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Published Version

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Creswell, C., Taylor, L., Giles, S., Howitt, S., Radley, L., Whitaker, E., Brooks, E., Knight, F., Raymont, V., Hill, C., van Santen, J., Williams, N., Mort, S., Harris, V., Yu, S., Pollard, J., Violato, M., Waite, P. and Yu, L.-M. (2024) Digitally augmented, parent-led CBT versus treatment as usual for child anxiety problems in child mental health services in England and Northern Ireland: a pragmatic, non-inferiority, clinical effectiveness and cost-effectiveness randomised controlled trial. The Lancet Psychiatry, 11 (3). pp. 193-209. ISSN 2215-0374 doi: 10.1016/S2215-0366(23)00429-7 Available at https://centaur.reading.ac.uk/115322/

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To link to this article DOI: http://dx.doi.org/10.1016/S2215-0366(23)00429-7

Publisher: Elsevier

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Digitally augmented, parent-led CBT versus treatment as usual for child anxiety problems in child mental health services in England and Northern Ireland: a pragmatic, non-inferiority, clinical effectiveness and cost-effectiveness randomised controlled trial

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Summary

Background Anxiety problems are common in children, yet few affected children access evidence-based treatment. Digitally augmented psychological therapies bring potential to increase availability of effective help for children with mental health problems. This study aimed to establish whether therapist-supported, digitally augmented, parent-led cognitive behavioural therapy (CBT) could increase the efficiency of treatment without compromising clinical effectiveness and acceptability.

Methods We conducted a pragmatic, unblinded, two-arm, multisite, randomised controlled non-inferiority trial to evaluate the clinical effectiveness and cost-effectiveness of therapist-supported, parent-led CBT using the Online Support and Intervention (OSI) for child anxiety platform compared with treatment as usual for child (aged 5–12 years) anxiety problems in 34 Child and Adolescent Mental Health Services in England and Northern Ireland. We examined acceptability of OSI plus therapist support via qualitative interviews. Participants were randomly assigned (1:1) to OSI plus therapist support or treatment as usual, minimised by child age, gender, service type, and baseline child anxiety interference. Outcomes were assessed at week 14 and week 26 after randomisation. The primary clinical outcome was parent-reported interference caused by child anxiety at week 26 assessment, using the Child Anxiety Impact Scale–parent report (CAIS-P). The primary measure of health economic effect was quality-adjusted life-years (QALYs). Outcome analyses were conducted blind in the intention-to-treat (ITT) population with a standardised non-inferiority margin of 0·33 for clinical analyses. The trial was registered with ISRCTN, 12890382.

Findings Between Dec 5, 2020, and Aug 3, 2022, 706 families (706 children and their parents or carers) were referred to the study information. 444 families were enrolled. Parents reported 255 (58%) child participants' gender to be female, 184 (41%) male, three (<1%) other, and one (<1%) preferred not to report their child's gender. 400 (90%) children were White and the mean age was 9·20 years (SD 1·79). 85% of families for whom clinicians provided information in the treatment as usual group received CBT. OSI plus therapist support was non-inferior for parent-reported anxiety interference on the CAIS-P (SMD 0·01, 95% CI –0·15 to 0·17; p<0·0001) and all secondary outcomes. The mean difference in QALYs across trial arms approximated to zero, and OSI plus therapist support was associated with lower costs than treatment as usual. OSI plus therapist support was likely to be cost effective under certain scenarios, but uncertainty was high. OSI plus therapist support acceptability was good. No serious adverse events were reported.

Interpretation Digitally augmented intervention brought promising savings without compromising outcomes and as such presents a valuable tool for increasing access to psychological therapies and meeting the demand for treatment of child anxiety problems.

Funding Department for Health and Social Care and United Kingdom Research and Innovation Research Grant, National Institute for Health and Care (NIHR) Research Policy Research Programme, Oxford and Thames Valley NIHR Applied Research Collaboration, Oxford Health NIHR Biomedical Research Centre.

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Lancet Psychiatry 2024; 11: 193–209

Published Online February 6, 2024 https://doi.org/10.1016/S2215-0366(23)00429-7

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Introduction

Child mental health services are notoriously stretched around the world, with stark gaps between needed and available care.[1] Digitally augmented psychological treatments bring potential to dramatically increase capacity within clinical services;[2] however, such treatments have not been established in routine child mental health services. Nonetheless, the implementation

Research in context

Evidence before this study

A recent Cochrane review highlighted that there is now robust evidence for cognitive behavioural therapy (CBT) for child anxiety problems, however few children who might benefit from CBT are able to access it. Supporting parents to implement CBT strategies in their children's day-to-day lives (parent-led CBT) has been shown to be a clinically effective and cost-effective way to provide treatment, and digital augmentation could further increase accessibility. We searched OVID PsycINFO, PubMed, Web of Science, OVID EMBASE, CINAHL via EBSCOhost, and the Cochrane Central Register of Controlled Trials (CENTRAL) on Jan 26, 2023, using terms relating to child or adolescent or youth, parent or family, anxiety, and cognitive behavioural therapy (appendix p 193). We placed no restrictions on publication date or language. Thirteen papers were identified. Only one small randomised controlled trial reported on the use of therapist-supported, digitally augmented parent-led CBT. The trial included 52 pre-school children (age 3–6 years) and suggested the approach was feasible and well received by parents, and that there was some evidence of efficacy compared to a wait-list control. Economic evaluations of digitally augmented psychological interventions for child mental health problems are sparse, with none specifically focusing on anxiety problems in children. No trials to date have evaluated whether digitally augmented CBT generally, and parent-led CBT specifically, is non-inferior and cost-effective compared to routine treatment in child mental health services. In the UK, the National Institute of Health and Care Excellence has recently identified this as the critical information required in order to make clinical recommendations.

Added value of this study

To our knowledge, this is the first randomised controlled trial to test the clinical and cost-effectiveness of therapist-supported, digitally augmented parent-led CBT for child anxiety problems in routine child mental health settings compared to usual treatment. The digital platform used in this study (Online Support and Intervention [OSI] for child anxiety) was designed with therapists and families to help parents to help their children overcome problems with anxiety, with remote and brief therapist support. OSI plus therapist support brought substantial reductions in therapist time taken to deliver treatment without compromising treatment outcomes, when compared with (predominantly) evidence-based treatment as usual. When we considered the joint distribution of incremental mean costs and effects, OSI was likely to be cost effective under certain scenarios, but uncertainty was high. Parent and therapist feedback was positive—they found OSI easy to access and use and reported a wide range of benefits.

Implications of all the available evidence

CBT is well established as an effective treatment for child anxiety problems, yet few children who could benefit are able to access it. Parent-led CBT has been shown to provide an efficient way to deliver effective treatment yet barriers remain for both families and clinical teams. OSI plus therapist support is a promising new approach to increase access to effective treatment for child anxiety problems. Both the main study outcomes and therapist and parents' descriptions of their experiences suggest that implementation of this online therapist-supported parent-led CBT approach has potential to substantially increase capacity within busy child mental health services while bringing accessibility benefits for families.

See Online for appendix

of digitally enabled care within children and young people's mental health services is a current priority area, as reflected in England, for example, by a National Institute of Health and Care Excellence (NICE) Early Value Assessment.[3] Here we focus on anxiety problems as they affect over a quarter of the population during their lives,[4] bring substantial personal and economic costs,[5] and often start early in life, with a peak age of onset at 5 years.[6]

Cognitive behavioural therapy (CBT) is an effective treatment for childhood anxiety disorders[7] but only a minority of children with anxiety disorders access evidence-based treatment.[8–10] Families face extensive barriers, including high demands on services, limited available support, and long waiting lists,[11] highlighting the need for efficient mechanisms for treatment delivery. Brief forms of CBT for childhood anxiety can be effective.[7] For pre-adolescent children, they typically involve a therapist-guided, parent-led approach,[7] in which therapists support parents to implement CBT strategies in their children's day-to-day lives. In addition to reducing overall therapy time, this approach has potential to increase access to effective treatment by reducing the perceived stigma and disruption to children's usual activities by not requiring them to attend regular clinic appointments and enabling difficulties to be managed as a family.[11] There is now good evidence for this approach[12] and it is widely implemented, for example, in England,[13] as a first-line treatment approach.

