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Reardon, Tessa, Ukoumunne, Obioha C., Taylor, Lucy et al. (2026) Screening-to-intervention pathway for child anxiety problems alongside usual school practice versus usual school practice only (iCATSi2i): a cluster-randomised, controlled trial in primary schools in England. The Lancet Psychiatry. pp. 396-412. ISSN: 2215-0374

https://doi.org/10.1016/S2215-0366(26)00064-7

Screening-to-intervention pathway for child anxiety problems alongside usual school practice versus usual school practice only (iCATSi2i): a cluster-randomised, controlled trial in primary schools in England

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Lancet Psychiatry 2026; 13: 396–412

Published Online April 9, 2026 https://doi.org/10.1016/S2215-0366(26)00064-7

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Summary

Background Screening for anxiety problems in primary schools and offering parent-led cognitive behavioural therapy (CBT) via online and telephone support for those who screen positive could address key barriers to effective early intervention for some of the most prevalent child mental disorders. We aimed to evaluate outcomes from a screening-to-intervention pathway for child anxiety problems alongside usual school provision compared with assessment and usual school provision only.

Methods iCATSi2i was a pragmatic, parallel-group, superiority, cluster-randomised, controlled trial in 84 primary and junior schools in England with at least two year-4 classes. Children aged 8–9 years in participating classes who were not opted out by their parent were eligible to participate. After baseline assessments, schools (clusters) were randomly assigned (1:1) to screening, feedback, and intervention, alongside usual school practice (intervention group) or assessment and usual school practice only (control group), stratified by school-level deprivation. Before allocation, schools were ordered by the number of children who screened positive for anxiety problems at baseline (target population). Block randomisation was used with block sizes of two and four. Trial statisticians were masked to group allocation until datasets were ready for final analysis. In schools in the intervention group all parents in sampled classes were invited to complete a two-item screening questionnaire (iCATS-2) at baseline and received feedback on the screening outcome (after randomisation); parents of children who screened positive for anxiety problems (target population) were offered parent-led CBT delivered via online and telephone support, using the Online Support and Intervention for Child Anxiety (OSI) platform (and this was available for other families on request); a single whole-class session on identifying and managing fears and worries was also provided. In both groups, assessments (including the screening questionnaire) were completed and schools continued with usual provision. The primary outcome was screen-negative for anxiety problems (score 0–2 on the parent-reported iCATS-2) versus screen-positive (score 3–6) in the target population at 12 months. Primary analyses were conducted in the intention-to-treat population, with missing data imputed. Adverse events were monitored and recorded throughout. The trial was registered with the ISRCTN registry, ISRCTN76119074, and the study is complete. The study management group included individuals with relevant lived experience.

Findings We recruited participants and collected baseline assessments between Jan 6, and Nov 30, 2022. Parents of 1459 children (27% of 5335 children in participating classes) completed the screening questionnaire, and 409 screened positive (target population). On the basis of parent report, 222 (54%) of 408 children who screened positive were female, 185 (45%) were male, and one (<1%) preferred not to report child gender. 325 (85%) of 384 children were reported by the school as White. The mean age was 8·8 years (SD 0·3). 42 schools were randomly assigned to the intervention group (target population: 205 children) and 42 to the control group (target population: 204 children). In the target population at 12 months, more children screened negative for anxiety problems in the intervention group (89 [61%] of 145 children) than the control group (62 [38%] of 163 children), with an adjusted odds ratio of 2·32 (95% CI 1·41–3·81; p=0·0009) in the primary analysis based on imputed data. No serious adverse events related to trial procedures or the intervention or adverse events related to the intervention were reported.

Interpretation An integrated screening-to-intervention pathway for child anxiety problems in primary schools reduced parent-reported child anxiety problems compared with assessment and usual provision only, providing a promising way to improve access to effective early intervention.

Funding National Institute for Health and Care Research Programme Grants for Applied Research.

Research in context

Evidence before this study

Cognitive behavioural therapy (CBT) is an effective treatment for child anxiety disorders, which for primary-school-aged children can be delivered effectively via parents. A trial in child and adolescent mental health services in 2020–23 in the UK showed that parent-led CBT with online and telephone support for parents of children (aged 5–12 years) with anxiety problems was non-inferior to usual (mostly evidence-based) care but with lower delivery costs. However, difficulties identifying anxiety problems in children and navigating a complex help-seeking process often prevent families from reaching services. Screening for child anxiety problems in primary schools and offering parent-led CBT with online and telephone support for parents of children who screen positive for anxiety problems could reduce identification and help-seeking barriers.
A comprehensive systematic review of school-based identification programmes conducted in 2017 identified no randomised controlled trials evaluating an integrated screening and intervention approach for child anxiety problems in primary schools. We searched PubMed from Jan 1, 2017 to Aug 17, 2025, using search terms related to anxiety, screening, schools, and randomised (see appendix p 92 for full search terms), placed no restrictions on language, and found no relevant randomised controlled trials. In previous research that informed this study, we found that: a two-item parent-reported screening questionnaire discriminated between children with and without diagnosable anxiety disorders with acceptable accuracy, whereas child-reported and teacher-reported measures of child anxiety symptoms and interference did not; co-designed procedures for administering screening, sharing screening outcomes with families, and offering parent-led CBT with online and telephone support for parents of identified children were feasible and acceptable; and school staff and family feedback emphasised the importance of providing some universal support alongside targeted parent-led intervention.

Added value of this study

To our knowledge, this is the first randomised controlled trial to test the effectiveness of an integrated screening-to-intervention pathway for child anxiety problems in primary schools. Compared with assessment and usual school practice alone, the screening-to-intervention pathway increased remission from parent-reported child anxiety problems up to 2 years later and brought wider benefits for children with anxiety problems based on parent-reported and teacher-reported outcomes. We found no evidence of benefits for child self-reported outcomes, which might relate to the lower validity for child-reported outcomes compared with parent-reported outcomes in this age group. There was little evidence of benefits for the wider population of all children in the class, and in this wider population (where children mostly just participated in the whole-class lesson and completed questionnaires) there was a small increase in child self-reported anxiety symptoms up to 1 year later in the intervention group compared with the control group.

Implications of all the available evidence

Evidence suggests that parent-led CBT with online and telephone support for parents is an effective and efficient treatment for primary-school-aged children with anxiety problems. Screening for anxiety problems in primary schools, sharing screening outcomes with families, and providing identified children with parent-led CBT with online and telephone support for their parents could increase access to effective early intervention for parent-reported child anxiety problems. Outcomes for the wider population of all children in participating classes do not support integrating the whole-class (universal) session.

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See **Online** for appendix

Introduction

Addressing the gap between need and mental health-care provision for children and adolescents is a global priority.[1] The global burden of mental health disorders in youth is increasing,[2] and many children and adolescents worldwide do not receive the mental health care they need and are entitled to.[1] Anxiety disorders are the most prevalent type of mental disorder across childhood and adolescence.[3] With a peak age of onset of 5·5 years,[4] anxiety disorders are characterised by particularly early onset and account for a higher proportion of disease burden than any other mental disorder among children aged 5–9 years;[3] as such, efforts to reduce the treatment gap for anxiety disorders need to include children of primary-school age.

Cognitive behavioural therapy (CBT) interventions are effective[5] and recommended as the first line of treatment for anxiety disorders in children.[6,7] For children of primary-school age, CBT delivered via parents and carers (hereafter referred to as parents) achieves similar outcomes to interventions provided directly to children, with reduced therapist contact time.[5] Digital delivery can increase efficiency and address barriers related to attending face-to-face appointments. A trial in child and adolescent mental health services in 2020–23 in the UK found that a parent-led CBT programme (Online Support and Intervention for Child Anxiety; OSI) for children aged 5–12 years with online and telephone therapist support for parents brought cost savings without compromising outcomes compared with usual care.[8] This increased efficiency provides an opportunity to increase the number of children that mental health services are able to support and reduce waiting times, but families need to reach these services in order to benefit.

Families face substantial barriers to identifying anxiety difficulties in children and navigating a complex process to reach child mental health services.[9,10] Offering support and interventions through schools provides a way to

reduce these barriers. Universal interventions can maximise reach and remove the need for help-seeking, but findings from universal interventions targeting anxiety are inconsistent. Children with elevated anxiety symptoms might not benefit,[11] and there is some evidence of possible harms from universal mental health interventions for some subgroups of children.[12,13] Systematic screening to identify children most likely to benefit and offering them evidence-based, targeted interventions would reduce key barriers to reaching external services. To our knowledge, no previous study has evaluated an integrated screening-to-intervention approach for anxiety problems in primary schools in a randomised controlled trial[14] (appendix p 92). In previous research, we developed a short parent-report screening tool (iCATS-2) that is able to identify children with anxiety disorders with reasonable accuracy[15] and worked with children, parents, and school staff to co-design procedures for administering screening in primary schools in England, sharing screening outcomes with families and offering CBT via online and telephone support for parents, using the OSI platform.[16] School staff and parents highlighted the importance of integrating some support for children whose parents do not participate so, alongside the targeted, parent-led intervention, a single whole-class session and resources for school staff were provided. Feedback from school staff and families and outcomes from a single-arm feasibility study supported progressing to a definitive trial.[17]

The primary aim of this study was to establish whether screening, feedback, and intervention for child anxiety problems in children in school-year 4 (aged 8–9 years), alongside usual school practice, brings clinical benefits or harms compared with assessment and usual school practice alone. The target population was children who screened positive for anxiety problems at baseline. We also evaluated outcomes for all children in participating classes (total population).

Methods

Study design

iCATSi2i was a pragmatic, parallel-group, superiority, cluster-randomised, controlled trial with an internal pilot. Cluster randomisation helped improve acceptability, prevent contamination within schools (clusters), and evaluate targeted and universal components.

Primary and junior schools in England were recruited in two cohorts (28 schools in the internal pilot, phase 1, and 56 schools in phase 2), with progression criteria assessed by an independent steering committee before commencing phase 2 (appendix p 4). Schools were required to have at least two classes with pupils in year 4 (children aged 8–9 years) and a minimum of 40 children in year 4. Two or three classes per school participated (where schools had two or three eligible classes, all eligible classes participated; where schools had more than three eligible classes, three classes were randomly sampled). To participate, headteachers needed to provide written agreement and schools needed to confirm they did not have a mental health support team (MHST)[18] in place at the point of recruitment. MHSTs deliver evidence-based interventions for common mental health problems in schools in England and at the outset of the trial were established in only a minority of primary schools. As MHSTs did not reflect usual practice at this time, including these schools might have hindered interpretation of findings and caused confusion for families and staff.

