BMJ Open

Protocol for the process evaluation for a cluster randomised controlled trial evaluating primary school-based screening and intervention delivery for childhood anxiety problems

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-082691
Article Type:	Protocol
Date Submitted by the Author:	01-Dec-2023
Complete List of Authors:	Williamson, Victoria; King's College London, Larkin, Michael; Aston University Reardon, Tessa; University of Oxford, Experimental Psychology Stallard, Paul; University of Bath, Department for Health Spence, Susan; Griffith University Macdonald, Ian; Charlie Waller Memorial Trust, ; The Open University, Ukoumunne, Obioha; University of Exeter Medical School, NIHR CLAHRC South West Peninsula (PenCLAHRC) Ford, Tamsin; University of Cambridge, Psychiatry Violato, Mara; Oxford University, UK, Health Economics Research Centre, Nuffield Department of Population Health Sniehotta, Falko F.; Newcastle University; Heidelberg University, Department of Public Health, Preventive and Social Medicine Stainer, Jason; Richmond School and Sixth Form College, Stanley Primary School, Strathmore Road, Teddington, Middlesex, TW11 8UH Gray, Alastair; University of Oxford, Nuffield Department of Population Health Brown, Paul; Bransgore Church of England Primary School, Bransgore C Of E Primary School, Ringwood Rd, Bransgore, Christchurch BH23 8JH Sancho, Michelle; West Berkshire Council, West Berkshire Council, Council Offices, Market St, Newbury RG14 5LD Morgan, Fran; University of Oxford, Department of Experimental Psychology Jasper, Bec; Square Peg, Square Peg Taylor, Lucy; Oxford University, Experimental Psychology Creswell, Cathy; Oxford University
Keywords:	Anxiety disorders < PSYCHIATRY, Child & adolescent psychiatry < PSYCHIATRY, QUALITATIVE RESEARCH

Protocol for the process evaluation for a cluster randomised controlled trial evaluating primary school-based screening and intervention delivery for childhood anxiety problems

Williamson, V.[a,b,c], Larkin, M.[d,] Tessa Reardon [a,], Paul Stallard, [e], Susan H. Spence, [f,], Ian Macdonald [g], Obioha C Ukoumunne [h], Tamsin Ford [i], Mara Violato [j], Falko F Sniehotta [k], Jason Stainer [n], Alastair Gray [j], Paul Brown [o], Michelle Sancho [p], Fran Morgan [m], Bec Jasper [l], Lucy Taylor [a], Cathy Creswell, [a].

[a] Department of Experimental Psychology, Anna Watts Building, University of Oxford, Oxford, OX2 6 GG.

[b] Department of Psychiatry, University of Oxford, Oxford OX3 7JX.

[c] Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, SE5 9RJ.

[d,] Institute for Health and Neurodevelopment, Aston University, Birmingham, B4 7ET.

[e] University of Bath, Claverton Down, Bath BA2 7AY

[f,]Australian Institute of Suicide Research and Prevention and School of Applied Psychology, Griffith University, Brisbane, QLD 4121, Australia.

[g] Charlie Waller Trust, 23 Kingfisher Court, Newbury, Berkshire RG14 5SJ.

[h] NIHR ARC South West Peninsula, University of Exeter, Heavitree Rd, Exeter EX1 2LU

[i] Department of Psychiatry, University of Cambridge

[j] Health Economics Research Centre, Nuffield Department of Population Health, University of Oxford.

[k] Division of Public Health, Social and Preventive Medicine, Centre for Preventive Medicine and Digital Health (CPD), Medical Faculty Mannheim, Heidelberg University.

[l] PACT Parents and Carers Together CIC, UK

[m] Square Peg (Team Square Peg CIC), UK

[n] Stanley Primary School, Strathmore Road, Teddington, Middlesex, TW11 8UH

[o] Bransgore C Of E Primary School, Ringwood Rd, Bransgore, Christchurch BH23 8JH

[p] West Berkshire Council, Council Offices, Market St, Newbury RG14 5LD

*Correspondence: Dr Michael Larkin, Department of Psychology, Institute for Health and Neurodevelopment, Aston University, Birmingham, B4 7ET, m.larkin@aston.ac.uk

Funding: This paper represents independent research funded by the National Institute for Health Research (NIHR; PGfAR - RP-PG-0218-20010) (PI: CC) and hosted by Oxford Health NHS Foundation Trust. CC and MV acknowledge support from the Oxford and Thames Valley NIHR Applied Research Collaboration and the NIHR Oxford Health Biomedical Research Centre. OU was supported by the NIHR Applied Research Collaboration (ARC) for the South West Peninsula at the Royal Devon and Exeter NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Competing interests: TF's Department receives funds from her advisory role at Place2Be, a third sector organisation that provides mental health training and support to schools in the UK.

Data sharing statement: No additional data are available.

Word count: 3839

Acknowledgements: We would like to thank those who participated in our patient and public involvement (PPI) activities for their contribution to this research. We also wish to thank our colleagues on the wider research team (especially Sue Ball) and advisory group (especially Paul Flowers) for their contributions.

Ethical approval: The study has received ethical approval from the University of Oxford CUREC (R66068_RE003).

Abstract

Introduction: Anxiety problems are prevalent in childhood and, without intervention, can persist into adulthood. Effective evidence-based interventions for childhood anxiety disorders exist, specifically cognitive behavioural therapy (CBT) in a range of formats. However, only a small proportion of children successfully access and receive treatment. Conducting mental health screening in schools and integrating evidence-based interventions for childhood anxiety problems may be an effective way to ensure support reaches children in need. The Identifying Child Anxiety Through Schools – Identification to Intervention (iCATS i2i) programme involves screening for childhood anxiety problems and offering a brief online parent-led CBT intervention. This paper presents the protocol for the process evaluation of the iCATS i2i programme.

Methods and analysis: This process evaluation will use both quantitative and qualitative methods to evaluate the implementation and acceptability of and barriers/facilitators to engagement and delivery of the iCATS screening/intervention procedures. Quantitative data sources will include opt-out and completion rates of baseline measures and usage analytics extracted from the online intervention platform. Qualitative interviews will be conducted with children, parents, school staff, iCATS i2i clinicians and researchers delivering study procedures. The Medical Research Council (MRC) framework for process evaluations will guide study design and analysis.

Ethics and dissemination: This study has received ethical approval from the University of Oxford Research Ethics Committee (R66068_RE003). Findings from the study will be

disseminated via peer-reviewed publications in academic journals, conferences, digital and social media platforms and stakeholder meetings.

Trial registration number: ISRCTN registry ISRCTN76119074. Prospectively registered on 4.1.2022.

Keywords: anxiety, school, parent, child, intervention, process evaluation

Strengths and limitations

A strength of this study is the examination of acceptability and barriers/facilitators of iCATS i2i via mixed method data collection from children, parents, school staff, iCATS i2i researchers and clinicians.

A potential limitation is the majority of participants who opt-out or later drop-out of iCATS i2i procedures may not participate in interviews which could lead to a more positive overall evaluation of study procedures.

The intervention will be delivered by English-speaking practitioners which may unduly exclude participants who are not English speaking.

Introduction

Anxiety problems are among the most prevalent mental health problems in childhood and, without intervention, can often persist into adulthood [1]. Cognitive behavioural therapy (CBT) is an effective evidence-based intervention for childhood anxiety disorders [2]; however, only a very small proportion of children successfully access and receive treatment. For example, a recent study found that less than three percent of UK children with diagnoseable anxiety problems were able to access evidence-based treatments [3]. Effective and efficient treatments for child anxiety problems now exist, such as parent-led CBT, that can facilitate early access to support [4]. However, barriers to care are numerous [5], and Child and Adolescent Mental Health Services (CAMHS) are often unable to meet the demand for non-urgent care [6].

One promising way to address these barriers is to deliver interventions directly to parents through their children's schools (e.g. see [7]). While some universal schools-based interventions in schools show promise for some child outcomes (e.g. see [8]), there are indicators that when those interventions are intended to improve mental health specifically (e.g. see [9]) - rather than to improve indirect factors such as health literacy [10], help-seeking [11] or resilience [12] - a more targeted approach is likely to be required. One way to identify who interventions should target is through universal school-screening. This involves the administration of validated questionnaires to a year group (or entire school) to identify likely mental health problems [13]. The implementation and uptake of school screening programmes is often low [13,14]. Research has found that parents may be reluctant to engage with school-based mental health screening/intervention initiatives if they have previously felt blamed by them for their child's difficulties, or if they felt their child's school

had been unsupportive of their child's mental health in the past [15]. As such, prior to implementing a screening and intervention programme in schools, it is critical to establish whether the programme is acceptable; what barriers and facilitators to participation exist, whether any external factors impact programme delivery or engagement, and which adaptations are needed to ensure the programme results in effective delivery and engagement [16].

The iCATS i2i trial

Our proposed process evaluation is embedded within The Identifying Child Anxiety Through Schools – Identification to Intervention (iCATS i2i) programme. This programme has involved the development of a brief screening tool for child anxiety problems, a co-design phase of work to develop procedures for delivering universal screening and targeted intervention [17], a feasibility study [7], and a cluster randomised controlled trial (RCT) [18]. We include a brief summary of the cluster randomised controlled trial here to provide context to the process evaluation design.

In the main trial, participating schools (target 80 schools) from across England have been randomised in a 1:1 ratio into one of two arms: the iCATS-i2i (intervention) arm and the usual school practice (control) arm. The screening/intervention procedures in the iCATS i2i intervention arm consist of four key stages (see Figure 1): i) parent-report screening questionnaires for child anxiety problems are administered for all Year 4 (Y4; aged 8-9 years) children; ii) screening questionnaires are scored by the research team to determine whether a child is likely to have anxiety problems; iii) feedback on questionnaire scores and likelihood of anxiety problems is provided to parents; iv) parents of children who screen 'positive' for likely anxiety problems are offered an online parent-led CBT intervention for

child anxiety problems with telephone therapist support (OSI: Online Support and Intervention for Child Anxiety); all parents (regardless of screening outcome) are given the opportunity to request OSI. OSI consists of seven online modules for parents which are supported by a weekly telephone call with a Children's Wellbeing Practitioner (CWP, NHS Band 5), with a follow-up telephone call 4-weeks later [19]. Families in the usual school practice (control) arm do not receive feedback on questionnaire responses and are not offered OSI – instead they can access whatever support is available as part of their 'usual school practice,' as required.

Children in the intervention arm schools are also provided with a whole class interactive lesson which provides psycho-education and information about coping strategies (problem solving and help-seeking), and school staff are provided with information and resources about the OSI intervention.

For the purposes of the trial outcomes, participants are followed up at 4,12- and 24-months post-randomisation using standardised questionnaire measures for quantitative evaluation (see [18], for details).

For the purposes of the process evaluation, qualitative interviews are also conducted with children, parents, school staff, iCATS researchers and CWPs/supervisors (target 55 interviews in total) to explore their experiences of the screening process and intervention procedures.

[INSERT FIGURE 1 HERE]

.

MRC Guidelines

This process evaluation has been informed by the MRC advice on the process evaluation of complex interventions [20]. The MRC guidance highlights three evaluation components– implementation, mechanisms of impact, and context.

i) *Implementation:* An exploration of whether the intervention was delivered as intended (fidelity), the quantity of what was implemented (dose), and the 'reach' of the intervention', as well as identifying any adaptations made.

ii) *Mechanisms of impact*: An examination of the mechanisms through which an intervention brings about change by understanding how participants interact with the procedures.

iii) *Context*: An exploration of factors external to the intervention which may have affected the intervention's acceptability, engagement or delivery (e.g. home life for the family, school life for the child, comorbidities, COVID-19 social restrictions). MRC guidance suggests that researchers should relate contextual variations to *a priori* hypothesised causal mechanisms, or those arising from qualitative data analysis, to gain insights into context-mechanism-outcome patterns. In particular, this is likely to involve exploring differences between schools.

The iCATS i2i process evaluations aims and objectives.

Best practice in carrying out process evaluations is to outline the process evaluation methodology *a priori* [21]. Using MRC guidelines and previous protocols of process evaluations as a guide [22,23], we outline our methodological approach and detail the planned process evaluation for the iCATS i2i trial. We include key questions that we will explore in the process evaluation, which are organised under the headings Implementation and Acceptability, Mechanisms, and Context, to be broadly consistent with MRC guidelines

[16,22]. While the MRC guidance for examining implementation often focuses on whether the intervention was delivered as intended in terms of fidelity, dose and reach [24,25] we will also focus on the acceptability of the implemented procedures given concerns about potential acceptability challenges identified in our previous iCATS i2i co-design work [17]. We intend that this process evaluation will contribute towards the development of a set of transferable principles regarding school-based screening and intervention for mental ill-health more broadly, which could be offered in schools in the future.

Specific questions that will be addressed by this process evaluation are:

1. Implementation and acceptability.

Key questions: Were the iCATS i2i screening/intervention procedures implemented as intended or were adaptations needed? Do the screening/intervention procedures reach children with anxiety problems? Are the screening/intervention procedures acceptable to schools and families? What is the variation in implementation and acceptability between schools and does variation relate to features of schools?

2. **Mechanisms.**

Key questions: How do the screening/intervention procedures produce change? What barriers/facilitators to engagement and delivery exist? How could these potentially be overcome?

3. **Context.**

Key questions: What - if any - external factors have an impact on iCATS i2i screening/intervention procedure engagement or delivery? Does context explain differences in outcomes or experiences between schools?

Method

Ethical approval and consent

The iCATS i2i RCT has received ethical approval from the University of Oxford CUREC (R66068_RE003). Participant information sheets are provided to all potentially eligible participants prior to participation. Parents are given the opportunity to opt their child out of the research. Prior to providing any data, written informed consent is obtained from parents, teachers, and qualitative interview participants, and children provide assent.

Patient and Public Involvement (PPI)

As detailed in our previous publications, the iCATS i2i procedures were co-designed in collaboration with extensive input from PPI [17,26].

Logic Model

The MRC guidance on the development and evaluation of complex interventions notes that a key part of a process evaluation is to outline the processes of the intervention procedures and the outcomes it aims to attain using a logic model. The simplified logic model for the iCATSi2i screening/intervention procedures is shown in Figure 2. Data collection and sources, as well as how these will address our process evaluation aims can be found in Table 1.

[INSERT FIGURE 2 HERE]

Overall design

This process evaluation will use a mixed methods design with purposively sampled qualitative data, supplemented by quantitative data from the trial, to strengthen our insights via triangulation. Quantitative data will include opt-out rates, completion rates for screening/baseline measures, feedback and support calls, and online modules, and time associated with OSI delivery (e.g. time spent on feedback/support calls, online modules).

Responses to a bespoke parent-report acceptability questionnaire, and routine measures collected within OSI (Session Rating Scale and Module Feedback Questionnaire) will also be used to assess the acceptability of procedures.

Qualitative data will include semi-structured interviews conducted with children, parents, school staff, CWPs and research team members. Our intention is to create a comprehensive picture of families and schools' experiences of the screening/intervention pathway procedures.

Data collection procedure.

Table 1 illustrates the mapping between data sources and the questions which our evaluation will address.

[INSERT TABLE 1 HERE]

Quantitative data collection

Quantitative data collection is detailed in full in the trial protocol [18]. Parents will have an opportunity to opt their child out of the research. When this does not happen, then parents, children and teachers will complete baseline questionnaires. For parents, the baseline assessment includes the 2-item child anxiety screening measure (iCATS-2) used in the screening/intervention procedures. School-level demographic information will be collected from publicly available information, and family-level demographic information will be collected from school records and parents.

CWPs and supervisors will complete activity logs to record completion and duration of feedback and OSI support calls, and supervision activities. OSI usage data (online module completion, completion of optional interactive activities within modules, time spent of

module pages, number of times module pages are viewed) are collected within the OSI platform. Parents who use OSI complete measures built into each online module (including the Session Rating Scale and Module Feedback Questionnaire), and parents who complete screening questionnaires will be asked to complete a bespoke 7-item acceptability questionnaire to assess parent views of the procedures 4 months after randomisation.

Qualitative data collection

The qualitative design is framed as a multiple perspective study (e.g. see [27]), with interrelated sub-samples. Interviews will be conducted with sub-samples of parents (target N=20), children (target N=20) and school staff (target N=5) in the intervention arm, and with the CWPs and clinical psychologists facilitating the delivery of feedback and intervention (target N=5) and members of the research team who facilitated screening and data collection activities and delivered the anxiety lessons in schools (target N=5). This is a large total sample size for a qualitative study (total expected N=55) but it is necessary given the evaluative focus, and the need for diversity in the larger sub-samples (parents, children). Interviews will be conducted during and after the feedback and intervention delivery period and will be completed prior to the 12-month follow-up. All interviews will be carried out by telephone or online video calling (Microsoft Teams) and audio-recorded.

Parent, child and school staff will be purposively sampled with the aim of collecting data from a diverse cohort to include varying views on the screening/intervention programme. This approach will include ensuring perspectives from a range of socio-economic, geographical location, gender and ethnicity backgrounds, and levels of interaction with OSI are included. We aim to collect interview data from families of children who screened 'positive,' screened 'negative', families who declined OSI, and families who

dropped out of OSI. We also aim to speak to participants in schools with higher rates of eligibility for free school meals, pupils with English as an additional language, and parents opting out of the research. We anticipate that this sampling strategy will result in sufficient diversity to provide examples of both relatively poor and relatively good engagement with the iCATS i2i screening/intervention programme and allow for the identification of barriers and facilitators to programme implementation.

Interview schedules will be informed by the research aims and existing literature on school-based screening/interventions for anxiety [14,17] (Supplementary Material 1). To answer our study aims, interview questions will focus on what features of the iCATS i2i screening/intervention procedures worked well; whether any adaptations to procedures were needed; whether taking part was considered to be beneficial (or not) and why; whether any barriers to engagement or delivery were experienced; and if any external factors affected engagement/delivery.

Data Analysis

Quantitative data analysis. To assess reach and acceptability of procedures, we will investigate participation rates in each element of the screening/intervention procedures. This will include examining the number and proportion of 1) parent opt-outs, 2) completed screening questionnaires (parent-report iCATS-2), 3) screen positives (child scores 3-6 on parent-report iCATS-2) among all eligible year 4 children. The number and proportion of completed 4) feedback calls with a CWP, 5) online modules and support calls (separately for each module), and 6) core intervention content (first five modules) will be examined for both screen positives and all eligible year 4 children. We will also examine the number and proportion of completed baseline measures for eligible year 4 children (coded as yes, no,

partial) for each reporter (parent, child, teacher). To further assess engagement with and delivery of OSI, descriptive statistics will be used to summarise the following among parents who start OSI: completion of optional questions/activities within online modules, time (minutes) spent on online modules, number of times online module pages are viewed, time (minutes) spent on support calls, CWP/clinical psychologist time (minutes) spent on associated administrative and supervision activities. Responses to the parent-report acceptability questionnaire, the Session Rating Scale and Module Feedback Questionnaire will also be summarised using descriptive statistics.

To explore factors that may influence engagement with the screening/intervention procedures, we will examine participation rates among schools with above/below average proportion of pupils eligible for free school meals and above/below average proportion of pupils with English as an additional language, and examine school and family-level characteristics associated with completion of the OSI online modules, feedback and OSI support calls, core intervention content, time spent on online modules, number of times online module pages are viewed, time spent on support calls and associated administrative/supervision activities.

Qualitative data analysis.