Digital augmentation brings potential to further increase the efficiency and accessibility of psychological interventions such as parent-led CBT, by enabling parents to access and engage with core treatment content in their own time and space with personalised therapist support. One small trial has provided promising findings for pre-school children in comparison with a waitlist control.[14] Here we evaluated a novel, therapist-supported, parent-led CBT approach using Online Support and Intervention (OSI) for child anxiety—a platform that was designed in collaboration with families and NHS therapists[15] with the specific aims of enabling efficient, engaging, and accessible treatment for child anxiety disorders.

Therapist-supported OSI has so far shown promising evidence[16,17] but is yet to be systematically evaluated for clinical effectiveness and cost-effectiveness and acceptability in routine practice. Therefore, the primary objective of this trial was to determine whether this therapist-supported, digitally augmented, parent-led CBT brings cost savings in routine children's mental health services without compromising clinical outcomes, meeting the recent call from England's NICE for essential evidence to inform clinical recommendations.[18]

Methods

Study design and participants

We conducted a pragmatic, two-arm, multisite, randomised, controlled, non-inferiority trial of OSI plus therapist support and treatment as usual in Child and Adolescent Mental Health Services for child anxiety problems. We also examined the acceptability of OSI plus therapist support via qualitative interviews with parents and therapists. The trial was registered with the ISRCTN (12890382) and the study protocol was published.[19]

To participate, sites needed to provide child mental health care on behalf of the National Health Service (NHS) or local authorities in England and Northern Ireland. There were 34 participating sites: 29 NHS Trusts and five local authority or voluntary or community sector providers. These sites included 73 different recruiting Child Mental Health Teams; 42 teams were Mental Health Support Teams providing mental health support through schools.

To be eligible, children needed to be aged 5–12 years at intake, have a primary problem of anxiety (as determined by clinical teams in line with their usual practice), and be willing and able to assent. Parents were required to have sufficient English language to complete measures and access interventions, have access to the Internet, and be willing and able to provide consent. Participants were not eligible if the children had comorbid conditions that were likely to interfere with treatment delivery (established diagnosis of autism or learning disability, suicidal intent, or recurrent or potentially life-limiting self-harm); were identified by social services as having child protection concerns; or were a potential participant in another study where the child might receive the OSI intervention. Participants were also ineligible if the participating parent had a significant intellectual impairment or severe mental health problem that was likely to interfere with treatment delivery.

Of note, this study started when restrictions were in place due to the COVID-19 pandemic, a time when there were particular concerns about increases in demand for child mental health services[20] and when services had to quickly pivot to delivering services remotely.[21] In our study protocol we referred to "treatment as usual in the COVID-19 context", however as COVID-19 restrictions were not in place throughout the trial, and because services have continued to use strategies employed in the COVID-19 context, we have adopted the term "child mental health service treatment as usual" as this is a better reflection of what was delivered within this arm.

This study was approved by London-City & East Research Ethics Committee (20/HRA/4421).

Randomisation and masking

Participants were randomly assigned in a 1:1 ratio to OSI plus therapist support or child mental health service treatment as usual for child anxiety problems (referred to henceforth as treatment as usual). Minimisation by child age (≤8 years and ≥9 years), gender, service type (school based or not school based), and baseline anxiety-associated interference, including permuted block size, was used to ensure balance across arms. Participants were randomly assigned using a fully validated and secured web-based randomisation system called Sortition[22] that acted automatically after the participating parent completed the consent and baseline measures, and the child completed assent. Sortition then automatically sent an email, including the result of the allocation treatment arm, to the trial team, the clinical team, and the participant. Due to the nature of the trial, blinding to intervention was not possible for trial participants, however statistical analyses were conducted blind to treatment allocation.

Procedures

Participants were identified within clinical services following their usual assessment procedures. Eligible families were invited to take part in the trial at the point in time when the clinical team were confident that they could deliver either treatment arm within 12 weeks of randomisation. Members of the clinical team introduced the study to potential participants and registered them on a study website where they could access study information for parents and children (in written and video form), access contact details for further enquiries, and, if willing, provide consent (parents) or assent (children) via a secure online system. After consent or assent was provided, parents and children were asked to complete online baseline assessments (all questionnaires) before randomisation. After randomisation, parents were asked to complete the treatment expectations and acceptability measure.

Treatment in both arms was organised by the clinical teams, who were requested to start as soon as possible and at most within 12 weeks of randomisation. Participating parents and children in both arms were sent a link to complete further assessments (questionnaires) at week 14 and week 26 after randomisation via a secured online web-based database system.[23,24] The full schedule of enrolment, interventions, and assessments is provided in the trial protocol.[19]

Parents received a welcome phone call from the trial team and monthly parent bulletins with trial updates. A scheduled series of emails, text messages, and telephone

calls was made to families during the 1-month periods in which their 14-week questionnaire and 26-week questionnaire were due, to promote participant retention. Families received a £10 voucher as a thank you for completing their final assessment.

Qualitative interviews were conducted one-to-one by a researcher with qualitative expertise (FK), who was not involved in any other aspects of the trial. Purposively sampled participants were interviewed at a date and time convenient to the participant after their week 14 assessment. Participants received a £20 voucher for taking part.

Treatment in both arms could be delivered by any therapists in participating clinical services, who routinely provided psychological treatments for child anxiety problems. 188 therapists across 73 clinical teams delivered treatment within the trial. Therapists' professional backgrounds were provided for 167 of the therapists, as shown in the appendix (pp 4–5).

OSI for child anxiety was designed to digitally augment parent-led CBT for the treatment of anxiety problems in pre-adolescent children by providing parents with all the core treatment content that they need in accessible forms, including information (in text, audio, and video) and exercises (supported by worksheets and quizzes). The accompanying therapist case management system supports therapists to help parents to personalise the content for their child and overcome potential barriers that they might face. There is also an optional child game app that parents can use to motivate their child to engage with the intervention. The core intervention content is centred on empowering parents to help their child by developing an understanding of their child's anxious predictions, putting these predictions to the test in a manageable (gradual) way, and promoting problem solving to address issues that arise. The OSI intervention is provided across seven modules, and parents are supported to apply it by weekly 20-min telephone or video call sessions between the parent and a therapist, and a review session, 4 weeks after the final treatment session. Therapists were provided with a written manual and a brief training video (45 min). Ongoing supervision of the therapists was provided within their clinical services following usual procedures. The research team offered weekly drop-in sessions for therapists to address technical questions or challenges, but very few therapists regularly attended them (60 [76%] of 79 therapists who delivered an OSI case attended at least one drop-in session; median drop-in sessions attended was 1). OSI plus therapist support is considered to be a complete treatment so, although participants were not prevented from accessing other support, OSI plus therapist support was considered to be an alternative rather than an adjunct to treatment as usual.

For more on **game app** see https://osiresearch.org.uk/osi/

The comparator was whatever treatments the participating services were otherwise delivering to treat child anxiety problems. Therapists provided information on the therapeutic approach being followed, the format (individual or group), modality (in person or online), and who they worked with (child, parent, or both). Therapists in both arms also provided detailed information on the time taken to deliver the intervention, including preparation, administrative tasks, and supervision.

Outcomes

The primary outcome was the Child Anxiety Impact Scale–parent report (CAIS-P)[25] at week 26 after randomisation. Secondary clinical outcomes included child-reported anxiety interference (CAIS-C total and global scores)[25] and anxiety symptoms (Revised Child Anxiety and Depression Scale [RCADS-C]),[26] parent-reported child anxiety symptoms (RCADS–P),[27] CAIS-P global score,[25] overall functioning (Outcome Rating Scale),[28] and common comorbid emotional and behavioural problems (Strengths and Difficulties Questionnaire–parent report [SDQ-P])[29] measured at week 14 and week 26 after randomisation, and the CAIS-P at week 14 after randomisation. For all these scales, a higher score indicates worse functioning, with the exception of the Outcome Rating Scale, in which a higher score indicates better functioning. For brevity, other secondary outcomes are described in the appendix (pp 32–36).

To capture adverse events, therapists were requested to monitor and report any harms and adverse events during the treatment phase. Additionally, parents and children were invited to report any negative impact of participating in the study as part of their assessment at week 14 and 26 after randomisation.