Ethics approval was obtained from the University of Oxford Medical Sciences Interdivisional Research Ethics Committee (reference R66068). The study was prospectively registered with the ISRCTN registry (ISRCTN76119074) and the study is complete. The protocol[19] and statistical analysis plan[20] are publicly available (see appendix pp 93–94 for details on an adjustment made to the timing of the first follow-up assessment that was agreed after phase 1 baseline data collection commenced but before randomisation).

The study management group, comprising all investigators (including members of school staff and parents who were able to represent their own and other families' lived experience of child anxiety disorders) and senior team members, met regularly throughout the study to discuss and agree all key decisions related to trial design, delivery, and reporting. An independent programme steering committee and separate data monitoring and ethics committee met annually to monitor trial progress.

Participants

Children in year 4 in participating classes (who were not opted out by their parent), their parent, and a class teacher or member of staff who worked regularly with them were eligible to participate. For children to be included in the total population at least one outcome measure (at any timepoint) had to be collected for the child, and a maximum of one child per household or family (on the basis of parent report) was included. The children from the total population who screened positive for anxiety problems (score 3–6 on the parent-reported iCATS-2) at baseline formed the target population. The iCATS-2 includes two items ("Do fears, worries, or anxiety upset or distress your child?" and "Do your child's fears, worries, or anxiety make things difficult for your family as a whole?") rated on a four-point scale (0–3) and summed to provide a total score (0–6).

Adults (parents and school staff) needed to provide written informed consent on paper or online before providing data about themselves or participating children. Children were provided with age-appropriate study information and needed to provide agreement by completing an assent form on paper before completing any child-reported measures. At each timepoint, the

children's current class teacher or staff who work regularly with them were invited to participate and complete teacher-reported measures. Parents of children in the total population who did not consent at baseline were able to request to join later. Children who did not assent at baseline were given the opportunity to assent at follow-up assessments. Demographic information about children (including gender [female; male; other; prefer not to say] and ethnicity) was collected from parents and school records; demographic information about adults (including gender [female; male; other; prefer not to say] and ethnicity) was collected via self-reported questionnaires.

Randomisation and masking

The trial statistician created an algorithm for school random assignment using R software and an independent statistician who was unconnected to the trial conducted the randomisation using this algorithm.

Schools (clusters) were randomly assigned (1:1) to screening, feedback, and intervention, alongside usual school practice (intervention group), or assessment and usual school practice only (control group) after all baseline assessments were complete for a phase. Randomisation was stratified according to level of deprivation among pupils on the school roll (above or below the 2020–21 national median of 21·6% of pupils eligible for free school meals[21]). Before allocation, schools were ordered by the number of children in the target population and block sizes of two and four were used to minimise imbalance in sample size between the groups.

The independent statistician shared the allocation with the study team who then informed schools and parents. It was not possible to mask trial group allocation for schools, participants, clinicians, or the study team. Trial statisticians remained masked to group status until final datasets were ready for analysis; they were not given access to data that revealed group status before this point.

Procedures

A full schedule of enrolment, intervention, and assessment is provided in the protocol.[19] Schools distributed paper and digital versions of study information in English to all parents of year-4 children in participating classes. Parents who chose to opt their child out of the study notified the school.

Parents could provide consent and their contact details and complete baseline questionnaires on paper or online using a secure online platform. Study team staff visited each school to invite children who had not been opted out to participate and administer child-reported baseline questionnaires on paper. Class teachers (or another nominated staff member who worked regularly with the class) were provided with digital study information and were asked to complete online teacher-reported baseline questionnaires for each child in the class who had not been opted out (see appendix p 95 for details).

Schools were asked to provide demographic information about children from the school records and to nominate a member of staff to provide information about usual activities related to social, emotional, and mental health and wellbeing for pupils via an online survey or a telephone call.

Follow-up questionnaires were collected at 4 months, 12 months, and 24 months for all participating children in the total and target populations. Follow-up questionnaires were sent directly to parents online or as paper versions with return envelopes. Study team members visited schools to administer follow-up child-reported questionnaires on paper, with the option for children to complete at home or at school on another day. Follow-up teacher-reported questionnaires were collected from the current class teacher or staff using the same procedure at each assessment. A range of strategies was used to promote retention, including thank you payments for parents, teachers, and schools (see appendix p 95 for full details).

In schools allocated to the intervention group only, parents who completed the iCATS-2 at baseline received a letter to let them know whether their responses indicated their child might be experiencing anxiety problems (screen positive) or was unlikely to be experiencing anxiety problems (screen negative), and that provided information about the intervention. When a child screened positive, parents were contacted to arrange a feedback call with a children's wellbeing practitioner (National Health Service band 5) to discuss the screening outcome and offer the parent-led CBT intervention using the OSI platform; other parents were able to request a feedback call and take up the intervention. Schools received a list of the names of children who screened positive, where parents provided explicit consent for this.

Study team staff visited schools in the intervention group to facilitate a whole-class interactive session for each participating class (total population; appendix pp 96–97); school staff arranged alternative activities for children who opted out. The session was developed in response to feedback from school staff and families in the previous co-design research. The session provided information on recognising and managing fears and worries and a problem-solving activity (based on similar content on the OSI platform), and guidance on asking for help. Schools were provided with session materials and information to share with parents after the session.

OSI is a parent-led CBT intervention. Parents complete seven online modules (modules 0–6), each of which is 20–30 min long, and have a short call of approximately 20 min with a children's wellbeing practitioner after each module and about 4 weeks after the final intervention content (module 7). Modules provide parents with strategies to explore and test their child's anxious

For **OSI** see https://osiresearch.org.uk/osi/

thoughts (exposure), problem solve, and develop independence, and include questionnaires, simple text, interactive activities, videos and animations, and audio versions of written content. Parents had access to an optional mobile game app (Monster's Journey: Facing Fears, version 1.2) for their child, which is designed to help motivate children to engage with the intervention activities.

Eight trial therapists (seven children's wellbeing practitioners and one trainee clinical psychologist) received initial training in OSI delivery through written material, discussion, role-play, and observation, and were provided with highly structured standardised guidance on how to support parents. Therapists received weekly supervision from a clinical psychologist with expertise in child anxiety treatment and OSI. Supervisors closely monitored intervention adherence, including through using audio-recordings of support calls, and therapists and supervisors recorded time spent on intervention and supervision activities throughout.

Schools and families in both the intervention and control groups were able to continue to seek, access, and provide any usual social, emotional, and mental health support and intervention for children and families. After the 24-month assessment, all parents in both groups were given access to written and audio versions of the OSI modules and schools in the control group received the whole-class session materials.

Outcomes

The primary outcome (binary) was screen-negative for child anxiety problems (score 0–2 on the parent-reported iCATS-2) versus screen-positive (score 3–6) in the target population at 12 months after randomisation.

Secondary outcomes included screen-negative on the iCATS-2 versus screen-positive between the two groups for the target population at 4 months and 24 months after randomisation, and for the total population at 4, 12, and 24 months after randomisation.

We assessed the following continuous secondary clinical outcomes for both the target population and the total population at 4, 12, and 24 months after randomisation: child anxiety symptoms (parent-reported, child-reported, and teacher-reported versions of the brief Spence Children's Anxiety Scale [SCAS-8-P, SCAS-8-C, and SCAS-8-T]; and parent-reported and child-reported versions of the Revised Children's Anxiety and Depression Scale-Anxiety scale [RCADS-P-Anxiety and RCADS-C-Anxiety]); interference related to child anxiety symptoms (child-reported and teacher-reported interference items [Anxiety Impact-C and Anxiety Impact-T]); child depression symptoms (parent-reported and child-reported versions of the RCADS-Depression scale [RCADS-P-Depression and RCADS-C-Depression]); child behaviour problems (parent-reported and child-reported versions of the Strengths and Difficulties Questionnaire-conduct problems subscale [SDQ-P-conduct, SDQ-C-conduct] and SDQ-hyperactivity/inattention subscale [SDQ-P-hyperactivity/inattention and SDQ-C-hyperactivity/inattention]).

The study team monitored and recorded potential adverse events and serious adverse events throughout and reported on these to the programme steering committee and data monitoring and ethics committee. Participants were asked specific questions about their views and experiences of trial procedures (including possible harms) using a bespoke acceptability questionnaire at each assessment.

Secondary educational, health economic and qualitative interview outcomes will be reported separately to enable detailed reporting.

Choice of primary outcome

The iCATS-2 was developed in a large study (n=463) in primary schools in England that examined the extent to which parent-reported, child-reported, and teacher-reported measures of child anxiety symptoms and interference aligned with diagnostic outcomes (presence or absence of an anxiety disorder) determined by diagnostic interviews administered by independent assessors. The cutoff score of 3 was found to discriminate children (aged 8–11 years) with and without diagnosable anxiety disorders with sensitivity and specificity values of more than 75%.[15] We selected the iCATS-2 as the primary outcome because although, to our knowledge, it has not previously been used as a trial outcome, it has several advantages. The iCATS-2 is very quick to complete and has been shown to have a similar level of diagnostic accuracy as longer parent-reported measures of child anxiety symptoms and interference, and a higher level of accuracy than either child-reported or teacher-reported measures of child anxiety symptoms or interference in this age group.[15] It is freely available in English and can be translated at no cost.

Statistical analysis

We sought to recruit 80 schools and 398 children with anxiety problems (40 schools and 199 children per group) as this sample size is large enough to detect a difference of 20 percentage points in those who screen negative for anxiety problems at 12 months between the trial groups (70% screen negative in the intervention group *vs* 50% screen negative in the control group) with just over 90% power at the two-sided 5% level of significance. The calculation assumes: 2·3 classes per school participate in the study; the mean number of children per class is 27; 40% of parents complete the iCATS-2 at baseline; 20% of children screen positive; 20% loss to follow-up; the intracluster (intraschool) correlation coefficient of the primary outcome is 0·05 (recent methodological research indicates that this is a conservative assumption[22]); and the coefficient of variation of the cluster size is 0·4.

