer report, Approach subscale of the Short Temperament Scale for Children-parent/carer report, Generalised Anxiety Disorder-7 (GAD-7) Scale
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5.3. 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
5.4. Time spent on intervention delivery measured using therapist and supervisor completed logs throughout

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Schools: mainstream infant/primary school in England, with a minimum of two classes per target year.
2. Screening: child in Reception, Year 1 or Year 2 in a participating school (aged 4-7 years). One parent/carer will complete screening questionnaires for each child.
3. Trial: child screens positive on child anxiety symptoms, and/or behavioural inhibition, and/or parent/carer anxiety symptoms.
4. Qualitative interviews: parents/carers who take part in screening, school staff in participating schools and children of parents/carers who take part in the intervention

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
865

Key exclusion criteria

1. Parent/carer does not have sufficient use of English to provide consent, complete measures and/or take part in the intervention
2. Parent/carer does not have frequent access to the internet, either at home or elsewhere

Date of first enrolment
01/02/2021

Date of final enrolment
31/07/2022

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
Charity

Funder Name
Kavli Fondet [Kavli Trust]

Results and Publications

Individual participant data (IPD) sharing plan

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		19/02/2026	20/02/2026	Yes	No
Protocol article		16/02/2022	11/03/2022	Yes	No
Participant information sheet	version V1.0	22/10/2020	04/02/2021	No	Yes
Statistical Analysis Plan		28/12/2022	28/12/2022	No	No
Study website		11/11/2025	11/11/2025	No	Yes