Qualitative interviews will be transcribed verbatim, with identifying personal information removed on transcription. Transcripts will be checked against audio-recordings and then audio-recordings will be destroyed. Transcripts will be imported into Nvivo 12 to facilitate data management. Reporting of qualitative findings will follow the CORE-Q checklist [28].

A subset of the transcripts will be analysed separately first to create a coding template which will cover how the screening/intervention procedures are experienced in the context of participant's distinctive lives. This analysis will be used to develop a template framework. All transcripts will then be analysed against this framework using template analysis, with modifications to the template made after careful consideration of each transcript [29]. We expect the developed template will include: what aspects of the screening/intervention procedures were acceptable; if any adaptations to the pathway procedures were needed; barriers or facilitators to engagement and delivery; and whether any external factors impacted the engagement or delivery of the procedures.

Integration of data analysis

The qualitative and quantitative data will be analysed separately and then mixed during analysis for triangulation to provide a more complete picture as described below [30]. The quantitative and qualitative strands will play an equally significant role in addressing the process evaluation research questions. A triangulation protocol will be followed [31] involving:

i. Sorting findings from the qualitative and quantitative datasets into categories or 'meta-themes' that address the research questions to determine overlap and divergence.

ii. Comparing findings from the data sources using a convergence coding scheme to determine the degree and type of convergence within category or theme areas. Researchers will consider if there is agreement, partial agreement, silence or dissonance between findings from different datasets. 'Silence' is where a finding that arises from one dataset is not found in another and can help with the interpretation of the results and lead to further investigations [31].

iii. Reviewing all meta-themes to assess the level of convergence and where/when researchers have different perspectives of the findings.

iv. Multiple researchers (VW, TR, CC, ML) will examine the set of findings to clarify the interpretation and determine the level of agreement among researchers. Disagreements will be managed by re-examining the data as a group, with final decisions made by CC and ML.

The process evaluation data will be analysed independently from the main trial clinical and cost-effectiveness outcomes. The statisticians (OU, SB) and health economist (MV) conducting the main trial quantitative data analysis [18] will be unaware of the findings from the process evaluation until the primary and secondary clinical and health economic outcomes have been analysed. The combined quantitative and qualitative data in the process evaluation is expected to help develop an in-depth understanding of the main trial outcomes.

Rigour and reliability

This process evaluation will be conducted by a team of experienced researchers with considerable expertise of both mixed methods and undertaking large-scale intervention trials for childhood anxiety disorders. Several steps will be taken to ensure a rigorous approach to data collection and analysis: (i) cluster (school) and purposive sampling will be conducted for qualitative interviews to ensure a broad and diverse sample and, thus, fair conceptual transferability; (ii) data collection and analysis will follow a systematic approach, including a range of both qualitative and quantitative data; (iii) researchers will reflect on their role and input in data generation and analysis; (iv) credibility checking will be conducted through reflective discussions with co-authors and a small expert reference group; (v) results will be triangulated across several sources of data; and (vi) 'sensitivity to context' will be considered

by incorporating relevant literature and theory as well as examining differing perspectives and the context in which data and results have been generated [32].

Discussion

This article outlines the rationale, design and methodological approach for the mixed methods process evaluation of the iCATSi2i screening and intervention procedures for children with anxiety problems. The process evaluation is designed to examine whether the screening/intervention procedures are implemented as intended or if adaptions are needed; if procedures are acceptable to schools and families; how the screening/intervention procedures produce change; whether barriers/facilitators to engagement and delivery exist; and whether any external factors impact procedure engagement or delivery. By detailing our process evaluation approach, as informed by the MRC guidelines [25] this article not only adds to the literature on process evaluation protocols with a mixed methods design but will also improve the integrity of our process evaluation and overall randomised controlled trial quality [21,33].

Strengths and challenges

It is anticipated that actively combining both qualitative and quantitative data in the process evaluation will help us to better understand and interpret the overall iCATS i2i trial outcome data. For example, by comprehensively examining whether the iCATS i2i screening/intervention procedures were adhered to and acceptable and the contexts surrounding that, this process evaluation will help determine both potential positive and negative aspects of the iCATS i2i procedures. If some negative outcomes are found from using the iCATS i2i screening/intervention procedures, the process evaluation will be a beneficial resource to determine whether a failure of procedure implementation occurred and

if this was due to, for example, factors associated with participants' experiences or circumstances (e.g. lack of motivation or resources; beliefs about online interventions; etc). This could potentially help with future implementations of iCATS i2i, if indicated, and also help inform the development and implementation of wider school-based screening and intervention programmes aimed at supporting children with mental health problems.

Collecting data from a range of participants (i.e. children, parents, teachers, researchers, CWPs) using multiple methods will produce a nuanced understanding of the mechanisms contributing towards the experience of the iCATS i2i procedures. Including teachers, children and parent report measures may also provide data about the acceptability of carrying out such screening procedures which would be beneficial beyond the iCATS i2i study and inform future screening/intervention trials. Moreover, the target sample size for qualitative interviews (N=55) and inclusive sampling approach (e.g. conducting interviews with screen 'positive' as well as 'negative' families, families who drop out of OSI, etc) is expected to be adequate to capture a range of perspectives, providing rich detailed data.

One potential limitation that may arise is that the majority of participants who opt-out or later drop out of the iCATS i2i procedures are more likely to decline to complete interviews which could lead to a more positive overall evaluation of the procedures. We will attempt to overcome this by making a concerted effort to recruit parents who drop out of or choose not to take up OSI or, if this is not possible, those who complete fewer OSI modules to interviews. Second, while we will be able to provide translated copies of the information sheets, OSI will be delivered by English-speaking CWPs for practical reasons, and this may unduly exclude parents who are not English speaking. Third, it is possible wider trial research activities influence engagement with the screening/intervention procedures in ways that

would not apply if the procedures were to be implemented in practice. For example, the screening questionnaire is a 2-item parent-report measure, but in the trial parents, children and teachers also each complete a number of measures to assess secondary trial outcomes. In addition, the team of researchers with responsibility for conducting this process evaluation will also be involved in carrying out the trial procedures and some will be involved in conducting the trial outcome analysis. This integration will help facilitate data sharing but there is potential for bias in the interpretation of procedure functioning to arise. A reflective approach to data collection and analysis will be employed to improve the reliability and validity of the findings.

The iCATS i2i screening/intervention procedures are complex and involve a range of interrelated components and multiple stakeholders. There may be some differences in procedure implementation across schools and there is likely to be adaption to and learning from the procedures as delivery proceeds [34,35]. Moreover, given that schools and families are each unique and complex ecosystems where a community of individuals interact and co-exist, school and family contexts cannot be considered 'static'. We will need to recognise that the iCATS i2i procedures are being delivered within shifting environments and the rolling out of the iCATS i2i school screening/intervention procedures may also have some influence on the environment. There may be considerable challenges in monitoring and precisely assessing the various iCATS i2i procedure implementation processes, components and changing environments and how they relate to outcomes. It is hoped that by including 'adaptations' as a core aim in our process evaluation, that any necessary departures from study procedures are recognised and captured. Overall, this process evaluation is expected to further our

understanding of the acceptability of screening/intervention procedures for child anxiety problems in a school context to inform future efforts to address child mental health problems.

Trial status

Recruitment of participants is ongoing.

References

1 Pollard J, Reardon T, Williams C, *et al.* The multifaceted consequences and economic costs of child anxiety problems: A systematic review and meta-analysis. *JCPP Advances*. 2023;3:e12149.

2 James AC, Reardon T, Soler A, *et al.* Cognitive behavioural therapy for anxiety disorders in children and adolescents. *Cochrane Database of Systematic Reviews*. 2020;2020. doi: 10.1002/14651858.CD013162.PUB2/PDF/CDSR/CD013162/CD013162.PDF

3 Reardon T, Harvey K, Creswell C. Seeking and accessing professional support for child anxiety in a community sample. *Eur Child Adolesc Psychiatry*. 2020;29:649–64.

4 Creswell C, Chessell C, Halliday G. Parent-led cognitive behaviour therapy for child anxiety problems: overcoming challenges to increase access to effective treatment. *Behavioural and cognitive psychotherapy*. 2022;1–21.

5 Reardon T, Harvey K, Baranowska M, *et al.* What do parents perceive are the barriers and facilitators to accessing psychological treatment for mental health problems in children and adolescents? A systematic review of qualitative and quantitative studies. *Eur Child Adolesc Psychiatry*. 2017;26:623–47.

6 Children's mental health services 2021-2022 | Children's Commissioner for England. https://www.childrenscommissioner.gov.uk/resource/29751/ (accessed 28 November 2023)

7 Green I, Reardon T, Button R, *et al.* Increasing access to evidence-based treatment for child anxiety problems: online parent-led CBT for children identified via schools. *Child Adolesc Ment Health*. 2023;28:42–51.

8 Durlak JA, Mahoney JL, Boyle AE. What We Know, and What We Need to Find Out About Universal, School-Based Social and Emotional Learning Programs for Children and Adolescents: A Review of Meta-Analyses and Directions for Future Research. *Psychol Bull*. 2022;148:765–82.

9 Kuyken W, Ball S, Crane C, *et al.* Effectiveness of universal school-based mindfulness training compared with normal school provision on teacher mental health and school climate: results of the MYRIAD cluster randomised controlled trial. *BMJ Ment Health*. 2022;25:125–34.

10 Ma KKY, Anderson JK, Burn AM. Review: School-based interventions to improve mental health literacy and reduce mental health stigma – a systematic review. *Child Adolesc Ment Health*. 2023;28:230–40.

11 Hayes D, Mansfield R, Mason C, *et al.* The impact of universal, school based, interventions on help seeking in children and young people: a systematic literature review. *Eur Child Adolesc Psychiatry*. 2023;1:1–18.

12 Higgen S, Mösko M. Development and pilot evaluation of a universal intervention – Enhancing resilience in culturally and linguistically diverse primary school classrooms. *Int J Educ Res*. 2021;108:101757.

13 Burns JR, Rapee RM. Barriers to Universal Mental Health Screening in Schools: The Perspective of School Psychologists. *https://doi.org/101080/15377903202119414 70*. Published Online First: 2021. doi: 10.1080/15377903.2021.1941470

14 Anderson JK, Ford T, Soneson E, *et al.* A systematic review of effectiveness and cost-effectiveness of school-based identification of children and young people at risk of, or currently experiencing mental health difficulties. *Psychol Med*. 2019;49:9–19.

15 Williamson V, Larkin M, Reardon T, *et al.* Primary school-based screening for childhood mental health problems and intervention delivery: a qualitative study of parents in challenging circumstances. *Emotional and Behavioural Difficulties*. 2022;27:267–79.

16 Oakley A, Strange V, Bonell C, *et al.* Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 2006;332:413–6.

17 Williamson V, Larkin M, Reardon T, *et al.* School-based screening for childhood anxiety problems and intervention delivery: a codesign approach. *BMJ Open*. 2022;12:e058089.

18 Reardon T, Ukoumunne OC, Violato M, *et al.* Identifying Child Anxiety Through Schools-identification to intervention (iCATS-i2i): protocol for a cluster randomised controlled trial to compare screening, feedback and intervention for child anxiety problems to usual school practice. *Trials*. 2022;23. doi: 10.1186/S13063-022-06773-0

19 Hill C, Reardon T, Taylor L, *et al.* Online Support and Intervention for Child Anxiety (OSI): Development and Usability Testing. *JMIR Form Res*. 2022;6. doi: 10.2196/29846

20 Moore G, Audrey S, Barker M, *et al.* Process evaluation of complex interventions. UK Medical Research Council (MRC) guidance. *Br Med J*. 2015.

21 Grant A, Treweek S, Dreischulte T, *et al.* Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials*. 2013;14. doi: 10.1186/1745-6215-14-15

22 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 2015;350. doi: 10.1136/BMJ.H1258

23 Hansford L, Sharkey S, Edwards V, *et al.* Understanding influences on teachers' uptake and use of behaviour management strategies within the STARS trial: Process evaluation protocol for a randomised controlled trial. *BMC Public Health*. 2015;15:1–8.

24 Skivington K, Matthews L, Simpson SA, *et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374. doi: 10.1136/BMJ.N2061

25 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ (Online)*. 2015;350. doi: 10.1136/bmj.h1258

26 Williamson V, Larkin M, Reardon T, *et al.* Codesign and development of a primary school based pathway for child anxiety screening and intervention delivery: a protocol, mixed-methods feasibility study. *BMJ Open*. 2021;11:e044852.

27 Larkin M, Shaw R, Flowers P. Multiperspectival designs and processes in interpretative phenomenological analysis research. *Qual Res Psychol*. 2019;16:182–98.

28 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007;19:349–57.

29 Brooks J, McCluskey S, Turley E, *et al.* The Utility of Template Analysis in Qualitative Psychology Research. *Qual Res Psychol*. 2015;12:202–22.

30 O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *BMJ*. 2010;341:1147–50.

31 Farmer T, Robinson K, Elliott SJ, *et al.* Developing and implementing a triangulation protocol for qualitative health research. *Qual Health Res*. 2006;16:377–94.

32 Yardley L. Dilemmas in qualitative health research. *Psychol Health*. 2000;15:215–28.

33 Lockwood I, Walker RM, Latimer S, *et al.* Process evaluations undertaken alongside randomised controlled trials in the hospital setting: A scoping review. *Contemp Clin Trials Commun*. 2022;26:100894.
34 Ling T. Evaluating complex and unfolding interventions in real time. *Evaluation*. 2012;18:79–91.
35 Rogers PJ. Using Programme Theory to Evaluate Complicated and Complex Aspects of Interventions. *http://dx.doi.org/101177/1356389007084674*. 2008;14:29–48.

Table 1. Relationship between process evaluation questions, explanatory data, data sources and outcomes

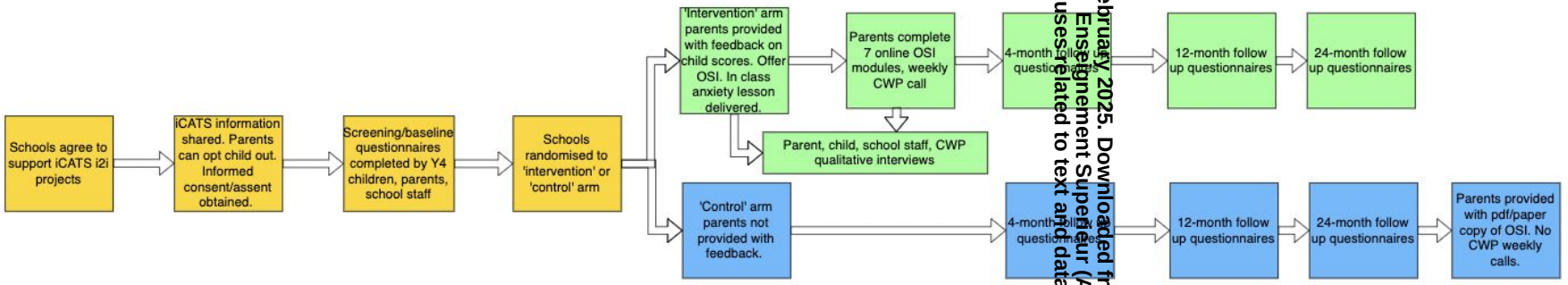
		Explanatory data				Key Questions					
Participants	**Mode of data collection**	**Data outcomes**	**Timepoint**	**Number/ frequency**	**Trial arm**	**Were the screening/intervention procedures implemented as intended or were adaptations needed?**	**Do the screening/intervention procedures reach children with anxiety problems?**	**Are the screening/intervention procedures acceptable?**	**How do the screening/intervention procedures produce change?**	**What barriers/facilitators to engagement with and delivery of the screening/intervention procedures exist?**	**What - if any - external factors impact screening/intervention engagement or delivery?**
Y4 children	Questionnaires	Completion of baseline measures	Baseline	Baseline (all Y4)	Both		X	X			
	Interview	Experience of being involved in the screening/intervention pathway, including anxiety lesson	After baseline, before 1 year follow up.	20 interviews	Intervention	X	X	X	X	X	X
Y4 parents	Questionnaires	Opt-out rates, completion of screening and baseline measures, screen positive rates	Baseline	Baseline (all Y4)	Both		X	X		X	X

	Interview	Experience of being involved in the screening/intervention pathway	After baseline, before 1 year follow up	20 interviews	Intervention	X	X	X	X	X	X
	Questionnaires	Bespoke acceptability questionnaire	4 month follow-up	4 month-follow-up for all parents who complete screening questionnaires	Intervention arm			X		X	
	OSI usage	Completion of online modules and online module activities, time spent on each module and number of times module pages are viewed	Throughout OSI delivery	Data collected for all parents who use OSI	Intervention	X	X	X			
	Questionnaire measures to guide future OSI developments	Session Rating Scale Module Feedback Questionnaire	8 online modules (Module 0 to Follow-up)	Data collected for all parents who use OSI	Intervention arm			X		X	
Y4 teachers & school staff	Questionnaires	Completion of baseline measures	Baseline	Baseline (for all Y4)	Both			X			

	Interview	Experience of being involved in the screening/intervention pathway	After baseline, before 1 year follow up	5 interviews	Intervention	X	X	X	X	X	X
CWPs/supervisors	Interview	Experience of delivering feedback and OSI to families	Throughout feedback and intervention delivery	5 interviews	Intervention	X		X	X	X	X
	CWP-parent contact time and supervision time	Completion of feedback and support calls, time spent on calls and supervision activities	Throughout feedback and intervention delivery	Data collected for all parents who use OSI	Interview	X	X	X		X	X
iCATS research team	Interview	Experience of delivering screening/intervention activities	After baseline, before 1 year follow up.	5 interviews	Both	X	X	X	X	X	X

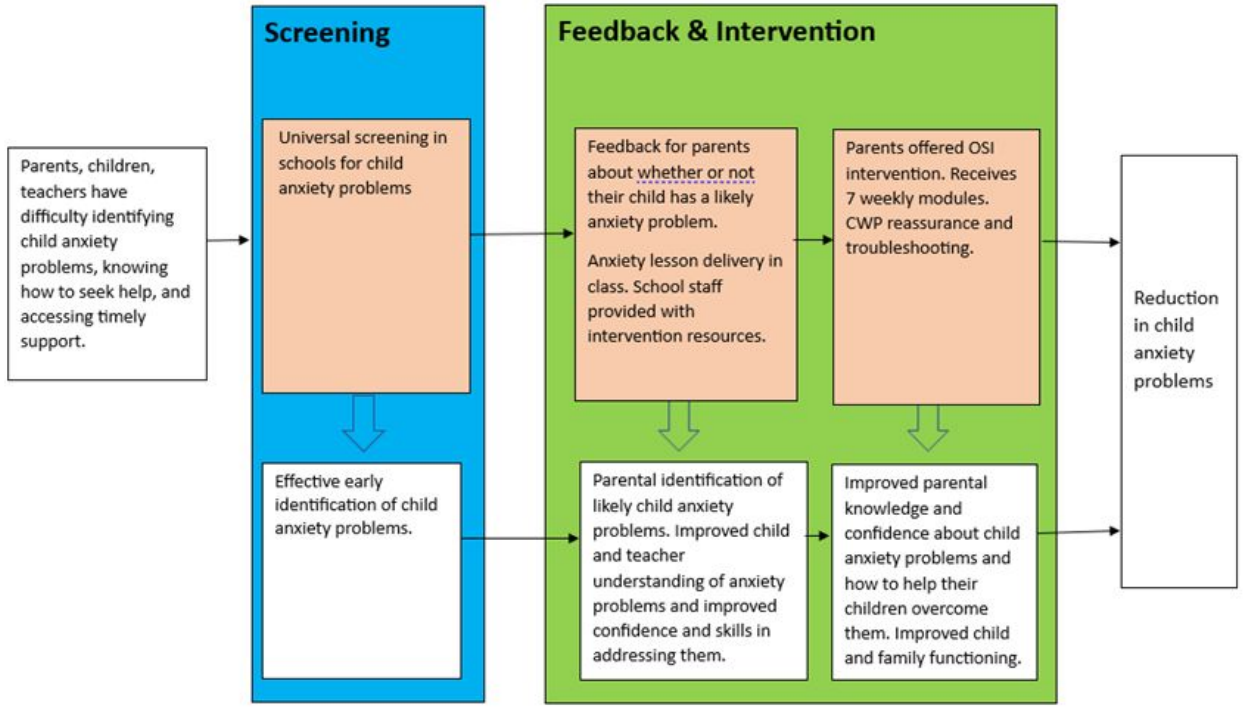
Note: Qualitative interviews (N=55) will be conducted during and after the intervention delivery period and will be completed prior to the 12-month follow-up. CWP = children's wellbeing practitioner. OSI = online support and intervention. Y4 = year four.