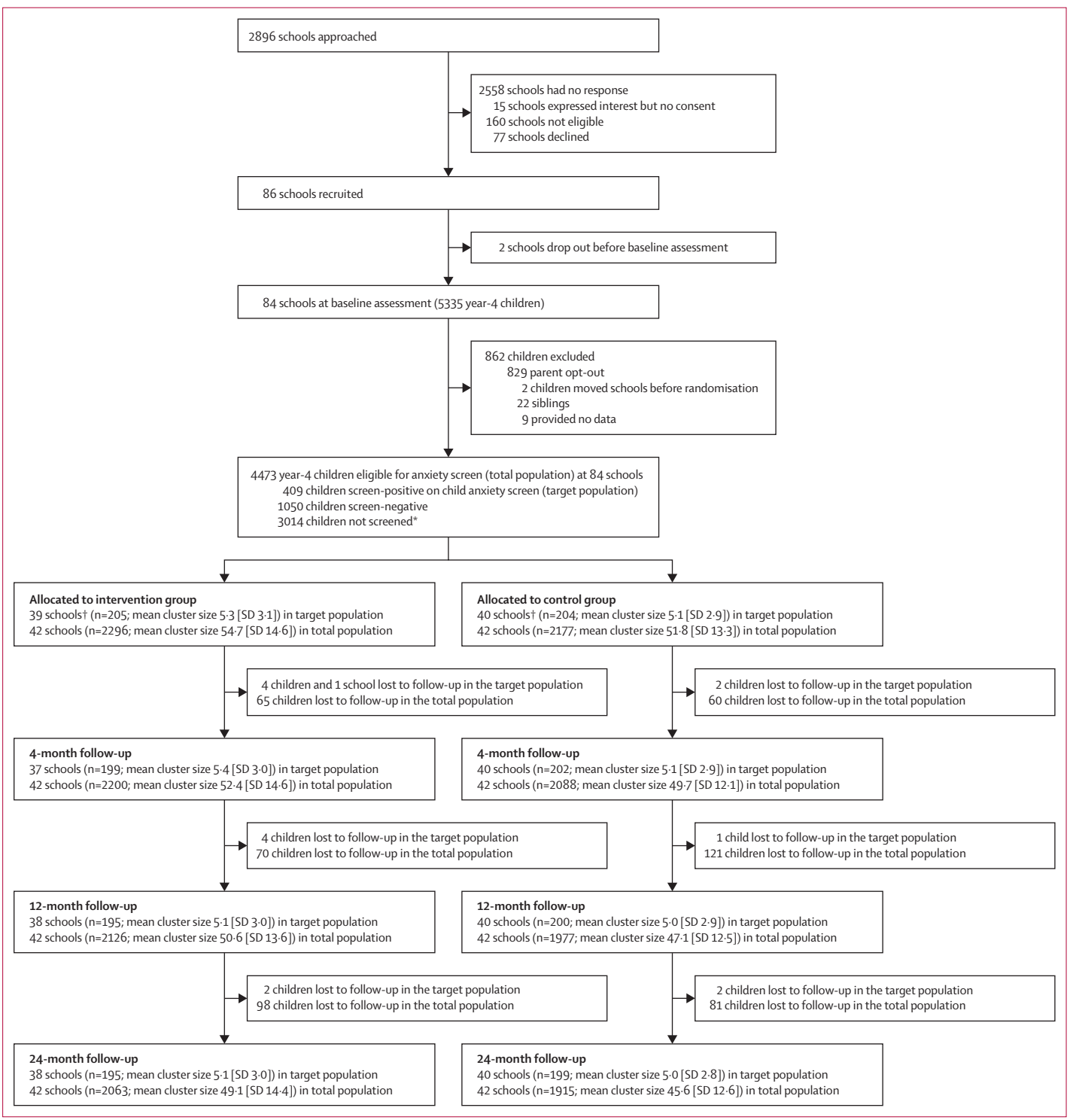

Figure: **Trial profile**

Children or schools were lost to follow-up if no data were provided from any reporter at this follow-up or any subsequent follow-up. When participants did not complete a follow-up, they were invited to complete subsequent follow-ups unless they withdrew from the trial or, in the case of children without participating parents, they were invited to complete subsequent follow-up unless the school withdrew from data collection activities or the child moved schools. One school in the control group withdrew from data collection activities in the school after the 4-month follow-up and before completing the 12-month follow-up. *Parent did not complete the screening questionnaire. †In five schools (three intervention and two control), no children screened positive for anxiety problems.

	Target population			Total population		
	Intervention group (n=205)	Control group (n=204)	Total (n=409)	Intervention group (n=2296)	Control group (n=2177)	Total (n=4473)
Gender						
Female	110/191 (58%)	101/199 (51%)	211/390 (54%)	1106/2177 (51%)	994/2032 (49%)	2100/4209 (50%)
Male	81/191 (42%)	98/199 (49%)	179/390 (46%)	1071/2177 (49%)	1038/2032 (51%)	2109/4209 (50%)
Ethnicity						
Asian*	19/191 (10%)	10/193 (5%)	29/384 (8%)	323/2164 (15%)	282/1978 (14%)	605/4142 (15%)
Black†	1/191 (1%)	1/193 (1%)	2/384 (<1%)	71/2164 (3%)	79/1978 (4%)	150/4142 (4%)
Mixed‡	9/191 (5%)	13/193 (7%)	22/384 (6%)	128/2164 (6%)	128/1978 (6%)	256/4142 (6%)
White§	160/191 (84%)	165/193 (85%)	325/384 (85%)	1564/2164 (72%)	1406/1978 (71%)	2970/4142 (72%)
Other¶	1/191 (1%)	3/193 (2%)	4/384 (1%)	62/2164 (3%)	78/1978 (4%)	140/4142 (3%)
Not stated	1/191 (1%)	1/193 (1%)	2/384 (1%)	16/2164 (1%)	5/1978 (<1%)	21/4142 (1%)
Eligible for free school meals						
No	147/191 (77%)	157/200 (79%)	304/391 (78%)	1548/2176 (71%)	1454/2060 (71%)	3002/4236 (71%)
Yes	44/191 (23%)	43/200 (22%)	87/391 (22%)	628/2176 (29%)	606/2060 (29%)	1234/4236 (29%)
English as an additional language						
No	163/191 (85%)	184/197 (93%)	347/388 (89%)	1676/2175 (77%)	1614/2047 (79%)	3290/4222 (78%)
Yes	28/191 (15%)	13/197 (7%)	41/388 (11%)	499/2175 (23%)	433/2047 (21%)	932/4222 (22%)
Special educational needs						
No	141/191 (74%)	151/201 (75%)	292/392 (74%)	1761/2175 (81%)	1700/2087 (81%)	3461/4262 (81%)
Yes	50/191 (26%)	50/201 (25%)	100/392 (26%)	414/2175 (19%)	387/2087 (19%)	801/4262 (19%)
Education health-care plan						
No	178/185 (96%)	145/162 (90%)	323/347 (93%)	1991/2058 (97%)	1728/1792 (96%)	3719/3850 (97%)
Yes	7/185 (4%)	17/162 (10%)	24/347 (7%)	67/2058 (3%)	64/1792 (4%)	131/3850 (3%)
iCATS-2						
Screen-positive	205/205 (100%)	204/204 (100%)	409/409 (100%)	205/2296 (9%)	204/2177(9%)	409/4473 (9%)
Screen-negative	0/205	0/204	0/409	551/2296 (24%)	499/2177 (23%)	1050/4473 (23%)
No screening outcome	0/205	0/204	0/409	1540/2296 (67%)	1474/2177 (68%)	3014/4473 (67%)
SCAS-8-P	11·1 (4·0; 205)	10·9 (4·0; 204)	11·0 (4·0; 409)	6·6 (4·2; 767)	6·6 (4·1; 705)	6·6 (4·1; 1472)
RCADS-P-Anxiety	38·0 (14·8; 171)	38·2 (14·0; 184)	38·1 (14·4; 355)	22·7 (14·6; 620)	23·4 (14·8; 586)	23·0 (14·7; 1206)
RCADS-P-Depression	7·6 (4·5; 171)	8·0 (4·5; 184)	7·8 (4·5; 355)	4·2 (3·9; 620)	4·6 (4·1; 586)	4·3 (4·0; 1206)
SDQ-P-conduct	2·6 (2·4; 168)	2·9 (2·2; 183)	2·7 (2·3; 351)	1·8 (1·9; 615)	1·9 (1·9; 584)	1·8 (1·9; 1199)
SDQ-P-hyperactivity/inattention	5·4 (3·1; 168)	5·3 (3·0; 183)	5·4 (3·1; 351)	4·1 (2·9; 615)	4·1 (2·9; 584)	4·1 (2·9; 1199)
Anxiety Impact-C	3·6 (2·2; 185)	3·4 (2·1; 187)	3·5 (2·1; 372)	2·9 (2·0; 1922)	2·9 (2·1; 1768)	2·9 (2·1; 3690)
SCAS-8-C	9·1 (4·8; 186)	9·0 (4·7; 190)	9·0 (4·7; 376)	7·7 (4·7; 1948)	7·5 (4·7; 1788)	7·6 (4·7; 3736)
RCADS-C-Anxiety	45·9 (20·2; 187)	45·3 (22·4; 188)	45·6 (21·3; 375)	40·7 (22·0; 1941)	39·7 (22·5; 1775)	40·2 (22·2; 3716)
RCADS-C-Depression	11·7 (5·7; 187)	11·8 (5·8; 189)	11·7 (5·7; 376)	10·8 (6·0; 1948)	10·4 (6·0; 1783)	10·6 (6·0; 3731)
SDQ-C-conduct	3·1 (2·2; 186)	3·1 (2·1; 189)	3·1 (2·1; 375)	2·9 (2·1; 1948)	2·9 (2·0; 1776)	2·9 (2·1; 3724)
SDQ-C-hyperactivity/inattention	5·0 (2·4; 184)	4·8 (2·2; 189)	4·9 (2·3; 373)	4·6 (2·3; 1940)	4·5 (2·3; 1776)	4·5 (2·3; 3716)
Anxiety Impact-T	1·9 (1·6; 203)	1·4 (1.4; 200)	1·6 (1·5; 403)	1·0 (1·4; 2239)	0·9 (1·2; 2083)	1·0 (1·3; 4322)
SCAS-8-T	6·5 (4·8; 203)	5·7 (4·3; 200)	6·1 (4·6; 403)	4·1 (3·9; 2239)	4·0 (3·9; 2083)	4·0 (3·9; 4322)

