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# BMJ Open

## Protocol for the co-design and development of a school-based pathway for child anxiety screening and intervention delivery

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3 Protocol for the co-design and development of a school-based  
4 pathway for child anxiety screening and intervention delivery  
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14  
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20  
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22

23  
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25  
26 design of the study protocol, contributed towards the writing  
27  
28 of the manuscript and approved the final version of the  
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30 protocol  
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## Abstract

**Introduction:** Anxiety disorders are among the most common mental health problems in childhood. Despite this, few children access evidence-based interventions and school may be an ideal setting to improve children's access to treatment. This paper describes the design, sampling methods, and expected data collection of the Identifying Child Anxiety Through Schools - Identification to Intervention (iCATS i2i) study which aims to develop acceptable school-based procedures to identify and support child anxiety difficulties.

**Methods and analysis:** iCATS i2i will use a mixed-methods approach to co-design and deliver a set of procedures - or 'pathway' - to improve access to evidence-based intervention for child anxiety difficulties through primary schools in England. The study will consist of four stages, initially involving in-depth interviews with parents, children, school staff, stakeholders (Stage 1) to inform the development of the pathway. The pathway will then be administered in two primary schools, including screening, feedback to parents, and the offer of treatment where indicated (Stage 2), with participating children, parents and school staff invited to provide feedback on their experience (Stages 3 & 4). Data will be analysed using Template Analysis.

**Ethics and dissemination:** The iCATS i2i study was approved by the University of Oxford's Research Ethics Committee (REF R64620/RE001). It is expected that this co-design study will lead on to a future

1  
2  
3 feasibility study and, if indicated, a randomised controlled  
4  
5 trial. By providing information on child, parent, school-staff  
6  
7 and other stakeholder's experiences, we anticipate that the  
8  
9 findings will inform the development of an acceptable  
10  
11 evidence-based pathway for identification and intervention for  
12  
13 children with anxiety disorders in primary schools and may  
14  
15 also inform broader approaches to screening for and treating  
16  
17 youth mental health problems outside of clinics.  
18  
19

20  
21 **Strengths and limitations of this study:**  
22

- 23 • Focus on child anxiety disorders, one of the most common  
24 mental health problems in childhood.  
25
- 26 • By using a co-design approach which incorporates feedback  
27 from children, parents, school-staff and stakeholders,  
28 this study will lead to the development of acceptable  
29 procedures for screening and offering treatment for child  
30 anxiety difficulties in primary schools.  
31
- 32 • The study is limited by the use of an 'opt-in' approach  
33 to consent which could introduce participation bias.  
34
- 35 • The primary use of online platforms for consent,  
36 screening and delivery of the CBT intervention may  
37 exclude families who have limited access to technology or  
38 lack technical skills; although ways to facilitate the  
39 participation of those in these situations will be  
40 explored.  
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## Introduction

Anxiety disorders are among the most common mental health problems in childhood (6.5% prevalence; [1]) and approximately half of all anxiety disorders emerge by the age of 11 years. Childhood anxiety disorders are often chronic and pervasive, and have an adverse effect on social, education and familial functioning. Childhood anxiety disorders often persist into adulthood when left untreated [2] and are associated with comorbid mental health difficulties, including major depression and substance abuse [3,4]. The societal cost of a child with an anxiety disorder is estimated to be 21 times that of a non-anxious child [5]. As such, effective identification and treatment of anxiety disorders in childhood is important.

Effective treatments for childhood anxiety disorders exist. However, very few children are offered or are able to access them [6,7]. For example, previous research has shown that only 2% of pre-adolescent children who meet criteria for an anxiety disorder in England receive an evidence-based intervention [7]. Barriers to receiving evidence-based treatment include difficulties with identification of anxiety difficulties, concerns regarding stigma to the child or family, and long waiting lists at Child and Adolescent Mental Health Services (CAMHS) [7]. In recent years, increasing evidence for the effectiveness of online, remotely delivered treatments for childhood anxiety difficulties has been found

1  
2  
3 and the delivery of online treatment may overcome some of  
4  
5 these barriers to care [8]. The vast majority of children  
6  
7 attend school [9] where they spend much of their time,  
8  
9 therefore schools are also an ideal setting to overcome many  
10  
11 of these barriers. However, there are not clear mechanisms for  
12  
13 identifying youth mental health difficulties in schools nor  
14  
15 clear pathways for those who would benefit to access evidence-  
16  
17 based treatments.  
18  
19

20  
21 One approach often used in healthcare service design and  
22  
23 development is 'co-design', where the knowledge and lived  
24  
25 experiences of service users themselves are drawn upon to  
26  
27 enhance the quality and experiences of care [10,11]. Co-design  
28  
29 aims to develop an in-depth understanding of how stakeholders  
30  
31 and service users perceive and experience the look, feel,  
32  
33 procedures and structures of a service [12]. By engaging  
34  
35 stakeholders and service users in co-designing a service, this  
36  
37 is thought to lead to better quality of care and improved  
38  
39 service performance by highlighting individual's subjective  
40  
41 feelings at various points in the care pathway, which, in  
42  
43 turn, may lead to improvements in health outcomes and more  
44  
45 efficient allocation of limited healthcare resources [13].  
46  
47 Given the importance of early intervention, an acceptable  
48  
49 pathway that effectively identifies anxious children and  
50  
51 successfully increases access to evidence-based treatment is  
52  
53 urgently needed. The Identifying Child Anxiety Through Schools  
54  
55 - Identification to Intervention (iCATS i2i) study will  
56  
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1  
2  
3 develop procedures to identify and support child anxiety  
4  
5 difficulties through schools informed by a co-design approach.  
6

7 This article describes the iCATS i2i co-design protocol.  
8  
9 The co-designed procedures will be evaluated in a subsequent  
10  
11 feasibility study and, if indicated, randomised control trial  
12  
13 beginning in 2021.  
14  
15

## 16 Method

17  
18 This protocol and associated procedures were approved by  
19  
20 the Central University Research Ethics Committee at the  
21  
22 University of Oxford (REF R64620/RE001).  
23  
24

## 25 Study design

26  
27 We will apply a mixed-methods approach to co-design,  
28  
29 produce and deliver a set of procedures - or 'pathway' - to  
30  
31 improve access to evidence-based intervention for child  
32  
33 anxiety difficulties through primary schools in England.  
34  
35 Several of the key elements of the pathway were specified in  
36  
37 advance of the co-design work based on the existing empirical  
38  
39 literature and parent and school staff consultation.  
40  
41 Specifically, it was pre-specified that children's anxiety  
42  
43 difficulties would be screened using questionnaire measures,  
44  
45 parents would receive feedback, and, where indicated, a brief  
46  
47 online treatment for child anxiety difficulties would be  
48  
49 offered.  
50  
51  
52  
53

54  
55 In parallel to this work we are working on refining  
56  
57 measures for screening for child anxiety problems (Reardon et  
58  
59 al. under review), but in the interim we will screen using  
60

1  
2  
3 brief child, parent and teacher versions of the Spence Child  
4 Anxiety Scale (SCAS-8; [14]) together with four items that  
5  
6 assess the extent of interference in everyday life generated  
7  
8 to assess the impact and chronicity of and perceived need for  
9  
10 help for anxiety difficulties. We will consider a child to  
11  
12 have screened 'positive' for likely anxiety difficulties if  
13  
14 they score above the cut off on the SCAS-8 on the basis of any  
15  
16 reporter (score of 7.5 for parents, 6.5 for children, 4.5 for  
17  
18 teachers) and/or indicate that anxiety interferes at least 1  
19  
20 'only a little' on any of the interference items. This  
21  
22 interference-based cut off score was based on feedback from  
23  
24 the dedicated stakeholder group. The use of a screening  
25  
26 questionnaire to determine which children may benefit from  
27  
28 additional support with anxiety was a prespecified component  
29  
30 of the study as this approach shows promise for increasing  
31  
32 access to support (e.g. [15]).  
33  
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39 The treatment to be offered is an online version of a  
40  
41 brief therapist-guided parent-delivered CBT approach for child  
42  
43 anxiety disorders (OSI; Online Support and Intervention for  
44  
45 child anxiety). OSI was originally developed for use in  
46  
47 National Health Service (NHS) clinics and was co-designed by  
48  
49 NHS clinicians, parents and children who had received  
50  
51 treatment for anxiety (Hill et al., in preparation). This  
52  
53 treatment was selected as it is brief, effective [16] and more  
54  
55 cost-effective than brief face-to-face psychological therapy  
56  
57 [17] and can be delivered by non-expert practitioners (e.g.  
58  
59  
60

1  
2  
3 [18]). The approach of working directly with the parent,  
4 rather than the child, also addressed particular barriers to  
5 seeking and accessing help for anxiety highlighted by parents,  
6 including the preference to be supported to manage the  
7 difficulties as a family and for the child not to be singled  
8 out [7]. The online version of this intervention involves 7  
9 online modules for parents, supported by a weekly 20-minute  
10 telephone call with a Children's Wellbeing Practitioner (CWP,  
11 NHS Band 5), with a follow-up telephone session 4-weeks later.  
12 Modules teach parents how to explore their child's anxious  
13 thoughts, put them to the test through facing fears, and to  
14 problem solve challenges that arise. This is accompanied by a  
15 game app for the child to help motivate them to face their  
16 fears.

17 We will use a mixed-method co-design process to determine  
18 how the pre-specified parts of the pathway should be  
19 presented, who by, and to address any important considerations  
20 to optimise accessibility of and engagement with the pathway.  
21 The co-design process will consist of four stages (see Figure  
22 1) involving initial interviews and focus groups with parents,  
23 children, school staff, stakeholders (Stage 1) to inform the  
24 development of a set of procedures that will be applied in two  
25 schools. These procedures will be delivered with participating  
26 children, parents and school staff (Stage 2) who will provide  
27 feedback on their experience (Stage 3 & 4), including cued-  
28 recall specifically on the experience of receiving feedback on  
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whether their child experiences difficulties with anxiety. Feedback from those families who choose not to be involved in the study or dropped out will also be sought to ensure any barriers to engagement are captured (Stage 4).