Figure 1. iCATS cluster RCT procedures



Note. Y4 = Year Four. OSI = Online Support and Intervention for Child Anxiety. CWP = Children's Wellbeing Practitioner. Qualitative interviews (conducted after baseline and before one year follow up) explore experiences of participation in the pathway, including screening and intervention.

Figure 2. iCATS i2i Simplified Logic Model.



Note. Screening/intervention activity is detailed in the orange boxes (top) and the mechanism of change is detailed in the white box (bottom). CWP = child wellbeing practitioner (NHS Band 5 psychological therapist).

Supplementary Material 1

Indicative guide for in-depth interviews with parents

Topics to explore in the interview

- How have you found taking part in the iCATS study so far?
  - Were there any issues or concerns you were hoping iCATS would help with?
  - Did you have any concerns or worries that made you hesitant to get involved?
  - Was there anything you think could have been done to encourage you/others to get involved?
- How did you get on with the initial questionnaires and consent forms?
  - Did you fill these in or did your child's other parent? Why was this?
  - Was there anything that you found difficult in filling in the questionnaires?
  - Was there anything that could've been made easier for you here?
  - How did you find accessing these online (or by paper)?
  - How did you feel about how your data was being managed/stored? What was important for you here?
  - How did you feel about taking part being opt out?
- How did your child get on with these questionnaires?
  - Did they do the questionnaire at home with you or at school? What did you think about this approach?
  - What do you think about this study looking at anxiety in Y4 as an age group?
- Was there anything you feel you or your child gained or learnt from filling in the questionnaires?
- How did you feel about your child's teacher also filling in a questionnaire about your child?
- How did you find the feedback about your responses to the questions about your child's fears and worries?
  - Did you have any concerns at this stage?
  - Was there any more information you would have liked to have had?
- Did the feedback you received on the questionnaires affect how you felt about doing the OSI intervention?
- How did you find accessing OSI?
  - What did you think about everything being online/remote?
  - How do you think this would compare to a F2F course?
  - When do you find time to work through OSI?
  - How did you decide which parent would do OSI?
  - How did you find doing the activities with your child?
- What impact do you think the activities have had on their fears and worries?
  - How do you feel about managing your child's difficulties with fears and worries having done OSI?
  - Has your knowledge or confidence in supporting your child changed following OSI?
  - Has there been any changes in your family life since taking up OSI?
  - Has doing OSI had any impact on your own wellbeing?
  - Have you become aware of any new sources of support as a result of being part of OSI?
- What did you think of the weekly phone calls?
  - How do you feel about the number or length of sessions?
  - How have you found the 1 month break?
    - OR How do you feel about there being a 1 month break?
  - How do you feel about your child's 'discharge' letter?
    - Will you share this with your child's school? Why or why not?
  - In an ideal world, is there any other support or help you would've liked to receive?
  - Could anything have been made easier for you/others to keep engaging with OSI?

- Have you spoken to or interacted with your child's school about iCATS?
    - What was this experience like?
    - Could anything have been improved here?
    - Do you think a parent-school conversation is needed? Or is this not necessary?
- Have you spoken with other people about iCATS?
    - Have you spoken to any parents who dropped out of or chose not to take part in iCATS? Do you know why they made this decision?
    - After finishing OSI do you think you will speak to other people about it?
- Is there anything we can do to make sure iCATS works well for other families in future?
- How would you describe your child's school culture or attitude towards mental health or anxiety?
    - Do you think iCATS may have any broader effects on your child's school or your community?
    - For those families who have a difficult relationship with their child's school, what impact on the parent-school do you think running iCATS may have?

Indicative guide for in-depth interviews with school staff

Topics to explore in the interview

- How have you found being part of the iCATS study so far?
- What made you and your school want to get involved?
    - Were there any particular motivators for your school to want to join in?
    - Are there any factors that made you or your school hesitant to take part?
    - Was there anything we could have done differently to encourage your school (or other schools) to get involved?
- What did you hope you/your pupils/your school would get out of taking part in iCATS?
- How did you get on with the initial questionnaires and consent forms?
    - What did you think about the number/length of questionnaires?
    - How did you find accessing these online?
    - Did you have dedicated time to fill them in?
    - Is there is anything you feel you learned from filling in the questionnaires?
    - How did you feel about how your data was managed/kept secure? What was important for you here?
    - Did filling in the questionnaires have any impact on your knowledge or confidence in supporting children in your class?
    - Was there anything that could've been made easier for you here?
- How did your pupils get on with their questionnaires?
    - Did they do the questionnaire at home or at school? What did you think about this approach?
    - Did they need any help to fill them in?
    - Was there anything that could have been done differently here?
- Do you know how any of your class's parents got on with filling in their initial questionnaires?
    - Did any parents have any difficulties accessing or filling them in?
    - Why may some parents have a tough time filling in the questionnaires?
    - Was there anything we could do to support parents better during this process?
- Did you see the feedback about pupils' scores?
    - Did you see the list of the pupils who screened 'positive'?
        - If no, why was this? Would you have liked to see it?
    - Were the outcomes what you were expecting?
    - Initially we planned for the school iCATS lead to give this feedback, how do you feel about the feedback coming from the research team instead?
    - Could anything have been done differently here?
- What did you think about the Y4 anxiety lesson?
    - Was there anything that was difficult to understand?
- Did taking part in iCATS and/or any of the information we have shared make any differences to how you feel you manage anxiety or other problems within the classroom? If so, in what way?
- Have you spoken to or interacted with your pupils or parents about their experience of iCATS?
    - What was this experience like?
    - Did you get asked any questions by pupils/parents? How did this go?
    - Did you speak with any parents/pupils who didn't want to take part or dropped out? What seemed to contribute towards this?
    - Did you speak to any parents that received the online intervention? How did they get on?
    - Did you speak to any parents that were offered OSI who didn't take it up? What have their experiences been?

- Have you spoken with other people about iCATS? (e.g. colleagues, your own friends/family). What have their reactions been?
- Have you had any situations or instances that stand out to you about how people have understood what we're doing with iCATS?
- What do you think about iCATS being for Y4 children? How does this fit with existing school procedures (e.g. exams in Y5)?
- How would you describe your school's culture or attitude towards child mental health or anxiety?
    - Do you think iCATS has had or may have any broader effects on your school or your community?
    - For those families who have a more difficult/strained relationship with their child's school, what impact do you think iCATS could have on that parent-school relationship?
- Is there anything we can do to make sure iCATS works well for other schools or families in future?

Indicative guide in-depth interviews with Y4 children

Topics to explore in the interview

- What did you think about the iCATS when iCATS was first talked about at your school?
- Was there any more information you would have liked to know about iCATS before joining in?
    - What did you think about filling in the questionnaire about your fears and worries?
    - Did you do the questionnaire at home or at school?
    - Did you do the questionnaire in big groups or small groups?
    - Did you learn anything from filling in the questionnaire?
    - Could anything have been done differently to make filling in the questionnaire easier for you?
- What did you think about the lesson on fears and worries?
    - What bits did you like about the lesson?
    - What bits did you not like?
    - What did you think about the strategies it explained for what to do when you are worried?
    - Have you used any of the strategies?
- What did you think about your parent(s) doing the course to help you with your fears and worries?
    - How did doing the iCATS activities with your parent(s) make you feel?
    - Were there any activities you found really fun?
    - Were any activities hard? Why do you think that was?
- How did you find using the Monster's Journey game?
- Did you speak to anyone (e.g. friends, family, teachers) about your parents doing the course to help you with your fears and worries?
    - What did you say? How did they respond?
    - If you didn't speak to anyone, why was this?
- Do you think your parents doing the lessons about your fears and worries had any impact on other members of your family or how your family gets along?
    - Why or why not?
- Is there any extra help for your fears or worries that you would have liked to have?
- Are there any other thoughts you have about the iCATS project that we should know?

Indicative guide for in-depth interviews with iCATS researchers

Topics to explore in the interview

- Have you been involved in any iCATS i2i school recruitment?
  - What has encouraged schools to get involved?
  - Are there any barriers to school's getting involved?
  - What sorts of questions or concerns do school's have before signing up?
- How have you found interacting with school staff?
  - What factors would you say make for an 'engaged' school?
  - What does an 'engaged' school look like?
  - What factors would you say make a school more difficult to interact or engage with?
  - What does a 'not engaged' school look like?
  - Can anything be done to improve school engagement? How?
- How have you found working with iCATS school leads?
  - How have you found working with school staff?
  - What questions/concerns do school staff typically have?
- How have you found interacting with iCATS parents?
  - What sorts of questions/concerns do parents usually have?
  - Have you spoken to any parents who dropped out of the study? What were their reasons?
- How have you found doing the questionnaire administration and data collection?
  - Did you send out and collect parent questionnaires?
    - Have you had to support any parents in filling these in?
    - What sort of support did parents need?
  - Did you go to schools and help administer child questionnaires?
    - What was this like?
    - What things are needed for this to go well?
  - Did you help any teachers to do their questionnaires?
    - What sort of support did they need?
- How did you find being part of the Y4 child anxiety lesson?
  - Did you help to deliver this in a school?
  - What factors are important in making the lesson go well?
  - What things can mean the lesson doesn't get delivered well?
  - Do you think running the anxiety lesson has any broader impacts in schools?
- Have you had any situations or instances that stand out to you about how people have understood what we're doing with iCATS?
- How would you describe the general climate/culture with regard to mental health in the schools that you visited?
- What do you think cuts through to schools most clearly, in terms of the appeal/advantages of iCATs?
  - What about to families?

Indicative guide for in-depth interviews with iCATS CWPs and clinical psychologists.

Topics to explore in the interview

- How have you found the feedback calls with parents/carers in in the iCATS-i2i trial?
    - How did the feedback we provided families on the questionnaire responses seem to affect how parents/carers felt about doing OSI?
    - Have parents/carers raised any concerns related to the feedback they received?
    - What are your thoughts on the feedback coming from the research team, rather than the school?
    - Have you had any calls with parents/carers who did not complete the initial questionnaires?
    - Could anything have been done differently in how we provide feedback to families and offer OSI?
    - Was there any more information parents/carers would have liked to have had?
    - Are there any changes you think could be made to how we share feedback with families/how we offer OSI?
- How have you found delivering [and/or supervising the delivery of] OSI?
- What did you think about everything being online/remotely?
    - Did the online/remote delivery present challenges for you? And for parents? How did you try to manage these challenges and what worked/worked less well and why?
    - Did the online/remote delivery bring any benefits for you? And for parents?
- What impact do you think OSI has had on children's fears and worries?
- What impact do you think OSI has had on other aspects of family life?
- From your experience of working with parents, do you think OSI and iCATS more generally has had any impacts on the environment within participating schools or classes?
- How do you feel about the structure of the OSI programme? E.g. the number and length of online modules, the number and length of support calls, the 1 month follow-up
- How do you find keeping to the OSI guidance when supporting families?
    - Are all calls with parents generally the same or do some differ?
    - How do you manage this?
- Have you had contact with school staff or other professionals about families who received OSI? How have you found that?
- Are there any changes you think that we need to make to OSI for future delivery through primary schools?

BMJ Open

Protocol for the process evaluation for a cluster randomised controlled trial evaluating primary school-based screening and intervention delivery for childhood anxiety problems

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-082691.R1
Article Type:	Protocol
Date Submitted by the Author:	10-Jun-2024
Complete List of Authors:	Williamson, Victoria; King's College London, Larkin, Michael; Aston University Reardon, Tessa; University of Oxford, Experimental Psychology Stallard, Paul; University of Bath, Department for Health Spence, Susan; Griffith University Macdonald, Ian; Charlie Waller Memorial Trust, ; The Open University, Ukoumunne, Obioha; University of Exeter Medical School, NIHR CLAHRC South West Peninsula (PenCLAHRC) Ford, Tamsin; University of Cambridge, Psychiatry Violato, Mara; Oxford University, UK, Health Economics Research Centre, Nuffield Department of Population Health Sniehotta, Falko F.; Newcastle University; Heidelberg University, Department of Public Health, Preventive and Social Medicine Stainer, Jason; Richmond School and Sixth Form College, Stanley Primary School, Strathmore Road, Teddington, Middlesex, TW11 8UH Gray, Alastair; University of Oxford, Nuffield Department of Population Health Brown, Paul; Bransgore Church of England Primary School, Bransgore C Of E Primary School, Ringwood Rd, Bransgore, Christchurch BH23 8JH Sancho, Michelle; West Berkshire Council, West Berkshire Council, Council Offices, Market St, Newbury RG14 5LD Jasper, Bec; Square Peg, Square Peg Taylor, Lucy; Oxford University, Experimental Psychology Creswell, Cathy; Oxford University Morgan, Fran; University of Oxford, Department of Experimental Psychology
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Qualitative research
Keywords:	Anxiety disorders < PSYCHIATRY, Child & adolescent psychiatry < PSYCHIATRY, QUALITATIVE RESEARCH

Protocol for the process evaluation for a cluster randomised controlled trial evaluating primary school-based screening and intervention delivery for childhood anxiety problems

Williamson, V.[a,b,c], Larkin, M.[d,] Tessa Reardon [a,], Paul Stallard, [e], Susan H. Spence, [f,], Ian Macdonald [g], Obioha C Ukoumunne [h], Tamsin Ford [i], Mara Violato [j], Falko F Sniehotta [k], Jason Stainer [n], Alastair Gray [j], Paul Brown [o], Michelle Sancho [p], Fran Morgan [m], Bec Jasper [l], Lucy Taylor [a], Cathy Creswell, [a].

[a] Department of Experimental Psychology, Anna Watts Building, University of Oxford, Oxford, OX2 6 GG.

[b] Department of Psychiatry, University of Oxford, Oxford OX3 7JX.

[c] Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, SE5 9RJ.

[d,] Institute for Health and Neurodevelopment, Aston University, Birmingham, B4 7ET.

[e] University of Bath, Claverton Down, Bath BA2 7AY

[f,]Australian Institute of Suicide Research and Prevention and School of Applied Psychology, Griffith University, Brisbane, QLD 4121, Australia.

[g] Charlie Waller Trust, 23 Kingfisher Court, Newbury, Berkshire RG14 5SJ.

[h] NIHR ARC South West Peninsula, University of Exeter, Heavitree Rd, Exeter EX1 2LU

[i] Department of Psychiatry, University of Cambridge

[j] Health Economics Research Centre, Nuffield Department of Population Health, University of Oxford.

[k] Division of Public Health, Social and Preventive Medicine, Centre for Preventive Medicine and Digital Health (CPD), Medical Faculty Mannheim, Heidelberg University.

[l] PACT Parents and Carers Together CIC, UK

[m] Square Peg (Team Square Peg CIC), UK

[n] Stanley Primary School, Strathmore Road, Teddington, Middlesex, TW11 8UH

[o] Bransgore C Of E Primary School, Ringwood Rd, Bransgore, Christchurch BH23 8JH

[p] West Berkshire Council, Council Offices, Market St, Newbury RG14 5LD

*Correspondence: Dr Michael Larkin, Department of Psychology, Institute for Health and Neurodevelopment, Aston University, Birmingham, B4 7ET, m.larkin@aston.ac.uk

.

Word count: 3839

Acknowledgements: We would like to thank those who participated in our patient and public involvement (PPI) activities for their contribution to this research. We also wish to thank our colleagues on the wider research team (especially Sue Ball) and advisory group (especially Paul Flowers) for their contributions.

Ethical approval: The study has received ethical approval from the University of Oxford CUREC (R66068_RE003).

Abstract

Introduction: Anxiety problems are prevalent in childhood and, without intervention, can persist into adulthood. Effective evidence-based interventions for childhood anxiety disorders exist, specifically cognitive behavioural therapy (CBT) in a range of formats. However, only a small proportion of children successfully access and receive treatment. Conducting mental health screening in schools and integrating evidence-based interventions for childhood anxiety problems may be an effective way to ensure support reaches children in need. The Identifying Child Anxiety Through Schools – Identification to Intervention (iCATS i2i) trial involves screening for childhood anxiety problems and offering a brief online parent-led CBT intervention. This paper presents the protocol for the process evaluation of the iCATS i2i trial which aims to examine the implementation and acceptability of the study procedures, the mechanisms of change and whether any external factors had an impact on procedure engagement or delivery.

Methods and analysis: This process evaluation will use both quantitative and qualitative methods to evaluate the implementation and acceptability of and barriers/facilitators to engagement and delivery of the iCATS screening/intervention procedures. Quantitative data sources will include opt-out and completion rates of baseline measures and usage analytics extracted from the online intervention platform. Qualitative interviews will be conducted with children, parents, school staff, iCATS i2i clinicians and researchers delivering study procedures. The Medical Research Council (MRC) framework for process evaluations will guide study design and analysis.

Ethics and dissemination: This study has received ethical approval from the University of Oxford Research Ethics Committee (R66068_RE003). Findings from the study will be disseminated via peer-reviewed publications in academic journals, conferences, digital and social media platforms and stakeholder meetings.

Trial registration number: ISRCTN registry ISRCTN76119074. Prospectively registered on 4.1.2022.

Keywords: anxiety, school, parent, child, intervention, process evaluation

Strengths and limitations

A strength of this study is the examination of acceptability and barriers/facilitators of iCATS i2i via mixed method data collection from children, parents, school staff, iCATS i2i researchers and clinicians.

A potential limitation is the majority of participants who opt-out or later drop-out of iCATS i2i procedures may not participate in interviews which could lead to a more positive overall evaluation of study procedures.

The intervention will be delivered by English-speaking practitioners which may unduly exclude participants who are not English speaking.

Introduction

Anxiety problems are among the most prevalent mental health problems in childhood and, without intervention, can often persist into adulthood [1]. Cognitive behavioural therapy (CBT) is an effective evidence-based intervention for childhood anxiety disorders [2]; however, only a very small proportion of children successfully access and receive treatment. For example, a recent study found that less than three percent of UK children with diagnoseable anxiety problems were able to access evidence-based treatments [3]. Effective and efficient treatments for child anxiety problems now exist, such as parent-led CBT, that can facilitate early access to support [4]. However, barriers to care are numerous [5], including a lack of help-seeking knowledge and stigma-related concerns [3,5], and pressures on Child and Adolescent Mental Health Services (CAMHS) which means that they are often unable to meet the demand for non-urgent care [6].