Data are n/N (%) or mean (SD; n). Screen-positive is an iCATS-2 score 3–6. Screen-negative is an iCATS-2 score 0–2. For continuous measures, high score indicates worse functioning. Anxiety Impact-C=anxiety interference items-child-reported. Anxiety Impact-T=anxiety interference items-teacher-reported. RCADS-C=Revised Children's Anxiety and Depression Scale-child-reported. RCADS-P=Revised Children's Anxiety and Depression Scale-parent-reported. SCAS-8-C=brief Spence Children's Anxiety Scale-child-reported. SCAS-8-P=brief Spence Children's Anxiety Scale-parent-reported. SCAS-8-T=brief Spence Children's Anxiety Scale-teacher-reported. SDQ-C=Strengths and Difficulties Questionnaire-child-reported. SDQ-P=Strengths and Difficulties Questionnaire-parent-reported. *Includes Asian or Asian British Indian, Pakistani, Bangladeshi, and any other Asian background. †Includes Black or Black British African, Caribbean, and any other Black background. ‡Includes White and Black Caribbean, White and Black African, White and Asian, and any other mixed background. §Includes British, Irish, and any other White background. ¶Includes Chinese and any other ethnic background.

Table 1: **Baseline characteristics of participants, including child demographic characteristics reported by schools and clinical outcome measures for the target population and total population**

Separate analyses were undertaken for the total population. Based on the assumptions we have described and that 10% of children would be opted out, we anticipated recruiting 4470 children in the total population; this is enough participants to detect a standardised mean difference (effect size) of 0·2 between the trial groups with 88% power at the 5% level of significance.

Analyses were undertaken as specified in the statistical analysis plan,[20] which was signed off by the principal investigator, programme steering committee, and data monitoring and ethics committee before data lock.

Participant and school characteristics were summarised using means (SDs) for continuous variables and frequencies and percentages for categorical variables.

Analysis methods that allow for non-independence of observations in the same school (cluster) were used to compare the outcomes at 4, 12, and 24 months between the trial groups. Separate timepoint-specific models were fitted for each follow-up for each outcome. Marginal logistic regression models using generalised estimating equations with information sandwich (robust) standard errors were fitted to compare the binary primary outcome between trial groups, reporting odds ratios (ORs). An exchangeable correlation structure was specified for the main analyses. An additional generalised estimating equation analysis was undertaken, specifying an independent correlation structure to assess sensitivity of the findings to informative cluster size.[23] Mixed-effects (multilevel) linear regression models using restricted maximum likelihood estimation (REML) were fitted to compare continuous outcomes between the trial groups, reporting the mean difference and the standardised mean difference (effect size) calculated as the raw mean difference between trial groups divided by the standard deviation in the control group. Where analyses using REML did not converge, ordinary maximum likelihood estimation (MLE) was used. When neither REML nor MLE converged, ordinary linear regression models were fitted with information sandwich standard errors to allow for non-independence.

The trial groups were compared in crude, unadjusted analyses and analyses adjusted for the potential prognostic factors: baseline score on the outcome (including iCATS-2 score when analysing the primary outcome), trial phase, number of children in the target population in the school, whether the school had higher than the median proportion (21·6%[21]) of children eligible for free school meals, and free school meal status of the child. Analysis of screen-negative status outcomes in the total population was additionally adjusted for the proportion of children in the school who screened positive for anxiety problems at baseline. The adjusted analyses are the main analyses.

The main analyses of all outcomes were based on the intention-to-treat principle with participants analysed according to the allocated group of their school. For the primary outcome in the target population, we carried out a complier average causal effect (CACE) analysis to quantify the intervention effect in those who complied

	Intervention group (n=205)	Control group (n=204)	Total (n=409)
Child age, years	8·8 (0·3; 201)	8·8 (0·3; 201)	8·8 (0·3; 402)
Child gender			
Female	118/205 (58%)	104/203 (51%)	222/408 (54%)
Male	86/205 (42%)	99/203 (49%)	185/408 (45%)
Other	0/205	0/203	0/408
Prefer not to say	1/205 (<1%)	0/203	1/408 (<1%)
Child ethnicity			
Asian*	17/205 (8%)	9/200 (5%)	26/405 (6%)
Black†	2/205 (1%)	1/200 (1%)	3/405 (1%)
Mixed‡	12/205 (6%)	13/200 (7%)	25/405 (6%)
White§	172/205 (84%)	174/200 (87%)	346/405 (85%)
Other¶	1/205 (<1%)	2/200 (1%)	3/405 (1%)
Not stated	1/205 (<1%)	1/200 (1%)	2/405 (<1%)
Parent age, years	38·3 (5·6; 193)	38·8 (6·1; 189)	38·5 (5·8; 382)
Parent gender			
Female	190/205 (93%)	196/203 (97%)	386/408 (95%)
Male	14/205 (7%)	7/203 (3%)	21/408 (5%)
Other	1/205 (<1%)	0/203	1/408 (<1%)
Parent ethnicity			
Asian*	19/203 (9%)	10/200 (5%)	29/403 (7%)
Black†	3/203 (1%)	2/200 (1%)	5/403 (1%)
Mixed‡	3/203 (1%)	5/200 (3%)	8/403 (2%)
White§	174/203 (86%)	179/200 (90%)	353/403 (88%)
Other¶	3/203 (1%)	3/200 (2%)	6/403 (1%)
Not stated	1/203 (<1%)	1/200 (1%)	2/403 (<1%)
Type of housing			
Privately rented	36/205 (18%)	41/202 (20%)	77/407 (19%)
Council rented	22/205 (11%)	25/202 (12%)	47/407 (12%)
Housing association	14/205 (7%)	9/202 (4%)	23/407 (6%)
Mortgage or fully owned	127/205 (62%)	125/202 (62%)	252/407 (62%)
Other	4/205 (2%)	2/202 (1%)	6/407 (1%)
Prefer not to say	2/205 (1%)	0/202	2/407 (<1%)
Parent has a partner			
Yes	170/205 (83%)	157/203 (77%)	327/408 (80%)
No	32/205 (16%)	40/203 (20%)	72/408 (18%)
Prefer not to say	3/205 (1%)	6/203 (3%)	9/408 (2%)
Parent cohabits with partner‖			
Yes	160/168 (95%)	141/155 (91%)	301/323 (93%)
No	6/168 (4%)	13/155 (8%)	19/323 (6%)
Prefer not to say	2/168 (1%)	1/155 (1%)	3/323 (1%)
Parent's highest level of education			
School completion	22/203 (11%)	21/202 (10%)	43/405 (11%)
Further education	53/203 (26%)	41/202 (20%)	94/405 (23%)
Higher education	61/203 (30%)	70/202 (35%)	131/405 (32%)
Postgraduate qualification	50/203 (25%)	60/202 (30%)	110/405 (27%)
None of the above	10/203 (5%)	7/202 (3%)	17/405 (4%)
Prefer not to say	7/203 (3%)	3/202 (1%)	10/405 (2%)

(Table 2 continues on next page)

	Intervention group (n=205)	Control group (n=204)	Total (n=409)
(Continued from previous page)			
Parent's partner's highest level of education			
School completion	37/163 (23%)	25/148 (17%)	62/311 (20%)
Further education	54/163 (33%)	46/148 (31%)	100/311 (32%)
Higher education	36/163 (22%)	41/148 (28%)	77/311 (25%)
Postgraduate qualification	27/163 (17%)	31/148 (21%)	58/311 (19%)
None of the above	5/163 (3%)	3/148 (2%)	8/311 (3%)
Prefer not to say	4/163 (2%)	2/148 (1%)	6/311 (2%)
Parent's employment			
Unemployed	21/204 (10%)	22/203 (11%)	43/407 (11%)
Part-time	69/204 (34%)	64/203 (32%)	133/407 (33%)
Full-time	80/204 (39%)	81/203 (40%)	161/407 (40%)
Student	6/204 (3%)	7 /203 (3%)	13/407 (3%)
Retired	0/204	0/203	0/407
Homemaker	11/204 (5%)	21/203 (10%)	32/407 (8%)
Other	12/204 (6%)	7/203 (3%)	19/407 (5%)
Prefer not to say	5/204 (2%)	1/203 (<1%)	6/407 (1%)
Partner's employment			
Unemployed	3/165 (2%)	5/148 (3%)	8/313 (3%)
Part-time	13/165 (8%)	7/148 (5%)	20/313 (6%)
Full-time	128/165 (78%)	127/148 (86%)	255/313 (81%)
Student	0/165	0/148	0/313
Retired	0/165	1/148 (1%)	1/313 (<1%)
Homemaker	2/165 (1%)	2/148 (1%)	4/313 (1%)
Other	14/165 (8%)	5/148 (3%)	19/313 (6%)
Prefer not to say	5/165 (3%)	1/148 (1%)	6/313 (2%)
Household annual income			
Up to £16 000	24/203 (12%)	27/196 (14%)	51/399 (13%)
£16 001–30 000	31/203 (15%)	27/196 (14%)	58/399 (15%)
£30 001–40 000	18/203 (9%)	22/196 (11%)	40/399 (10%)
£40 001–50 000	22/203 (11%)	18/196 (9%)	40/399 (10%)
£50 001–60 000	17/203 (8%)	19/196 (10%)	36/399 (9%)
£60 001–70 000	18/203 (9%)	14/196 (7%)	32/399 (8%)
£70 001–80 000	6/203 (3%)	10/196 (5%)	16/399 (4%)
£80 001–90 000	11/203 (5%)	14/196 (7%)	25/399 (6%)
£90 001–120 000	10/203 (5%)	11/196 (6%)	21/399 (5%)
>£120 000	11/203 (5%)	12/196 (6%)	23/399 (6%)
Prefer not to say	35/203 (17%)	22/196 (11%)	57/399 (14%)

(Table 2 continues on next page)

with the intervention, where compliance is defined as completing at least modules 0 to 4 of the intervention.