Indicative topic guides were used to guide the post-treatment interviews with parents and therapists about their experiences of the trial and the OSI treatment, including what they found helpful and unhelpful, potential improvements, the involvement of others in treatment, and how things had been since treatment ended.

The primary economic outcome was child quality-adjusted life years (QALYs), derived from the validated parent report version of the Child Health Utility 9-Dimension measured at baseline, week 14, and week 26.[30] As no established guidelines exist on which value set is most appropriate for UK preadolescent children, individual responses were converted to utilities using preference weights obtained from both a sample of the UK adult general population[31] and of Australian adolescents aged 11–17 years.[32] Parent QALYs were derived from the EuroQol-5 dimensions, 5 levels (EQ-5D-5L) administered to parents at baseline, week 14, and week 16.[33] Utility values were derived using a validated mapping function from the UK EQ-5D-3L value set,[34] as recommended by NICE.[35] Child and parent QALYs were each calculated by combining the utility values at baseline, week 14, and week 26 assessment using the area under the curve approach, which assumes a linear relationship between utilities at different time points.[36] Parent–child QALYs were

obtained by additively combining individual parent and child QALYs.[37] The CAIS-P was used as a secondary economic outcome.

Data collected on patient-level resource use included treatment, additional health and personal social service use, and time off school for children and work for parents. To calculate the total cost of the intervention, therapists completed bespoke economic logs capturing treatment duration and type of contact, and time spent on preparation, clinical supervision, administration, and travel, as applicable. Child and parent resource use data were collected from parents at baseline (referring to the preceding 3 months) and at weeks 14 and 26 after randomisation using a modified (with PPI input) Client Service Receipt Inventory[38] including information on primary and secondary health and social care and medication use, school missed by the child, work missed by the parent, child and parent travel time, and direct costs for health and social care and for participating in the intervention. For each trial participant, resource use data were multiplied by the appropriate unit cost to calculate the total mean cost in each trial arm (appendix pp 8–22). The cost of the OSI technology is not included in our economic analyses as it is still unknown (but see appendix pp 188–190).

Parents were asked to complete the Credibility and Expectation of Improvement Scale[39] to assess their expectations and views regarding treatment credibility, after they had been randomly assigned and informed of the treatment arm (with higher scores reflecting more positive responses). Parents and therapists also completed an adapted form at week 14 after randomisation, to give a retrospective account of treatment credibility.

Choice of primary outcome

The CAIS-P captures the degree to which anxiety is interfering in the child and family's life. Although it has not previously been used as a primary outcome in trials, the CAIS-P was selected as the primary outcome because (1) measures of interference have been considered more relevant and valid than symptom measures by experts by experience in previous consultations;[40] (2) the CAIS-P has been found to align better with diagnostic measures of child anxiety disorders than anxiety symptom measures;[41] and (3) measures of interference, and the CAIS in particular, have recently been highlighted as crucial socially and ecologically valid markers of treatment need.[42] The total score is the sum of responses to 25 items rated on a 4-point scale (from 0 [not at all] to 3 [very much]; range 0–75) across three psychosocial domains (academic, social activities, and home and family environment). Two of the original items were not included as they were not appropriate for the pre-adolescent age group. We are not aware of translations into non-English languages. The CAIS-P is freely available from the authors.

Statistical analysis

We aimed to recruit between 418 and 560 children (209–280 per group) as this was considered to be sufficient to provide a standardised non-inferiority margin of 0·33 (ie, the upper bound of the confidence interval must be less than 0·33 when comparing OSI plus therapist support to treatment as usual to claim non-inferiority) with between 80% and 90% power (allowing for 30% attrition) at 2·5% one-side level of significance. This standardised non-inferiority margin was equivalent to a 4-point change in mean CAIS-P and standard deviation of 12, which is half of the standardised change in the primary outcome (of 0·63 by 6 months in treatment as usual for child anxiety problems, from a previous trial conducted in routine child mental health services).[43] The required sample size was calculated using PASS 2019.

For the qualitative interviews, we purposively sampled parents and therapists from the first 70 clinical cases to reach week 14 after randomisation until we reached saturation in terms of representation on a range of demographic and clinical characteristics. The sample comprised 12 parents and ten therapists (see appendix pp 2–3 for further information on both samples).

Statistical analyses of clinical outcomes were pre-specified in the Statistical Analysis Plan (appendix pp 23–50) before the end of the trial. Analyses were conducted using Stata version 16.1. Analysis of the primary outcome was performed using a generalised linear mixed effects model adjusting for minimisation factors to determine the treatment effect and two-sided 95% CI. The mixed effect models included the outcome as the response variable, time point, randomised group, and baseline score as fixed effects and a participant-specific random intercept. The model specified an unstructured variance-covariance structure for the random effects. An interaction between time and randomised group was fitted as a fixed effect to allow estimation of treatment effect at all time points. Non-inferiority would be claimed if the upper limit of the 95% CI around the standardised effect size was less than 0·33. A p value for non-inferiority was also calculated. The models did not deviate from normality assumptions of the generalised linear mixed effects model. A similar approach was used for the other secondary outcomes. Treatment credibility, acceptability, and experience scores were calculated and compared for both treatment groups, using a Mann–Whitney U test.

The primary analysis population was defined as all participants for whom data were available, analysed according to the groups to which they were randomly allocated, regardless of treatment compliance (ie, actual treatment received). For the primary analysis, they must have completed their assessment within 4 weeks of the week 14 and week 26 timepoints, but sensitivity analyses were carried out based on altering the timeframe allowed for the assessments. A secondary analysis was also carried

out based on a per-protocol population who had (1) received five or more treatment sessions, (2) received the treatment they were originally assigned to, (3) submitted their final questionnaire within 30 weeks of randomisation, and (4) started treatment within 12 weeks of being randomly assigned (appendix p 150). Characteristics that were found to be predictive of missingness (if the parent was partnered and if the parent was cohabiting) were included in the model in a pre-planned sensitivity analysis of the primary outcome. Post-hoc sensitivity analyses, such as best-case and worst-case scenarios, and multiple imputation, were also carried out. Multiple imputation was conducted using chained equations. The following were included in the multiple imputation model: random allocation; minimisation variables; child's age; child's gender; baseline anxiety associated interference; service type (school or clinic); and factors found to be predictive of the primary outcome being missing (not partnered and not cohabiting). Adverse events were summarised by treatment arm; no other analyses were conducted.

The Health Economics Analysis Plan (appendix pp 51–78) was signed off before the end of the trial and it adhered to current best practice.[44] The primary analysis (base-case analysis) was a within-trial cost-utility analysis comparing OSI plus therapist support with treatment as usual, with incremental costs (reported with their associated 95% CI) and incremental child QALYs (reported with their associated 95% CI) combined to calculate an incremental cost-effectiveness ratio from the NHS and Personal Social Services perspective as recommended by NICE.[35] Costs were expressed in pounds sterling (£) in 2020–21 prices. Due to the short timeframe of the trial and follow-up, discounting was not applied to costs or effects. Both an intention-to-treat and per-protocol approach were adopted in the base-case analysis. Missing data were imputed by use of mean imputation conditional on treatment arm for missing items, and multiple imputation for missing responses and cases under the assumption of missing at random.[45]

Differences in costs and QALYs between OSI plus therapist support and treatment as usual were estimated using linear regression, controlling for baseline costs and utility, respectively. A secondary cost-effectiveness analysis was undertaken, with outcomes measured using the difference in CAIS-P at week 26 and incremental costs from the NHS and Personal Social Services perspective (base-case analysis).