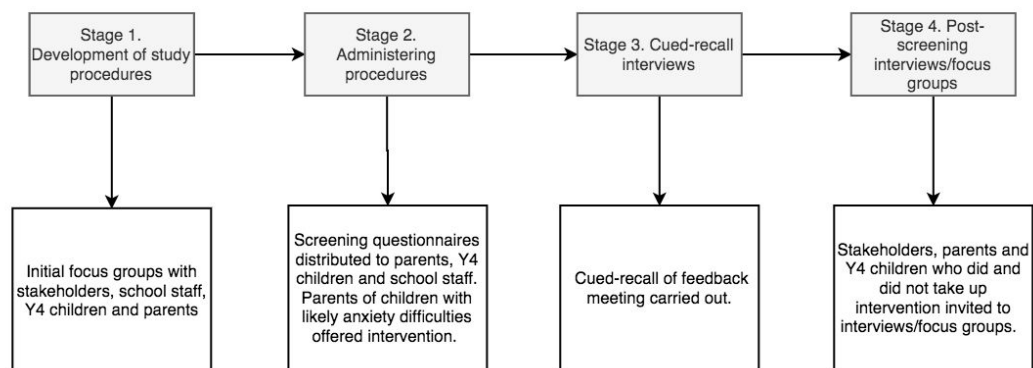


Figure 1. Overview of the co-design process for developing the iCATS i2i protocol

Note. Y4 = year four.

### Patient and public involvement (PPI)

Involvement from parents, school staff and wider stakeholders informed the development of this protocol, the pre-specified elements of the pathway and will contribute throughout the delivery of the co-design project. At the protocol development stage, consultation was carried out with parents, school staff/governors, leading experts in universal screening and interventions in primary school settings, and representatives from key policy and practitioner

1  
2  
3 organisations. Examples of decisions that were made on the  
4  
5 basis of this consultation include specifically focussing  
6  
7 recruitment on children in Year 4 (age 8-9 years) on the basis  
8  
9 that this would be a manageable time for primary schools,  
10  
11 would allow primary schools to see the benefit, and for  
12  
13 children to benefit when managing subsequent key transitions  
14  
15 (e.g. to secondary school).  
16  
17

18  
19 Throughout the co-design process we will consult with  
20  
21 stakeholders in the following ways: (i) two parents with  
22  
23 relevant lived experience, two school leaders and one school  
24  
25 mental health lead for a charity are members of the study  
26  
27 management group and will contribute to all decisions made at  
28  
29 a strategic level; (ii) this dedicated stakeholder group will  
30  
31 meet to review data and to make decisions to address how to  
32  
33 solve problems and manage potentially conflicting points of  
34  
35 view that have arisen through the co-design process; and (iii)  
36  
37 an online PPI group will be formed to access wider views and  
38  
39 will be invited to provide feedback on key issues that arise  
40  
41 and need to be resolved throughout the co-design process.  
42  
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44  
45

#### 46 **Co-design Participants**

47  
48 Participants will include Y4 children (aged 8-9 years),  
49  
50 parents of Y4 children, primary school staff and other  
51  
52 stakeholders. Expected participant numbers for each group and  
53  
54 at each stage in the co-design process are outlined in Table  
55  
56 1. These numbers are approximate and final numbers will be  
57  
58  
59  
60

1  
2  
3 informed by reviewing the range of perspectives represented in  
4  
5 the sample and the information provided by participants.  
6

7  
8 To recruit participants with a broad range of  
9  
10 perspectives to Stage 1 we will circulate study invitations to  
11  
12 parents of all Year 4 children in two primary schools in the  
13  
14 local Oxfordshire area, as well as using online on social  
15  
16 media, and mailing lists to recruit parents with particular  
17  
18 experiences. For the subsequent stages we will first contact  
19  
20 school leaders to invite their school to participate, and  
21  
22 circulate study information to Y4 parents and children  
23  
24 inviting them to participate.  
25  
26

27  
28 All adult participants will be required to give consent  
29  
30 and children will be required to assent to participate in all  
31  
32 stages of the project.  
33  
34

35 ***Inclusion criteria:***

36  
37 Children will be eligible to participate if they are in  
38  
39 Y4 in a mainstream primary school in England, with  
40  
41 parent/carer consent for their participation (Stages 1-4).  
42  
43

44 Parent/carers of children in Y4 in mainstream primary  
45  
46 schools in England will be eligible to take part in Stages 1-  
47  
48 4. However for Stage 1, we will also recruit parents through  
49  
50 other routes in order to capture a range of experiences that  
51  
52 might be particularly relevant to parents' engagement with and  
53  
54 the accessibility of the pathway procedures, specifically  
55  
56 parents who have a child with past/present mental health  
57  
58 problem(s) or who is adopted/fostered, or where a parent has  
59  
60



1  
2  
3 past/present mental health problem(s), or is in the military  
4  
5 (due to their experience of frequent relocations, extended  
6  
7 separation from parents, and parental physical or  
8  
9 psychological injuries [19]).  
10  
11

12 School staff will be included if they are employed in a  
13  
14 mainstream primary/junior school in England (e.g. class  
15  
16 teacher, headteacher) (Stages 1-4).  
17  
18

19 The inclusion criteria for wider stakeholders is that  
20  
21 they must be a member of an organisation that is responsible  
22  
23 for policy or practice relating to mental health provision in  
24  
25 primary schools in England (e.g. commissioning group, local  
26  
27 authority, mental health service provider, local policy maker  
28  
29 organisation, or a governor in mainstream primary/junior  
30  
31 schools) (Stage 1 and 4).  
32  
33  
34  
35  
36

### 37 **Table 1**

38  
39 *Recruitment estimates for the co-design*

Assessment	Planned N			
	Stakeholders	Teachers	Parents	Children
Stage 1. Initial focus groups	2	7	16	9
Stage 2. Administering procedures			144	144

1					
2					
3	Stage 3. Cued		4	12	
4					
5	recall				
6					
7	interviews				
8					
9					
10	Stage 4. Post-	12	12	12	12
11					
12	screening				
13					
14	interviews/focus				
15					
16	groups				
17					
18					
19	<hr/>				

## Procedure

We will collect data at four stages to inform the development of the pathway (see Figure 1).

**Stage 1.** In this stage we will carry out in-depth one-to-one interviews and focus groups with stakeholders, school staff, children and parents. Focus groups and interviews will draw on questioning techniques informed by the Critical Incident Approach [20] to explore participants' views about features of the pathway which might help or hinder a positive experience, or which might have been overlooked by the pathway planners altogether. Focus groups and interviews will include table-top activities where participants are shown visual representations of different aspects of the pathway and they will be asked to discuss and write on provided notecards which will be placed on the table about their thoughts, feelings and concerns, with questions including: "What would be the best way to do this?", "Who do you think would be best placed to do

1  
2  
3 this?", "What might need to be done to help this part  
4  
5 happening?", "Where would be the best place for this to  
6  
7 happen?", "When is the best time to do this?", "Do you have any  
8  
9 concerns about this part of the pathway?". Photographs will be  
10  
11 taken of the visuals produced in the focus groups and  
12  
13 interviews for analysis. Interviews and focus groups will be  
14  
15 audio-recorded and transcribed verbatim. This data will be  
16  
17 used to develop a detailed prototype set of procedures for  
18  
19 screening, feedback and intervention delivery through schools  
20  
21 to be tested and developed further. The dedicated stakeholder  
22  
23 group will be consulted at key decision making points in the  
24  
25 process to generate solutions to problems raised or  
26  
27 inconsistent messages elicited from the interviews.  
28  
29  
30  
31

32  
33 **Stage 2.** The detailed prototype set of procedures  
34  
35 developed in Stage 1 will be administered in two primary  
36  
37 schools, including screening, feedback to parents, and the  
38  
39 offer of treatment where indicated. We will conduct interviews  
40  
41 with school staff, children and parents (including children  
42  
43 who screened 'negative' and those who screened 'positive' for  
44  
45 anxiety and their parents, and parents that did and did not  
46  
47 take up the intervention) to examine their experiences of the  
48  
49 pathway and potential barriers/facilitators to engagement.  
50  
51

52  
53 **Stage 3.** On the basis of the dedicated stakeholder input  
54  
55 at the protocol design stage, we anticipate that parents will  
56  
57 be given written feedback on their child's screening outcomes  
58  
59 by a member of school staff, with the option of a face-to-face  
60

1  
2  
3 feedback appointment. To understand how this feedback is  
4  
5 experienced, what works well and what parents (and school  
6  
7 staff) find both helpful and challenging, participating  
8  
9 parents and staff will be invited to take part in a cued-  
10  
11 recall interview meeting to allow for the refinement of future  
12  
13 feedback delivery and staff training. To this effect, the  
14  
15 parent-staff feedback meetings will be video recorded by the  
16  
17 research team. Recordings of the meeting will be watched back  
18  
19 by parents with a member of the research team to facilitate  
20  
21 discussions about how questionnaire scores were fed back and  
22  
23 how the opportunity to take up the intervention was shared  
24  
25 with parents by school staff. The researcher will invite the  
26  
27 parent to stop the recording periodically to comment at points  
28  
29 that are relevant to particular cues, for example, at points  
30  
31 where the parent felt the information delivered was unhelpful,  
32  
33 or where they felt listened to. The cued-recall interview will  
34  
35 be audio-recorded and transcribed verbatim.  
36  
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41 **Stage 4.** Following the administration of the pathway  
42  
43 procedures, interviews and focus groups will also be carried  
44  
45 out with Y4 children, their parents and school staff in Stage  
46  
47 4. We will carry out interviews with participating parents and  
48  
49 children who completed the screening questionnaires and engage  
50  
51 with the treatment modules, but also with any parents and  
52  
53 children who withdraw and parents and children who choose not  
54  
55 to enroll in the study. School staff in participating schools  
56  
57 will be interviewed about their experience of facilitating the  
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2  
3 iCATS pathway in Y4. Relevant stakeholders will also be  
4  
5 interviewed about their views of the pathway and how well it  
6  
7 will fit within school settings.  
8