The main analyses (both those based on imputed data and those based on complete cases) used only outcome data provided by participants within plus or minus 4 weeks of when the follow-up was due. Sensitivity analyses were carried out that included outcome data provided by participants outside the collection range.

The main analyses were based on datasets where missing data were filled in using multiple imputation based on the missing-at-random assumption. A multivariate linear mixed-effects model[24] was used to impute missing data while recognising the clustering in the dataset, creating 50 imputed datasets. The imputation model included all study outcomes, variables used as prognostic factors in the analysis model, trial group status, baseline screen status (positive, negative, or not screened), and the auxiliary variable number of intervention modules completed (set to zero for participants in the control group). The imputation model assumes all variables are normally distributed and missing values for binary variables are imputed as continuous. The imputed values for binary variables are dichotomised by rounding to 0 or 1 based on whether they are below or above 0·5.[25] Rubin's rules[26] were used to combine estimated effects across the imputed datasets and calculate the standard errors on which the reported 95% CIs and p values were based. Sensitivity analyses for primary and secondary outcomes were undertaken including only participants that provided data (complete case analyses).

A tipping point analysis[27] was undertaken to test the sensitivity of the findings for the primary outcome analysis to the missing-at-random assumption. This involved determining, for participants with missing data, by how much the imputed proportion of children who screen negative would have to change in the intervention group to change the result from being statistically significant ($p<0·05$) to non-significant, or vice versa.

No adjustments were made for multiple comparisons, and analyses of all secondary outcomes were treated as exploratory.

The analyses were undertaken using Stata version 18.5 statistical software. Missing data were imputed using the pan and mitml packages in R version 4.4.3 software.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

We recruited participants and collected baseline assessments between Jan 6 and March 8, 2022 (phase 1; 28 schools) and between Sept 15 and Nov 30, 2022 (phase 2; 56 schools). Of the 5335 year-4 children in participating classes: 829 were opted out, two moved schools during the baseline assessment, and 31 were excluded from the study (22 siblings and nine who provided no data; figure). The total population therefore included 4473 children (84% of 5335 invited). Parents of 1459 children (27% of 5335 invited; 33% of 4473 total population) completed the screening questionnaire and 409 screened positive (target population; 8% of 5335 invited; 9% of 4473 total population; figure).

Participating schools were geographically spread across England, and varied in size (two classes participated in 56 [67%] of 84 schools and three classes participated in 28 [33%] schools), deprivation (36 [43%] schools had

above the national median proportion of pupils eligible for free school meals), and pupil language (28 [33%] schools had above the national median proportion of pupils with English as an additional language; appendix pp 5–6). Social, emotional, and mental health provision reported by schools was similar across trial groups (appendix pp 5–6).

42 schools were randomly assigned to the intervention group (target population: 205 children; total population: 2296 children) and 42 to the control group (target population: 204 children; total population: 2177 children; figure). In the intervention group, parents of 173 (84%) of 205 children in the target population completed the feedback call, 165 (80%) started the intervention, and 127 (62%) completed the core intervention content, with a mean therapist contact time of 150 min (SD 75) per family (appendix pp 7–8). Parents of an additional 50 children not in the target population started OSI (43 screened negative and seven did not complete the screening questionnaire), 36 of whom completed the core intervention content. The whole-class session was delivered in all participating classes in the intervention group.

Baseline characteristics reported by schools and parents for the target and total populations are shown in tables 1 and 2 and in the appendix (pp 19–23). In the target population, there were more female (222 [54%] of 408) than male (185 [45%]) on the basis of parent report (one [<1%] preferred not to report gender) and most participating parents were female (386 [95%] of 408; table 2). There was variation in sociodemographic characteristics in both the target and total populations, but children from minoritised ethnic backgrounds and economically disadvantaged families were under-represented in the target population; in the target population, 325 (85%) of 384 children were reported by the school as White and 87 (22%) of 391 as eligible for free school meals, compared with 2970 (72%) of 4142 and 1234 (29%) of 4236 in the total population (table 1).

For the primary outcome, iCATS-2 data were recorded at 12 months for 145 (71%) of 205 children in the target population in the intervention group and 163 (80%) of 204 in the control group (completion data for all outcomes are provided in the appendix pp 9–10). Of 101 parents of children without primary outcome data, 26 (26%) reported that they did not have a partner and 25 (25%) had a household income of up to £16 000 per year, compared with 46 (15%) and 26 (8%) of 308 with primary outcome data. The mean on the RCADS-C-Anxiety was 50·7 (SD 18·8) compared with 44·0 (21·8) in those without primary outcome data compared with those with primary outcome data. Baseline characteristics according to provision of primary and any outcome data for the target and total populations are in the appendix (pp 11–18).

The main comparisons based on imputed data for the target and total population are shown in tables 3 and 4. At 12 months, 89 (61%) of 145 assessed children in the target population screened negative for anxiety problems in the intervention group compared with 62 (38%) of 163 in the control group; this difference was statistically significant in the main analysis, with an adjusted OR of 2·32 (95% CI 1·41–3·81; p=0·0009; table 3). Sensitivity analyses for the primary outcome showed the same pattern, with positive intervention effects in the complete case analysis (appendix pp 24–25), CACE analysis based on imputed data and complete cases (appendix p 26), and analysis including data provided by participants outside the data collection window (appendix pp 27–28). Additional planned analyses for the primary outcome confirmed the robustness of the result from the main analysis (see appendix pp 29–30).

Differences in parent-reported secondary outcomes for the target population consistently favoured the intervention group over the control group. In the main analysis, more children in the target population screened negative for anxiety problems in the intervention group than the control group at 4 months and 24 months (table 3). There were significant positive intervention effects on parent-reported child anxiety and depression symptoms at each follow-up (on SCAS-8-P, RCADS-P-Anxiety, and RCADS-P-Depression), SDQ-P-conduct at 4 months, and SDQ-P-hyperactivity/inattention at 4 months and 12 months (table 3).

Teacher-reported anxiety impact for the target population also favoured the intervention group at each follow-up (on Anxiety Impact-T), but there were no statistically significant group differences in teacher-reported SCAS-8-T (table 3). There were no group differences in any child-reported outcomes for the target population (table 3).

	Intervention group (n=205)	Control group (n=204)	Total (n=409)
(Continued from previous page)			
Index of multiple deprivation decile**			
1st	22/204 (11%)	31/204 (15%)	53/408 (13%)
2nd	17/204 (8%)	20/204 (10%)	37/408 (9%)
3rd	18/204 (9%)	16/204 (8%)	34/408 (8%)
4th	10/204 (5%)	15/204 (7%)	25/408 (6%)
5th	18/204 (9%)	14/204 (7%)	32/408 (8%)
6th	26/204 (13%)	18/204 (9%)	44/408 (11%)
7th	12/204 (6%)	14/204 (7%)	26/408 (6%)
8th	23/204 (11%)	18/204 (9%)	41/408 (10%)
9th	25/204 (12%)	24/204 (12%)	49/408 (12%)
10th	33/204 (16%)	34/204 (17%)	67/408 (16%)

Data are n/N (%) or mean (SD; n). *Includes Asian or Asian British Indian, Pakistani, Bangladeshi, and any other Asian background. †Includes Black or Black British African, Caribbean, and any other Black background. ‡Includes White and Black Caribbean, White and Black African, White and Asian, and any other mixed background. §Includes British, Irish, and any other White background. ¶Includes Chinese and any other ethnic background. ||Only includes those who are partnered. **Based on family postcode: 1=most deprived; 10=least deprived.

Table 2: **Baseline child and parent and family characteristics reported by parents in the target population**