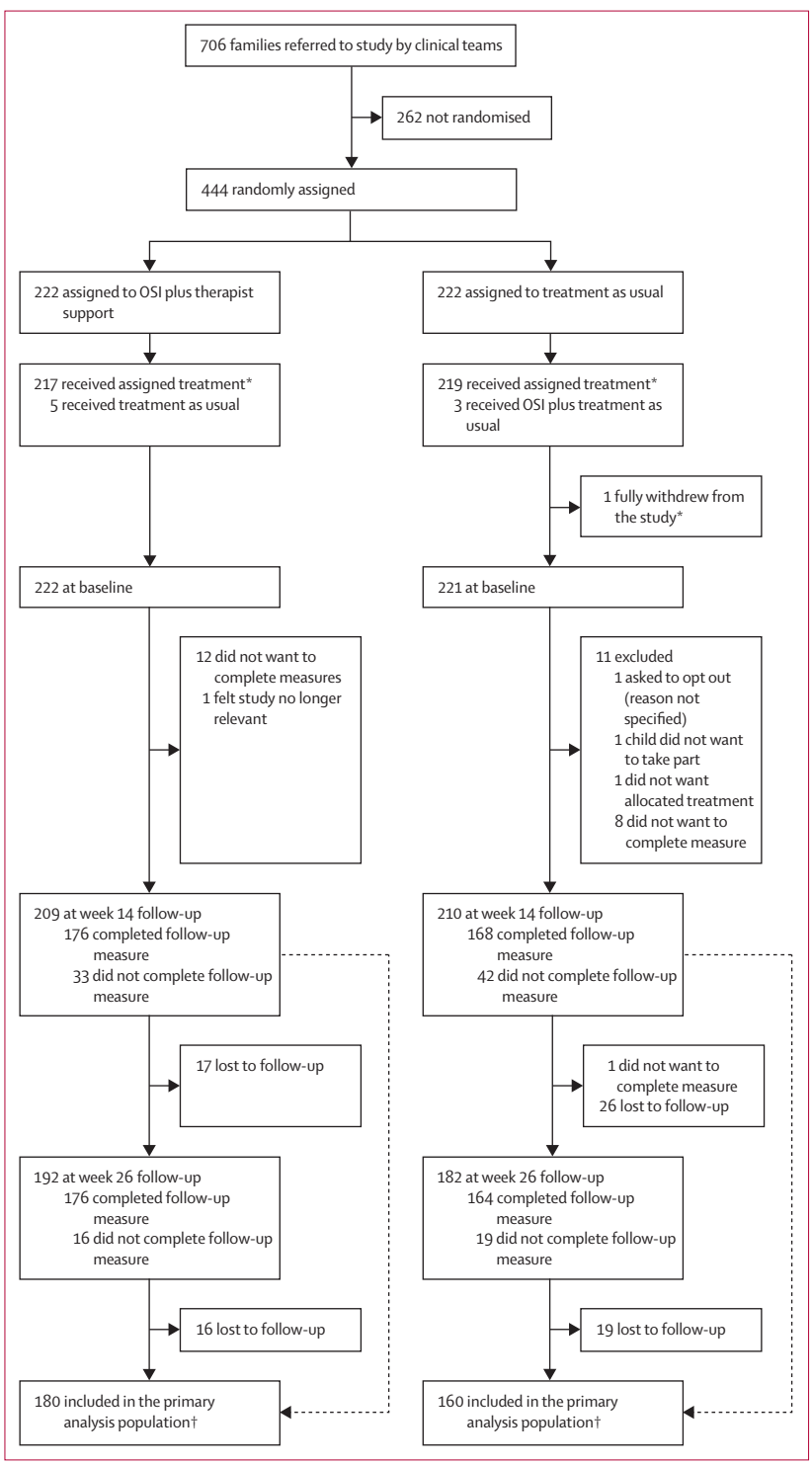

Figure 1: **Trial profile**
There was one child per family. Participants in the treatment as usual arm received treatment for child anxiety problems from child mental health services. Participants in the OSI plus therapist arm received parent-led OSI for child anxiety with therapist support. OSI=Online Support and Intervention. *One participant fully withdrew from the study and requested all data that had been collected so far to be deleted. This participant has been excluded from the analysis population. †Number of participants that completed the primary outcome of CAIS-P at week 14, or 26, or both: 21 participants in the OSI plus therapist support arm and 30 participants in the treatment as usual arm completed CAIS-P at week 14 only, and 17 participants in the OSI plus therapist support arm and 15 participants in the treatment as usual arm completed CAIS-P at week 26 only. 142 participants in the OSI plus therapist support arm and 115 participants in the treatment as usual arm completed CAIS-P at both week 14 and 26 assessments. 42 participants in the OSI plus therapist support arm and 62 participants in the treatment as usual arm were missing CAIS-P at both week 14 and 26, and are not included in the primary analysis.

	OSI plus therapist support (n=222)	Treatment as usual (n=221)	Mean/% difference
Child baseline characteristics			
Age, years	9·31 (1·83)	9·08 (1·74)	0·23
Gender			
Male	92 (41%)	92 (41%)	–0·19
Female	127 (57%)	128 (58%)	–0·71
Other	2 (1%)	1 (<1%)	0·45
Prefer not to say	1 (<1%)	0	0·45
Ethnicity			
White*	194 (87%)	206 (93%)	–5·82
Mixed†	19 (9%)	14 (6%)	2·23
Asian or Asian British‡	3 (1%)	0	1·35
Black or Black British§	1 (<1%)	1 (<1%)	0·00
Other ethnic groups¶	2 (1%)	0	0·90
Not stated	3 (1%)	0	1·35
Previous treatment for anxiety or other psychological difficulties	46 (21%)	30 (14%)	7·15
Prescribed medication for anxiety or other psychological difficulties	2 (1%)	6 (3%)	–1·81
Education			
State school	214 (96%)	209 (95%)	1·83
Independent school	4 (2%)	7 (3%)	–1·37
Special provision school	2 (1%)	2 (1%)	0·00
Home educated	2 (1%)	3 (1%)	–0·46
Special educational needs	33 (15%)	32 (14%)	0·38
Type of special educational needs||			
Communicating and interacting	15 (45%)	11 (34%)	11·07
Cognition and learning	16 (48%)	15 (47%)	1·60
Social, emotional, and mental health difficulties	24 (73%)	20 (63%)	10·23
Sensory, or physical, or both, needs	13 (39%)	12 (38%)	1·89
CAIS-P: total score	26·87 (15·26)	25·96 (14·63)	0·91
CAIS-P: global items	6·20 (3·00)	5·86 (2·95)	0·34
CAIS-C: total score	26·13 (14·44; n=210)	25·75 (15·06; n=212)	0·38
CAIS-C: global items	5·30 (2·85; n=210)	5·17 (3·18; n=212)	0·13
RCADS-P: total anxiety score	46·35 (19·83)	45·91 (19·93)	0·44
RCADS-P: total anxiety and depression score	56·18 (23·79)	55·40 (24·17)	0·77
RCADS-C: total anxiety score	47·14 (19·68; n=204)	46·26 (19·96; n=209)	0·87
RCADS-C: total anxiety and depression score	56·98 (23·54; n=204)	55·84 (24·14; n=209)	1·13
ORS	26·25 (8·15)	27·19 (7·78)	–0·93
SDQ-P: total problems score	17·95 (7·05)	17·26 (6·53)	0·69
Parent baseline characteristics			
Age, years	39·00 (5·93)	38·28 (5·67)	0·73
Gender			
Male	9 (4%)	8 (4%)	0·43
Female	212 (96%)	213 (96%)	–0·88
Other	0	0	0·00
Prefer not to say	1 (<1%)	0	0·45
Ethnicity			
White*	203 (91%)	215 (97%)	–5·85
Mixed†	11 (5%)	2 (1%)	4·05
Asian or Asian British‡	3 (1%)	1 (<1%)	0·90
Black or Black British§	1 (<1%)	2 (1%)	–0·45
Other ethnic groups¶	2 (1%)	1 (<1%)	0·45
Not stated	2 (1%)	0	0·90

(Table 1 continues on next page)