One promising way to address these barriers is to deliver interventions directly to parents through their children's schools (e.g. see [7]). While some universal schools-based interventions in schools show promise for some child outcomes (e.g. see [8]), there are indicators that when those interventions are intended to improve mental health specifically (e.g. see [9]) - rather than to improve indirect factors such as health literacy [10], help-seeking [11] or resilience [12] - a more targeted approach is likely to be required. One way to identify who interventions should target is through universal school-screening. This involves the administration of validated questionnaires to a year group (or entire school) to identify likely mental health problems [13]. The implementation and uptake of school screening programmes is often low [13,14]. Research has found that parents may be reluctant to engage with school-based mental health screening/intervention initiatives if they have

previously felt blamed by them for their child's difficulties, or if they felt their child's school had been unsupportive of their child's mental health in the past [15]. As such, prior to implementing a screening and intervention programme in schools, it is critical to establish whether the programme is acceptable; what barriers and facilitators to participation exist, whether any external factors impact delivery or engagement, and which adaptations are needed to ensure the programme results in effective delivery and engagement [16].

The iCATS i2i trial

Our proposed process evaluation is embedded within The Identifying Child Anxiety Through Schools – Identification to Intervention (iCATS i2i) trial. This trial has involved the development of a brief screening tool for child anxiety problems, a co-design phase of work to develop procedures for delivering universal screening and targeted intervention [17], a feasibility study [7], and a cluster randomised controlled trial (RCT) [18]. We include a brief summary of the cluster randomised controlled trial here to provide context to the process evaluation design.

In the main trial, participating schools (target 80 schools) from across England have been randomised in a 1:1 ratio into one of two arms: the iCATS-i2i (intervention) arm and the usual school practice (control) arm. Full details on the trial procedures, including school randomisation process can be found in [19,20].The screening/intervention procedures in the iCATS i2i intervention arm consist of four key stages (see Figure 1): i) parent-report screening questionnaires for child anxiety problems are administered for all Year 4 (Y4; aged 8-9 years) children; ii) screening questionnaires are scored by the research team to determine whether a child is likely to have anxiety problems; iii) feedback on questionnaire scores and likelihood of anxiety problems is provided to parents; iv) parents of children who screen

'positive' for likely anxiety problems are offered an online parent-led CBT intervention for child anxiety problems with telephone therapist support (OSI: Online Support and Intervention for Child Anxiety); all parents (regardless of screening outcome) are given the opportunity to request OSI. OSI consists of seven online modules for parents which are supported by a weekly telephone call with a Children's Wellbeing Practitioner (CWP, NHS Band 5), with a follow-up telephone call 4-weeks later [21]. OSI is only made available during the trial to families in the intervention arm. Families in the treatment arm of the trial who screen positive are actively offered treatment and those that screen negative can request treatment. Families in the usual school practice (control) arm do not receive feedback on questionnaire responses and are not offered OSI – instead they can access whatever support is available as part of their 'usual school practice,' as required. Usual school practice support for childhood anxiety varies somewhat across schools in the UK [3,5,22]. We will systematically collect data on what usual school practice entails for all participating schools.

Children in the intervention arm schools are also provided with a whole class interactive lesson which provides psycho-education and information about coping strategies (problem solving and help-seeking), and school staff are provided with information and resources about the OSI intervention.

For the purposes of the trial outcomes, participants are followed up at 4,12- and 24-months post-randomisation using standardised questionnaire measures for quantitative evaluation (see [18], for details).

For the purposes of the process evaluation, qualitative interviews are also conducted with children, parents, school staff, iCATS researchers and CWPs/supervisors (target 55

interviews in total) to explore their experiences of the screening process and intervention procedures.

[INSERT FIGURE 1 HERE]

.

MRC Guidelines

This process evaluation has been informed by the MRC advice on the process evaluation of complex interventions [23]. The MRC guidance highlights three evaluation components– implementation, mechanisms of impact, and context.

i) *Implementation:* An exploration of whether the intervention was delivered as intended (fidelity), the quantity of what was implemented (dose), and the 'reach' of the intervention', as well as identifying any adaptations made.

ii) *Mechanisms of impact*: An examination of the mechanisms through which an intervention brings about change by understanding how participants interact with the procedures.

iii) *Context*: An exploration of factors external to the intervention which may have affected the intervention's acceptability, engagement or delivery (e.g. home life for the family, school life for the child, comorbidities, COVID-19 social restrictions). MRC guidance suggests that researchers should relate contextual variations to *a priori* hypothesised causal mechanisms, or those arising from qualitative data analysis, to gain insights into context-mechanism-outcome patterns. In particular, this is likely to involve exploring differences between schools.

The iCATS i2i process evaluations aims and objectives.

Best practice in carrying out process evaluations is to outline the process evaluation methodology *a priori* [24]. Using MRC guidelines and previous protocols of process evaluations as a guide [25,26], we outline our methodological approach and detail the planned process evaluation for the iCATS i2i trial. We include key questions that we will explore in the process evaluation, which are organised under the headings Implementation and Acceptability, Mechanisms, and Context, to be broadly consistent with MRC guidelines [16,25]. While the MRC guidance for examining implementation often focuses on whether the intervention was delivered as intended in terms of fidelity, dose and reach [27,28] we will also focus on the acceptability of the implemented procedures given concerns about potential acceptability challenges identified in our previous iCATS i2i co-design work [17]. We intend that this process evaluation will contribute towards the development of a set of transferable principles regarding school-based screening and intervention for mental ill-health more broadly, which could be offered in schools in the future.

Specific questions that will be addressed by this process evaluation are:

1. Implementation and acceptability.

Key questions: Were the iCATS i2i screening/intervention procedures implemented as intended or were adaptations needed? Do the screening/intervention procedures reach children with anxiety problems? Are the screening/intervention procedures acceptable to schools and families? What is the variation in implementation and acceptability between schools and does variation relate to features of schools?

2. **Mechanisms.**

Key questions: How do the screening/intervention procedures produce change? What barriers/facilitators to engagement and delivery exist? How could these potentially be overcome?

3. **Context.**

Key questions: What - if any - external factors have an impact on iCATS i2i screening/intervention procedure engagement or delivery? Does context explain differences in outcomes or experiences between schools?

Method

Ethical approval and dissemination

The iCATS i2i RCT has received ethical approval from the University of Oxford CUREC (R66068_RE003). Participant information sheets are provided to all potentially eligible participants prior to participation. Parents are given the opportunity to opt their child out of the research. Prior to providing any data, written informed consent is obtained from parents, teachers, and qualitative interview participants, and children provide assent. Further information about trial procedures is available in full in the trial protocol [18]. We will disseminate the findings in a number of ways, including at national/international conferences, in academic publications and funder reports.

Patient and Public Involvement (PPI)

As detailed in our previous publications, the iCATS i2i procedures were co-designed in collaboration with extensive input from PPI [17,29].

Logic Model

The MRC guidance on the development and evaluation of complex interventions notes that a key part of a process evaluation is to outline the processes of the intervention

procedures and the outcomes it aims to attain using a logic model. The simplified logic model for the iCATSi2i screening/intervention procedures is shown in Figure 2. Data collection and sources, as well as how these will address our process evaluation aims can be found in Table 1 in Supplementary Material 1.

[INSERT FIGURE 2 HERE]

Overall design

This process evaluation will use a mixed methods design with purposively sampled qualitative data, supplemented by quantitative data from the trial, to strengthen our insights via triangulation. Quantitative data will include opt-out rates, completion rates for screening/baseline measures, feedback and support calls, and online modules, and time associated with OSI delivery (e.g. time spent on feedback/support calls, online modules). Responses to a bespoke parent-report acceptability questionnaire, and routine measures collected within OSI (Session Rating Scale and Module Feedback Questionnaire) will also be used to assess the acceptability of procedures.

Qualitative data will include semi-structured interviews conducted with children, parents, school staff, CWPs and research team members. Our intention is to create a comprehensive picture of families and schools' experiences of the screening/intervention pathway procedures.

Data collection procedure.

Table 1 (Supplementary Material 1) illustrates the mapping between data sources and the questions which our evaluation will address.

[INSERT TABLE 1 Supplementary Material 1 HERE]

Quantitative data collection

Quantitative data collection is detailed in full in the trial protocol [18]. Parents will have an opportunity to opt their child out of the research. When this does not happen, then parents, children and teachers will complete baseline questionnaires. For parents, the baseline assessment includes the 2-item child anxiety screening measure (iCATS-2) used in the screening/intervention procedures. School-level demographic information will be collected from publicly available information, and family-level demographic information will be collected from school records and parents.

CWPs and supervisors will complete activity logs to record completion and duration of feedback and OSI support calls, and supervision activities. OSI usage data (online module completion, completion of optional interactive activities within modules, time spent of module pages, number of times module pages are viewed) are collected within the OSI platform. Parents who use OSI complete measures built into each online module (including the Session Rating Scale and Module Feedback Questionnaire), and parents who complete screening questionnaires will be asked to complete a bespoke 7-item acceptability questionnaire to assess parent views of the procedures 4 months after randomisation.

Qualitative data collection

The qualitative design is framed as a multiple perspective study (e.g. see [30]), with interrelated sub-samples. Interviews will be conducted with sub-samples of parents (target N=20), children (target N=20) and school staff (target N=5) in the intervention arm, and with the CWPs and clinical psychologists facilitating the delivery of feedback and intervention (target N=5) and members of the research team who facilitated screening and data collection activities and delivered the anxiety lessons in schools (target N=5). This is a large total sample size for a qualitative study (total expected N=55) but it is necessary given the

evaluative focus, and the need for diversity in the larger sub-samples (parents, children). Interviews will be conducted during and after the feedback and intervention delivery period and will be completed prior to the 12-month follow-up. All interviews will be carried out by telephone or online video calling (Microsoft Teams) and audio-recorded.

Parent, child and school staff will be purposively sampled with the aim of collecting data from a diverse cohort to include varying views on the screening/intervention trial programme. This approach will include ensuring perspectives from a range of socio-economic, geographical location, gender and ethnicity backgrounds, and levels of interaction with OSI are included. We aim to collect interview data from families of children who screened 'positive,' screened 'negative', families who declined OSI, and families who dropped out of OSI. We also aim to speak to participants in schools with higher rates of eligibility for free school meals, pupils with English as an additional language, and parents opting out of the research. We anticipate that this sampling strategy will result in sufficient diversity to provide examples of both relatively poor and relatively good engagement with the iCATS i2i screening/intervention trial and allow for the identification of barriers and facilitators to implementation. School staff and parents who are participating in the ICATS i2i trial and who provided consent to take part in study interviews will be sent information about the opportunity to participate in interviews. Parents will be sent information about the opportunity for their child to take part in an interview.

Interview schedules will be informed by the research aims and existing literature on school-based screening/interventions for anxiety [14,17] (Supplementary Material 2). To answer our study aims, interview questions will focus on what features of the iCATS i2i screening/intervention procedures worked well; whether any adaptations to procedures were

needed; whether taking part was considered to be beneficial (or not) and why; whether any barriers to engagement or delivery were experienced; and if any external factors affected engagement/delivery.

Data Analysis

Quantitative data analysis. To assess reach and acceptability of procedures, we will investigate participation rates in each element of the screening/intervention procedures. This will include examining the number and proportion of 1) parent opt-outs, 2) completed screening questionnaires (parent-report iCATS-2), 3) screen positives (child scores 3-6 on parent-report iCATS-2) among all eligible year 4 children. The number and proportion of completed 4) feedback calls with a CWP, 5) online modules and support calls (separately for each module), and 6) core intervention content (first five modules) will be examined for both screen positives and all eligible year 4 children. We will also examine the number and proportion of completed baseline measures for eligible year 4 children (coded as yes, no, partial) for each reporter (parent, child, teacher). To further assess engagement with and delivery of OSI, descriptive statistics will be used to summarise the following among parents who start OSI: completion of optional questions/activities within online modules, time (minutes) spent on online modules, number of times online module pages are viewed, time (minutes) spent on support calls, CWP/clinical psychologist time (minutes) spent on associated administrative and supervision activities. Responses to the parent-report acceptability questionnaire, the Session Rating Scale and Module Feedback Questionnaire will also be summarised using descriptive statistics.

To explore factors that may influence engagement with the screening/intervention procedures, we will examine participation rates among schools with above/below average

proportion of pupils eligible for free school meals and above/below average proportion of pupils with English as an additional language, and examine school and family-level characteristics associated with completion of the OSI online modules, feedback and OSI support calls, core intervention content, time spent on online modules, number of times online module pages are viewed, time spent on support calls and associated administrative/supervision activities.

Qualitative data analysis.

Qualitative interviews will be transcribed verbatim, with identifying personal information removed on transcription. Transcripts will be checked against audio-recordings and then audio-recordings will be destroyed. Transcripts will be imported into Nvivo 12 to facilitate data management. Reporting of qualitative findings will follow the CORE-Q checklist [31].

A subset of the transcripts will be analysed separately first to create a coding template which will cover how the screening/intervention procedures are experienced in the context of participant's distinctive lives. This analysis will be used to develop a template framework. All transcripts will then be analysed against this framework using template analysis, with modifications to the template made after careful consideration of each transcript [32]. We expect the developed template will include: what aspects of the screening/intervention procedures were acceptable; if any adaptations to the pathway procedures were needed; barriers or facilitators to engagement and delivery; and whether any external factors impacted the engagement or delivery of the procedures.

Integration of data analysis

The qualitative and quantitative data will be analysed separately and then mixed during analysis for triangulation to provide a more complete picture as described below [33]. The quantitative and qualitative strands will play an equally significant role in addressing the process evaluation research questions. A triangulation protocol will be followed [34] involving:

i. Sorting findings from the qualitative and quantitative datasets into categories or 'meta-themes' that address the research questions to determine overlap and divergence.

ii. Comparing findings from the data sources using a convergence coding scheme to determine the degree and type of convergence within category or theme areas. Researchers will consider if there is agreement, partial agreement, silence or dissonance between findings from different datasets. 'Silence' is where a finding that arises from one dataset is not found in another and can help with the interpretation of the results and lead to further investigations [34].

iii. Reviewing all meta-themes to assess the level of convergence and where/when researchers have different perspectives of the findings.

iv. Multiple researchers (VW, TR, CC, ML) will examine the set of findings to clarify the interpretation and determine the level of agreement among researchers. Disagreements will be managed by re-examining the data as a group, with final decisions made by CC and ML.

The process evaluation data will be analysed independently from the main trial clinical and cost-effectiveness outcomes. The statisticians (OU, SB) and health economist (MV) conducting the main trial quantitative data analysis [18] will be unaware of the findings from the process evaluation until the primary and secondary clinical and health economic

outcomes have been analysed. The combined quantitative and qualitative data in the process evaluation is expected to help develop an in-depth understanding of the main trial outcomes.

Rigour and reliability

This process evaluation will be conducted by a team of experienced researchers with considerable expertise of both mixed methods and undertaking large-scale intervention trials for childhood anxiety disorders. Several steps will be taken to ensure a rigorous approach to data collection and analysis: (i) cluster (school) and purposive sampling will be conducted for qualitative interviews to ensure a broad and diverse sample and, thus, fair conceptual transferability; (ii) data collection and analysis will follow a systematic approach, including a range of both qualitative and quantitative data; (iii) researchers will reflect on their role and input in data generation and analysis; (iv) credibility checking will be conducted through reflective discussions with co-authors and a small expert reference group; (v) results will be triangulated across several sources of data; and (vi) 'sensitivity to context' will be considered by incorporating relevant literature and theory as well as examining differing perspectives and the context in which data and results have been generated [35].

Discussion

This article outlines the rationale, design and methodological approach for the mixed methods process evaluation of the iCATSi2i screening and intervention procedures for children with anxiety problems. The process evaluation is designed to examine whether the screening/intervention procedures are implemented as intended or if adaptions are needed; if procedures are acceptable to schools and families; how the screening/intervention procedures produce change; whether barriers/facilitators to engagement and delivery exist; and whether

any external factors impact procedure engagement or delivery. By detailing our process evaluation approach, as informed by the MRC guidelines [28] this article not only adds to the literature on process evaluation protocols with a mixed methods design but will also improve the integrity of our process evaluation and overall randomised controlled trial quality [24,36].

Strengths and challenges

It is anticipated that actively combining both qualitative and quantitative data in the process evaluation will help us to better understand and interpret the overall iCATS i2i trial outcome data. For example, by comprehensively examining whether the iCATS i2i screening/intervention procedures were adhered to and acceptable and the contexts surrounding that, this process evaluation will help determine both potential positive and negative aspects of the iCATS i2i procedures. If some negative outcomes are found from using the iCATS i2i screening/intervention procedures, the process evaluation will be a beneficial resource to determine whether a failure of procedure implementation occurred and if this was due to, for example, factors associated with participants' experiences or circumstances (e.g. lack of motivation or resources; beliefs about online interventions; etc). This could potentially help with future implementations of iCATS i2i, if indicated, and also help inform the development and implementation of wider school-based screening and intervention programmes aimed at supporting children with mental health problems.

Collecting data from a range of participants (i.e. children, parents, teachers, researchers, CWPs) using multiple methods will produce a nuanced understanding of the mechanisms contributing towards the experience of the iCATS i2i procedures. Including teachers, children and parent report measures may also provide data about the acceptability of carrying out such screening procedures which would be beneficial beyond the iCATS i2i

study and inform future screening/intervention trials. Moreover, the target sample size for qualitative interviews (N=55) and inclusive sampling approach (e.g. conducting interviews with screen 'positive' as well as 'negative' families, families who drop out of OSI, etc) is expected to be adequate to capture a range of perspectives, providing rich detailed data.

One potential limitation that may arise is that the majority of participants who opt-out or later drop out of the iCATS i2i procedures are more likely to decline to complete interviews which could lead to a more positive overall evaluation of the procedures. We will attempt to overcome this by making a concerted effort to recruit parents who drop out of or choose not to take up OSI or, if this is not possible, those who complete fewer OSI modules to interviews. Second, while we will be able to provide translated copies of the information sheets, OSI will be delivered by English-speaking CWPs for practical reasons, and this may unduly exclude parents who are not English speaking. Third, it is possible wider trial research activities influence engagement with the screening/intervention procedures in ways that would not apply if the procedures were to be implemented in practice. For example, the screening questionnaire is a 2-item parent-report measure, but in the trial parents, children and teachers also each complete a number of measures to assess secondary trial outcomes. In addition, the team of researchers with responsibility for conducting this process evaluation will also be involved in carrying out the trial procedures and some will be involved in conducting the trial outcome analysis. This integration will help facilitate data sharing but there is potential for bias in the interpretation of procedure functioning to arise. A reflective approach to data collection and analysis will be employed to improve the reliability and validity of the findings.

The iCATS i2i screening/intervention procedures are complex and involve a range of interrelated components and multiple stakeholders. There may be some differences in procedure implementation across schools and there is likely to be adaption to and learning from the procedures as delivery proceeds [37,38]. Moreover, given that schools and families are each unique and complex ecosystems where a community of individuals interact and co-exist, school and family contexts cannot be considered 'static'. We will need to recognise that the iCATS i2i procedures are being delivered within shifting environments and the rolling out of the iCATS i2i school screening/intervention procedures may also have some influence on the environment. There may be considerable challenges in monitoring and precisely assessing the various iCATS i2i procedure implementation processes, components and changing environments and how they relate to outcomes. It is hoped that by including 'adaptations' as a core aim in our process evaluation, that any necessary departures from study procedures are recognised and captured. Overall, this process evaluation is expected to further our understanding of the acceptability of screening/intervention procedures for child anxiety problems in a school context to inform future efforts to address child mental health problems.