	Intervention group		Control group		Unadjusted		Adjusted		
	N	Mean (SD) or n (%)	N	Mean (SD) or n (%)	Mean difference or OR*	Standardised mean difference	Mean difference (95% CI) or OR (95% CI)*	Standardised mean difference (95% CI)	p value
Parent-reported absence of child anxiety problems†									
4 months	135	77 (57%)	158	51 (32%)	2·46	..	2·76 (1·65 to 4·62)	..	0·0001
12 months (primary outcome)	145	89 (61%)	163	62 (38%)	2·16	..	2·32 (1·41 to 3·81)	..	0·0009
24 months	150	93 (62%)	161	74 (46%)	1·72	..	1·78 (1·10 to 2·86)	..	0·018
SCAS-8-P									
4 months	135	7·3 (3·9)	158	9·9 (4·0)	−2·0	−0·49	−2·1 (−2·7 to −1·5)	−0·52 (−0·68 to −0·37)	<0·0001
12 months	145	7·3 (4·4)	163	9·4 (3·9)	−1·6	−0·40	−1·6 (−2·4 to −0·9)	−0·42 (−0·61 to −0·24)	<0·0001
24 months	150	7·3 (4·2)	161	9·1 (4·3)	−1·6	−0·37	−1·7 (−2·4 to −0·9)	−0·39 (−0·56 to −0·22)	<0·0001
RCADS-P-Anxiety									
4 months	135	26·3 (15·1)	158	34·9 (15·2)	−6·6	−0·43	−6·4 (−8·6 to −4·2)	−0·42 (−0·56 to −0·28)	<0·0001
12 months	145	25·8 (15·7)	161	33·6 (14·9)	−6·3	−0·42	−6·0 (−8·4 to −3·5)	−0·40 (−0·56 to −0·24)	<0·0001
24 months	150	27·8 (16·1)	161	33·6 (16·7)	−5·0	−0·30	−4·8 (−7·5 to −2·0)	−0·29 (−0·45 to −0·12)	0·0006
RCADS-P-Depression									
4 months	135	5·2 (4·0)	158	7·1 (4·5)	−1·5	−0·34	−1·2 (−1·8 to −0·6)	−0·27 (−0·40 to −0·13)	0·0001
12 months	145	5·3 (4·3)	161	7·0 (4·7)	−1·5	−0·32	−1·2 (−1·9 to −0·5)	−0·25 (−0·40 to −0·11)	0·0006
24 months	150	6·2 (4·8)	161	7·5 (5·0)	−1·3	−0·26	−0·9 (−1·7 to −0·1)	−0·19 (−0·35 to −0·03)	0·023
SDQ-P-conduct									
4 months	135	2·0 (2·0)	157	2·8 (2·2)	−0·6	−0·30	−0·5 (−0·8 to −0·2)	−0·22 (−0·35 to −0·10)	0·0005
12 months	145	2·2 (2·2)	159	2·6 (2·2)	−0·4	−0·17	−0·2 (−0·5 to 0·1)	−0·09 (−0·22 to 0·05)	0·23
24 months	150	2·2 (2·3)	160	2·5 (2·2)	−0·3	−0·14	−0·1 (−0·5 to 0·2)	−0·06 (−0·21 to 0·09)	0·41
SDQ-P-hyperactivity/inattention									
4 months	135	4·8 (2·9)	157	5·5 (2·9)	−0·5	−0·17	−0·5 (−0·9 to −0·2)	−0·18 (−0·31 to −0·06)	0·0046
12 months	145	4·6 (2·9)	159	5·2 (3·0)	−0·6	−0·20	−0·6 (−1·0 to −0·2)	−0·21 (−0·34 to −0·08)	0·0015
24 months	150	4·8 (3·1)	160	5·2 (3·1)	−0·4	−0·12	−0·4 (−0·8 to 0·0)	−0·12 (−0·26 to 0·02)	0·083
Anxiety Impact-C									
4 months	177	3·6 (2·0)	174	3·4 (2·0)	0·1	0·07	0·0 (−0·4 to 0·4)	0·02 (−0·19 to 0·22)	0·87
12 months	167	3·4 (2·2)	182	3·2 (1·9)	0·2	0·11	0·1 (−0·3 to 0·5)	0·06 (−0·14 to 0·27)	0·56
24 months	163	3·2 (2·0)	174	3·4 (2·2)	−0·2	−0·07	−0·2 (−0·6 to 0·2)	−0·11 (−0·29 to 0·07)	0·23
SCAS-8-C									
4 months	178	8·8 (4·9)	181	9·0 (4·5)	−0·2	−0·04	−0·3 (−1·1 to 0·5)	−0·07 (−0·25 to 0·11)	0·46
12 months	170	7·7 (4·5)	182	7·9 (4·5)	−0·2	−0·04	−0·3 (−1·0 to 0·5)	−0·06 (−0·24 to 0·12)	0·53
24 months	166	6·7 (4·5)	175	6·9 (4·6)	−0·2	−0·04	−0·2 (−1·1 to 0·7)	−0·05 (−0·24 to 0·15)	0·64
RCADS-C-Anxiety									
4 months	178	43·5 (22·4)	177	44·4 (22·0)	−0·6	−0·03	−1·1 (−4·7 to 2·5)	−0·05 (−0·22 to 0·12)	0·55
12 months	170	41·3 (20·3)	179	38·8 (21·9)	1·7	0·08	1·3 (−2·4 to 5·1)	0·06 (−0·11 to 0·23)	0·48
24 months	166	38·3 (21·2)	175	37·7 (22·5)	0·7	0·03	0·3 (−3·9 to 4·4)	0·01 (−0·17 to 0·20)	0·90
RCADS-C-Depression									
4 months	179	11·2 (6·3)	176	11·6 (6·1)	0·3	−0·05	−0·3 (−1·3 to 0·8)	−0·05 (−0·22 to 0·12)	0·60
12 months	170	10·8 (5·5)	179	10·4 (5·9)	0·2	0·03	0·2 (−0·8 to 1·3)	0·04 (−0·14 to 0·22)	0·66
24 months	165	10·2 (6·3)	175	10·3 (6·4)	−0·2	−0·02	0·0 (−1·2 to 1·1)	−0·01 (−0·19 to 0·17)	0·93
SDQ-C-conduct									
4 months	178	3·2 (2·0)	177	3·1 (1·9)	0·0	0·02	0·00 (−0·3 to 0·4)	0·02 (−0·16 to 0·19)	0·86
12 months	168	3·2 (2·2)	178	3·0 (2·0)	0·1	0·05	0·1 (−0·3 to 0·5)	0·06 (−0·14 to 0·26)	0·57
24 months	165	2·9 (2·0)	175	2·8 (1·9)	0·1	0·06	0·1 (−0·2 to 0·5)	0·06 (−0·13 to 0·25)	0·51
SDQ-C-hyperactivity/inattention									
4 months	177	4·9 (2·4)	177	5·1 (2·3)	−0·1	−0·05	−0·2 (−0·6 to 0·2)	−0·10 (−0·26 to 0·07)	0·25
12 months	168	5·5 (2·4)	178	5·1 (2·5)	0·3	0·13	0·2 (−0·2 to 0·6)	0·08 (−0·10 to 0·26)	0·37
24 months	164	5·2 (2·7)	174	5·1 (2·6)	0·0	0·01	0·0 (−0·5 to 0·5)	−0·01 (−0·20 to 0·18)	0·91

(Table 3 continues on next page)

	Intervention group		Control group		Unadjusted		Adjusted		
	N	Mean (SD) or n (%)	N	Mean (SD) or n (%)	Mean difference or OR*	Standardised mean difference	Mean difference (95% CI) or OR (95% CI)*	Standardised mean difference (95% CI)	p value
(Continued from previous page)									
Anxiety Impact-T									
4 months	167	1·5 (1·5)	182	1·7 (1·6)	−0·1	−0·10	−0·4 (−0·7 to −0·1)	−0·27 (−0·45 to −0·08)	0·0050
12 months	175	1·5 (1·4)	183	1·8 (1·7)	−0·3	−0·20	−0·5 (−0·9 to −0·2)	−0·32 (−0·51 to −0·14)	0·0006
24 months	163	1·3 (1·4)	171	1·6 (1·6)	−0·3	−0·19	−0·5 (−0·8 to −0·1)	−0·29 (−0·49 to −0·09)	0·0047
SCAS-8-T									
4 months	167	5·4 (4·4)	182	5·6 (4·2)	−0·1	−0·03	−0·6 (−1·4 to 0·1)	−0·15 (−0·33 to 0·03)	0·093
12 months	175	5·8 (4·4)	183	6·2 (4·7)	−0·4	−0·09	−0·7 (−1·7 to 0·3)	−0·14 (−0·36 to 0·07)	0·19
24 months	163	5·4 (4·3)	171	5·9 (4·3)	−0·4	−0·10	−0·7 (−1·7 to 0·3)	−0·16 (−0·39 to 0·06)	0·15

Summary statistics are based on provided data and comparisons are based on imputed data. For all continuous outcomes higher scores indicate worse functioning. Anxiety Impact-C=anxiety interference items-child-reported. Anxiety Impact-T=anxiety interference items-teacher-reported. OR=odds ratio. RCADS-C=Revised Children's Anxiety and Depression Scale-child-reported. RCADS-P=Revised Children's Anxiety and Depression Scale-parent-reported. SCAS-8-C=brief Spence Children's Anxiety Scale-child-reported. SCAS-8-P=brief Spence Children's Anxiety Scale-parent-reported. SCAS-8-T=brief Spence Children's Anxiety Scale-teacher-reported. SDQ-C=Strengths and Difficulties Questionnaire-child-reported. SDQ-P=Strengths and Difficulties Questionnaire-parent-reported. *Mean difference reported for continuous outcomes and OR reported for binary outcomes; mean differences are intervention–control and ORs are intervention/control. †Score 0–2 on iCATS-2.

Table 3: **Summary statistics and main comparisons for primary and secondary outcomes for the target population**

For the total population, there were no significant group differences in the screen-negative status outcome at any follow-up (table 4). There were group differences favouring the intervention group in the total population on most parent-reported continuous outcomes (SCAS-8-P, RCADS-P-Anxiety, RCADS-P-Depression, and SDQ-P-conduct) at the 4-month follow-up, and on parent-reported SDQ-P-hyperactivity/inattention at 12 months and 24 months (table 4). There were no statistically significant group differences on any other parent-reported outcomes or any teacher-reported anxiety outcomes for the total population.

The only child-reported outcomes for the total population with significant differences between groups favoured the control group, with slightly higher self-reported anxiety symptoms in the intervention group compared with the control group at 4 months on the SCAS-8-C and the RCADS-C-Anxiety, and at 12 months on the RCADS-C-Anxiety (table 4).

Findings from planned sensitivity analyses (complete case analyses and analyses including data provided outside the data collection window) for secondary outcomes for the target and total population were consistent with the main analyses (appendix pp 24–25, 27–28, 31–34).

No serious adverse events related to the trial procedures or the screening-to-intervention pathway were recorded. Six adverse events related to trial procedures were recorded: five related to distress caused by child-reported questionnaires (two in the intervention group and three in the control group), and one potential loss of confidential information in the intervention group before randomisation. Three adverse events related to female children, one related a male child, and in two cases gender was not available (see appendix pp 35–36).

Feedback on the acceptability of questionnaires was predominantly positive, with more than 80% of parent respondents in the intervention group for the target population indicating that they found taking part helpful (113 [89%] of 127 at 4 months; 108 [82%] of 131 at 12 months; and 116 [83%] of 140 at 24 months) compared with fewer than 60% in the control group (87 [59%] of 148 at 4 months; 81 [54%] of 150 at 12 months; and 79 [54%] of 147 at 24 months). In the total population, most teachers (from 120 [92%] of 131 at 4 months to 131 [96%] of 137 at 24 months) and children (from 2413 [69%] of 3505 at 12 months to 2688 [74%] of 3653 at baseline) indicated that they were happy to complete questionnaires. In the total population, from 238 (7%) of 3338 children at 24 months to 441 (12%) of 3649 children at 4 months reported that there was something they did not like about completing the questionnaires, and some of the most frequent negative feedback in free-text responses across reporters related to concerns about child-reported trial questionnaires triggering some upset or distress for some children (appendix pp 37–91).