### 9 10 **Data analysis**

11  
12 Focus groups and one-to-one interviews (Stages 1 and 4) will be analysed using two  
13  
14 approaches: 'fast and direct' and 'in-depth and detailed'. The 'fast and direct' analysis will  
15  
16 use the visual outputs from focus groups and interviews to collate themes and written  
17  
18 summaries will provide readily understandable feedback about the pathway. Brief,  
19  
20 complementary descriptions will be produced by following a simple protocol for verbalising  
21  
22 'multi-modal data' [21] The combination of thematised images and verbal summary will  
23  
24 provide immediate, easily-understood feedback about the pathway.  
25  
26

27  
28 The 'in-depth and detailed' analysis will involve  
29  
30 Template Analysis [22] where an initial template is structured  
31  
32 by categories drawn from relevant literature and further  
33  
34 developed by preliminary coding of the data using a 'bottom  
35  
36 up' approach. Once the template is developed, all transcripts  
37  
38 will be analysed in a 'top down' manner following the  
39  
40 provisional structure of the template. This will provide  
41  
42 nuanced feedback about the acceptability of the pathway to  
43  
44 fine-tune the final iteration. This analysis will capture  
45  
46 areas of disagreement that may be missed in the 'fast and  
47  
48 direct' analysis. Cued-recall data (Stage 3) will also be  
49  
50 analysed using Template Analysis [22]. Credibility will be  
51  
52 checked via analytic triangulation using reflective  
53  
54 discussions with co-analysts.  
55  
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### 59 **Ethics and dissemination** 60

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2  
3 This research is being conducted in a community setting and ethical approval has  
4  
5 been obtained from the University of Oxford's Research Ethics Committee. We will seek  
6  
7 consent from parents, school staff and other stakeholders and assent from children. Research  
8  
9 data will be kept secure and confidential. Audio/video-recordings will require explicit  
10  
11 consent.  
12  
13

14  
15 A key part of this project will involve developing  
16  
17 acceptable procedures for feeding back outcomes from screening  
18  
19 questionnaires which may bring potential to cause participant  
20  
21 distress. Given that existing screening questionnaires have  
22  
23 modest sensitivity and specificity, this includes explaining  
24  
25 the possibility of an inaccurate result. We will pay  
26  
27 particular attention to this throughout the co-design process  
28  
29 to ensure we develop acceptable procedures and will seek out  
30  
31 families who received 'false-positive' screening feedback to  
32  
33 specifically explore their experience. Given the risk of  
34  
35 'false negatives', during this co-design phase the online  
36  
37 intervention will be made available to all families who take  
38  
39 part, along with information about additional resources,  
40  
41 support and services.  
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46  
47 This project aims to develop an effective pathway to  
48  
49 identify child anxiety difficulties in mainstream schools and  
50  
51 deliver a parent-led intervention through ongoing  
52  
53 collaborative work with schools, parents, children and  
54  
55 stakeholders, while fostering avenues for disseminating the  
56  
57 results directly to the community. Specifically, this co-  
58  
59 design study will lead on to a future feasibility study and,  
60

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3 if indicated, a randomised controlled trial. To disseminate  
4 the findings from this initial stage research, we will produce  
5 and disseminate a report that summarises outcomes in lay-  
6 language to participating schools, which will also be shared  
7 with participating families on request. The findings will be  
8 published in high-quality, open access journals that reach  
9 both academic, educational and clinical audiences. The  
10 research team will also present the findings at national and  
11 international clinical/educational conferences. We will also  
12 collaborate with our dedicated stakeholder group to further  
13 develop the dissemination plans to ensure maximum impact.

### 27 **Discussion**

28  
29  
30 There is currently no evidence-based pathway for  
31 identification and intervention for children with anxiety  
32 disorders in primary schools. Despite the existence of cost-  
33 effective psychological treatments, very few children who  
34 could benefit are able to access them [7]. This project aims  
35 to generate knowledge using a co-design approach to inform the  
36 development of such a pathway that links screening with the  
37 direct provision of support for primary school aged children  
38 to ensure that it is acceptable and ultimately implementable  
39 within schools in England. By providing information on  
40 children, parents, school-staff and other stakeholder's  
41 experiences of this school-based pathway which includes  
42 screening for likely child anxiety difficulties, feedback on  
43 scores and the offer of an online intervention, we anticipate  
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3 that the findings will also inform broader approaches to  
4 screening for and treating youth mental health problems  
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6 outside of clinics.  
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10 This research has several methodological limitations that  
11 warrant consideration. First, because of the nature of child  
12 and parent involvement in this study, we will use an 'opt-in'  
13 approach to consent, where parents must consent to their and  
14 their child's completion of the screening measures. This is  
15 likely to introduce bias in participation, and we risk failing  
16 to capture experiences of the pathway procedures for a  
17 sufficiently broad and diverse group of families where child  
18 anxiety difficulties (including for example, families who do  
19 not have concerns about child anxiety or where other barriers  
20 may exist, such as concerns about stigma). To address this, we  
21 will actively invite parents to Stage 1 and 4 interviews who  
22 both did and did not consent to screening as well as examine  
23 in interviews whether an 'opt-out' approach to screening would  
24 be acceptable in future iterations. A second potential  
25 limitation is that the study will primarily use online  
26 platforms for consent, and screening procedures, and to  
27 deliver the CBT intervention. This decision was informed by  
28 feedback from the dedicated stakeholder group who recommended  
29 that online participation was often considered more secure in  
30 terms of data protection and privacy. However, it introduces a  
31 risk of excluding families who have limited access to  
32 technology/Wi-Fi or lack technical skills or confidence. We  
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3 will explore ways to enable participants in these situations  
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5 to participate, and participant experiences of online access  
6  
7 to the study will be examined.  
8  
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10 With these potential limitations in mind, it is our  
11  
12 intention that this study will collaboratively create a  
13  
14 pathway to care for children who have problems with anxiety  
15  
16 and their families, informed by children themselves, parents,  
17  
18 school staff and other stakeholders, that will ultimately  
19  
20 improve access to effective treatment and support.  
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# BMJ Open

## Protocol for the co-design and development of a primary school-based pathway for child anxiety screening and intervention delivery: A mixed-methods feasibility study

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3 Protocol for the co-design and development of a primary  
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5 school-based pathway for child anxiety screening and  
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7 intervention delivery: A mixed-methods feasibility study  
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48 **Word Count:** 3944

## Abstract

**Introduction:** Anxiety difficulties are among the most common mental health problems in childhood. Despite this, few children access evidence-based interventions and school may be an ideal setting to improve children's access to treatment. This paper describes the design, sampling methods, and expected data collection of the Identifying Child Anxiety Through Schools - Identification to Intervention (iCATS i2i) study which aims to develop acceptable school-based procedures to identify and support child anxiety difficulties.

**Methods and analysis:** iCATS i2i will use a mixed-methods approach to co-design and deliver a set of procedures - or 'pathway' - to improve access to evidence-based intervention for child anxiety difficulties through primary schools in England. The study will consist of four stages, initially involving in-depth interviews with parents, children, school staff, stakeholders (Stage 1) to inform the development of the pathway. The pathway will then be administered in two primary schools, including screening, feedback to parents, and the offer of treatment where indicated (Stage 2), with participating children, parents and school staff invited to provide feedback on their experience (Stages 3 & 4). Data will be analysed using Template Analysis.

**Ethics and dissemination:** The iCATS i2i study was approved by the University of Oxford's Research Ethics Committee (REF R64620/RE001). It is expected that this co-design study will lead on to a future

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3 feasibility study and, if indicated, a randomised controlled  
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5 trial. By providing information on child, parent, school-staff  
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7 and other stakeholder's experiences, we anticipate that the  
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9 findings will inform the development of an acceptable  
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11 evidence-based pathway for identification and intervention for  
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13 children with anxiety difficulties in primary schools and may  
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15 also inform broader approaches to screening for and treating  
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17 youth mental health problems outside of clinics.  
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21 **Strengths and limitations of this study:**  
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- 23 • Focus on child anxiety difficulties, one of the most  
24 common mental health problems in childhood.  
25
- 26 • By using a co-design approach which incorporates feedback  
27 from children, parents, school-staff and stakeholders,  
28 this study will lead to the development of acceptable  
29 procedures for screening and offering treatment for child  
30 anxiety difficulties in primary schools.  
31
- 32 • The study is limited by the use of an 'opt-in' approach  
33 to consent which could introduce participation bias.  
34
- 35 • The primary use of online platforms for consent,  
36 screening and delivery of the CBT intervention may  
37 exclude families who have limited access to technology or  
38 lack technical skills; although ways to facilitate the  
39 participation of those in these situations will be  
40 explored.  
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For peer review only

## Introduction

Anxiety difficulties are among the most common mental health problems in childhood (6.5% prevalence; [1]) and approximately half of all anxiety difficulties emerge by the age of 11 years. Childhood anxiety difficulties are often chronic and pervasive, and have an adverse effect on social, education and familial functioning. Childhood anxiety difficulties often persist into adulthood when left untreated [2] and are associated with comorbid mental health difficulties, including major depression and substance abuse [3,4]. The societal cost of a child with an anxiety difficulty is estimated to be 21 times that of a non-anxious child [5]. As such, effective identification and treatment of anxiety difficulties in childhood is important.