Trial status

Recruitment of participants is ongoing.

Competing interests: TF's Department receives funds from her advisory role at Place2Be, a third sector organisation that provides mental health training and support to schools in the UK.

Contributor statement: All authors (ML, VM, TR, PS, SS, IM, OU, TF, MV, FS, JS, AG, PB, MS, BJ, LT, CC, FM) contributed towards the study design. All authors reviewed and approved the manuscript prior to submission.

Data sharing statement: No additional data are available

Funding: This paper represents independent research funded by the National Institute for Health Research (NIHR; PGfAR - RP-PG-0218-20010) (PI: CC) and hosted by Oxford Health NHS Foundation Trust. CC and MV acknowledge support from the Oxford and Thames Valley NIHR Applied Research Collaboration and the NIHR Oxford Health Biomedical Research Centre. OU was supported by the NIHR Applied Research Collaboration (ARC) for the South West Peninsula at the Royal Devon and Exeter NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

References

1 Pollard J, Reardon T, Williams C, *et al.* The multifaceted consequences and economic costs of child anxiety problems: A systematic review and meta-analysis. *JCPP Advances*. 2023;3:e12149.

2 James AC, Reardon T, Soler A, *et al.* Cognitive behavioural therapy for anxiety disorders in children and adolescents. *Cochrane Database of Systematic Reviews*. 2020;2020. doi: 10.1002/14651858.CD013162.PUB2/PDF/CDSR/CD013162/CD013162.PDF

3 Reardon T, Harvey K, Creswell C. Seeking and accessing professional support for child anxiety in a community sample. *Eur Child Adolesc Psychiatry*. 2020;29:649–64.

4 Creswell C, Chessell C, Halliday G. Parent-led cognitive behaviour therapy for child anxiety problems: overcoming challenges to increase access to effective treatment. *Behavioural and cognitive psychotherapy*. 2022;1–21.

5 Reardon T, Harvey K, Baranowska M, *et al.* What do parents perceive are the barriers and facilitators to accessing psychological treatment for mental health problems in children and adolescents? A systematic review of qualitative and quantitative studies. *Eur Child Adolesc Psychiatry*. 2017;26:623–47.

6 Children's mental health services 2021-2022 | Children's Commissioner for England. https://www.childrenscommissioner.gov.uk/resource/29751/ (accessed 28 November 2023)

7 Green I, Reardon T, Button R, *et al.* Increasing access to evidence-based treatment for child anxiety problems: online parent-led CBT for children identified via schools. *Child Adolesc Ment Health*. 2023;28:42–51.

8 Durlak JA, Mahoney JL, Boyle AE. What We Know, and What We Need to Find Out About Universal, School-Based Social and Emotional Learning Programs for Children and Adolescents: A Review of Meta-Analyses and Directions for Future Research. *Psychol Bull*. 2022;148:765–82.

9 Kuyken W, Ball S, Crane C, *et al.* Effectiveness of universal school-based mindfulness training compared with normal school provision on teacher mental health and school climate: results of the MYRIAD cluster randomised controlled trial. *BMJ Ment Health*. 2022;25:125–34.

10 Ma KKY, Anderson JK, Burn AM. Review: School-based interventions to improve mental health literacy and reduce mental health stigma – a systematic review. *Child Adolesc Ment Health*. 2023;28:230–40.

11 Hayes D, Mansfield R, Mason C, *et al.* The impact of universal, school based, interventions on help seeking in children and young people: a systematic literature review. *Eur Child Adolesc Psychiatry*. 2023;1:1–18.

12 Higgen S, Mösko M. Development and pilot evaluation of a universal intervention – Enhancing resilience in culturally and linguistically diverse primary school classrooms. *Int J Educ Res*. 2021;108:101757.

13 Burns JR, Rapee RM. Barriers to Universal Mental Health Screening in Schools: The Perspective of School Psychologists. *https://doi.org/101080/15377903202119414 70*. Published Online First: 2021. doi: 10.1080/15377903.2021.1941470

14 Anderson JK, Ford T, Soneson E, *et al.* A systematic review of effectiveness and cost-effectiveness of school-based identification of children and young people at risk of, or currently experiencing mental health difficulties. *Psychol Med*. 2019;49:9–19.

15 Williamson V, Larkin M, Reardon T, *et al.* Primary school-based screening for childhood mental health problems and intervention delivery: a qualitative study of parents in challenging circumstances. *Emotional and Behavioural Difficulties*. 2022;27:267–79.

16 Oakley A, Strange V, Bonell C, *et al.* Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 2006;332:413–6.

17 Williamson V, Larkin M, Reardon T, *et al.* School-based screening for childhood anxiety problems and intervention delivery: a codesign approach. *BMJ Open*. 2022;12:e058089.

18 Reardon T, Ukoumunne OC, Violato M, *et al.* Identifying Child Anxiety Through Schools-identification to intervention (iCATS-i2i): protocol for a cluster randomised controlled trial to compare screening, feedback and intervention for child anxiety problems to usual school practice. *Trials*. 2022;23. doi: 10.1186/S13063-022-06773-0

19 Ball S, Reardon T, Creswell C, *et al.* Statistical analysis plan for a cluster randomised controlled trial to compare screening, feedback and intervention for child anxiety problems to usual school practice: identifying Child Anxiety Through Schools-identification to intervention (iCATS-i2i). *Trials*. 2024;25. doi: 10.1186/S13063-023-07898-6

20 Reardon T, Ukoumunne OC, Violato M, *et al.* Identifying Child Anxiety Through Schools-identification to intervention (iCATS-i2i): protocol for a cluster randomised controlled trial to compare screening, feedback and intervention for child anxiety problems to usual school practice. *Trials*. 2022;23:1–19.

21 Hill C, Reardon T, Taylor L, *et al.* Online Support and Intervention for Child Anxiety (OSI): Development and Usability Testing. *JMIR Form Res*. 2022;6. doi: 10.2196/29846

22 Williamson V, Larkin M, MacDonald I, *et al.* Primary school based mental health practitioners' perspectives of school-based screening for childhood mental disorders and intervention delivery: A qualitative study. *Emotional and Behavioural Difficulties*. 2022;27. doi: 10.1080/13632752.2022.2110704

23 Moore G, Audrey S, Barker M, *et al.* Process evaluation of complex interventions. UK Medical Research Council (MRC) guidance. *Br Med J*. 2015.

24 Grant A, Treweek S, Dreischulte T, *et al.* Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials*. 2013;14. doi: 10.1186/1745-6215-14-15

25 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 2015;350. doi: 10.1136/BMJ.H1258

26 Hansford L, Sharkey S, Edwards V, *et al.* Understanding influences on teachers' uptake and use of behaviour management strategies within the STARS trial: Process evaluation protocol for a randomised controlled trial. *BMC Public Health*. 2015;15:1–8.

27 Skivington K, Matthews L, Simpson SA, *et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374. doi: 10.1136/BMJ.N2061

28 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ (Online)*. 2015;350. doi: 10.1136/bmj.h1258

29 Williamson V, Larkin M, Reardon T, *et al.* Codesign and development of a primary school based pathway for child anxiety screening and intervention delivery: a protocol, mixed-methods feasibility study. *BMJ Open*. 2021;11:e044852.

30 Larkin M, Shaw R, Flowers P. Multiperspectival designs and processes in interpretative phenomenological analysis research. *Qual Res Psychol*. 2019;16:182–98.
31 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007;19:349–57.
32 Brooks J, McCluskey S, Turley E, *et al.* The Utility of Template Analysis in Qualitative Psychology Research. *Qual Res Psychol*. 2015;12:202–22.
33 O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *BMJ*. 2010;341:1147–50.
34 Farmer T, Robinson K, Elliott SJ, *et al.* Developing and implementing a triangulation protocol for qualitative health research. *Qual Health Res*. 2006;16:377–94.
35 Yardley L. Dilemmas in qualitative health research. *Psychol Health*. 2000;15:215–28.
36 Lockwood I, Walker RM, Latimer S, *et al.* Process evaluations undertaken alongside randomised controlled trials in the hospital setting: A scoping review. *Contemp Clin Trials Commun*. 2022;26:100894.
37 Ling T. Evaluating complex and unfolding interventions in real time. *Evaluation*. 2012;18:79–91.
38 Rogers PJ. Using Programme Theory to Evaluate Complicated and Complex Aspects of Interventions. *http://dx.doi.org/101177/1356389007084674*. 2008;14:29–48.

Table 1. Relationship between process evaluation questions, explanatory data, data sources and outcomes

Note: Qualitative interviews (N=55) will be conducted during and after the intervention delivery period and will be completed prior to the 12-month follow-up. CWP = children's wellbeing practitioner. OSI = online support and intervention. Y4 = year four.

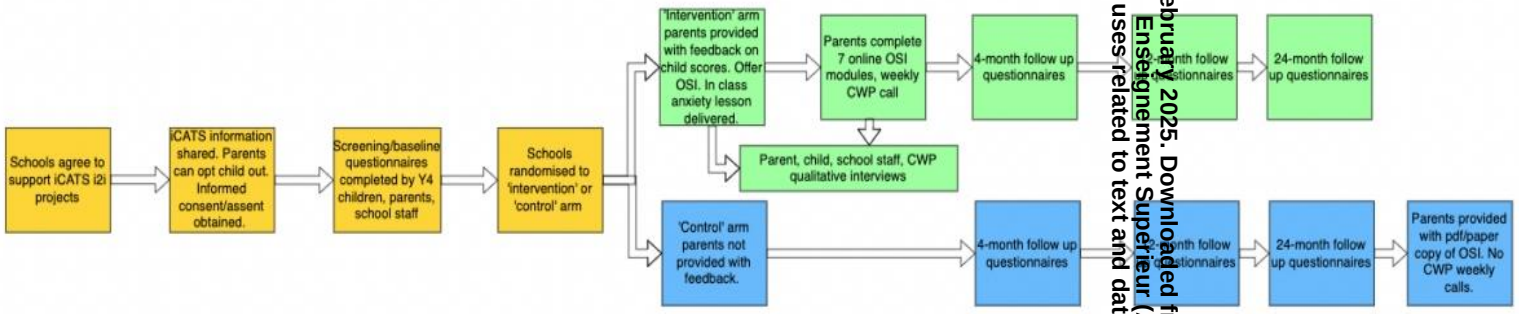
Figure 1.

Note. Y4 = Year Four. OSI = Online Support and Intervention for Child Anxiety. CWP = Children's Wellbeing Practitioner. Qualitative interviews (conducted after baseline and before one year follow up) explore experiences of participation in the pathway, including screening and intervention.

Figure 2

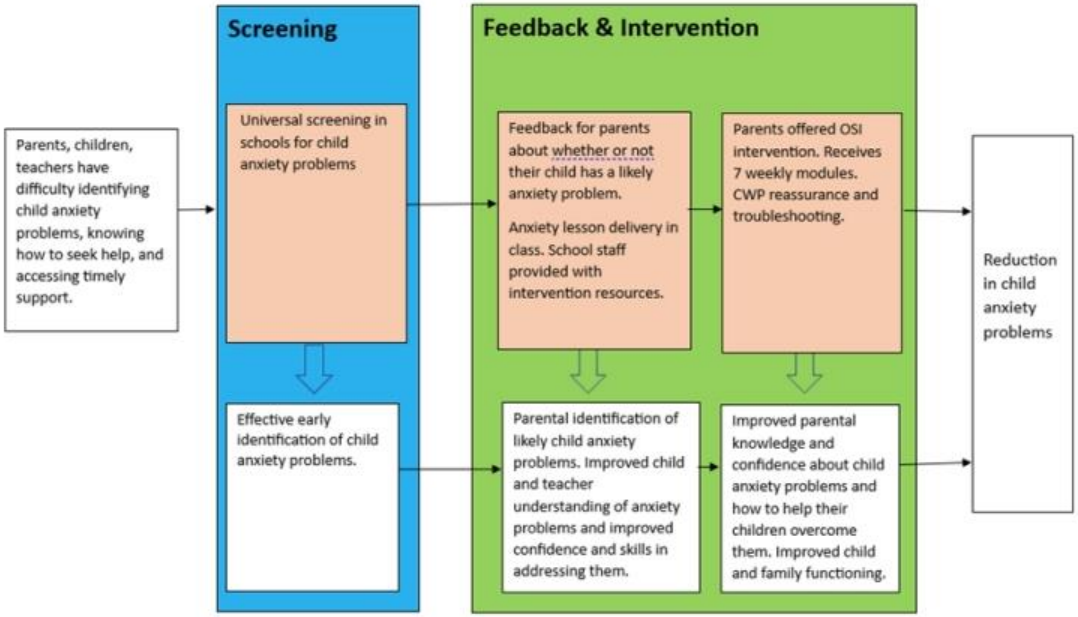
Note. Screening/intervention activity is detailed in the orange boxes (top) and the mechanism of change is detailed in the white box (bottom). CWP = child wellbeing practitioner (NHS Band 5 psychological therapist).

Figure 1. iCATS cluster RCT procedures



Note. Y4 = Year Four. OSI = Online Support and Intervention for Child Anxiety. CWP = Children's Wellbeing Practitioner. Qualitative interviews (conducted after baseline and before one year follow up) explore experiences of participation in the pathway, including screening and intervention.

Figure 2. iCATS i2i Simplified Logic Model.



Note. Screening/intervention activity is detailed in the orange boxes (top) and the mechanism of change is detailed in the white box (bottom). CWP = child wellbeing practitioner (NHS Band 5 psychological therapist).

Supplementary Material 2

Indicative guide for in-depth interviews with parents

Topics to explore in the interview

- How have you found taking part in the iCATS study so far?
  - Were there any issues or concerns you were hoping iCATS would help with?
  - Did you have any concerns or worries that made you hesitant to get involved?
  - Was there anything you think could have been done to encourage you/others to get involved?
- How did you get on with the initial questionnaires and consent forms?
  - Did you fill these in or did your child's other parent? Why was this?
  - Was there anything that you found difficult in filling in the questionnaires?
  - Was there anything that could've been made easier for you here?
  - How did you find accessing these online (or by paper)?
  - How did you feel about how your data was being managed/stored? What was important for you here?
  - How did you feel about taking part being opt out?
- How did your child get on with these questionnaires?
  - Did they do the questionnaire at home with you or at school? What did you think about this approach?
  - What do you think about this study looking at anxiety in Y4 as an age group?
- Was there anything you feel you or your child gained or learnt from filling in the questionnaires?
- How did you feel about your child's teacher also filling in a questionnaire about your child?
- How did you find the feedback about your responses to the questions about your child's fears and worries?
  - Did you have any concerns at this stage?
  - Was there any more information you would have liked to have had?

- Did the feedback you received on the questionnaires affect how you felt about doing the OSI intervention?
- How did you find accessing OSI?
  - What did you think about everything being online/remote?
  - How do you think this would compare to a F2F course?
  - When do you find time to work through OSI?
  - How did you decide which parent would do OSI?
  - How did you find doing the activities with your child?
- What impact do you think the activities have had on their fears and worries?
  - How do you feel about managing your child's difficulties with fears and worries having done OSI?
  - Has your knowledge or confidence in supporting your child changed following OSI?
  - Has there been any changes in your family life since taking up OSI?
  - Has doing OSI had any impact on your own wellbeing?
  - Have you become aware of any new sources of support as a result of being part of OSI?
- What did you think of the weekly phone calls?
  - How do you feel about the number or length of sessions?
  - How have you found the 1 month break?
    - OR How do you feel about there being a 1 month break?
  - How do you feel about your child's 'discharge' letter?
    - Will you share this with your child's school? Why or why not?
  - In an ideal world, is there any other support or help you would've liked to receive?
  - Could anything have been made easier for you/others to keep engaging with OSI?

- Have you spoken to or interacted with your child's school about iCATS?
    - What was this experience like?
    - Could anything have been improved here?
    - Do you think a parent-school conversation is needed? Or is this not necessary?
- Have you spoken with other people about iCATS?
    - Have you spoken to any parents who dropped out of or chose not to take part in iCATS? Do you know why they made this decision?
    - After finishing OSI do you think you will speak to other people about it?
- Is there anything we can do to make sure iCATS works well for other families in future?
- How would you describe your child's school culture or attitude towards mental health or anxiety?
    - Do you think iCATS may have any broader effects on your child's school or your community?
    - For those families who have a difficult relationship with their child's school, what impact on the parent-school do you think running iCATS may have?

Indicative guide for in-depth interviews with school staff

Topics to explore in the interview

- How have you found being part of the iCATS study so far?
- What made you and your school want to get involved?
  - Were there any particular motivators for your school to want to join in?
  - Are there any factors that made you or your school hesitant to take part?
  - Was there anything we could have done differently to encourage your school (or other schools) to get involved?
- What did you hope you/your pupils/your school would get out of taking part in iCATS?
- How did you get on with the initial questionnaires and consent forms?
  - What did you think about the number/length of questionnaires?
  - How did you find accessing these online?
  - Did you have dedicated time to fill them in?
  - Is there is anything you feel you learned from filling in the questionnaires?
  - How did you feel about how your data was managed/kept secure? What was important for you here?
  - Did filling in the questionnaires have any impact on your knowledge or confidence in supporting children in your class?
  - Was there anything that could've been made easier for you here?
- How did your pupils get on with their questionnaires?
  - Did they do the questionnaire at home or at school? What did you think about this approach?
  - Did they need any help to fill them in?
  - Was there anything that could have been done differently here?
- Do you know how any of your class's parents got on with filling in their initial questionnaires?
  - Did any parents have any difficulties accessing or filling them in?
  - Why may some parents have a tough time filling in the questionnaires?
  - Was there anything we could do to support parents better during this process?
- Did you see the feedback about pupils' scores?
  - Did you see the list of the pupils who screened 'positive'?
    - If no, why was this? Would you have liked to see it?
  - Were the outcomes what you were expecting?
  - Initially we planned for the school iCATS lead to give this feedback, how do you feel about the feedback coming from the research team instead?
  - Could anything have been done differently here?
- What did you think about the Y4 anxiety lesson?
  - Was there anything that was difficult to understand?
- Did taking part in iCATS and/or any of the information we have shared make any differences to how you feel you manage anxiety or other problems within the classroom? If so, in what way?
- Have you spoken to or interacted with your pupils or parents about their experience of iCATS?
  - What was this experience like?
  - Did you get asked any questions by pupils/parents? How did this go?
  - Did you speak with any parents/pupils who didn't want to take part or dropped out? What seemed to contribute towards this?
  - Did you speak to any parents that received the online intervention? How did they get on?
  - Did you speak to any parents that were offered OSI who didn't take it up? What have their experiences been?

- Have you spoken with other people about iCATS? (e.g. colleagues, your own friends/family). What have their reactions been?
- Have you had any situations or instances that stand out to you about how people have understood what we're doing with iCATS?
- What do you think about iCATS being for Y4 children? How does this fit with existing school procedures (e.g. exams in Y5)?
- How would you describe your school's culture or attitude towards child mental health or anxiety?
    - Do you think iCATS has had or may have any broader effects on your school or your community?
    - For those families who have a more difficult/strained relationship with their child's school, what impact do you think iCATS could have on that parent-school relationship?
- Is there anything we can do to make sure iCATS works well for other schools or families in future?