Discussion

We found that the screening-to-intervention pathway for child anxiety problems alongside usual provision was superior to assessment and usual provision alone at reducing anxiety problems: children who screened positive for anxiety problems at baseline had 2·32 times the odds of screening negative for anxiety problems at 12 months in the intervention group compared with the control group. A difference in the absence of anxiety problems in the target population was also observed at 4 months and maintained at 24 months. Although the absence of anxiety problems in the target population in the intervention group was similar at 12 months and

	Intervention group		Control group		Unadjusted		Adjusted		
	N	Mean (SD) or n (%)	N	Mean (SD) or n (%)	Mean difference or OR*	Standardised mean difference	Mean difference (95% CI) or OR (95% CI)*	Standardised mean difference (95% CI)	p value
Parent-report absence of child anxiety problems†									
4 months, all participants	580	485 (84%)	543	396 (73%)	1·32	..	1·39 (1·00 to 1·93)	..	0·052
4 months, screen-negative	409	378 (92%)	366	332 (91%)	1·37	..	1·45 (0·89 to 2·39)	..	0·14
12 months, all participants	565	467 (83%)	568	423 (74%)	1·07	..	1·03 (0·75 to 1·42)	..	0·86
12 months, screen-negative	387	355 (92%)	383	344 (90%)	1·07	..	1·11 (0·71 to 1·74)	..	0·65
24 months, all participants	585	486 (83%)	544	413 (76%)	1·10	..	1·05 (0·76 to 1·45)	..	0·76
24 months, screen-negative	401	364 (91%)	365	325 (89%)	1·05	..	1·08 (0·68 to 1·70)	..	0·75
SCAS-8-P									
4 months	580	5·4 (3·4)	543	6·4 (3·9)	−0·4	−0·09	−0·4 (−0·7 to −0·1)	−0·10 (−0·18 to −0·02)	0·013
12 months	565	5·6 (3·7)	568	6·3 (3·8)	0·0	0·00	0·0 (−0·4 to 0·3)	−0·01 (−0·10 to 0·08)	0·86
24 months	585	5·4 (3·6)	544	6·2 (4·1)	−0·2	−0·06	−0·3 (−0·6 to 0·1)	−0·07 (−0·16 to 0·02)	0·15
RCADS-P-Anxiety									
4 months	575	18·3 (12·7)	543	21·9 (14·3)	−1·9	−0·13	−1·4 (−2·5 to −0·4)	−0·10 (−0·17 to −0·02)	0·0089
12 months	563	19·0 (13·0)	563	21·7 (14·2)	−0·9	−0·06	−0·4 (−1·6 to 0·7)	−0·03 (−0·11 to 0·05)	0·44
24 months	581	19·1 (13·7)	541	21·6 (15·4)	−0·5	−0·03	−0·1 (−1·3 to 1·2)	0·00 (−0·08 to 0·08)	0·93
RCADS-P-Depression									
4 months	575	3·1 (3·4)	542	4·1 (3·9)	−0·6	−0·16	−0·4 (−0·7 to −0·1)	−0·10 (−0·19 to −0·02)	0·017
12 months	563	3·5 (3·7)	563	4·2 (4·1)	−0·3	−0·08	−0·1 (−0·5 to 0·2)	−0·03 (−0·12 to 0·05)	0·48
24 months	581	3·7 (4·0)	541	4·4 (4·3)	−0·3	−0·06	−0·1 (−0·4 to 0·3)	−0·01 (−0·10 to 0·08)	0·80
SDQ-P-conduct									
4 months	566	1·5 (1·7)	536	1·9 (1·9)	−0·3	−0·14	−0·2 (−0·4 to −0·1)	−0·13 (−0·23 to −0·03)	0·010
12 months	561	1·5 (1·8)	559	1·7 (1·9)	−0·2	−0·09	−0·2 (−0·4 to 0·1)	−0·08 (−0·19 to 0·03)	0·16
24 months	581	1·5 (1·8)	537	1·6 (1·8)	0·0	0·00	0·0 (−0·2 to 0·2)	0·01 (−0·10 to 0·12)	0·85
SDQ-P-hyperactivity/inattention									
4 months	566	3·7 (2·7)	536	4·1 (2·9)	−0·3	−0·10	−0·1 (−0·4 to 0·1)	−0·05 (−0·13 to 0·04)	0·28
12 months	561	3·6 (2·7)	559	4·1 (2·8)	−0·5	−0·19	−0·4 (−0·6 to −0·1)	−0·14 (−0·22 to −0·05)	0·0024
24 months	581	3·6 (2·8)	537	4·1 (2·9)	−0·5	−0·17	−0·3 (−0·6 to −0·1)	−0·11 (−0·20 to −0·03)	0·0088
Anxiety Impact-C									
4 months	1898	2·8 (2·0)	1854	2·7 (1·9)	0·1	0·07	0·1 (0·0 to 0·2)	0·05 (−0·02 to 0·11)	0·19
12 months	1865	2·8 (2·0)	1760	2·6 (1·9)	0·2	0·10	0·1 (0·0 to 0·3)	0·07 (0·00 to 0·15)	0·052
24 months	1794	2·7 (1·9)	1709	2·6 (1·9)	0·1	0·07	0·1 (−0·1 to 0·2)	0·04 (−0·04 to 0·13)	0·29
SCAS-8-C									
4 months	1923	7·3 (4·7)	1878	6·9 (4·5)	0·5	0·12	0·4 (0·1 to 0·7)	0·08 (0·02 to 0·15)	0·016
12 months	1886	6·7 (4·4)	1781	6·4 (4·4)	0·4	0·09	0·3 (0·0 to 0·6)	0·06 (−0·01 to 0·14)	0·082
24 months	1817	5·7 (4·1)	1731	5·6 (4·1)	0·2	0·05	0·1 (−0·2 to 0·5)	0·03 (−0·05 to 0·11)	0·44
RCADS-C-Anxiety									
4 months	1919	38·8 (22·6)	1860	37·0 (21·9)	2·5	0·11	1·5 (0·1 to 2·9)	0·07 (0·00 to 0·13)	0·041
12 months	1872	37·2 (22·5)	1756	35·0 (21·7)	2·6	0·12	1·8 (0·4 to 3·1)	0·08 (0·02 to 0·14)	0·0098
24 months	1804	34·2 (21·3)	1718	32·5 (21·2)	2·2	0·10	1·5 (−0·1 to 3·1)	0·07 (−0·01 to 0·15)	0·070
RCADS-C-Depression									
4 months	1921	10·1 (6·1)	1866	10·0 (6·0)	0·2	0·04	0·0 (−0·4 to 0·4)	0·00 (−0·07 to 0·07)	0·99
12 months	1875	9·9 (6·3)	1762	9·6 (6·0)	0·3	0·05	0·1 (−0·3 to 0·5)	0·02 (−0·04 to 0·09)	0·52
24 months	1811	9·4 (6·2)	1725	9·0 (6·0)	0·5	0·09	0·4 (−0·1 to 0·8)	0·06 (−0·01 to 0·14)	0·11
SDQ-C-conduct									
4 months	1915	2·9 (2·1)	1864	2·9 (2·0)	0·1	0·04	0·1 (−0·1 to 0·2)	0·03 (−0·05 to 0·10)	0·47
12 months	1869	2·9 (2·1)	1754	2·9 (2·0)	0·1	0·05	0·1 (−0·1 to 0·2)	0·04 (−0·04 to 0·12)	0·29
24 months	1799	2·9 (2·0)	1715	2·7 (1·9)	0·1	0·08	0·1 (0·0 to 0·3)	0·07 (0·00 to 0·15)	0·061

(Table 4 continues on next page)

	Intervention group		Control group		Unadjusted		Adjusted		
	N	Mean (SD) or n (%)	N	Mean (SD) or n (%)	Mean difference or OR*	Standardised mean difference	Mean difference (95% CI) or OR (95% CI)*	Standardised mean difference (95% CI)	p value
(Continued from previous page)									
SDQ-C-hyperactivity/inattention									
4 months	1912	4·6 (2·4)	1857	4·6 (2·3)	0·1	0·03	0·0 (–0·1 to 0·2)	0·02 (–0·05 to 0·08)	0·60
12 months	1859	4·8 (2·5)	1747	4·7 (2·5)	0·1	0·05	0·1 (–0·1 to 0·3)	0·04 (–0·02 to 0·11)	0·20
24 months	1788	5·0 (2·6)	1704	4·9 (2·6)	0·1	0·03	0·1 (–0·2 to 0·3)	0·02 (–0·07 to 0·11)	0·66
Anxiety impact-T									
4 months	1914	0·9 (1·2)	1871	0·9 (1·3)	0·0	–0·03	–0·1 (–0·3 to 0·0)	–0·09 (–0·19 to 0·01)	0·068
12 months	1881	1·0 (1·3)	1808	1·1 (1·4)	–0·1	–0·07	–0·2 (–0·4 to 0·0)	–0·11 (–0·24 to 0·02)	0·090
24 months	1817	0·8 (1·2)	1739	0·9 (1·4)	–0·1	–0·05	–0·1 (–0·3 to 0·1)	–0·08 (–0·20 to 0·05)	0·23
SCAS-8-T									
4 months	1914	3·6 (3·7)	1871	3·8 (3·8)	–0·3	–0·07	–0·3 (–0·7 to 0·0)	–0·08 (–0·18 to 0·01)	0·084
12 months	1881	4·2 (3·9)	1808	4·2 (3·9)	0·0	0·00	0·0 (–0·7 to 0·7)	0·00 (–0·18 to 0·18)	0·97
24 months	1818	3·9 (3·6)	1739	4·1 (4·1)	0·0	–0·01	0·0 (–0·6 to 0·6)	–0·01 (–0·16 to 0·14)	0·92

Summary statistics are based on provided data and comparisons are based on imputed data. For all continuous outcomes higher scores indicate worse functioning. Anxiety Impact-C=anxiety interference items-child-reported. Anxiety Impact-T=anxiety interference items-teacher-reported. OR=odds ratio. RCADS-C=Revised Children's Anxiety and Depression Scale-child-reported. RCADS-P=Revised Children's Anxiety and Depression Scale-parent-reported. SCAS-8-C=brief Spence Children's Anxiety Scale-child-reported. SCAS-8-P=brief Spence Children's Anxiety Scale-parent-reported. SCAS-8-T=brief Spence Children's Anxiety Scale-teacher-reported. SDQ-C=Strengths and Difficulties Questionnaire-child-reported. SDQ-P=Strengths and Difficulties Questionnaire-parent-reported. *Mean difference reported for continuous outcomes and OR reported for binary outcomes; mean differences are intervention–control and ORs are intervention/control. †Score 0–2 on iCATS-2.