Effective treatments for childhood anxiety exist. However, very few children are offered or are able to access them [6,7]. For example, previous research has shown that only 2% of pre-adolescent children who meet criteria for an anxiety disorder in England receive an evidence-based intervention [7]. Barriers to receiving evidence-based treatment can include problems with the identification of anxiety difficulties, concerns regarding stigma to the child or family, as well as a scarcity of trained mental health professionals and long waiting lists for specialist services [8,9]. Practically speaking, attending group or face-to-face programs can also bring logistical barriers for parents with

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3 young families including time demands, and difficulties with  
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5 arranging transportation or child care [10-12].  
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8 The vast majority of children attend and spend much of  
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10 their time at school, therefore schools are also an ideal  
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12 setting to overcome many of these barriers [12,13]. However,  
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14 there is not a clear set of procedures for identifying youth  
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16 mental health difficulties and promoting access to evidence-  
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18 based treatments in schools. Moreover, previous international  
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20 studies have found mixed support for school based screening  
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22 and interventions for childhood anxiety, with some studies  
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24 reporting reductions in child anxiety symptoms [12,14], while  
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26 other studies have not [15]. Furthermore, some studies have  
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28 reported low uptake to school-based interventions, for reasons  
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30 including parents finding screening questionnaires too time  
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32 consuming, parent concerns about stigma, as well as fears that  
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34 their child may become more anxious from having had to discuss  
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36 their worries [14]. This highlights the need for novel  
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38 approaches to promote school based approaches to increase  
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40 access to early intervention for childhood anxiety  
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42 difficulties that are acceptable and well tolerated in order  
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44 to to increase parent participation.  
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51 One approach often used in healthcare service design and  
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53 development is 'co-design', where the knowledge and lived  
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55 experiences of service users themselves are drawn upon to  
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57 enhance the quality and experiences of care [16,17]. Co-design  
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59 aims to develop an in-depth understanding of how stakeholders  
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3 and service users perceive and experience the look, feel,  
4 procedures and structures of a service [18]. By engaging  
5 stakeholders and service users in co-designing a service, this  
6 is thought to lead to better quality of care and improved  
7 service performance by highlighting individual's subjective  
8 experiences at various points in the care pathway, which, in  
9 turn, may lead to improvements in health outcomes and more  
10 efficient allocation of limited healthcare resources [19].  
11 Given the importance of early intervention, an acceptable  
12 school-based pathway that incorporates the identification of  
13 children with anxiety difficulties and promotes uptake of  
14 evidence-based intervention is urgently needed. The  
15 Identifying Child Anxiety Through Schools - Identification to  
16 Intervention (iCATS i2i) study will develop procedures to  
17 identify and support child anxiety difficulties through  
18 schools informed by a co-design approach.

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40 This article describes the iCATS i2i co-design protocol.  
41 Data collection for this study will take place between  
42 December 2019 - December 2020. The co-designed procedures will  
43 be evaluated in a subsequent feasibility study and, if  
44 indicated, randomised control trial beginning in 2021.

#### 45 46 47 48 49 50 51 **Method**

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53 This protocol and associated procedures were approved by  
54 the Central University Research Ethics Committee at the  
55 University of Oxford (REF R64620/RE001).

#### 56 57 58 59 60 **Study design**



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3 We will apply a mixed-methods approach to co-design,  
4  
5 produce and deliver a set of procedures - or 'pathway' - to  
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7 improve access to evidence-based intervention for child  
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9 anxiety difficulties through primary schools (i.e. ages 5-11)  
10  
11 in England. Several of the key elements of the pathway were  
12  
13 specified in advance of the co-design work based on the  
14  
15 existing empirical literature and parent and school staff  
16  
17 consultation. Specifically, it was pre-specified that  
18  
19 children's anxiety difficulties would be screened using  
20  
21 questionnaire measures, parents would receive feedback, and,  
22  
23 where indicated, a brief, parent-led online intervention for  
24  
25 child anxiety difficulties would be offered. The delivery of  
26  
27 online treatment directly to parents was included as it has  
28  
29 potential to overcome many of the barriers to care described  
30  
31 above, such as logistical issues for parents and parental  
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33 concerns about negative impacts on the child of participating  
34  
35 in treatment [7,8].  
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41 In parallel to this work we are working on refining  
42  
43 measures for screening for child anxiety problems (Reardon et  
44  
45 al. under review), but in the interim we will screen using  
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47 brief child, parent and teacher versions of the Spence Child  
48  
49 Anxiety Scale (SCAS-8;[20]) together with four items that  
50  
51 assess the extent of interference in everyday life (e.g. "Do  
52  
53 fears and worries stop you from doing things?") generated to  
54  
55 assess the impact and chronicity of and perceived need for  
56  
57 help for anxiety difficulties. The addition of interference  
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3 items is known to improve the efficacy of similar self-report  
4 measures [21]. We will consider a child to have screened  
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7 'positive' for likely anxiety difficulties if they score above  
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10 the cut off on the SCAS-8 on the basis of any reporter (score  
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12 of 7.5 for parents, 6.5 for children, 4.5 for teachers) and/or  
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14 indicate that anxiety interferes at least 1 'only a little' on  
15  
16 any of the interference items. This interference-based cut off  
17  
18 score was based on feedback from the dedicated stakeholder  
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20 group. The use of a screening questionnaire to determine which  
21  
22 children may benefit from additional support with anxiety was  
23  
24 a prespecified component of the study as this approach shows  
25  
26 promise for increasing access to support (e.g. [22]).  
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30 The intervention to be offered is an online version of a  
31  
32 brief therapist-guided parent-delivered CBT approach for child  
33  
34 anxiety difficulties (OSI; Online Support and Intervention for  
35  
36 child anxiety). OSI was originally developed for use in  
37  
38 National Health Service (NHS) clinics and was co-designed by  
39  
40 NHS clinicians, parents and children who had received  
41  
42 treatment for anxiety (Hill et al., in preparation). This  
43  
44 intervention was selected as it is brief, effective [23] and  
45  
46 more cost-effective than brief face-to-face psychological  
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48 therapy [24] and can be delivered by non-expert practitioners  
49  
50 (e.g. [25]). The approach of working directly with the parent,  
51  
52 rather than the child, also addressed particular barriers to  
53  
54 seeking and accessing help for anxiety highlighted by parents,  
55  
56 including the preference to be supported to manage the  
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3 difficulties as a family and for the child not to be singled  
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5 out [7]. The online version of this intervention involves 7  
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7 online modules for parents, supported by a weekly 20-minute  
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9 telephone call with a Children's Wellbeing Practitioner (CWP,  
10  
11 NHS Band 5), with a follow-up telephone session 4-weeks later.  
12  
13 Modules teach parents how to explore their child's anxious  
14  
15 thoughts, put them to the test through facing fears, and to  
16  
17 problem solve challenges that arise. This is accompanied by a  
18  
19 game app for the child to help motivate them to face their  
20  
21 fears. The CWPs are postgraduate psychological therapists who  
22  
23 have received specific (12 month) training in the delivery of  
24  
25 brief psychological therapies for children and young people  
26  
27 who have difficulties with anxiety, low mood, and behavioural  
28  
29 disturbance. CWPs are based within settings where they can  
30  
31 offer rapid access to psychological therapies, often including  
32  
33 school based clinical services, and so are the ideal workforce  
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35 to implement the approach being developed if indicated.  
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41 We will use a mixed-method co-design process to determine  
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43 how the pre-specified parts of the pathway should be  
44  
45 presented, who by, and to address any important considerations  
46  
47 to optimise accessibility of and engagement with the pathway.  
48  
49 The co-design process will consist of four stages (see Figure  
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51 1) involving initial interviews and focus groups with parents,  
52  
53 children, school staff, stakeholders (Stage 1) to inform the  
54  
55 development of a set of procedures that will be applied in two  
56  
57 schools. These procedures will be delivered with participating  
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3 children, parents and school staff (Stage 2) who will provide  
4  
5 feedback on their experience (Stage 3 & 4), including cued-  
6  
7 recall specifically on the experience of receiving feedback on  
8  
9 whether their child experiences difficulties with anxiety.  
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11 Feedback from those families who choose not to be involved in  
12  
13 the study or dropped out will also be sought to ensure any  
14  
15 barriers to engagement are captured (Stage 4).  
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### 23 **Patient and public involvement (PPI)**

24  
25 Involvement from parents, school staff and wider  
26  
27 stakeholders informed the development of this protocol, the  
28  
29 pre-specified elements of the pathway and will contribute  
30  
31 throughout the delivery of the co-design project. At the  
32  
33 protocol development stage, consultation was carried out with  
34  
35 parents, school staff/governors, leading experts in universal  
36  
37 screening and interventions in primary school settings, and  
38  
39 representatives from key policy and practitioner  
40  
41 organisations. Examples of decisions that were made on the  
42  
43 basis of this consultation include specifically focussing  
44  
45 recruitment on children in Year 4 (age 8-9 years) on the basis  
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47 that this would be a manageable time for primary schools,  
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49 would allow primary schools to see the benefit, and for  
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51 children to benefit when managing subsequent key transitions  
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53 (e.g. to secondary school).  
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3 Throughout the co-design process we will consult with  
4 stakeholders in the following ways: (i) two parents with  
5 relevant lived experience, two school leaders and one mental  
6 health lead for a charity are members of the study management  
7 group and will contribute to all decisions made at a strategic  
8 level; (ii) this dedicated stakeholder group will meet to  
9 review data and to make decisions to address how to solve  
10 problems and manage potentially conflicting points of view  
11 that have arisen through the co-design process; and (iii) a  
12 distinct, separate online PPI group will also be formed, made  
13 up primarily of parents. Members will be invited to join via  
14 the circulation of adverts about the online group (e.g. advert  
15 shared on social media, circulation of advert to parents from  
16 participating Stage 2 schools), with the purpose of the group  
17 being to access wider parental views about study procedures  
18 and on key issues that arise during the study.

### 39 **Co-design Participants**

41 Participants will include Y4 children (aged 8-9 years),  
42 parents of Y4 children, primary school staff and other  
43 stakeholders. Expected participant numbers for each group and  
44 at each stage in the co-design process are outlined in Table  
45 1. These numbers are approximate and final numbers will be  
46 informed by reviewing the range of perspectives represented in  
47 the sample and the information provided by participants.

48 To recruit participants with a broad range of  
49 perspectives to Stage 1 we will circulate study invitations to  
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3 parents of all Year 4 children in two primary schools in the  
4 local Oxfordshire area, as well as using online on social  
5 media, and mailing lists to recruit parents with particular  
6 experiences. For the subsequent stages we will first contact  
7 school leaders to invite their school to participate, and  
8 circulate study information to Y4 parents and children  
9 inviting them to participate.  
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19 All adult participants will be required to give written  
20 consent and children will be required to give written assent  
21 to participate in all stages of the project.  
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26 ***Inclusion criteria:***  
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28 Children will be eligible to participate if they are in  
29 Y4 in a mainstream primary school in England, with  
30 parent/carer consent for their participation (Stages 1-4).  
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35 Parent/carers of children in Y4 in mainstream primary  
36 schools in England will be eligible to take part in Stages 1-  
37 4. However for Stage 1, we will also recruit parents through  
38 other routes in order to capture a range of experiences that  
39 might be particularly relevant to parents' engagement with and  
40 the accessibility of the pathway procedures, specifically  
41 parents who have a child with past/present mental health  
42 problem(s) or who is adopted/fostered, or where a parent has  
43 past/present mental health problem(s), or is in the military  
44 (due to their experience of frequent relocations, extended  
45 separation from parents, and parental physical or  
46 psychological injuries [26]).  
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School staff will be included if they are employed in a mainstream primary/junior school in England (e.g. class teacher, headteacher) (Stages 1-4).