Indicative guide in-depth interviews with Y4 children

Topics to explore in the interview

- What did you think about the iCATS when iCATS was first talked about at your school?
- Was there any more information you would have liked to know about iCATS before joining in?
    - What did you think about filling in the questionnaire about your fears and worries?
    - Did you do the questionnaire at home or at school?
    - Did you do the questionnaire in big groups or small groups?
    - Did you learn anything from filling in the questionnaire?
    - Could anything have been done differently to make filling in the questionnaire easier for you?
- What did you think about the lesson on fears and worries?
    - What bits did you like about the lesson?
    - What bits did you not like?
    - What did you think about the strategies it explained for what to do when you are worried?
    - Have you used any of the strategies?
- What did you think about your parent(s) doing the course to help you with your fears and worries?
    - How did doing the iCATS activities with your parent(s) make you feel?
    - Were there any activities you found really fun?
    - Were any activities hard? Why do you think that was?
- How did you find using the Monster's Journey game?
- Did you speak to anyone (e.g. friends, family, teachers) about your parents doing the course to help you with your fears and worries?
    - What did you say? How did they respond?
    - If you didn't speak to anyone, why was this?
- Do you think your parents doing the lessons about your fears and worries had any impact on other members of your family or how your family gets along?
    - Why or why not?
- Is there any extra help for your fears or worries that you would have liked to have?
- Are there any other thoughts you have about the iCATS project that we should know?

Indicative guide for in-depth interviews with iCATS researchers

Topics to explore in the interview

- Have you been involved in any iCATS i2i school recruitment?
  - What has encouraged schools to get involved?
  - Are there any barriers to school's getting involved?
  - What sorts of questions or concerns do school's have before signing up?
- How have you found interacting with school staff?
  - What factors would you say make for an 'engaged' school?
  - What does an 'engaged' school look like?
  - What factors would you say make a school more difficult to interact or engage with?
  - What does a 'not engaged' school look like?
  - Can anything be done to improve school engagement? How?
- How have you found working with iCATS school leads?
  - How have you found working with school staff?
  - What questions/concerns do school staff typically have?
- How have you found interacting with iCATS parents?
  - What sorts of questions/concerns do parents usually have?
  - Have you spoken to any parents who dropped out of the study? What were their reasons?
- How have you found doing the questionnaire administration and data collection?
  - Did you send out and collect parent questionnaires?
    - Have you had to support any parents in filling these in?
    - What sort of support did parents need?
  - Did you go to schools and help administer child questionnaires?
    - What was this like?
    - What things are needed for this to go well?
  - Did you help any teachers to do their questionnaires?
    - What sort of support did they need?
- How did you find being part of the Y4 child anxiety lesson?
  - Did you help to deliver this in a school?
  - What factors are important in making the lesson go well?
  - What things can mean the lesson doesn't get delivered well?
  - Do you think running the anxiety lesson has any broader impacts in schools?
- Have you had any situations or instances that stand out to you about how people have understood what we're doing with iCATS?
- How would you describe the general climate/culture with regard to mental health in the schools that you visited?
- What do you think cuts through to schools most clearly, in terms of the appeal/advantages of iCATs?
  - What about to families?

Indicative guide for in-depth interviews with iCATS CWPs and clinical psychologists.

Topics to explore in the interview

- How have you found the feedback calls with parents/carers in in the iCATS-i2i trial?
    - How did the feedback we provided families on the questionnaire responses seem to affect how parents/carers felt about doing OSI?
    - Have parents/carers raised any concerns related to the feedback they received?
    - What are your thoughts on the feedback coming from the research team, rather than the school?
    - Have you had any calls with parents/carers who did not complete the initial questionnaires?
    - Could anything have been done differently in how we provide feedback to families and offer OSI?
    - Was there any more information parents/carers would have liked to have had?
    - Are there any changes you think could be made to how we share feedback with families/how we offer OSI?
- How have you found delivering [and/or supervising the delivery of] OSI?
- What did you think about everything being online/remotely?
    - Did the online/remote delivery present challenges for you? And for parents? How did you try to manage these challenges and what worked/worked less well and why?
    - Did the online/remote delivery bring any benefits for you? And for parents?
- What impact do you think OSI has had on children's fears and worries?
- What impact do you think OSI has had on other aspects of family life?
- From your experience of working with parents, do you think OSI and iCATS more generally has had any impacts on the environment within participating schools or classes?
- How do you feel about the structure of the OSI programme? E.g. the number and length of online modules, the number and length of support calls, the 1 month follow-up
- How do you find keeping to the OSI guidance when supporting families?
    - Are all calls with parents generally the same or do some differ?
    - How do you manage this?
- Have you had contact with school staff or other professionals about families who received OSI? How have you found that?
- Are there any changes you think that we need to make to OSI for future delivery through primary schools?

Supplementary Material 1, Table 1

		Explanatory data				Key Questions					
Participants	**Mode of data collection**	**Data outcomes**	**Timepoint**	**Number/ frequency**	**Trial arm**	**Were the screening/intervention procedures implemented as intended or were adaptations needed?**	**Do the screening/intervention procedures reach children with anxiety problems?**	**Are the screening/intervention procedures acceptable?**	**How do the screening/intervention procedures produce change?**	**What barriers/facilitators to engagement with and delivery of the screening/intervention procedures exist?**	**What - if any - external factors impact screening/intervention engagement or delivery?**
Y4 children	Questionnaires	Completion of baseline measures	Baseline	Baseline (all Y4)	Both		X	X			
	Interview	Experience of being involved in the screening/intervention pathway, including anxiety lesson	After baseline, before 1 year follow up.	20 interviews	Intervention	X	X	X	X	X	X
Y4 parents	Questionnaires	Opt-out rates, completion of screening and baseline measures, screen positive rates	Baseline	Baseline (all Y4)	Both		X	X		X	X
	Interview	Experience of being involved in the screening/intervention pathway	After baseline, before 1 year follow up	20 interviews	Intervention	X	X	X	X	X	X
	Questionnaires	Bespoke acceptability questionnaire	4 month follow-up	4 month-follow-up for all parents who complete screening questionnaires	Intervention arm			X		X	
	OSI usage	Completion of online modules and online module activities, time spent on each module and number of times	Throughout OSI delivery	Data collected for all parents who use OSI	Intervention	X	X	X			

		module pages are viewed									
	Questionnaire measures to guide future OSI developments	Session Rating Scale Module Feedback Questionnaire	8 online modules (Module 0 to Follow-up)	Data collected for all parents who use OSI	Intervention arm			X		X	
Y4 teachers & school staff	Questionnaires	Completion of baseline measures	Baseline	Baseline (for all Y4)	Both			X			
	Interview	Experience of being involved in the screening/intervention pathway	After baseline, before 1 year follow up	5 interviews	Intervention	X	X	X	X	X	X
CWPs/supervisors	Interview	Experience of delivering feedback and OSI to families	Throughout feedback and intervention delivery	5 interviews	Intervention	X		X	X	X	X
	CWP-parent contact time and supervision time	Completion of feedback and support calls, time spent on calls and supervision activities	Throughout feedback and intervention delivery	Data collected for all parents who use OSI	Interview	X	X	X		X	X
iCATS research team	Interview	Experience of delivering screening/intervention activities	After baseline, before 1 year follow up.	5 interviews	Both	X	X	X	X	X	X

Table 1. Relationship between process evaluation questions, explanatory data, data sources and outcomes

Note: Qualitative interviews (N=55) will be conducted during and after the intervention delivery period and will be completed prior to the 12-month follow-up. CWP = children's wellbeing practitioner. OSI = online support and intervention. Y4 = year four.

BMJ Open

Protocol for the process evaluation for a cluster randomised controlled trial evaluating primary school-based screening and intervention delivery for childhood anxiety problems

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-082691.R2
Article Type:	Protocol
Date Submitted by the Author:	26-Jul-2024
Complete List of Authors:	Williamson, Victoria; King's College London, Larkin, Michael; Aston University Reardon, Tessa; University of Oxford, Experimental Psychology Stallard, Paul; University of Bath, Department for Health Spence, Susan; Griffith University Macdonald, Ian; Charlie Waller Memorial Trust, ; The Open University, Ukoumunne, Obioha; University of Exeter Medical School, NIHR CLAHRC South West Peninsula (PenCLAHRC) Ford, Tamsin; University of Cambridge, Psychiatry Violato, Mara; Oxford University, UK, Health Economics Research Centre, Nuffield Department of Population Health Sniehotta, Falko F.; Newcastle University; Heidelberg University, Department of Public Health, Preventive and Social Medicine Stainer, Jason; Richmond School and Sixth Form College, Stanley Primary School, Strathmore Road, Teddington, Middlesex, TW11 8UH Gray, Alastair; University of Oxford, Nuffield Department of Population Health Brown, Paul; Bransgore Church of England Primary School, Bransgore C Of E Primary School, Ringwood Rd, Bransgore, Christchurch BH23 8JH Sancho, Michelle; West Berkshire Council, West Berkshire Council, Council Offices, Market St, Newbury RG14 5LD Jasper, Bec; Square Peg, Square Peg Taylor, Lucy; Oxford University, Experimental Psychology Creswell, Cathy; Oxford University Morgan, Fran; University of Oxford, Department of Experimental Psychology
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Qualitative research
Keywords:	Anxiety disorders < PSYCHIATRY, Child & adolescent psychiatry < PSYCHIATRY, QUALITATIVE RESEARCH

Protocol for the process evaluation for a cluster randomised controlled trial evaluating primary school-based screening and intervention delivery for childhood anxiety problems

Williamson, V.[a,b,c], Larkin, M.[d,] Tessa Reardon [a,], Paul Stallard, [e], Susan H. Spence, [f,], Ian Macdonald [g], Obioha C Ukoumunne [h], Tamsin Ford [i], Mara Violato [j], Falko F Sniehotta [k], Jason Stainer [n], Alastair Gray [j], Paul Brown [o], Michelle Sancho [p], Fran Morgan [m], Bec Jasper [l], Lucy Taylor [a], Cathy Creswell, [a].

[a] Department of Experimental Psychology, Anna Watts Building, University of Oxford, Oxford, OX2 6 GG.

[b] Department of Psychiatry, University of Oxford, Oxford OX3 7JX.

[c] Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, SE5 9RJ.

[d,] Institute for Health and Neurodevelopment, Aston University, Birmingham, B4 7ET.

[e] University of Bath, Claverton Down, Bath BA2 7AY

[f,]Australian Institute of Suicide Research and Prevention and School of Applied Psychology, Griffith University, Brisbane, QLD 4121, Australia.

[g] Charlie Waller Trust, 23 Kingfisher Court, Newbury, Berkshire RG14 5SJ.

[h] NIHR ARC South West Peninsula, University of Exeter, Heavitree Rd, Exeter EX1 2LU

[i] Department of Psychiatry, University of Cambridge

[j] Health Economics Research Centre, Nuffield Department of Population Health, University of Oxford.

[k] Division of Public Health, Social and Preventive Medicine, Centre for Preventive Medicine and Digital Health (CPD), Medical Faculty Mannheim, Heidelberg University.

[l] PACT Parents and Carers Together CIC, UK

[m] Square Peg (Team Square Peg CIC), UK

[n] Stanley Primary School, Strathmore Road, Teddington, Middlesex, TW11 8UH

[o] Bransgore C Of E Primary School, Ringwood Rd, Bransgore, Christchurch BH23 8JH

[p] West Berkshire Council, Council Offices, Market St, Newbury RG14 5LD

*Correspondence: Dr Michael Larkin, Department of Psychology, Institute for Health and Neurodevelopment, Aston University, Birmingham, B4 7ET, m.larkin@aston.ac.uk

.

Word count: 3839

Abstract

Introduction: Anxiety problems are prevalent in childhood and, without intervention, can persist into adulthood. Effective evidence-based interventions for childhood anxiety disorders exist, specifically cognitive behavioural therapy (CBT) in a range of formats. However, only a small proportion of children successfully access and receive treatment. Conducting mental health screening in schools and integrating evidence-based interventions for childhood anxiety problems may be an effective way to ensure support reaches children in need. The Identifying Child Anxiety Through Schools – Identification to Intervention (iCATS i2i) trial involves screening for childhood anxiety problems and offering a brief online parent-led CBT intervention. This paper presents the protocol for the process evaluation of the iCATS i2i trial which aims to examine the implementation and acceptability of the study procedures, the mechanisms of change and whether any external factors had an impact on procedure engagement or delivery.

Methods and analysis: This process evaluation will use both quantitative and qualitative methods to evaluate the implementation and acceptability of and barriers/facilitators to engagement and delivery of the iCATS screening/intervention procedures. Quantitative data sources will include opt-out and completion rates of baseline measures and usage analytics extracted from the online intervention platform. Qualitative interviews will be conducted with children, parents, school staff, iCATS i2i clinicians and researchers delivering study procedures. The Medical Research Council (MRC) framework for process evaluations will guide study design and analysis.

Ethics and dissemination: This study has received ethical approval from the University of Oxford Research Ethics Committee (R66068_RE003). Findings from the study will be disseminated via peer-reviewed publications in academic journals, conferences, digital and social media platforms and stakeholder meetings.

Trial registration number: ISRCTN registry ISRCTN76119074. Prospectively registered on 4.1.2022.

Keywords: anxiety, school, parent, child, intervention, process evaluation

Strengths and limitations

A strength of this study is the examination of acceptability and barriers/facilitators of iCATS i2i via mixed method data collection from children, parents, school staff, iCATS i2i researchers and clinicians.

A potential limitation is the majority of participants who opt-out or later drop-out of iCATS i2i procedures may not participate in interviews which could lead to a more positive overall evaluation of study procedures.

The intervention will be delivered by English-speaking practitioners which may unduly exclude participants who are not English speaking.

Introduction

Anxiety problems are among the most prevalent mental health problems in childhood and, without intervention, can often persist into adulthood [1]. Cognitive behavioural therapy (CBT) is an effective evidence-based intervention for childhood anxiety disorders [2]; however, only a very small proportion of children successfully access and receive treatment. For example, a recent study found that less than three percent of UK children with diagnoseable anxiety problems were able to access evidence-based treatments [3]. Effective and efficient treatments for child anxiety problems now exist, such as parent-led CBT, that can facilitate early access to support [4]. However, barriers to care are numerous [5], including a lack of help-seeking knowledge and stigma-related concerns [3,5], and pressures on Child and Adolescent Mental Health Services (CAMHS) which means that they are often unable to meet the demand for non-urgent care [6].

One promising way to address these barriers is to deliver interventions directly to parents through their children's schools (e.g. see [7]). While some universal schools-based interventions in schools show promise for some child outcomes (e.g. see [8]), there are indicators that when those interventions are intended to improve mental health specifically (e.g. see [9]) - rather than to improve indirect factors such as health literacy [10], help-seeking [11] or resilience [12] - a more targeted approach is likely to be required. One way to identify who interventions should target is through universal school-screening. This involves the administration of validated questionnaires to a year group (or entire school) to identify likely mental health problems [13]. The implementation and uptake of school screening programmes is often low [13,14]. Research has found that parents may be reluctant to engage with school-based mental health screening/intervention initiatives if they have

previously felt blamed by them for their child's difficulties, or if they felt their child's school had been unsupportive of their child's mental health in the past [15]. As such, prior to implementing a screening and intervention programme in schools, it is critical to establish whether the programme is acceptable; what barriers and facilitators to participation exist, whether any external factors impact delivery or engagement, and which adaptations are needed to ensure the programme results in effective delivery and engagement [16].

The iCATS i2i trial

Our proposed process evaluation is embedded within The Identifying Child Anxiety Through Schools – Identification to Intervention (iCATS i2i) trial. This trial has involved the development of a brief screening tool for child anxiety problems, a co-design phase of work to develop procedures for delivering universal screening and targeted intervention [17], a feasibility study [7], and a cluster randomised controlled trial (RCT) [18]. We include a brief summary of the cluster randomised controlled trial here to provide context to the process evaluation design.

In the main trial, participating schools (target 80 schools) from across England have been randomised in a 1:1 ratio into one of two arms: the iCATS-i2i (intervention) arm and the usual school practice (control) arm. Full details on the trial procedures, including school randomisation process can be found in [19,20].The screening/intervention procedures in the iCATS i2i intervention arm consist of four key stages (see Figure 1): i) parent-report screening questionnaires for child anxiety problems are administered for all Year 4 (Y4; aged 8-9 years) children; ii) screening questionnaires are scored by the research team to determine whether a child is likely to have anxiety problems; iii) feedback on questionnaire scores and likelihood of anxiety problems is provided to parents; iv) parents of children who screen

'positive' for likely anxiety problems are offered an online parent-led CBT intervention for child anxiety problems with telephone therapist support (OSI: Online Support and Intervention for Child Anxiety); all parents (regardless of screening outcome) are given the opportunity to request OSI. OSI consists of seven online modules for parents which are supported by a weekly telephone call with a Children's Wellbeing Practitioner (CWP, NHS Band 5), with a follow-up telephone call 4-weeks later [21]. OSI is only made available during the iCATS i2i trial to families in the intervention arm. Families in the treatment arm of the iCATS i2i trial who screen positive are actively offered treatment and those that screen negative can request the OSI treatment. Families in the usual school practice (control) arm do not receive feedback on questionnaire responses and are not offered OSI treatment – instead they can access whatever support is available as part of their 'usual school practice,' as required. Usual school practice support for childhood anxiety varies somewhat across schools in the UK [3,5,22]. We will systematically collect data on what usual school practice entails for all participating schools.

Children in the intervention arm schools are also provided with a whole class interactive lesson which provides psycho-education and information about coping strategies (problem solving and help-seeking), and school staff are provided with information and resources about the OSI intervention.

For the purposes of the trial outcomes, participants are followed up at 4,12- and 24-months post-randomisation using standardised questionnaire measures for quantitative evaluation (see [18], for details).

For the purposes of the process evaluation, qualitative interviews are also conducted with children, parents, school staff, iCATS researchers and CWPs/supervisors (target 55

interviews in total) to explore their experiences of the screening process and intervention procedures.

[INSERT FIGURE 1 HERE]

.

MRC Guidelines

This process evaluation has been informed by the MRC advice on the process evaluation of complex interventions [23]. The MRC guidance highlights three evaluation components– implementation, mechanisms of impact, and context.

i) *Implementation:* An exploration of whether the intervention was delivered as intended (fidelity), the quantity of what was implemented (dose), and the 'reach' of the intervention', as well as identifying any adaptations made.

ii) *Mechanisms of impact*: An examination of the mechanisms through which an intervention brings about change by understanding how participants interact with the procedures.

iii) *Context*: An exploration of factors external to the intervention which may have affected the intervention's acceptability, engagement or delivery (e.g. home life for the family, school life for the child, comorbidities, COVID-19 social restrictions). MRC guidance suggests that researchers should relate contextual variations to *a priori* hypothesised causal mechanisms, or those arising from qualitative data analysis, to gain insights into context-mechanism-outcome patterns. In particular, this is likely to involve exploring differences between schools.

The iCATS i2i process evaluations aims and objectives.