	OSI plus therapist support (n=222)	Treatment as usual (n=221)	Mean/% difference
(Continued from previous page)			
Household circumstances			
Mortgaged or owned	137 (62%)	122 (55%)	6·51
Council rented	29 (13%)	22 (10%)	3·11
Housing association	19 (9%)	30 (14%)	−5·01
Privately rented	32 (14%)	44 (20%)	−5·50
Other	5 (2%)	3 (1%)	0·89
Is child fostered?	0	0	0·00
Is child adopted?	1 (<1%)	1 (<1%)	0·00
Education			
School completion	35 (16%)	33 (15%)	0·84
Further education	103 (46%)	101 (46%)	0·70
Higher education	39 (18%)	53 (24%)	−6·41
Postgraduate qualification	45 (20%)	34 (15%)	4·89
Partnered	177 (80%)	176 (80%)	0·09
Cohabiting (living together)**	165 (93%)	163 (93%)	0·61
Partner's education**			
School completion	50 (28%)	38 (22%)	6·66
Further education	65 (37%)	76 (43%)	−6·46
Higher education	30 (17%)	27 (15%)	1·61
Postgraduate qualification	20 (11%)	22 (13%)	−1·20
Not stated	12 (7%)	13 (7%)	−0·61
Employment			
Full time	84 (38%)	82 (37%)	0·74
Part time	87 (39%)	73 (33%)	6·16
Sheltered or supported employment	1 (<1%)	0	0·45
Unemployed	7 (3%)	20 (9%)	−5·90
Student	3 (1%)	2 (1%)	0·45
Homemaker	26 (12%)	28 (13%)	−0·96
Retired	0	0	0·00
Other	14 (6%)	16 (7%)	−0·93
Total household income, £††			
≤16 000 per year	17 (12%)	18 (13%)	−1·18
16 001–30 000 per year	27 (19%)	25 (18%)	0·77
30 001–40 000 per year	14 (10%)	18 (13%)	−3·31
40 001–50 000 per year	11 (8%)	12 (9%)	−1·02
50 001–60 000 per year	12 (9%)	17 (13%)	−3·99
60 001–70 000 per year	11 (8%)	7 (5%)	2·65
70 001–80 000 per year	8 (6%)	10 (7%)	−1·68
80 001–90 000 per year	6 (4%)	5 (4%)	0·58
90 001–120 000 per year	8 (6%)	4 (3%)	2·73
>120 000 per year	3 (2%)	6 (4%)	−2·28
Prefer not to say	24 (17%)	14 (10%)	6·73

Data are n (%) or mean (SD). Participants in the treatment as usual arm received treatment for child anxiety problems from child mental health services. Participants in the OSI plus therapist arm received parent-led OSI for child anxiety with therapist support. Percentages have been computed with the number of participants with the response available as the denominator. For all scales, a higher score indicates worse functioning, with the exception of the ORS where a higher score indicates better functioning. CAIS-C=Child Anxiety Impact Scale–child report. CAIS-P=Child Anxiety Impact Scale–parent report. ORS=Outcome Rating Scale. OSI=Online Support and Intervention. RCADS-C=Revised Child Anxiety and Depression Scale–child report. RCADS-P=Revised Child Anxiety and Depression Scale–parent report. SDQ-P=Strengths and Difficulties Questionnaire–parent report. *Including British, Irish, and any other White background. †Including White and Black Caribbean, White and Black British, White and Asian, and any other mixed background. ‡Including Indian, Pakistani, Bangladeshi, and any other Asian background. §Including African, Caribbean, and any other Black background. ¶Including Chinese, and any other ethnic group. ||Only includes those with special educational needs. **Only includes those who are partnered. ††Data were available for 141 participants in the OSI plus therapist support arm and 136 in the treatment as usual arm.

Table 1: **Baseline characteristics of participants**

A willingness to pay threshold of £20 000–30 000 per QALY gained was used to evaluate whether OSI plus therapist support was cost effective compared to treatment as usual, as per NICE guidelines,[35] representing uncertainty around the cost and effectiveness estimates, by means of acceptability curves.[46] The same approach was used in the cost-effectiveness analyses, although the maximum threshold value that the NHS or society is willing to pay for an improvement in the CAIS-P is unknown so we presented a range of possible maximum values that a decision maker might be willing to pay for a unit improvement in outcome.

Various prespecified sensitivity analyses, including a societal perspective to capture wider impacts, were undertaken to explore uncertainties around assumptions made in the base-case analyses and test the robustness of the results (appendix pp 79–81).

Qualitative data were analysed using semantic interpretative deductive and inductive thematic analysis.[47] For this paper, we used the data to deductively explore the acceptability of OSI, particularly focusing on constructs in the theoretical framework of acceptability (eg, affective attitude, effort, degree of fit with the individual's value system, understanding of the intervention, perceived effectiveness, and self-efficacy).[48]

This study is registered as an International Standard Randomised Controlled trial (ISRCTN12890382) and the protocol is publicly available.[19]

Role of the funding source

The funder of the study had no role in study design, collection, analysis and interpretation of data, in the writing of the report or in the decision to submit for publication.

Results

Participants were recruited between Dec 5, 2020, and Aug 3, 2022. 706 families (706 children and their parents or carers) were referred to the study information by the clinical teams, of whom 444 families confirmed they met inclusion criteria, provided consent, and were randomly assigned (222 to OSI plus therapist support and 222 to child mental health service treatment as usual; figure 1). All participants completed baseline assessments, however one participant subsequently requested all their data be removed. Details of the type of primary anxiety problem as determined by the clinician are provided in the appendix (p 82). Despite study procedures requiring all participants to have started treatment within 12 weeks of randomisation, only 349 (79%) of 444 participants were reported to have started their allocated treatment by the end of the trial. 181 (82%) of 222 participants allocated to the OSI plus therapist support arm and 168 (76%) of 222 allocated to the treatment as usual arm started treatment. Eight participants were incorrectly assigned to treatments by clinical teams (five in the OSI plus therapist support arm were given treatment as usual and three in the treatment as usual arm were registered to OSI). 176 (79%) participants in the OSI plus therapist support arm and 168 (76%) in the treatment as usual arm completed the week 14 assessment, and 176 (79%) in the OSI plus therapist support arm and 164 (74%) in the treatment as usual arm completed the week 26 assessment. There were more girls than boys (255 [58%] girls and 184 [41%] boys)and the majority were described as White-British (table 1). The mean age of child participants was 9·20 (SD 1·79) years.

Breakdown of the treatment approach, format, modality, and who the sessions were conducted with are provided in the appendix (pp 151–52), and therapist characteristics are also provided in the appendix (pp 4–5). 110 (85%) of 130 treatment as usual cases where information was provided on treatment approach received CBT, for 79 (72%) this was delivered through parents (with the rest [28%] being delivered through both children and parents).

As shown in the appendix (p 153), before receiving treatment, parent reports across treatment arms did not differ on how logical the treatment seemed and how confident they were in it, but scores were significantly higher for their certainty in the success of the OSI plus therapist support arm. There were no differences at the week 14 assessment. Therapist ratings also did not differ after delivering the treatment on items relating to how logical the treatment was, how prepared they felt, how successful it was, and how much they would recommend it; however, therapists reported that they felt more comfortable in delivering treatment as usual than the novel online treatment and felt they were less likely to use OSI again in the future (note: services had time limited access to OSI associated with the research trial and so were uncertain about whether they would be able to continue to use it).

The standardised mean difference between arms was less than 0·33 for the primary outcome, indicating that OSI plus therapist support was significantly non-inferior to treatment as usual, with an extremely small standardised mean difference (table 2; figure 2). The same pattern was found across all sensitivity analyses (appendix p 150). OSI plus therapist support was also significantly non-inferior to treatment as usual across all secondary analyses (figures 2 and 3; table 2). More details on the clinical results are presented in the appendix (p 150).