The inclusion criteria for wider stakeholders is that they must be a member of an organisation that is responsible for policy or practice relating to mental health provision in primary schools in England (e.g. commissioning group, local authority, mental health service provider, local policy maker organisation, or a governor in mainstream primary/junior schools) (Stage 1 and 4).

**Table 1**

*Recruitment estimates for the co-design*

Assessment	Planned N			
	Stakeholders	Teachers	Parents	Children
Stage 1. Initial focus groups	2	7	16	9
Stage 2. Administering procedures			144	144
Stage 3. Cued recall interviews		4	12	
Stage 4. Post-screening	12	12	12	12

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2  
3 interviews/focus  
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5 groups  
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## 10 11 **Procedure**

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13 We will collect data at four stages to inform the  
14 development of the pathway (see Figure 1).  
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18 **Stage 1.** In this stage we will carry out in-depth one-to-  
19 one interviews and focus groups with stakeholders, school  
20 staff, children and parents. Focus groups and interviews will  
21 draw on questioning techniques informed by the Critical  
22 Incident Approach [27] to explore participants' views about  
23 features of the pathway which might help or hinder a positive  
24 experience, or which might have been overlooked by the pathway  
25 planners altogether. Focus groups and interviews will include  
26 table-top activities where participants are shown visual  
27 representations of different aspects of the pathway and they  
28 will be asked to discuss and write on provided notecards which  
29 will be placed on the table about their thoughts, feelings and  
30 concerns, with questions including: "What would be the best  
31 way to do this?", "Who do you think would be best placed to do  
32 this?", "What might need to be done to help this part  
33 happening?", "Where would be the best place for this to  
34 happen?", "When is the best time to do this?", "Do you have any  
35 concerns about this part of the pathway?". Photographs will be  
36 taken of the visuals produced in the focus groups and  
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3 interviews for analysis. Interviews and focus groups will be  
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5 audio-recorded and transcribed verbatim. This data will be  
6  
7 used to develop a detailed prototype set of procedures for  
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9 screening, feedback and intervention delivery through schools  
10  
11 to be tested and developed further. The dedicated stakeholder  
12  
13 group will be consulted at key decision making points in the  
14  
15 process to generate solutions to problems raised or  
16  
17 inconsistent messages elicited from the interviews.  
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21 **Stage 2.** The detailed prototype set of procedures  
22  
23 developed in Stage 1 will be administered in two primary  
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25 schools, including screening, feedback to parents, and the  
26  
27 offer of early intervention where indicated. We will encourage  
28  
29 each school to nominate a member of staff to be the 'pathway  
30  
31 lead' (e.g. a class teacher, the school's pastoral lead) who  
32  
33 will be given training and psychoeducation by the research  
34  
35 team about childhood anxiety difficulties and the proposed  
36  
37 pathway procedures. The 'pathway lead' will coordinate  
38  
39 recruitment efforts at their participating school, such as  
40  
41 circulating study information sheets amongst Y4 parents.  
42  
43 During Stage 2, we will quantitatively examine pathway  
44  
45 outcomes, including the proportion of parents in Y4 who agree  
46  
47 to participate in the screening, the number of eligible  
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49 parents who take up the intervention, the number of parents  
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51 who withdraw, and symptom improvement rates. We will also  
52  
53 conduct interviews with school staff, children and parents  
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55 (including children who screened 'negative' and those who  
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3 screened 'positive' for anxiety and their parents, and parents  
4 that did and did not take up the intervention) to examine  
5 their experiences of the pathway and potential  
6 barriers/facilitators to engagement.  
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12 **Stage 3.** On the basis of the dedicated stakeholder input  
13 at the protocol design stage, we anticipate that parents will  
14 be given written feedback on their child's screening outcomes  
15 by the school 'pathway lead', with the option of a face-to-  
16 face feedback appointment. The dedicated stakeholder group  
17 considered that feedback from the school 'pathway lead' would  
18 be preferred by families as families would likely have pre-  
19 existing relationships with the school and a member of school  
20 staff would therefore be well placed to introduce the CWP and  
21 the option to access the intervention. If this is supported by  
22 the outcomes of the earlier stages, the school staff member  
23 that is nominated to be the 'pathway lead' will receive  
24 training and guidance from the research team on delivering  
25 feedback to parents. To understand how this feedback is  
26 experienced, what works well and what parents (and the school  
27 staff 'pathway lead') find both helpful and challenging,  
28 participating parents and staff will be invited to take part  
29 in a cued-recall interview meeting to allow for the refinement  
30 of future feedback delivery and staff training. To this  
31 effect, the parent-staff feedback meetings will be video  
32 recorded by the research team. Recordings of the meeting will  
33 be watched back by parents with a member of the research team  
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3 to facilitate discussions about how questionnaire scores were  
4 fed back and how the opportunity to take up the intervention  
5 was shared with parents by 'pathway lead' school staff member.  
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7 The researcher will invite the parent to stop the recording  
8 periodically to comment at points that are relevant to  
9 particular cues, for example, at points where the parent felt  
10 the information delivered was unhelpful, or where they felt  
11 listened to. The cued-recall interview will be audio-recorded  
12 and transcribed verbatim.  
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23 **Stage 4.** Following the administration of the pathway  
24 procedures, interviews and focus groups will also be carried  
25 out with Y4 children, their parents and school staff in Stage  
26 4. We will carry out interviews with participating parents and  
27 children who completed the screening questionnaires and engage  
28 with the intervention modules, but also with any parents and  
29 children who withdraw and parents and children who choose not  
30 to enrol in the study. School staff (e.g., the 'pathway lead',  
31 Y4 class teachers) in participating schools will be  
32 interviewed about their experience of facilitating the pathway  
33 in Y4. Relevant stakeholders will also be interviewed about  
34 their views of the pathway and how well it will fit within  
35 school settings.  
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#### 52 **Data analysis**

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55 Focus groups and one-to-one interviews (Stages 1 and 4) will be analysed using two  
56 approaches: 'fast and direct' and 'in-depth and detailed'. The 'fast and direct' analysis will  
57 use the visual outputs from focus groups and interviews to collate themes and written  
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3 summaries will provide readily understandable feedback about the pathway. Brief,  
4  
5 complementary descriptions will be produced by following a simple protocol for verbalising  
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7 'multi- modal data' [28]The combination of thematised images and verbal summary will  
8  
9 provide immediate, easily- understood feedback about the pathway.  
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12 The 'in-depth and detailed' analysis will involve  
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14 Template Analysis [29] where an initial template is structured  
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16 by categories drawn from relevant literature and further  
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18 developed by preliminary coding of the data using a 'bottom  
19  
20 up' approach. Once the template is developed, all transcripts  
21  
22 will be analysed in a 'top down' manner following the  
23  
24 provisional structure of the template. This will provide  
25  
26 nuanced feedback about the acceptability of the pathway to  
27  
28 fine-tune the final iteration. This analysis will capture  
29  
30 areas of disagreement that may be missed in the 'fast and  
31  
32 direct' analysis. Cued-recall data (Stage 3) will also be  
33  
34 analysed using Template Analysis [29]. Credibility will be  
35  
36 checked via analytic triangulation using reflective  
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38 discussions with co-analysts.  
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#### 44 **Ethics and dissemination**

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46 This research is being conducted in a community setting and ethical approval has  
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48 been obtained from the University of Oxford's Research Ethics Committee. We will seek  
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50 consent from parents, school staff and other stakeholders and assent from children. Research  
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52 data will be kept secure and confidential. Audio/video-recordings will require explicit  
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54 consent.  
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57 A key part of this project will involve developing  
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59 acceptable procedures for feeding back outcomes from screening  
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3 questionnaires which may bring potential to cause participant  
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5 distress. Given that existing screening questionnaires have  
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7 modest sensitivity and specificity, this includes explaining  
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9 the possibility of an inaccurate result. We will pay  
10  
11 particular attention to this throughout the co-design process  
12  
13 to ensure we develop acceptable procedures and will seek out  
14  
15 families who received 'false-positive' screening feedback to  
16  
17 specifically explore their experience. Given the risk of  
18  
19 'false negatives', during this co-design phase the online  
20  
21 intervention will be made available to all families who take  
22  
23 part, along with information about additional resources,  
24  
25 support and services.