Best practice in carrying out process evaluations is to outline the process evaluation methodology *a priori* [24]. Using MRC guidelines and previous protocols of process evaluations as a guide [25,26], we outline our methodological approach and detail the planned process evaluation for the iCATS i2i trial. We include key questions that we will explore in the process evaluation, which are organised under the headings Implementation and Acceptability, Mechanisms, and Context, to be broadly consistent with MRC guidelines [16,25]. While the MRC guidance for examining implementation often focuses on whether the intervention was delivered as intended in terms of fidelity, dose and reach [27,28] we will also focus on the acceptability of the implemented procedures given concerns about potential acceptability challenges identified in our previous iCATS i2i co-design work [17]. We intend that this process evaluation will contribute towards the development of a set of transferable principles regarding school-based screening and intervention for mental ill-health more broadly, which could be offered in schools in the future.

Specific questions that will be addressed by this process evaluation are:

1. Implementation and acceptability.

Key questions: Were the iCATS i2i screening/intervention procedures implemented as intended or were adaptations needed? Do the screening/intervention procedures reach children with anxiety problems? Are the screening/intervention procedures acceptable to schools and families? What is the variation in implementation and acceptability between schools and does variation relate to features of schools?

2. **Mechanisms.**

Key questions: How do the screening/intervention procedures produce change? What barriers/facilitators to engagement and delivery exist? How could these potentially be overcome?

3. **Context.**

Key questions: What - if any - external factors have an impact on iCATS i2i screening/intervention procedure engagement or delivery? Does context explain differences in outcomes or experiences between schools?

Method

Ethical approval and dissemination

The iCATS i2i RCT has received ethical approval from the University of Oxford CUREC (R66068_RE003). Participant information sheets are provided to all potentially eligible participants prior to participation. Parents are given the opportunity to opt their child out of the research. Prior to providing any data, written informed consent is obtained from parents, teachers, and qualitative interview participants, and children provide assent. Further information about trial procedures is available in full in the trial protocol [18]. We will disseminate the findings in a number of ways, including at national/international conferences, in academic publications and funder reports.

Patient and Public Involvement (PPI)

As detailed in our previous publications, the iCATS i2i procedures were co-designed in collaboration with extensive input from PPI [17,29].

Logic Model

The MRC guidance on the development and evaluation of complex interventions notes that a key part of a process evaluation is to outline the processes of the intervention

procedures and the outcomes it aims to attain using a logic model. The simplified logic model for the iCATSi2i screening/intervention procedures is shown in Figure 1. Data collection and sources, as well as how these will address our process evaluation aims can be found in Supplementary Table 1.

Overall design

This process evaluation will use a mixed methods design with purposively sampled qualitative data, supplemented by quantitative data from the trial, to strengthen our insights via triangulation. Quantitative data will include opt-out rates, completion rates for screening/baseline measures, feedback and support calls, and online modules, and time associated with OSI delivery (e.g. time spent on feedback/support calls, online modules). Responses to a bespoke parent-report acceptability questionnaire, and routine measures collected within OSI (Session Rating Scale and Module Feedback Questionnaire) will also be used to assess the acceptability of procedures.

Qualitative data will include semi-structured interviews conducted with children, parents, school staff, CWPs and research team members. Our intention is to create a comprehensive picture of families and schools' experiences of the screening/intervention pathway procedures.

Data collection procedure.

Supplementary Table 1 illustrates the mapping between data sources and the questions which our evaluation will address.

Quantitative data collection

Quantitative data collection is detailed in full in the trial protocol [18]. Parents will have an opportunity to opt their child out of the research. When this does not happen, then

parents, children and teachers will complete baseline questionnaires. For parents, the baseline assessment includes the 2-item child anxiety screening measure (iCATS-2) used in the screening/intervention procedures. School-level demographic information will be collected from publicly available information, and family-level demographic information will be collected from school records and parents.

CWPs and supervisors will complete activity logs to record completion and duration of feedback and OSI support calls, and supervision activities. OSI usage data (online module completion, completion of optional interactive activities within modules, time spent of module pages, number of times module pages are viewed) are collected within the OSI platform. Parents who use OSI complete measures built into each online module (including the Session Rating Scale and Module Feedback Questionnaire), and parents who complete screening questionnaires will be asked to complete a bespoke 7-item acceptability questionnaire to assess parent views of the procedures 4 months after randomisation.

Qualitative data collection

The qualitative design is framed as a multiple perspective study (e.g. see [30]), with interrelated sub-samples. Interviews will be conducted with sub-samples of parents (target N=20), children (target N=20) and school staff (target N=5) in the intervention arm, and with the CWPs and clinical psychologists facilitating the delivery of feedback and intervention (target N=5) and members of the research team who facilitated screening and data collection activities and delivered the anxiety lessons in schools (target N=5). This is a large total sample size for a qualitative study (total expected N=55) but it is necessary given the evaluative focus, and the need for diversity in the larger sub-samples (parents, children). Interviews will be conducted during and after the feedback and intervention delivery period

and will be completed prior to the 12-month follow-up. All interviews will be carried out by telephone or online video calling (Microsoft Teams) and audio-recorded.

Parent, child and school staff will be purposively sampled with the aim of collecting data from a diverse cohort to include varying views on the screening/intervention trial programme. This approach will include ensuring perspectives from a range of socio-economic, geographical location, gender and ethnicity backgrounds, and levels of interaction with OSI are included. We aim to collect interview data from families of children who screened 'positive,' screened 'negative', families who declined OSI, and families who dropped out of OSI. We also aim to speak to participants in schools with higher rates of eligibility for free school meals, pupils with English as an additional language, and parents opting out of the research. We anticipate that this sampling strategy will result in sufficient diversity to provide examples of both relatively poor and relatively good engagement with the iCATS i2i screening/intervention trial and allow for the identification of barriers and facilitators to implementation. School staff and parents who are participating in the ICATS i2i trial and who provided consent to take part in study interviews will be sent information about the opportunity to participate in interviews. Parents will be sent information about the opportunity for their child to take part in an interview.

Interview schedules will be informed by the research aims and existing literature on school-based screening/interventions for anxiety [14,17] (Supplementary Material 1). To answer our study aims, interview questions will focus on what features of the iCATS i2i screening/intervention procedures worked well; whether any adaptations to procedures were needed; whether taking part was considered to be beneficial (or not) and why; whether any

barriers to engagement or delivery were experienced; and if any external factors affected engagement/delivery.

Data Analysis

Quantitative data analysis. To assess reach and acceptability of procedures, we will investigate participation rates in each element of the screening/intervention procedures. This will include examining the number and proportion of 1) parent opt-outs, 2) completed screening questionnaires (parent-report iCATS-2), 3) screen positives (child scores 3-6 on parent-report iCATS-2) among all eligible year 4 children. The number and proportion of completed 4) feedback calls with a CWP, 5) online modules and support calls (separately for each module), and 6) core intervention content (first five modules) will be examined for both screen positives and all eligible year 4 children. We will also examine the number and proportion of completed baseline measures for eligible year 4 children (coded as yes, no, partial) for each reporter (parent, child, teacher). To further assess engagement with and delivery of OSI, descriptive statistics will be used to summarise the following among parents who start OSI: completion of optional questions/activities within online modules, time (minutes) spent on online modules, number of times online module pages are viewed, time (minutes) spent on support calls, CWP/clinical psychologist time (minutes) spent on associated administrative and supervision activities. Responses to the parent-report acceptability questionnaire, the Session Rating Scale and Module Feedback Questionnaire will also be summarised using descriptive statistics.

To explore factors that may influence engagement with the screening/intervention procedures, we will examine participation rates among schools with above/below average proportion of pupils eligible for free school meals and above/below average proportion of

pupils with English as an additional language, and examine school and family-level characteristics associated with completion of the OSI online modules, feedback and OSI support calls, core intervention content, time spent on online modules, number of times online module pages are viewed, time spent on support calls and associated administrative/supervision activities.

Qualitative data analysis.

Qualitative interviews will be transcribed verbatim, with identifying personal information removed on transcription. Transcripts will be checked against audio-recordings and then audio-recordings will be destroyed. Transcripts will be imported into Nvivo 12 to facilitate data management. Reporting of qualitative findings will follow the CORE-Q checklist [31].

A subset of the transcripts will be analysed separately first to create a coding template which will cover how the screening/intervention procedures are experienced in the context of participant's distinctive lives. This analysis will be used to develop a template framework. All transcripts will then be analysed against this framework using template analysis, with modifications to the template made after careful consideration of each transcript [32]. We expect the developed template will include: what aspects of the screening/intervention procedures were acceptable; if any adaptations to the pathway procedures were needed; barriers or facilitators to engagement and delivery; and whether any external factors impacted the engagement or delivery of the procedures.

Integration of data analysis

The qualitative and quantitative data will be analysed separately and then mixed during analysis for triangulation to provide a more complete picture as described below [33].

The quantitative and qualitative strands will play an equally significant role in addressing the process evaluation research questions. A triangulation protocol will be followed [34] involving:

i. Sorting findings from the qualitative and quantitative datasets into categories or 'meta-themes' that address the research questions to determine overlap and divergence.

ii. Comparing findings from the data sources using a convergence coding scheme to determine the degree and type of convergence within category or theme areas. Researchers will consider if there is agreement, partial agreement, silence or dissonance between findings from different datasets. 'Silence' is where a finding that arises from one dataset is not found in another and can help with the interpretation of the results and lead to further investigations [34].

iii. Reviewing all meta-themes to assess the level of convergence and where/when researchers have different perspectives of the findings.

iv. Multiple researchers (VW, TR, CC, ML) will examine the set of findings to clarify the interpretation and determine the level of agreement among researchers. Disagreements will be managed by re-examining the data as a group, with final decisions made by CC and ML.

The process evaluation data will be analysed independently from the main trial clinical and cost-effectiveness outcomes. The statisticians (OU, SB) and health economist (MV) conducting the main trial quantitative data analysis [18] will be unaware of the findings from the process evaluation until the primary and secondary clinical and health economic outcomes have been analysed. The combined quantitative and qualitative data in the process evaluation is expected to help develop an in-depth understanding of the main trial outcomes.

Rigour and reliability

This process evaluation will be conducted by a team of experienced researchers with considerable expertise of both mixed methods and undertaking large-scale intervention trials for childhood anxiety disorders. Several steps will be taken to ensure a rigorous approach to data collection and analysis: (i) cluster (school) and purposive sampling will be conducted for qualitative interviews to ensure a broad and diverse sample and, thus, fair conceptual transferability; (ii) data collection and analysis will follow a systematic approach, including a range of both qualitative and quantitative data; (iii) researchers will reflect on their role and input in data generation and analysis; (iv) credibility checking will be conducted through reflective discussions with co-authors and a small expert reference group; (v) results will be triangulated across several sources of data; and (vi) 'sensitivity to context' will be considered by incorporating relevant literature and theory as well as examining differing perspectives and the context in which data and results have been generated [35].

Discussion

This article outlines the rationale, design and methodological approach for the mixed methods process evaluation of the iCATSi2i screening and intervention procedures for children with anxiety problems. The process evaluation is designed to examine whether the screening/intervention procedures are implemented as intended or if adaptions are needed; if procedures are acceptable to schools and families; how the screening/intervention procedures produce change; whether barriers/facilitators to engagement and delivery exist; and whether any external factors impact procedure engagement or delivery. By detailing our process evaluation approach, as informed by the MRC guidelines [28] this article not only adds to the

literature on process evaluation protocols with a mixed methods design but will also improve the integrity of our process evaluation and overall randomised controlled trial quality [24,36].

Strengths and challenges

It is anticipated that actively combining both qualitative and quantitative data in the process evaluation will help us to better understand and interpret the overall iCATS i2i trial outcome data. For example, by comprehensively examining whether the iCATS i2i screening/intervention procedures were adhered to and acceptable and the contexts surrounding that, this process evaluation will help determine both potential positive and negative aspects of the iCATS i2i procedures. If some negative outcomes are found from using the iCATS i2i screening/intervention procedures, the process evaluation will be a beneficial resource to determine whether a failure of procedure implementation occurred and if this was due to, for example, factors associated with participants' experiences or circumstances (e.g. lack of motivation or resources; beliefs about online interventions; etc). This could potentially help with future implementations of iCATS i2i, if indicated, and also help inform the development and implementation of wider school-based screening and intervention programmes aimed at supporting children with mental health problems.

Collecting data from a range of participants (i.e. children, parents, teachers, researchers, CWPs) using multiple methods will produce a nuanced understanding of the mechanisms contributing towards the experience of the iCATS i2i procedures. Including teachers, children and parent report measures may also provide data about the acceptability of carrying out such screening procedures which would be beneficial beyond the iCATS i2i study and inform future screening/intervention trials. Moreover, the target sample size for qualitative interviews (N=55) and inclusive sampling approach (e.g. conducting interviews

with screen 'positive' as well as 'negative' families, families who drop out of OSI, etc) is expected to be adequate to capture a range of perspectives, providing rich detailed data.

One potential limitation that may arise is that the majority of participants who opt-out or later drop out of the iCATS i2i procedures are more likely to decline to complete interviews which could lead to a more positive overall evaluation of the procedures. We will attempt to overcome this by making a concerted effort to recruit parents who drop out of or choose not to take up OSI or, if this is not possible, those who complete fewer OSI modules to interviews. Second, while we will be able to provide translated copies of the information sheets, OSI will be delivered by English-speaking CWPs for practical reasons, and this may unduly exclude parents who are not English speaking. Third, it is possible wider trial research activities influence engagement with the screening/intervention procedures in ways that would not apply if the procedures were to be implemented in practice. For example, the screening questionnaire is a 2-item parent-report measure, but in the trial parents, children and teachers also each complete a number of measures to assess secondary trial outcomes. In addition, the team of researchers with responsibility for conducting this process evaluation will also be involved in carrying out the trial procedures and some will be involved in conducting the trial outcome analysis. This integration will help facilitate data sharing but there is potential for bias in the interpretation of procedure functioning to arise. A reflective approach to data collection and analysis will be employed to improve the reliability and validity of the findings.

The iCATS i2i screening/intervention procedures are complex and involve a range of interrelated components and multiple stakeholders. There may be some differences in procedure implementation across schools and there is likely to be adaption to and learning

from the procedures as delivery proceeds [37,38]. Moreover, given that schools and families are each unique and complex ecosystems where a community of individuals interact and co-exist, school and family contexts cannot be considered 'static'. We will need to recognise that the iCATS i2i procedures are being delivered within shifting environments and the rolling out of the iCATS i2i school screening/intervention procedures may also have some influence on the environment. There may be considerable challenges in monitoring and precisely assessing the various iCATS i2i procedure implementation processes, components and changing environments and how they relate to outcomes. It is hoped that by including 'adaptations' as a core aim in our process evaluation, that any necessary departures from study procedures are recognised and captured. Overall, this process evaluation is expected to further our understanding of the acceptability of screening/intervention procedures for child anxiety problems in a school context to inform future efforts to address child mental health problems.

Trial status

Recruitment of participants is ongoing.

Competing interests: TF's Department receives funds from her advisory role at Place2Be, a third sector organisation that provides mental health training and support to schools in the UK.

Data sharing statement: No additional data are available

Funding: This paper represents independent research funded by the National Institute for Health Research (NIHR; PGfAR - RP-PG-0218-20010) (PI: CC) and hosted by Oxford Health NHS Foundation Trust. CC and MV acknowledge support from the Oxford and

Thames Valley NIHR Applied Research Collaboration and the NIHR Oxford Health Biomedical Research Centre. OU was supported by the NIHR Applied Research Collaboration (ARC) for the South West Peninsula at the Royal Devon and Exeter NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Acknowledgements: We would like to thank those who participated in our patient and public involvement (PPI) activities for their contribution to this research. We also wish to thank our colleagues on the wider research team (especially Sue Ball) and advisory group (especially Paul Flowers) for their contributions.

Ethical approval: The study has received ethical approval from the University of Oxford CUREC (R66068_RE003).

Contributorship Statement:

Professor Cathy Creswell is the guarantor.

All authors contributed towards the study design (VW, ML, TR, PS, SS, IM, OCU, TF, MV, FFS, JS, AG, PB, MS, FM, BJ, LT, CC). All authors (VW, ML, TR, PS, SS, IM, OCU, TF, MV, FFS, JS, AG, PB, MS, FM, BJ, LT, CC) reviewed and approved the manuscript prior to submission.

References

1 Pollard J, Reardon T, Williams C, *et al.* The multifaceted consequences and economic costs of child anxiety problems: A systematic review and meta-analysis. *JCPP Advances*. 2023;3:e12149.

2 James AC, Reardon T, Soler A, *et al.* Cognitive behavioural therapy for anxiety disorders in children and adolescents. *Cochrane Database of Systematic Reviews*. 2020;2020. doi: 10.1002/14651858.CD013162.PUB2/PDF/CDSR/CD013162/CD013162.PDF

3 Reardon T, Harvey K, Creswell C. Seeking and accessing professional support for child anxiety in a community sample. *Eur Child Adolesc Psychiatry*. 2020;29:649–64.

4 Creswell C, Chessell C, Halliday G. Parent-led cognitive behaviour therapy for child anxiety problems: overcoming challenges to increase access to effective treatment. *Behavioural and cognitive psychotherapy*. 2022;1–21.

5 Reardon T, Harvey K, Baranowska M, *et al.* What do parents perceive are the barriers and facilitators to accessing psychological treatment for mental health problems in children and adolescents? A systematic review of qualitative and quantitative studies. *Eur Child Adolesc Psychiatry*. 2017;26:623–47.

6 Children's mental health services 2021-2022 | Children's Commissioner for England. https://www.childrenscommissioner.gov.uk/resource/29751/ (accessed 28 November 2023)

7 Green I, Reardon T, Button R, *et al.* Increasing access to evidence-based treatment for child anxiety problems: online parent-led CBT for children identified via schools. *Child Adolesc Ment Health*. 2023;28:42–51.

8 Durlak JA, Mahoney JL, Boyle AE. What We Know, and What We Need to Find Out About Universal, School-Based Social and Emotional Learning Programs for Children and Adolescents: A Review of Meta-Analyses and Directions for Future Research. *Psychol Bull*. 2022;148:765–82.

9 Kuyken W, Ball S, Crane C, *et al.* Effectiveness of universal school-based mindfulness training compared with normal school provision on teacher mental health and school climate: results of the MYRIAD cluster randomised controlled trial. *BMJ Ment Health*. 2022;25:125–34.

10 Ma KKY, Anderson JK, Burn AM. Review: School-based interventions to improve mental health literacy and reduce mental health stigma – a systematic review. *Child Adolesc Ment Health*. 2023;28:230–40.

11 Hayes D, Mansfield R, Mason C, *et al.* The impact of universal, school based, interventions on help seeking in children and young people: a systematic literature review. *Eur Child Adolesc Psychiatry*. 2023;1:1–18.

12 Higgen S, Mösko M. Development and pilot evaluation of a universal intervention – Enhancing resilience in culturally and linguistically diverse primary school classrooms. *Int J Educ Res*. 2021;108:101757.

13 Burns JR, Rapee RM. Barriers to Universal Mental Health Screening in Schools: The Perspective of School Psychologists. *https://doi.org/101080/15377903202119414 70*. Published Online First: 2021. doi: 10.1080/15377903.2021.1941470

14 Anderson JK, Ford T, Soneson E, *et al.* A systematic review of effectiveness and cost-effectiveness of school-based identification of children and young people at risk of, or currently experiencing mental health difficulties. *Psychol Med*. 2019;49:9–19.