Table 4: **Summary statistics and main comparisons for secondary outcomes for the total population**

24 months, the number who screened negative in the control group increased from 38% at 12 months to 46% at 24 months, which is similar to the previously reported 50% natural remission in anxiety disorders in children (aged 9–11 years) over a 2-year period.[28] Compared with assessment and usual provision alone, the screening-to-intervention pathway also brought wider clinical benefits for children with anxiety problems, with positive effects across a range of parent-reported outcomes (child anxiety and depression symptoms at all follow-ups; hyperactivity and inattention at 4 months and 12 months; and conduct problems at 4 months) and teacher-reported interference related to child anxiety symptoms at all follow-ups. No adverse events specifically related to the screening-to-intervention pathway were reported. These findings suggest that the screening-to-intervention pathway provides a route to effective early intervention for child anxiety problems in primary schools and that integrating delivery in schools has the potential to reduce the treatment gap for child anxiety problems.

The screening-to-intervention pathway alongside usual provision was not superior to assessment and usual provision alone for children with anxiety problems on the basis of child self-reporting, with no significant differences between the groups in child-reported outcomes in the target population. Different patterns across child-reported and parent-reported outcomes is not unexpected, given the low-to-moderate agreement between child-reported and parent-reported child anxiety symptoms in children aged 9–12 years.[29] For children younger than 12 years, parent-reported child anxiety measures have been shown to align more closely with outcomes from diagnostic interviews[30] than do child self-reported measures, and, for this reason, prioritising parent-reported outcomes has been recommended for anxiety treatment trials for this age group.[31] Indeed, it was because we previously found that child-reported questionnaires did not accurately discriminate between children with and without diagnosable anxiety disorders[15] that we opted to use a parent-reported screening tool and prioritised parent-reported outcomes. Meta-analyses have shown that effect sizes for CBT for child and adolescent anxiety disorders on self-reported outcomes vary according to child age,[5] and our null findings for child self-reported outcomes in the target population are consistent with the non-significant difference between CBT and no intervention for self-reported anxiety symptom outcomes found for the subgroup of previous trials of children younger than 12 years.[5] As OSI is parent led and only parents had direct contact with therapists in this study, there is a risk of bias for the parent-reported outcomes and so we were encouraged that positive effects were also found for some teacher-reported outcomes.

We found little evidence of benefits for the wider total population of all children in participating classes. Results showed positive intervention effects for the total population on parent-reported child anxiety, depression, and behaviour-related outcomes at the 4-month follow-up, but, with the exception of parent-reported hyperactivity and inattention, parent-reported outcomes at later follow-ups did not differ between groups. Given that only one-third of parents in the total population

participated in the trial, parent-reported outcomes for the total population should not be interpreted as representative of the whole class. OSI was actively offered to the target population but also available for others to request and it is notable that almost one-quarter of parents who started OSI (50 [23%] of 215) were not in the target population. This uptake for OSI in parents of children who did not screen positive for anxiety problems at baseline highlights the potential importance of making OSI available for children not identified through screening in future implementation efforts.

The only significant differences between the groups in child-reported and teacher-reported outcomes for the total population were small negative effects on child-reported anxiety symptoms at the 4-month and 12-month follow-ups. Child-reported and teacher-reported outcomes were collected for more than 79% of the total population at each assessment so reflect a much wider group of children in the total population than the parent-reported outcomes. In the intervention group, although a small subset of the total population received the parent-led intervention (215 [9%] of 2296 children), all classes received the single whole-class session (together with the assessment procedures delivered in both groups) so it is reasonable to attribute these observed group differences in child-reported outcomes to this whole-class session or the combination of this session and the assessment procedures. Although there are questions about the validity of child-reported measures of anxiety in this age group, it is plausible that the psycho-education content of the whole-class session increased children's self-reported anxiety symptoms by increasing children's ability to recognise pre-existing symptoms of anxiety, by triggering new fears and worries, or both. Equally, by normalising experiences of anxiety, the whole-class session might have increased children's endorsement of these normalised experiences, without increasing pathological symptoms of anxiety. With regard to assessment procedures, our previous findings highlight the greater utility of parent-reporting over child-reporting, so future implementation of the screening-to-intervention approach will not require child self-reported questionnaires. With regard to the whole-class session, a scoping review of school-based mental health interventions conducted in 2023 found that five of the 15 trials assessed to have a low risk of bias reported at least one negative outcome[12] (although it is notable that trials included in this review evaluated lengthier interventions comprising six to 12 sessions). Our findings raise questions about whether it is appropriate to deliver a single psychoeducation session for a whole class of children aged 8–9 years and suggest that the session delivered in this trial should not be used in the future. Importantly, although participant feedback on the whole-class session was consistently positive, some of the most frequent negative feedback on measures of acceptability, across reporters and trial groups, related to concerns that completing mental health measures at school caused upset or distress for some children. Future research needs to carefully consider potential harms related to both child-reported mental health assessments and intervention activities in whole-class settings in primary schools.

The study had some limitations. It was not possible for participants, schools, or study team members to be masked to trial group status, and this means there is a risk of bias for parent-reported and child-reported outcomes. Teacher-reported outcomes were collected from the children's current class teacher (or similar member of staff), which meant there was not a consistent reporter at all assessment points for these outcomes. Retention of parents in the target population was slightly below the original target of 80%, with the primary outcome collected for 308 (75%) of 409 parents, and there were differences in demographic characteristics and child-reported anxiety symptoms for those who did and did not provide primary outcome data. However, using imputed data reduced this source of potential bias. Although completion rates for the primary outcome were lower in the intervention group than the control group (145 [71%] of 205 *vs* 163 [80%] of 204), the tipping point analysis provides support for the robustness of the main result and showed that even if the true absence of anxiety problems for participants with missing data in the intervention group was 23% (compared with 50% estimated in the imputed data), there would still have been evidence of a significant positive intervention effect on the primary outcome. It was not possible to repeat the analyses of imputed data for the primary outcome separately by gender groups because some participants were missing gender data and their imputed gender status differs across the imputed datasets.

It is encouraging that the parent-led intervention required the similar modest amount of therapist contact time as reported elsewhere for this intervention (approximately 2·5 h per child) and most participants (62% of the target population) completed the core intervention content. However, the strengthened intervention effect on the primary outcome in the CACE analysis underscores that it will be important to find ways to support families to complete core intervention modules in future implementation efforts.

The screening-to-intervention pathway procedures were developed for a primary school context in England and future research should consider how best to tailor the approach for other countries. Finally, only a minority of parents in participating classes completed the screening questionnaire. Although the number of children who screened positive for anxiety problems (409 [8%] of 5335) was broadly in line with estimated prevalence rates for anxiety disorders in children,[32] children from economically disadvantaged and minoritised ethnic backgrounds were under-represented among those screened. Future research should investigate participation barriers for these particular

groups and how to help all families to participate and benefit in implementation efforts.

This trial provides robust evidence that screening for anxiety problems in primary schools in England, sharing screening outcomes with families, and offering CBT delivered with online and telephone support for parents of identified children reduces parent-reported child anxiety problems. Findings indicate that the parallel universal one-off psychoeducation session should not be integrated. Delivering the screening-to-intervention pathway in primary schools could increase reach for effective early intervention for childhood anxiety problems, but future implementation should prioritise ensuring increases in reach are equitable.

iCATS Team

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Contributors

CC took overall responsibility for all aspects of the study. OCU led the statistical analysis, MV led the health economics, and ML led the qualitative aspects. CC, OCU, MV, ML, TF, AG, CH, BJ, FM, MS, FFS, SHS, JS, and PS contributed to funding acquisition. CC, TR, OCU, SB, MV, ML, TF, AG, CH, BJ, FM, MS, FFS, SHS, JS, and PS contributed to conceptualisation and methodology. LT, JF, GH, SY, VW, IM, and JP contributed to methodology. CC, TR, LT, JF, GH, and VW contributed to investigation. CC, TR, LT, JF, and GH contributed to project administration and supervision. TR, LT, JF, and GH contributed to data curation. OCU, SB, CC, TR, MV, and SY contributed to formal analysis. TR prepared the original draft and all authors contributed to reviewing and editing. TR, OCU, SB, MV, and SY directly accessed and verified underlying data reported in this paper. All authors have full access to all the data in the study and accept final responsibility for the decision to submit for publication.

Declaration of interests

CC and CH are developers of the OSI platform. The University of Oxford receives consultancy and royalty payments linked to the distribution of the intervention outside of research; CC does not receive any personal payments. CH receives consultancy and royalty payments from the commercialisation of OSI. SHS owns the copyright to the items of the SCAS. Although the SCAS may be used free of charge for research and non-commercial clinical purposes with her permission, she may benefit financially from commercial licensing of the SCAS for use in large-scale commercial settings. TF's research group receives funding for research methods consultancy from Place2Be, a third sector organisation that provides mental health training and interventions in schools. All other authors declare no competing interests.

Data sharing

De-identified individual participant data, a data dictionary, and the analysis code will be made available on an open access data repository as soon as possible after publication; for more information contact the corresponding author (tessa.reardon@psych.ox.ac.uk). The data dictionary is available on the Open Science Framework and details on how to access the de-identified data and code will be added once they are available.

Acknowledgments

This study is funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research (reference number RP-PG-0218–20010). CC, TR, and MV were partly supported by the NIHR Oxford Health Biomedical Research Centre. CC and MV received funding from the NIHR Applied Research Collaboration Oxford and Thames Valley. TR is supported by a Prudence Trust Fellowship. OCU and SB are supported by the NIHR Applied Research Collaboration South West Peninsula. All research at the Department of Psychiatry in the University of Cambridge is supported by the NIHR Cambridge Biomedical Research Centre (NIHR203312) and the NIHR Applied Research Collaboration East of England. The views expressed are those of the authors and not necessarily those of the National Health Service, NIHR, or the Department of Health and Social Care. We thank our programme steering committee, data monitoring and ethics committee, and patient and public involvement representatives who provided support throughout the trial, all staff and students who supported with data collection activities, and all participating schools and families that contributed to the study.

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