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30 **Dissemination.** This project aims to develop an effective  
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32 pathway to identify child anxiety difficulties in mainstream  
33  
34 schools and deliver a parent-led intervention through ongoing  
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36 collaborative work with schools, parents, children and  
37  
38 stakeholders, while fostering avenues for disseminating the  
39  
40 results directly to the community. Specifically, this co-  
41  
42 design study will lead on to a future feasibility study and,  
43  
44 if indicated, a randomised controlled trial. To disseminate  
45  
46 the findings from this initial stage research, we will produce  
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48 and disseminate a report that summarises outcomes in lay-  
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50 language to participating schools, which will also be shared  
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52 with participating families on request. The findings will be  
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54 published in high-quality, open access journals that reach  
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56 both academic, educational and clinical audiences. The  
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3 research team will also present the findings at national and  
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5 international clinical/educational conferences. We will also  
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7 collaborate with our dedicated stakeholder group to further  
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9 develop the dissemination plans to ensure maximum impact.  
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## 12 **Discussion**

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14 There is currently no evidence-based pathway for  
15  
16 identification and intervention for children with anxiety  
17  
18 difficulties in primary schools. Despite the existence of  
19  
20 cost-effective psychological treatments, very few children who  
21  
22 could benefit are able to access them [7]. This project aims  
23  
24 to generate knowledge using a co-design approach to inform the  
25  
26 development of such a pathway that links screening with the  
27  
28 direct provision of support for primary school aged children  
29  
30 to ensure that it is acceptable and ultimately implementable  
31  
32 within schools in England. By providing information on  
33  
34 children, parents, school-staff and other stakeholder's  
35  
36 experiences of this school-based pathway which includes  
37  
38 screening for likely child anxiety difficulties, feedback on  
39  
40 scores and the offer of an online intervention, we anticipate  
41  
42 that the findings will also inform broader approaches to  
43  
44 screening for and treating youth mental health problems  
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46 outside of clinics.  
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53 This research has several methodological limitations that  
54  
55 warrant consideration. First, because of the nature of child  
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57 and parent involvement in this study, we will use an 'opt-in'  
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59 approach to consent, where parents must consent to their and  
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3 their child's completion of the screening measures. This is  
4 likely to introduce bias in participation, and we risk failing  
5 to capture experiences of the pathway procedures for a  
6 sufficiently broad and diverse group of families where child  
7 anxiety difficulties (including for example, families who do  
8 not have concerns about child anxiety or where other barriers  
9 may exist, such as concerns about stigma). To address this, we  
10 will actively invite parents to Stage 1 and 4 interviews who  
11 both did and did not consent to screening as well as examine  
12 in interviews whether an 'opt-out' approach to screening would  
13 be acceptable in future iterations (e.g., screening measures  
14 are administered to the entire Y4 class unless parents opt-out  
15 their child from participating). A second potential limitation  
16 is that the study will primarily use online platforms for  
17 consent, and screening procedures, and to deliver the CBT  
18 intervention. This decision was informed by feedback from the  
19 dedicated stakeholder group who recommended that online  
20 participation was often considered more secure in terms of  
21 data protection and privacy. However, it introduces a risk of  
22 excluding families who have limited access to technology/Wi-Fi  
23 or lack technical skills or confidence. We will explore ways  
24 to enable participants in these situations to participate, and  
25 participant experiences of online access to the study will be  
26 examined.

27  
28 With these potential limitations in mind, it is our  
29 intention that this study will collaboratively create a  
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3 pathway to care for children who have problems with anxiety  
4 and their families, informed by children themselves, parents,  
5 school staff and other stakeholders, that will ultimately  
6 improve access to effective treatment and support.  
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27  
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29

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31 Williamson.<sup>a,b\*</sup>, Michael Larkin.<sup>c</sup>, Tessa Reardon<sup>a</sup>, Samantha  
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36 contributed towards the design of the study protocol,  
37 contributed towards the writing of the manuscript and approved  
38 the final version of the protocol. Authors (Victoria,  
39 Williamson.<sup>a,b\*</sup>, Michael Larkin.<sup>c</sup>, Tessa Reardon<sup>a</sup>, Samantha  
40 Pearcey<sup>a</sup>, Sue Spence<sup>f</sup>, Ian Mcdonald<sup>g</sup>, Tamsin Ford<sup>h</sup>, Jason  
41 Stainer<sup>k</sup>, Paul Brown<sup>l</sup>, Cathy Creswell.<sup>a</sup>) contributed towards  
42 data collection and analysis.  
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3 *Figure 1.* Overview of the co-design process for developing the  
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5 iCATS i2i protocol  
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8 Note. Y4 = year four.  
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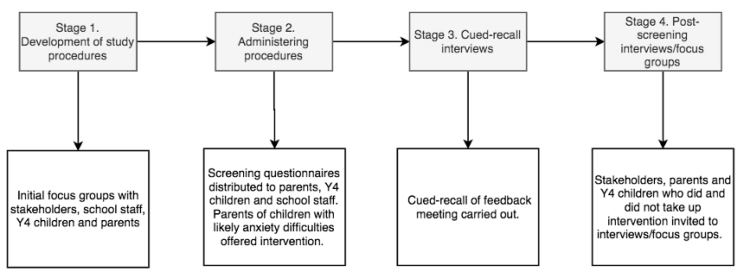


Figure 1. Overview of the co-design process for developing the iCATS i2i protocol

Note. Y4 = year four.

Figure 1

# BMJ Open

## Protocol for the co-design and development of a primary school-based pathway for child anxiety screening and intervention delivery: A mixed-methods feasibility study

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Keywords:	Anxiety disorders < PSYCHIATRY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MENTAL HEALTH, Child & adolescent psychiatry < PSYCHIATRY, QUALITATIVE RESEARCH

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## Abstract

**Introduction:** Anxiety difficulties are among the most common mental health problems in childhood. Despite this, few children access evidence-based interventions and school may be an ideal setting to improve children's access to treatment. This paper describes the design, methods, and expected data collection of the Identifying Child Anxiety Through Schools – Identification to Intervention (iCATS i2i) study which aims to develop acceptable school-based procedures to identify and support child anxiety difficulties.

**Methods and analysis:** iCATS i2i will use a mixed-methods approach to co-design and deliver a set of procedures – or 'pathway' – to improve access to evidence-based intervention for child anxiety difficulties through primary schools in England. The study will consist of four stages, initially involving in-depth interviews with parents, children, school staff, stakeholders (Stage 1) to inform the development of the pathway. The pathway will then be administered in two primary schools, including screening, feedback to parents, and the offer of treatment where indicated (Stage 2), with participating children, parents and school staff invited to provide feedback on their experience (Stages 3 & 4). Data will be analysed using Template Analysis.

**Ethics and dissemination:** The iCATS i2i study was approved by the University of Oxford's Research Ethics Committee (REF R64620/RE001). It is expected that this co-design study will lead on to a future feasibility study and, if indicated, a randomised controlled trial. The findings will be disseminated in several ways, including via lay summary report, publication in academic journals and presentation at conferences. By providing information on child, parent, school-staff and other stakeholder's experiences, we anticipate that the findings will inform the development of an acceptable evidence-based pathway for identification and intervention for children with

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3 anxiety difficulties in primary schools and may also inform broader approaches to  
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5 screening for and treating youth mental health problems outside of clinics.  
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8 **Strengths and limitations of this study:**  
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- 10
- 11 • Focus on child anxiety difficulties, one of the most common mental health  
12 problems in childhood.  
13
  - 14 • By using a co-design approach which incorporates feedback from children,  
15 parents, school-staff and stakeholders, this study will lead to the development of  
16 acceptable procedures for screening and offering treatment for child anxiety  
17 difficulties in primary schools.  
18
  - 19 • The study is limited by the use of an 'opt-in' approach to consent which could  
20 introduce participation bias.  
21
  - 22 • The primary use of online platforms for consent, screening and delivery of the  
23 CBT intervention may exclude families who have limited access to technology or  
24 lack technical skills; although ways to facilitate the participation of those in these  
25 situations will be explored.  
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## Introduction

Anxiety difficulties are among the most common mental health problems in childhood (6.5% prevalence; [1]) and approximately half of all anxiety difficulties emerge by the age of 11 years. Childhood anxiety difficulties are often chronic and pervasive, and have an adverse effect on social, education and familial functioning. Childhood anxiety difficulties often persist into adulthood when left untreated [2] and are associated with comorbid mental health difficulties, including major depression and substance abuse [3,4]. The societal cost of a child with an anxiety difficulty is estimated to be 21 times that of a non-anxious child [5]. As such, effective identification and treatment of anxiety difficulties in childhood is important.

Effective treatments for childhood anxiety exist. However, very few children are offered or are able to access them [6,7]. For example, previous research has shown that only 2% of pre-adolescent children who meet criteria for an anxiety disorder in England receive an evidence-based intervention [7]. Barriers to receiving evidence-based treatment can include problems with the identification of anxiety difficulties, concerns regarding stigma to the child or family, as well as a scarcity of trained mental health professionals and long waiting lists for specialist services [8,9]. Practically speaking, attending group or face-to-face programs can also bring logistical barriers for parents with young families including time demands, and difficulties with arranging transportation or child care [10–12].

The vast majority of children attend and spend much of their time at school, therefore schools are also an ideal setting to overcome many of these barriers [12,13]. However, there is not a clear set of procedures for identifying youth mental health difficulties and promoting access to evidence-based treatments in schools. Moreover, previous international studies have found mixed support for school based screening

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3 and interventions for childhood anxiety, with some studies reporting reductions in child  
4 anxiety symptoms [12,14], while other studies have not [15]. Furthermore, some  
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6 anxiety symptoms [12,14], while other studies have not [15]. Furthermore, some  
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8 studies have reported low uptake to school-based interventions, for reasons including  
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10 parents finding screening questionnaires too time consuming, parent concerns about  
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12 stigma, as well as fears that their child may become more anxious from having had to  
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14 discuss their worries [14]. This highlights the need for novel approaches to promote  
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16 school based approaches to increase access to early intervention for childhood anxiety  
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18 difficulties that are acceptable and well tolerated in order to to increase parent  
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20 participation.  
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25 One approach often used in healthcare service design and development is 'co-  
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27 design', where the knowledge and lived experiences of service users themselves are  
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29 drawn upon to enhance the quality and experiences of care [16,17]. Co-design aims to  
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31 develop an in-depth understanding of how stakeholders and service users perceive and  
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33 experience the look, feel, procedures and structures of a service [18]. By engaging  
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35 stakeholders and service users in co-designing a service, this is thought to lead to better  
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37 quality of care and improved service performance by highlighting individual's  
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39 subjective experiences at various points in the care pathway, which, in turn, may lead to  
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41 improvements in health outcomes and more efficient allocation of limited healthcare  
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43 resources [19]. Given the importance of early intervention, an acceptable school-based  
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45 pathway that incorporates the identification of children with anxiety difficulties and  
46  
47 promotes uptake of evidence-based intervention is urgently needed. The Identifying  
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49 Child Anxiety Through Schools – Identification to Intervention (iCATS i2i) study will  
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51 develop procedures to identify and support child anxiety difficulties through schools  
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53 informed by a co-design approach.  
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3 This article describes the iCATS i2i co-design protocol. Data collection for this  
4 study will take place between December 2019 - December 2020. The co-designed  
5 procedures will be evaluated in a subsequent feasibility study and, if indicated,  
6 randomised control trial beginning in 2021.  
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## 12 Method