Descriptive data for treatment, resource use outcomes, and costs are presented in the appendix (pp 155–56); there was little difference in utility scores and QALYs between arms, after adjusting for baseline values (p 169). Cost mean differences, adjusted for baseline costs, were lower in the OSI plus therapist support arm compared with treatment as usual (appendix p 170). This was primarily accounted for by lower costs for therapist delivery; the mean therapist time delivering treatment sessions for OSI plus

	OSI plus therapist support (n=222)	Treatment as usual (n=221)	Adjusted mean difference (95% CI)*†	Standardised mean difference (95% CI)	p value for non-inferiority‡
Primary outcome					
CAIS-P					
Baseline	26·87 (15·26)	25·96 (14·63)	..	..	..
14 weeks	19·64 (16·00; n=163)	18·89 (14·52; n=145)	0·00 (–2·34 to 2·34)	0·00 (–0·16 to 0·16)	<0·0001
26 weeks§	17·99 (15·39; n=159)	18·08 (15·08; n=130)	0·14 (–2·26 to 2·53)	0·01 (–0·15 to 0·17)	<0·0001
Secondary outcome					
CAIS-P: global items					
Baseline	6·20 (3·00)	5·86 (2·95)	..	..	..
14 weeks	4·07 (3·12; n=163)	3·97 (2·88; n=145)	–0·13 (–0·63 to 0·37)	–0·04 (–0·21 to 0·12)	<0·0001
26 weeks	3·60 (3·06; n=159)	3·62 (2·84; n=130)	0·08 (–0·42 to 0·59)	0·03 (–0·14 to 0·20)	0·0003
CAIS-C: total score					
Baseline	26·13 (14·44; n=210)	25·75 (15·06; n=212)	..	..	..
14 weeks	19·27 (15·13; n=127)	20·73 (14·50; n=114)	–1·61 (–4·55 to 1·33)	–0·11 (–0·31 to 0·09)	<0·0001
26 weeks	17·03 (15·83; n=124)	19·89 (16·64; n=111)	–2·67 (–5·64 to 0·30)	–0·18 (–0·38 to 0·02)	<0·0001
CAIS-C: global items					
Baseline	5·30 (2·85; n=210)	5·17 (3·18; n=212)	..	..	..
14 weeks	3·63 (3·05; n=127)	4·03 (2·62; n=114)	–0·30 (–0·90 to 0·30)	–0·10 (–0·30 to 0·10)	<0·0001
26 weeks	3·61 (3·28; n=123)	3·40 (3·18; n=111)	0·30 (–0·31 to 0·90)	0·10 (–0·10 to 0·30)	0·012
RCADS-P: total anxiety score					
Baseline	46·35 (19·83)	45·91 (19·93)	..	..	..
14 weeks	34·09 (23·01; n=161)	34·84 (19·92; n=143)	–2·22 (–5·49 to 1·04)	–0·11 (–0·28 to 0·05)	<0·0001
26 weeks	30·57 (23·29; n=157)	32·03 (20·98; n=129)	–0·96 (–4·27 to 2·36)	–0·05 (–0·22 to 0·12)	<0·0001
RCADS-P: total anxiety and depression score					
Baseline	56·18 (23·79)	55·40 (24·17)	..	..	..
14 weeks	41·25 (28·26; n=161)	41·55 (23·89; n=143)	–2·22 (–6·16 to 1·73)	–0·09 (–0·26 to 0·07)	<0·0001
26 weeks	37·45 (28·77; n=157)	38·22 (25·39; n=129)	–0·54 (–4·54 to 3·46)	–0·02 (–0·19 to 0·14)	<0·0001
RCADS-C: total anxiety score					
Baseline	47·14 (19·68; n=204)	46·26 (19·96; n=209)	..	..	..
14 weeks	31·40 (23·18; n=127)	32·10 (21·26; n=112)	–1·29 (–5·58 to 3·00)	–0·07 (–0·28 to 0·15)	0·0002
26 weeks	29·96 (24·91; n=122)	29·53 (22·75; n=111)	1·41 (–2·89 to 5·71)	0·07 (–0·15 to 0·29)	0·0098
RCADS-C: total anxiety and depression score					
Baseline	56·98 (23·54; n=204)	55·84 (24·14; n=209)	..	..	..
14 weeks	37·91 (28·37; n=127)	38·11 (25·38; n=112)	–0·99 (–6·15 to 4·17)	–0·04 (–0·26 to 0·18)	0·0004
26 weeks	36·30 (30·86; n=122)	35·04 (27·27; n=111)	2·31 (–2·86 to 7·49)	0·10 (–0·12 to 0·31)	0·018
ORS: total score (overall functioning)					
Baseline	26·25 (8·15)	27·19 (7·78)	..	..	..
14 weeks	29·80 (7·97; n=161)	30·94 (7·00; n=143)	–0·58 (–1·90 to 0·74)	–0·07 (–0·24 to 0·09)	0·0011
26 weeks	30·68 (8·11; n=154)	31·21 (6·77; n=127)	–0·21 (–1·58 to 1·15)	–0·03 (–0·20 to 0·14)	0·0003
SDQ-P: emotional symptoms					
Baseline	6·41 (2·29)	6·21 (2·40)	..	..	..
14 weeks	4·99 (2·89; n=161)	4·62 (2·61; n=143)	0·03 (–0·45 to 0·51)	0·01 (–0·19 to 0·22)	0·0011
26 weeks	4·40 (2·76; n=154)	4·51 (2·82; n=128)	–0·24 (–0·73 to 0·25)	–0·10 (–0·31 to 0·11)	<0·0001
SDQ-P: conduct problems					
Baseline	2·84 (2·08)	2·72 (2·02)	..	..	..
14 weeks	2·48 (2·12; n=161)	2·44 (2·07; n=143)	–0·01 (–0·30 to 0·29)	0·00 (–0·15 to 0·14)	<0·0001
26 weeks	2·55 (2·16; n=154)	2·39 (2·14; n=128)	–0·05 (–0·36 to 0·25)	–0·03 (–0·17 to 0·12)	<0·0001
SDQ-P: hyperactivity or inattention					
Baseline	5·94 (2·89)	5·66 (2·75)	..	..	..
14 weeks	5·19 (3·01; n=161)	4·85 (3·06; n=143)	–0·04 (–0·46 to 0·37)	–0·02 (–0·16 to 0·13)	<0·0001
26 weeks	5·44 (3·13; n=154)	4·85 (2·74; n=128)	0·01 (–0·41 to 0·44)	0·00 (–0·15 to 0·16)	<0·0001

(Table 2 continues on next page)

	OSI plus therapist support (n=222)	Treatment as usual (n=221)	Adjusted mean difference (95% CI)*†	Standardised mean difference (95% CI)	p value for non-inferiority‡
(Continued from previous page)					
SDQ-P: peer relationship problems					
Baseline	2·77 (2·34)	2·67 (2·14)	..	..	..
14 weeks	2·57 (2·33; n=161)	2·22 (2·16; n=143)	0·19 (–0·12 to 0·49)	0·08 (–0·05 to 0·22)	0·0002
26 weeks	2·55 (2·27; n=154)	2·27 (2·03; n=128)	0·09 (–0·22 to 0·41)	0·04 (–0·10 to 0·18)	<0·0001
SDQ-P: prosocial behaviour					
Baseline	7·42 (2·33)	7·48 (2·24)	..	..	..
14 weeks	7·47 (2·31; n=161)	7·50 (2·20; n=143)	–0·03 (–0·34 to 0·29)	–0·01 (–0·15 to 0·13)	<0·0001
26 weeks	7·27 (2·35; n=154)	7·61 (2·34; n=128)	–0·15 (–0·48 to 0·17)	–0·07 (–0·21 to 0·08)	0·0002
SDQ-P: total score					
Baseline	17·95 (7·05)	17·26 (6·53)	..	..	..
14 weeks	15·24 (8·37; n=161)	14·13 (7·58; n=143)	–0·05 (–1·07 to 0·97)	–0·01 (–0·16 to 0·14)	<0·0001
26 weeks	14·93 (8·35; n=154)	14·02 (7·49; n=128)	–0·41 (–1·46 to 0·64)	–0·06 (–0·21 to 0·09)	<0·0001
Health economics outcomes					
Parent report on child CHU-9D (UK adult value set)					
Baseline	0·771 (0·132)	0·793 (0·119)	..	..	..
14 weeks	0·827 (0·133; n=173)	0·841 (0·117; n=163)	–0·001 (–0·023 to 0·020)	..	..
26 weeks	0·833 (0·141; n=172)	0·846 (0·112; n=162)	–0·002 (–0·025 to 0·021)	..	..
Parent report on child CHU-9D (Australia adolescent value set)					
Baseline	0·541 (0·256)	0·578 (0·234)	..	..	..
14 weeks	0·656 (0·265; n=173)	0·671 (0·243; n=163)	0·006 (–0·037 to 0·049)	..	..
26 weeks	0·675 (0·275; n=172)	0·686 (0·232; n=162)	0·006 (–0·040 to 0·053)	..	..
Parent self-report EQ-5D-5L (UK adult value set)					
Baseline	0·792 (0·215)	0·835 (0·175)	..	..	..
14 weeks	0·825 (0·224; n=173)	0·860 (0·159; n=164)	0·003 (–0·028 to 0·035)	..	..
26 weeks	0·847 (0·200; n=172)	0·871 (0·143; n=162)	–0·002 (–0·033 to 0·029)		