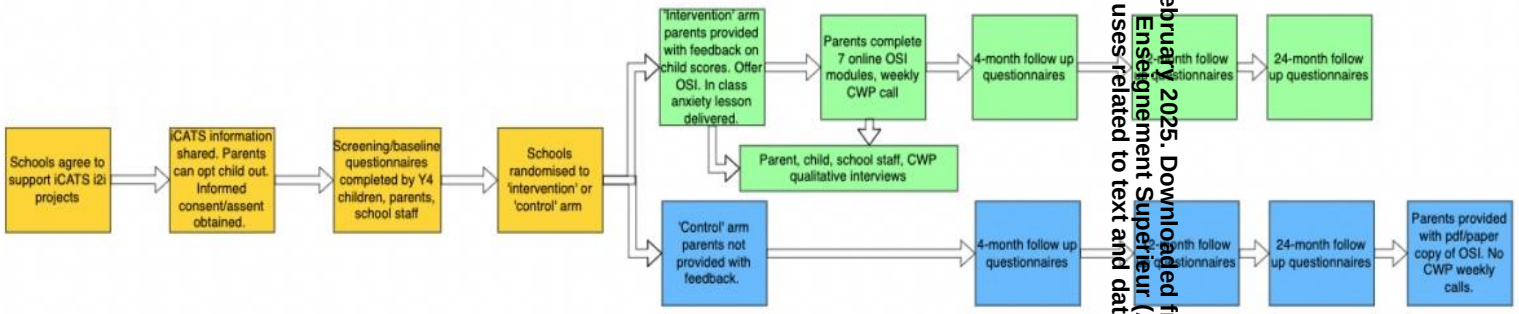
15 Williamson V, Larkin M, Reardon T, *et al.* Primary school-based screening for childhood mental health problems and intervention delivery: a qualitative study of parents in challenging circumstances. *Emotional and Behavioural Difficulties*. 2022;27:267–79.
16 Oakley A, Strange V, Bonell C, *et al.* Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 2006;332:413–6.
17 Williamson V, Larkin M, Reardon T, *et al.* School-based screening for childhood anxiety problems and intervention delivery: a codesign approach. *BMJ Open*. 2022;12:e058089.
18 Reardon T, Ukoumunne OC, Violato M, *et al.* Identifying Child Anxiety Through Schools-identification to intervention (iCATS-i2i): protocol for a cluster randomised controlled trial to compare screening, feedback and intervention for child anxiety problems to usual school practice. *Trials*. 2022;23. doi: 10.1186/S13063-022-06773-0
19 Ball S, Reardon T, Creswell C, *et al.* Statistical analysis plan for a cluster randomised controlled trial to compare screening, feedback and intervention for child anxiety problems to usual school practice: identifying Child Anxiety Through Schools-identification to intervention (iCATS-i2i). *Trials*. 2024;25. doi: 10.1186/S13063-023-07898-6
20 Reardon T, Ukoumunne OC, Violato M, *et al.* Identifying Child Anxiety Through Schools-identification to intervention (iCATS-i2i): protocol for a cluster randomised controlled trial to compare screening, feedback and intervention for child anxiety problems to usual school practice. *Trials*. 2022;23:1–19.
21 Hill C, Reardon T, Taylor L, *et al.* Online Support and Intervention for Child Anxiety (OSI): Development and Usability Testing. *JMIR Form Res*. 2022;6. doi: 10.2196/29846
22 Williamson V, Larkin M, MacDonald I, *et al.* Primary school based mental health practitioners' perspectives of school-based screening for childhood mental disorders and intervention delivery: A qualitative study. *Emotional and Behavioural Difficulties*. 2022;27. doi: 10.1080/13632752.2022.2110704
23 Moore G, Audrey S, Barker M, *et al.* Process evaluation of complex interventions. UK Medical Research Council (MRC) guidance. *Br Med J*. 2015.
24 Grant A, Treweek S, Dreischulte T, *et al.* Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials*. 2013;14. doi: 10.1186/1745-6215-14-15
25 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 2015;350. doi: 10.1136/BMJ.H1258
26 Hansford L, Sharkey S, Edwards V, *et al.* Understanding influences on teachers' uptake and use of behaviour management strategies within the STARS trial: Process evaluation protocol for a randomised controlled trial. *BMC Public Health*. 2015;15:1–8.
27 Skivington K, Matthews L, Simpson SA, *et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374. doi: 10.1136/BMJ.N2061
28 Moore GF, Audrey S, Barker M, *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ (Online)*. 2015;350. doi: 10.1136/bmj.h1258
29 Williamson V, Larkin M, Reardon T, *et al.* Codesign and development of a primary school based pathway for child anxiety screening and intervention delivery: a protocol, mixed-methods feasibility study. *BMJ Open*. 2021;11:e044852.

30 Larkin M, Shaw R, Flowers P. Multiperspectival designs and processes in interpretative phenomenological analysis research. *Qual Res Psychol*. 2019;16:182–98.
31 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007;19:349–57.
32 Brooks J, McCluskey S, Turley E, *et al.* The Utility of Template Analysis in Qualitative Psychology Research. *Qual Res Psychol*. 2015;12:202–22.
33 O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *BMJ*. 2010;341:1147–50.
34 Farmer T, Robinson K, Elliott SJ, *et al.* Developing and implementing a triangulation protocol for qualitative health research. *Qual Health Res*. 2006;16:377–94.
35 Yardley L. Dilemmas in qualitative health research. *Psychol Health*. 2000;15:215–28.
36 Lockwood I, Walker RM, Latimer S, *et al.* Process evaluations undertaken alongside randomised controlled trials in the hospital setting: A scoping review. *Contemp Clin Trials Commun*. 2022;26:100894.
37 Ling T. Evaluating complex and unfolding interventions in real time. *Evaluation*. 2012;18:79–91.
38 Rogers PJ. Using Programme Theory to Evaluate Complicated and Complex Aspects of Interventions. *http://dx.doi.org/101177/1356389007084674*. 2008;14:29–48.

Figure 1.

Note. Y4 = Year Four. OSI = Online Support and Intervention for Child Anxiety. CWP = Children's Wellbeing Practitioner. Qualitative interviews (conducted after baseline and before one year follow up) explore experiences of participation in the pathway, including screening and intervention.

Figure 1. iCATS cluster RCT procedures



Note. Y4 = Year Four. OSI = Online Support and Intervention for Child Anxiety. CWP = Children's Wellbeing Practitioner. Qualitative interviews (conducted after baseline and before one year follow up) explore experiences of participation in the pathway, including screening and intervention.

Supplementary Material 1

Indicative guide for in-depth interviews with parents

Topics to explore in the interview

- How have you found taking part in the iCATS study so far?
  - Were there any issues or concerns you were hoping iCATS would help with?
  - Did you have any concerns or worries that made you hesitant to get involved?
  - Was there anything you think could have been done to encourage you/others to get involved?
- How did you get on with the initial questionnaires and consent forms?
  - Did you fill these in or did your child's other parent? Why was this?
  - Was there anything that you found difficult in filling in the questionnaires?
  - Was there anything that could've been made easier for you here?
  - How did you find accessing these online (or by paper)?
  - How did you feel about how your data was being managed/stored? What was important for you here?
  - How did you feel about taking part being opt out?
- How did your child get on with these questionnaires?
  - Did they do the questionnaire at home with you or at school? What did you think about this approach?
  - What do you think about this study looking at anxiety in Y4 as an age group?
- Was there anything you feel you or your child gained or learnt from filling in the questionnaires?
- How did you feel about your child's teacher also filling in a questionnaire about your child?
- How did you find the feedback about your responses to the questions about your child's fears and worries?
  - Did you have any concerns at this stage?
  - Was there any more information you would have liked to have had?

- Did the feedback you received on the questionnaires affect how you felt about doing the OSI intervention?
- How did you find accessing OSI?
  - What did you think about everything being online/remote?
  - How do you think this would compare to a F2F course?
  - When do you find time to work through OSI?
  - How did you decide which parent would do OSI?
  - How did you find doing the activities with your child?
- What impact do you think the activities have had on their fears and worries?
  - How do you feel about managing your child's difficulties with fears and worries having done OSI?
  - Has your knowledge or confidence in supporting your child changed following OSI?
  - Has there been any changes in your family life since taking up OSI?
  - Has doing OSI had any impact on your own wellbeing?
  - Have you become aware of any new sources of support as a result of being part of OSI?
- What did you think of the weekly phone calls?
  - How do you feel about the number or length of sessions?
  - How have you found the 1 month break?
    - OR How do you feel about there being a 1 month break?
  - How do you feel about your child's 'discharge' letter?
    - Will you share this with your child's school? Why or why not?
  - In an ideal world, is there any other support or help you would've liked to receive?
  - Could anything have been made easier for you/others to keep engaging with OSI?

- Have you spoken to or interacted with your child's school about iCATS?
    - What was this experience like?
    - Could anything have been improved here?
    - Do you think a parent-school conversation is needed? Or is this not necessary?
- Have you spoken with other people about iCATS?
    - Have you spoken to any parents who dropped out of or chose not to take part in iCATS? Do you know why they made this decision?
    - After finishing OSI do you think you will speak to other people about it?
- Is there anything we can do to make sure iCATS works well for other families in future?
- How would you describe your child's school culture or attitude towards mental health or anxiety?
    - Do you think iCATS may have any broader effects on your child's school or your community?
    - For those families who have a difficult relationship with their child's school, what impact on the parent-school do you think running iCATS may have?

Indicative guide for in-depth interviews with school staff

Topics to explore in the interview

- How have you found being part of the iCATS study so far?
- What made you and your school want to get involved?
  - Were there any particular motivators for your school to want to join in?
  - Are there any factors that made you or your school hesitant to take part?
  - Was there anything we could have done differently to encourage your school (or other schools) to get involved?
- What did you hope you/your pupils/your school would get out of taking part in iCATS?
- How did you get on with the initial questionnaires and consent forms?
  - What did you think about the number/length of questionnaires?
  - How did you find accessing these online?
  - Did you have dedicated time to fill them in?
  - Is there is anything you feel you learned from filling in the questionnaires?
  - How did you feel about how your data was managed/kept secure? What was important for you here?
  - Did filling in the questionnaires have any impact on your knowledge or confidence in supporting children in your class?
  - Was there anything that could've been made easier for you here?
- How did your pupils get on with their questionnaires?
  - Did they do the questionnaire at home or at school? What did you think about this approach?
  - Did they need any help to fill them in?
  - Was there anything that could have been done differently here?
- Do you know how any of your class's parents got on with filling in their initial questionnaires?
  - Did any parents have any difficulties accessing or filling them in?
  - Why may some parents have a tough time filling in the questionnaires?
  - Was there anything we could do to support parents better during this process?
- Did you see the feedback about pupils' scores?
  - Did you see the list of the pupils who screened 'positive'?
    - If no, why was this? Would you have liked to see it?
  - Were the outcomes what you were expecting?
  - Initially we planned for the school iCATS lead to give this feedback, how do you feel about the feedback coming from the research team instead?
  - Could anything have been done differently here?
- What did you think about the Y4 anxiety lesson?
  - Was there anything that was difficult to understand?
- Did taking part in iCATS and/or any of the information we have shared make any differences to how you feel you manage anxiety or other problems within the classroom? If so, in what way?
- Have you spoken to or interacted with your pupils or parents about their experience of iCATS?
  - What was this experience like?
  - Did you get asked any questions by pupils/parents? How did this go?
  - Did you speak with any parents/pupils who didn't want to take part or dropped out? What seemed to contribute towards this?
  - Did you speak to any parents that received the online intervention? How did they get on?
  - Did you speak to any parents that were offered OSI who didn't take it up? What have their experiences been?

- Have you spoken with other people about iCATS? (e.g. colleagues, your own friends/family). What have their reactions been?
- Have you had any situations or instances that stand out to you about how people have understood what we're doing with iCATS?
- What do you think about iCATS being for Y4 children? How does this fit with existing school procedures (e.g. exams in Y5)?
- How would you describe your school's culture or attitude towards child mental health or anxiety?
    - Do you think iCATS has had or may have any broader effects on your school or your community?
    - For those families who have a more difficult/strained relationship with their child's school, what impact do you think iCATS could have on that parent-school relationship?
- Is there anything we can do to make sure iCATS works well for other schools or families in future?

Indicative guide in-depth interviews with Y4 children

Topics to explore in the interview

- What did you think about the iCATS when iCATS was first talked about at your school?
- Was there any more information you would have liked to know about iCATS before joining in?
    - What did you think about filling in the questionnaire about your fears and worries?
    - Did you do the questionnaire at home or at school?
    - Did you do the questionnaire in big groups or small groups?
    - Did you learn anything from filling in the questionnaire?
    - Could anything have been done differently to make filling in the questionnaire easier for you?
- What did you think about the lesson on fears and worries?
    - What bits did you like about the lesson?
    - What bits did you not like?
    - What did you think about the strategies it explained for what to do when you are worried?
    - Have you used any of the strategies?
- What did you think about your parent(s) doing the course to help you with your fears and worries?
    - How did doing the iCATS activities with your parent(s) make you feel?
    - Were there any activities you found really fun?
    - Were any activities hard? Why do you think that was?
- How did you find using the Monster's Journey game?
- Did you speak to anyone (e.g. friends, family, teachers) about your parents doing the course to help you with your fears and worries?
    - What did you say? How did they respond?
    - If you didn't speak to anyone, why was this?
- Do you think your parents doing the lessons about your fears and worries had any impact on other members of your family or how your family gets along?
    - Why or why not?
- Is there any extra help for your fears or worries that you would have liked to have?
- Are there any other thoughts you have about the iCATS project that we should know?

Indicative guide for in-depth interviews with iCATS researchers

Topics to explore in the interview

- Have you been involved in any iCATS i2i school recruitment?
  - What has encouraged schools to get involved?
  - Are there any barriers to school's getting involved?
  - What sorts of questions or concerns do school's have before signing up?
- How have you found interacting with school staff?
  - What factors would you say make for an 'engaged' school?
  - What does an 'engaged' school look like?
  - What factors would you say make a school more difficult to interact or engage with?
  - What does a 'not engaged' school look like?
  - Can anything be done to improve school engagement? How?
- How have you found working with iCATS school leads?
  - How have you found working with school staff?
  - What questions/concerns do school staff typically have?
- How have you found interacting with iCATS parents?
  - What sorts of questions/concerns do parents usually have?
  - Have you spoken to any parents who dropped out of the study? What were their reasons?
- How have you found doing the questionnaire administration and data collection?
  - Did you send out and collect parent questionnaires?
    - Have you had to support any parents in filling these in?
    - What sort of support did parents need?
  - Did you go to schools and help administer child questionnaires?
    - What was this like?
    - What things are needed for this to go well?
  - Did you help any teachers to do their questionnaires?
    - What sort of support did they need?
- How did you find being part of the Y4 child anxiety lesson?
  - Did you help to deliver this in a school?
  - What factors are important in making the lesson go well?
  - What things can mean the lesson doesn't get delivered well?
  - Do you think running the anxiety lesson has any broader impacts in schools?
- Have you had any situations or instances that stand out to you about how people have understood what we're doing with iCATS?
- How would you describe the general climate/culture with regard to mental health in the schools that you visited?
- What do you think cuts through to schools most clearly, in terms of the appeal/advantages of iCATs?
  - What about to families?

Indicative guide for in-depth interviews with iCATS CWPs and clinical psychologists.

Topics to explore in the interview

- How have you found the feedback calls with parents/carers in in the iCATS-i2i trial?
    - How did the feedback we provided families on the questionnaire responses seem to affect how parents/carers felt about doing OSI?
    - Have parents/carers raised any concerns related to the feedback they received?
    - What are your thoughts on the feedback coming from the research team, rather than the school?
    - Have you had any calls with parents/carers who did not complete the initial questionnaires?
    - Could anything have been done differently in how we provide feedback to families and offer OSI?
    - Was there any more information parents/carers would have liked to have had?
    - Are there any changes you think could be made to how we share feedback with families/how we offer OSI?
- How have you found delivering [and/or supervising the delivery of] OSI?
- What did you think about everything being online/remotely?
    - Did the online/remote delivery present challenges for you? And for parents? How did you try to manage these challenges and what worked/worked less well and why?
    - Did the online/remote delivery bring any benefits for you? And for parents?
- What impact do you think OSI has had on children's fears and worries?
- What impact do you think OSI has had on other aspects of family life?
- From your experience of working with parents, do you think OSI and iCATS more generally has had any impacts on the environment within participating schools or classes?
- How do you feel about the structure of the OSI programme? E.g. the number and length of online modules, the number and length of support calls, the 1 month follow-up
- How do you find keeping to the OSI guidance when supporting families?
    - Are all calls with parents generally the same or do some differ?
    - How do you manage this?
- Have you had contact with school staff or other professionals about families who received OSI? How have you found that?
- Are there any changes you think that we need to make to OSI for future delivery through primary schools?

Supplementary Material 1, Table 1

		Explanatory data				Key Questions					
Participants	**Mode of data collection**	**Data outcomes**	**Timepoint**	**Number/ frequency**	**Trial arm**	**Were the screening/intervention procedures implemented as intended or were adaptations needed?**	**Do the screening/intervention procedures reach children with anxiety problems?**	**Are the screening/intervention procedures acceptable?**	**How do the screening/intervention procedures produce change?**	**What barriers/facilitators to engagement with and delivery of the screening/intervention procedures exist?**	**What - if any - external factors impact screening/intervention engagement or delivery?**
Y4 children	Questionnaires	Completion of baseline measures	Baseline	Baseline (all Y4)	Both		X	X			
	Interview	Experience of being involved in the screening/intervention pathway, including anxiety lesson	After baseline, before 1 year follow up.	20 interviews	Intervention	X	X	X	X	X	X
Y4 parents	Questionnaires	Opt-out rates, completion of screening and baseline measures, screen positive rates	Baseline	Baseline (all Y4)	Both		X	X		X	X
	Interview	Experience of being involved in the screening/intervention pathway	After baseline, before 1 year follow up	20 interviews	Intervention	X	X	X	X	X	X
	Questionnaires	Bespoke acceptability questionnaire	4 month follow-up	4 month-follow-up for all parents who complete screening questionnaires	Intervention arm			X		X	
	OSI usage	Completion of online modules and online module activities, time spent on each module and number of times	Throughout OSI delivery	Data collected for all parents who use OSI	Intervention	X	X	X			

		module pages are viewed									
	Questionnaire measures to guide future OSI developments	Session Rating Scale Module Feedback Questionnaire	8 online modules (Module 0 to Follow-up)	Data collected for all parents who use OSI	Intervention arm			X		X	
Y4 teachers & school staff	Questionnaires	Completion of baseline measures	Baseline	Baseline (for all Y4)	Both			X			
	Interview	Experience of being involved in the screening/intervention pathway	After baseline, before 1 year follow up	5 interviews	Intervention	X	X	X	X	X	X
CWPs/supervisors	Interview	Experience of delivering feedback and OSI to families	Throughout feedback and intervention delivery	5 interviews	Intervention	X		X	X	X	X
	CWP-parent contact time and supervision time	Completion of feedback and support calls, time spent on calls and supervision activities	Throughout feedback and intervention delivery	Data collected for all parents who use OSI	Interview	X	X	X		X	X
iCATS research team	Interview	Experience of delivering screening/intervention activities	After baseline, before 1 year follow up.	5 interviews	Both	X	X	X	X	X	X

Table 1. Relationship between process evaluation questions, explanatory data, data sources and outcomes

Note: Qualitative interviews (N=55) will be conducted during and after the intervention delivery period and will be completed prior to the 12-month follow-up. CWP = children's wellbeing practitioner. OSI = online support and intervention. Y4 = year four.