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14 This protocol and associated procedures were approved by the Central  
15 University Research Ethics Committee at the University of Oxford (REF  
16 R64620/RE001).  
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### 22 Study design

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24 We will apply a mixed-methods approach to co-design, produce and deliver a set  
25 of procedures – or ‘pathway’ - to improve access to evidence-based intervention for  
26 child anxiety difficulties through primary schools (i.e. ages 5-11) in England. Several of  
27 the key elements of the pathway were specified in advance of the co-design work based  
28 on the existing empirical literature and parent and school staff consultation. Specifically,  
29 it was pre-specified that children’s anxiety difficulties would be screened using  
30 questionnaire measures, parents would receive feedback, and, where indicated, a brief,  
31 parent-led online intervention for child anxiety difficulties would be offered. The  
32 delivery of online treatment directly to parents was included as it has potential to  
33 overcome many of the barriers to care described above, such as logistical issues for  
34 parents and parental concerns about negative impacts on the child of participating in  
35 treatment [7,8].  
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52 In parallel to this work we are working on refining measures for screening for  
53 child anxiety problems (Reardon et al. under review), but in the interim we will screen  
54 using brief child, parent and teacher versions of the Spence Child Anxiety Scale (SCAS-  
55 8;[20]) together with four items that assess the extent of interference in everyday life  
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3 (e.g. “Do fears and worries stop you from doing things?”) generated to assess the impact  
4 and chronicity of and perceived need for help for anxiety difficulties. The addition of  
5 interference items is known to improve the efficacy of similar self-report measures [21].  
6  
7 We will consider a child to have screened ‘positive’ for likely anxiety difficulties if they  
8 score above the cut off on the SCAS-8 on the basis of any reporter (score of 7.5 for  
9 parents, 6.5 for children, 4.5 for teachers) and/or indicate that anxiety interferes at  
10 least 1 ‘only a little’ on any of the interference items. This interference-based cut off  
11 score was based on feedback from the dedicated stakeholder group. The use of a  
12 screening questionnaire to determine which children may benefit from additional  
13 support with anxiety was a prespecified component of the study as this approach shows  
14 promise for increasing access to support (e.g. [22]).  
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29 The intervention to be offered is an online version of a brief therapist-guided  
30 parent-delivered cognitive behavioural therapy (CBT) approach for child anxiety  
31 difficulties (OSI; Online Support and Intervention for child anxiety). OSI was originally  
32 developed for use in National Health Service (NHS) clinics and was co-designed by NHS  
33 clinicians, parents and children who had received treatment for anxiety (Hill et al., in  
34 preparation). This intervention was selected as it is brief, effective [23] and more cost-  
35 effective than brief face-to-face psychological therapy [24] and can be delivered by non-  
36 expert practitioners (e.g. [25]). The approach of working directly with the parent,  
37 rather than the child, also addressed particular barriers to seeking and accessing help  
38 for anxiety highlighted by parents, including the preference to be supported to manage  
39 the difficulties as a family and for the child not to be singled out [7]. The online version  
40 of this intervention involves 7 online modules for parents, supported by a weekly 20-  
41 minute telephone call with a Children’s Wellbeing Practitioner (CWP, NHS Band 5), with  
42 a follow-up telephone session 4-weeks later. Modules teach parents how to explore  
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3 their child's anxious thoughts, put them to the test through facing fears, and to problem  
4 solve challenges that arise. This is accompanied by a game app for the child to help  
5 motivate them to face their fears. The CWPs are postgraduate psychological therapists  
6 who have received specific (12 month) training in the delivery of brief psychological  
7 therapies for children and young people who have difficulties with anxiety, low mood,  
8 and behavioural disturbance. CWPs are based within settings where they can offer rapid  
9 access to psychological therapies, often including school based clinical services, and so  
10 are the ideal workforce to implement the approach being developed if indicated.  
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22 We will use a mixed-method co-design process to determine *how* the pre-  
23 specified parts of the pathway should be presented, who by, and to address any  
24 important considerations to optimise accessibility of and engagement with the pathway.  
25 The co-design process will consist of four stages (see Figure 1) involving initial  
26 interviews and focus groups with parents, children, school staff, stakeholders (Stage 1)  
27 to inform the development of a set of procedures that will be applied in two schools.  
28 These procedures will be delivered with participating children, parents and school staff  
29 (Stage 2) who will provide feedback on their experience (Stage 3 & 4), including cued-  
30 recall specifically on the experience of receiving feedback on whether their child  
31 experiences difficulties with anxiety. Feedback from those families who choose not to be  
32 involved in the study or dropped out will also be sought to ensure any barriers to  
33 engagement are captured (Stage 4).  
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#### 50 **Patient and public involvement (PPI)**

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52 Involvement from parents, school staff and wider stakeholders informed the  
53 development of this protocol, the pre-specified elements of the pathway and will  
54 contribute throughout the delivery of the co-design project. At the protocol  
55 development stage, consultation was carried out with parents, school staff/governors,  
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3 leading experts in universal screening and interventions in primary school settings, and  
4 representatives from key policy and practitioner organisations. Examples of decisions  
5 that were made on the basis of this consultation include specifically focussing  
6 recruitment on children in Year 4 (age 8-9 years) on the basis that this would be a  
7 manageable time for primary schools, would allow primary schools to see the benefit,  
8 and for children to benefit when managing subsequent key transitions (e.g. to  
9 secondary school).

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20 Throughout the co-design process we will consult with stakeholders in the  
21 following ways: (i) two parents with relevant lived experience, two school leaders and  
22 one mental health lead for a charity are members of the study management group and  
23 will contribute to all decisions made at a strategic level; (ii) this dedicated stakeholder  
24 group will meet to review data and to make decisions to address how to solve problems  
25 and manage potentially conflicting points of view that have arisen through the co-  
26 design process; and (iii) a distinct, separate online PPI group will also be formed, made  
27 up primarily of parents. Members will be invited to join via the circulation of adverts  
28 about the online group (e.g. advert shared on social media, circulation of advert to  
29 parents from participating Stage 2 schools), with the purpose of the group being to  
30 access wider parental views about study procedures and on key issues that arise during  
31 the study.

### 42 43 44 45 46 47 **Co-design Participants**

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50 Participants will include Y4 children (aged 8-9 years), parents of Y4 children,  
51 primary school staff and other stakeholders. Expected participant numbers for each  
52 group and at each stage in the co-design process are outlined in Table 1. These numbers  
53 are approximate and final numbers will be informed by reviewing the range of  
54 perspectives represented in the sample and the information provided by participants.  
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3 To recruit participants with a broad range of perspectives to Stage 1 we will  
4 circulate study invitations to parents of all Year 4 children in two primary schools in the  
5 local Oxfordshire area, as well as using online on social media, and mailing lists to  
6 recruit parents with particular experiences. For the subsequent stages we will first  
7 contact school leaders to invite their school to participate, and circulate study  
8 information to Y4 parents and children inviting them to participate.  
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17 All adult participants will be required to give written consent and children will  
18 be required to give written assent to participate in all stages of the project.  
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22 ***Inclusion criteria:***  
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24 Children will be eligible to participate if they are in Y4 in a mainstream primary  
25 school in England, with parent/carer consent for their participation (Stages 1-4).  
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29 Parent/carers of children in Y4 in mainstream primary schools in England will  
30 be eligible to take part in Stages 1-4. However for Stage 1, we will also recruit parents  
31 through other routes in order to capture a range of experiences that might be  
32 particularly relevant to parents' engagement with and the accessibility of the pathway  
33 procedures, specifically parents who have a child with past/present mental health  
34 problem(s) or who is adopted/fostered, or where a parent has past/present mental  
35 health problem(s), or is in the military (due to their experience of frequent relocations,  
36 extended separation from parents, and parental physical or psychological injuries [26]).  
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48 School staff will be included if they are employed in a mainstream  
49 primary/junior school in England (e.g. class teacher, headteacher) (Stages 1-4).  
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52 The inclusion criteria for wider stakeholders is that they must be a member of an  
53 organisation that is responsible for policy or practice relating to mental health  
54 provision in primary schools in England (e.g. commissioning group, local authority,  
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mental health service provider, local policy maker organisation, or a governor in mainstream primary/junior schools) (Stage 1 and 4).

**Table 1**

*Recruitment estimates for the co-design*

Assessment	Planned N			
	Stakeholders	Teachers	Parents	Children
Stage 1. Initial focus groups	2	7	16	9
Stage 2. Administering procedures			144	144
Stage 3. Cued recall interviews		4	12	
Stage 4. Post-screening interviews/focus groups	12	12	12	12

## Procedure

We will collect data at four stages to inform the development of the pathway (see Figure 1).

**Stage 1.** In this stage we will carry out in-depth one-to-one interviews and focus groups with stakeholders, school staff, children and parents. Focus groups and interviews will