Data are mean (SD), unless otherwise indicated. Participants in the OSI plus therapist arm received parent-led OSI for child anxiety with therapist support. Participants in the treatment as usual arm received treatment for child anxiety problems from child mental health services. For all scales, a higher score indicates worse functioning, with the exception of the ORS where a higher score indicates better functioning. Generalised linear mixed effects model adjusted for randomised arm, assessment timepoint, baseline score, minimisation variables (child's age, gender, baseline anxiety associated interference, and service type), an interaction between randomised arm and assessment timepoint as fixed effects, and a random intercept for each participant. CAIS-C=Child Anxiety Impact Scale–child report. CAIS-P=Child Anxiety Impact Scale–parent report. CHU-9D=Child Health Utility 9D. EQ-5D-5L=EuroQol-5 dimensions, 5 levels. ORS=Outcome Rating Scale. OSI=Online Support and Intervention. RCADS-C=Revised Child Anxiety and Depression Scale–child report. RCADS-P=Revised Child Anxiety and Depression Scale–parent report. SDQ-P=Strengths and Difficulties Questionnaire-parent report. *OSI plus therapist support versus treatment as usual. †For health economics outcomes, the mean difference was adjusted for baseline values using an OLS model and was computed on complete observations. ‡Wald test; one-sided; level of statistical significance p=0·025. §Primary outcome.

Table 2: **Summary statistics, adjusted mean differences, standardised mean differences, and the p value for non-inferiority for the primary and secondary analyses**

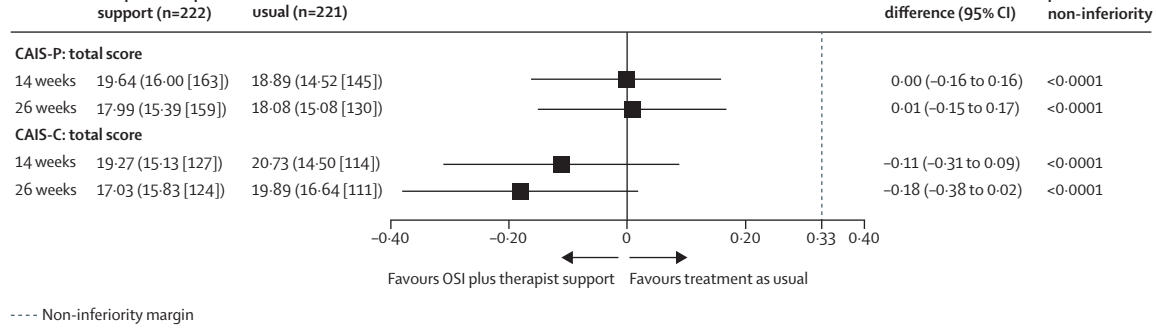

Figure 2: **Forest plot for primary and secondary outcomes: Child Anxiety Impact Scale**
Participants in the treatment as usual arm received treatment for child anxiety problems from child mental health services. Participants in the OSI plus therapist arm received parent-led OSI for child anxiety with therapist support.OSI=Online Support and Intervention. CAIS-P=Child Anxiety Impact Scale–parent report. CAIS-C=Child Anxiety Impact Scale–child report.

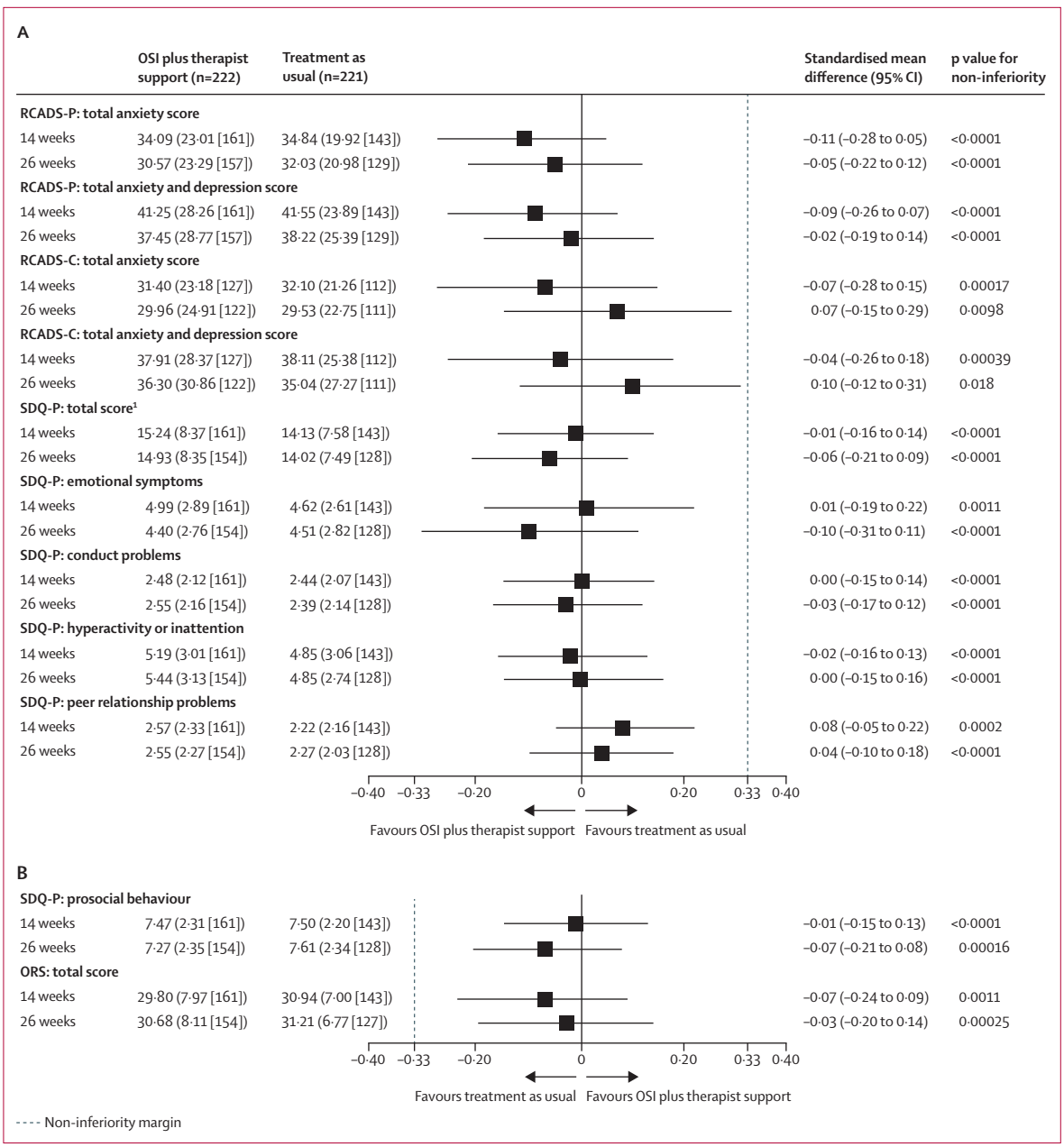

Figure 3: **Forest plot for other secondary outcomes**
Participants in the treatment as usual arm received treatment for child anxiety problems from child mental health services. Participants in the OSI plus therapist arm received parent-led OSI for child anxiety with therapist support.Additional secondary outcomes and sensitivity analyses are described and reported in the appendix (pp 111–22). OSI=Online Support and Intervention. RCADS-P=Revised Child Anxiety and Depression Scale–parent report. RCADS-C=Revised Child Anxiety and Depression Scale–child report. SDQ-P=Strengths and Difficulties Questionnaire–parent report. ORS=Outcome Rating Scale.

therapist support (182 minutes) was 59% of the time spent delivering treatment as usual (307 minutes; appendix p 155). The various cost utility analyses across ITT and per-protocol analyses suggested that OSI plus therapist support was likely to be cost effective under certain scenarios, with the exception of the ITT analysis using the UK adult preferences dataset (appendix pp 174–80). Cost-utility analysis results were not only sensitive to the underlying values set used for deriving QALYs, but also characterised by large uncertainty surrounding the cost-effectiveness estimates. For the cost-effectiveness analysis (appendix pp 174–81), the cost-effectiveness acceptability curve, which accounts for sampling uncertainty, indicated that OSI plus therapist support is likely to be cost effective, although uncertainty remained high. However, the maximum

threshold value that society is willing to pay for a unit improvement in the CAIS-P is unknown. More details on the health economic results are presented in the appendix (pp 155–72, 174–81).