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3 draw on questioning techniques informed by the Critical Incident Approach [27] to  
4 explore participants' views about features of the pathway which might help or hinder a  
5 positive experience, or which might have been overlooked by the pathway planners  
6 altogether. Focus groups and interviews will include table-top activities where  
7 participants are shown visual representations of different aspects of the pathway and  
8 they will be asked to discuss and write on provided notecards which will be placed on  
9 the table about their thoughts, feelings and concerns, with questions including: "What  
10 would be the best way to do this?", "Who do you think would be best placed to do this?",  
11 "What might need to be done to help this part happening?", "Where would be the best  
12 place for this to happen?", "When is the best time to do this?", "Do you have any concerns  
13 about this part of the pathway?". Photographs will be taken of the visuals produced in  
14 the focus groups and interviews for analysis. Interviews and focus groups will be audio-  
15 recorded and transcribed verbatim. This data will be used to develop a detailed  
16 prototype set of procedures for screening, feedback and intervention delivery through  
17 schools to be tested and developed further. The dedicated stakeholder group will be  
18 consulted at key decision making points in the process to generate solutions to  
19 problems raised or inconsistent messages elicited from the interviews.  
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43 **Stage 2.** The detailed prototype set of procedures developed in Stage 1 will be  
44 administered in two primary schools, including screening, feedback to parents, and the  
45 offer of early intervention where indicated. We will encourage each school to nominate  
46 a member of staff to be the 'pathway lead' (e.g. a class teacher, the school's pastoral  
47 lead) who will be given training and psychoeducation by the research team about  
48 childhood anxiety difficulties and the proposed pathway procedures. The 'pathway lead'  
49 will coordinate recruitment efforts at their participating school, such as circulating  
50 study information sheets amongst Y4 parents. During Stage 2, we will quantitatively  
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3 examine pathway outcomes, including the proportion of parents in Y4 who agree to  
4 participate in the screening, the number of eligible parents who take up the  
5 intervention, the number of parents who withdraw, and symptom improvement rates.  
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9 We will also conduct interviews with school staff, children and parents (including  
10 children who screened 'negative' and those who screened 'positive' for anxiety and their  
11 parents, and parents that did and did not take up the intervention) to examine their  
12 experiences of the pathway and potential barriers/facilitators to engagement.  
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19 *Stage 3.* On the basis of the dedicated stakeholder input at the protocol design  
20 stage, we anticipate that parents will be given written feedback on their child's  
21 screening outcomes by the school 'pathway lead', with the option of a face-to-face  
22 feedback appointment. The dedicated stakeholder group considered that feedback from  
23 the school 'pathway lead' would be preferred by families as families would likely have  
24 pre-existing relationships with the school and a member of school staff would therefore  
25 be well placed to introduce the CWP and the option to access the intervention. If this is  
26 supported by the outcomes of the earlier stages, the school staff member that is  
27 nominated to be the 'pathway lead' will receive training and guidance from the research  
28 team on delivering feedback to parents. To understand how this feedback is  
29 experienced, what works well and what parents (and the school staff 'pathway lead')  
30 find both helpful and challenging, participating parents and staff will be invited to take  
31 part in a cued-recall interview meeting to allow for the refinement of future feedback  
32 delivery and staff training. To this effect, the parent-staff feedback meetings will be  
33 video recorded by the research team. Recordings of the meeting will be watched back  
34 by parents with a member of the research team to facilitate discussions about how  
35 questionnaire scores were fed back and how the opportunity to take up the intervention  
36 was shared with parents by 'pathway lead' school staff member. The researcher will  
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3 invite the parent to stop the recording periodically to comment at points that are  
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5 relevant to particular cues, for example, at points where the parent felt the information  
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7 delivered was unhelpful, or where they felt listened to. The cued-recall interview will be  
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9 audio-recorded and transcribed verbatim.  
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12 **Stage 4.** Following the administration of the pathway procedures, interviews and  
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14 focus groups will also be carried out with Y4 children, their parents and school staff in  
15  
16 Stage 4. We will carry out interviews with participating parents and children who  
17  
18 completed the screening questionnaires and engage with the intervention modules, but  
19  
20 also with any parents and children who withdraw and parents and children who choose  
21  
22 not to enrol in the study. School staff (e.g., the 'pathway lead', Y4 class teachers) in  
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24 participating schools will be interviewed about their experience of facilitating the  
25  
26 pathway in Y4. Relevant stakeholders will also be interviewed about their views of the  
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28 pathway and how well it will fit within school settings.  
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### 33 **Data analysis**

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35 Focus groups and one-to-one interviews (Stages 1 and 4) will be analysed using two  
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37 approaches: 'fast and direct' and 'in-depth and detailed'. The 'fast and direct' analysis will  
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39 use the visual outputs from focus groups and interviews to collate themes and written  
40  
41 summaries will provide readily understandable feedback about the pathway. Brief,  
42  
43 complementary descriptions will be produced by following a simple protocol for verbalising  
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45 'multi-modal data' [28] The combination of thematised images and verbal summary will  
46  
47 provide immediate, easily-understood feedback about the pathway.  
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52 The 'in-depth and detailed' analysis will involve Template Analysis [29] where  
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54 an initial template is structured by categories drawn from relevant literature and  
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56 further developed by preliminary coding of the data using a 'bottom up' approach. Once  
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58 the template is developed, all transcripts will be analysed in a 'top down' manner  
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3 following the provisional structure of the template. This will provide nuanced feedback  
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5 about the acceptability of the pathway to fine-tune the final iteration. This analysis will  
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7 capture areas of disagreement that may be missed in the 'fast and direct' analysis. Cued-  
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9 recall data (Stage 3) will also be analysed using Template Analysis [29]. Credibility will  
10  
11 be checked via analytic triangulation using reflective discussions with co-analysts.  
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### 14 15 **Ethics and dissemination**

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17 This research is being conducted in a community setting and ethical approval has  
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19 been obtained from the University of Oxford's Research Ethics Committee. We will seek  
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21 consent from parents, school staff and other stakeholders and assent from children. Research  
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23 data will be kept secure and confidential. Audio/video-recordings will require explicit  
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25 consent.  
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29 A key part of this project will involve developing acceptable procedures for  
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31 feeding back outcomes from screening questionnaires which may bring potential to  
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33 cause participant distress. Given that existing screening questionnaires have modest  
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35 sensitivity and specificity, this includes explaining the possibility of an inaccurate result.  
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37 We will pay particular attention to this throughout the co-design process to ensure we  
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39 develop acceptable procedures and will seek out families who received 'false-positive'  
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41 screening feedback to specifically explore their experience. Given the risk of 'false  
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43 negatives', during this co-design phase the online intervention will be made available to  
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45 all families who take part, along with information about additional resources, support  
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47 and services.  
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52 ***Dissemination.*** This project aims to develop an effective pathway to identify  
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54 child anxiety difficulties in mainstream schools and deliver a parent-led intervention  
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56 through ongoing collaborative work with schools, parents, children and stakeholders,  
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58 while fostering avenues for disseminating the results directly to the community.  
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3 Specifically, this co-design study will lead on to a future feasibility study and, if  
4 indicated, a randomised controlled trial. To disseminate the findings from this initial  
5 stage research, we will produce and disseminate a report that summarises outcomes in  
6 lay-language to participating schools, which will also be shared with participating  
7 families on request. The findings will be published in high-quality, open access journals  
8 that reach both academic, educational and clinical audiences. The research team will  
9 also present the findings at national and international clinical/educational conferences.  
10 We will also collaborate with our dedicated stakeholder group to further develop the  
11 dissemination plans to ensure maximum impact.  
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### 24 Discussion

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26 There is currently no evidence-based pathway for identification and intervention  
27 for children with anxiety difficulties in primary schools. Despite the existence of cost-  
28 effective psychological treatments, very few children who could benefit are able to  
29 access them [7]. This project aims to generate knowledge using a co-design approach to  
30 inform the development of such a pathway that links screening with the direct  
31 provision of support for primary school aged children to ensure that it is acceptable and  
32 ultimately implementable within schools in England. By providing information on  
33 children, parents, school-staff and other stakeholder's experiences of this school-based  
34 pathway which includes screening for likely child anxiety difficulties, feedback on  
35 scores and the offer of an online intervention, we anticipate that the findings will also  
36 inform broader approaches to screening for and treating youth mental health problems  
37 outside of clinics.  
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54 This research has several methodological limitations that warrant consideration.  
55 First, because of the nature of child and parent involvement in this study, we will use an  
56 'opt-in' approach to consent, where parents must consent to their and their child's  
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3 completion of the screening measures. This is likely to introduce bias in participation,  
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5 and we risk failing to capture experiences of the pathway procedures for a sufficiently  
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7 broad and diverse group of families where child anxiety difficulties (including for  
8  
9 example, families who do not have concerns about child anxiety or where other barriers  
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11 may exist, such as concerns about stigma). To address this, we will actively invite  
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13 parents to Stage 1 and 4 interviews who both did and did not consent to screening as  
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15 well as examine in interviews whether an 'opt-out' approach to screening would be  
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17 acceptable in future iterations (e.g., screening measures are administered to the entire  
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19 Y4 class unless parents opt-out their child from participating). A second potential  
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21 limitation is that the study will primarily use online platforms for consent, and  
22  
23 screening procedures, and to deliver the CBT intervention. This decision was informed  
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25 by feedback from the dedicated stakeholder group who recommended that online  
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27 participation was often considered more secure in terms of data protection and privacy.  
28  
29 However, it introduces a risk of excluding families who have limited access to  
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31 technology/Wi-Fi or lack technical skills or confidence. We will explore ways to enable  
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33 participants in these situations to participate, and participant experiences of online  
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35 access to the study will be examined.

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43 With these potential limitations in mind, it is our intention that this study will  
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45 collaboratively create a pathway to care for children who have problems with anxiety  
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47 and their families, informed by children themselves, parents, school staff and other  
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49 stakeholders, that will ultimately improve access to effective treatment and support.  
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56  
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7  
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9

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20 a)

21  
22 contributed towards the design of the study protocol, contributed towards the writing  
23  
24 of the manuscript and approved the final version of the protocol. Authors (Victoria,  
25  
26 Williamson.<sup>a,b\*</sup>, Michael Larkin.<sup>c</sup> , Tessa Reardon<sup>a</sup> , Samantha Pearcey<sup>a</sup>, Sue Spence<sup>f</sup>, Ian  
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28 Mcdonald<sup>g</sup>, Tamsin Ford<sup>h</sup>, Jason Stainer<sup>k</sup>, Paul Brown<sup>l</sup>, Cathy Creswell. a) contributed  
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30 towards data collection and analysis.  
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*Figure 1.* Overview of the co-design process for developing the iCATS i2i protocol

*Note.* Y4 = year four.

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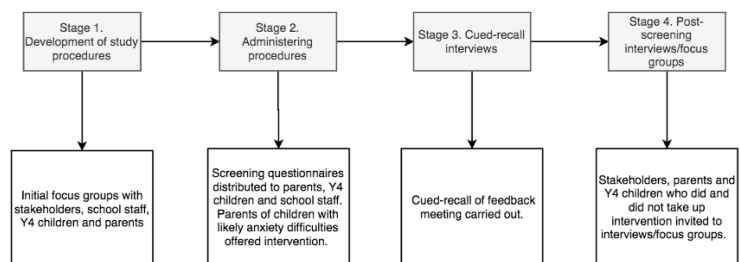


Figure 1. Overview of the co-design process for developing the iCATS i2i protocol

Note. Y4 = year four.

Figure 1