Summaries of the experiences of parents and therapists with illustrative quotes from the qualitative interviews are presented in table 3.

No serious adverse events were recorded. Ten adverse events were reported in each arm (coding by arm and details are presented in the appendix pp 123–28). The Trial Steering Committee considered all adverse events either not to relate to the treatments or trial procedures (eg, child injury after falling off bike) or to relate to routine aspects of clinical care (eg, child did not like completing standard measures).

Discussion

We found markedly similar and non-inferior treatment outcomes for the novel intervention, OSI plus therapist support, compared with the predominantly evidence-based treatment as usual. OSI plus therapist support brought substantial savings in therapist contact time and was considered to be cost-effective in several scenarios, although uncertainty in this was high. These findings highlight the potential for digitally augmented interventions like OSI plus therapist support to increase the number of children treated for anxiety problems without compromising treatment outcomes.

The novel treatment was credible to both parents and therapists, although unsurprisingly (given training was rapid and most therapists only delivered OSI plus

	Illustrative quotes	Implications
Parents' experiences of OSI plus therapist support		
Parents who initially had reservations about OSI or a parent-led approach could see the benefit once they started the programme.	"I was thinking, em, doing something online…maybe it's better to do this with speaking with somebody, like. But, actually, to be honest, actually it was much better, I found it more helpful in the end." (14P) "I didn't think it would work. You know, with like with 'me' doing it, I thought you know, she'd be better off with a professional 'cos I don't really know what I'm doing. But I mean it does help. "(19P) "I was hopeful that [my daughter] would have more involvement than she did…but if I'm honest, I got over that quite quickly 'cause the therapist was wonderful and it helped me to understand [my daughter]'s needs better. So, I saw the benefits of it once I started doing it." (04P)	It will be helpful to normalise and address any initial concerns with parents who are being offered OSI plus therapist support. Therapists would benefit from training around how to introduce this approach to parents in a way that allays any initial concerns. This could be more explicitly addressed in further developments to the OSI plus therapist support programme.
The programme was generally seen as user-friendly, well designed, and flexible, allowing parents to fit the sessions into daily life; parents appreciated being able to listen to the audio of the online content, complete sessions on a mobile phone, and download the materials.	"I'm a complete techno idiot. I'm not smart or savvy at all when it comes to tech. And if I can do it, anybody can do it." (06P) "I just thought it was really easy to navigate. It was very straightforward working through the modules." (12P) "I was washing the dishes and I was listening to it…the fact that I can come back and read the things again. I can download them. That was very good." (14P) "I could just log into it anytime that suited me. So even if it was the midnight and I was sat in bed, I could still say right, I want to get this done now." (04P)	Usability is good and for most parents there is good fit—this might provide reassurance to parents, therapists, services, and commissioners in deciding whether to receive, deliver and commission OSI plus therapist support.
Therapists were seen positively as providing support, problem-solving difficulties, and helping parents put strategies into practice.	"I had a little blockage with the step plan. She [child], she wasn't getting as far, you know she just sort of stopped at one level, and I was trying to think why that was and she [therapist] was really helpful for that." (12P) "The therapist at the time was fantastic. You know she was a massive support to me." (21P) "When I doubt myself, she picks me back up again." (09P)	Therapist support is highly valued and appears to be an essential part of treatment.
Many parents developed a sense of self-efficacy that enabled them to feel they had the tools to help their child (and other children) now and in the future.	"The course supported 'me' and empowered 'me'" (04P) "I feel confident enough that I now have the tools that if that happens with anything in life, not just the person receiving the treatment for myself and for my other child, it's changed my concept on how to deal with life as well." (09P) "I think I did learn a lot and will probably continue to evolve and learn that with her." (16P)	Parents who are being offered the programme, therapists, services, and commissioners might find it beneficial to know that the benefits appear to go beyond improvements in the child's anxiety and extend to parents' being equipped with skills to potentially manage future difficulties without the need for further professional input.
At the end of treatment, parents were generally positive about the parent-led approach and the OSI plus therapist support programme (even parents whose children were still experiencing some anxiety problems); for most parents, OSI plus therapist support led to improvements in their child's anxiety and emotional wellbeing, leading them to do things previously avoided, as well as increasing their confidence and resilience; some parents described this having a positive effect on relationships in the family.	"Where we've come from and where we are now in such a short space of time, in my eyes, is a miracle. I can't…back then I never ever dreamt that we could get to a stage where we are now. (09P) "I'd do it again in a heartbeat." (11P) "It just works, you know, so I'm, I'm really happy with it." (12P) "It hasn't particularly worked well for 'my' daughter, but I think there's a lot more going on there. But I'm so, so glad I've done it." (06P) "It's got him going back in his own bed and going to bed at a normal time without me either in there or him up all through the night." (13P) "Personally, me and my daughter are now closer. We got to a stage where we were sort of quite estranged…and we can now see a brighter future." (09P)	Providing information about the effectiveness of the treatment and parents' experiences of the programme might help parents, therapists, services, and commissioners in deciding whether to receive, deliver and commission OSI plus therapist support.
Two parents felt that they would have preferred their child to be involved in the sessions and longer face-to-face appointments where they could receive more support from the therapist; doing the programme on their own and having to manage other significant stressors in life appeared to make it difficult to engage in the programme.	"I do think there's real value of doing it face to face and involving the child." (17P) "If he'd had a bad week, I could. I mean, I can talk for England anyway, but I feel like I could have shared a lot more information…I think maybe like maybe, em, an allowance for debriefing for parents in, put into place would be good." (17P) "I think it would have been so much massively beneficial if there had been the support of the two parents… probably would have been a bit more beneficial if we were all singing off the same hymn sheet." (21P) "I'll most certainly use the techniques and I still do to a degree. But it's just so much other stuff going on to be honest with you." (21P)	It will be important to establish factors that are associated with poorer fit and outcomes for OSI plus therapist support and identify whether OSI plus therapist support could be further adapted to improve acceptability and outcomes for these families.

(Table 3 continues on next page)

	Illustrative quotes	Implications
(Continued from previous page)		
Therapists' experiences		
Generally, therapists were enthusiastic about the training and the programme in relation to its ease of use and effectiveness; therapists suggested some minor improvements and requested further training on routine outcome measures and videos illustrating the approach.	"So yeah, I felt like it was sort of good training to begin with." (02C) "I think it was really it was a great parent-led treatment definitely, and it works. And so you know, I've really enjoyed, really enjoyed, delivering it to be quite honest." (03C) "I think, generally on the whole, just kind of like, the way it was kind of easy to follow and it was really structured, the modules." (29C) "I think it's a really great way of working and I think it breaks down lots of barriers for families struggling to access treatments." (05C) "I thought would have been helpful was if the therapists, like myself, could have access to the parent website, like a test account sort of thing, so that we could actually see what they're seeing." (10C) "For those people who are kind of novice practitioners just a little 10-minute video on what each kind of ROM [routine outcome measure] means." (20C) "While it was well guided, in the instructions and the manuals, seeing in practice before would have been very helpful, I think." (02C)	In general, OSI plus therapist support is perceived as having the necessary characteristics to be implemented in services (ie, good usability and observable improvements in child anxiety). There are some minor improvements that could be made around usability, such as providing the therapist with the parent view of the programme; further training on routine outcome measures and more videos demonstrating the approach would be valued by less experienced therapists.
Therapists felt that having the questionnaires and content delivered online and being able to monitor engagement within the programme reduced burden and time for therapists; short phone calls with parents appeared to be broadly acceptable to therapists and parents.	"I can book more cases in and I can be much more flexible with them, so that's been really helpful." (05C) "I feel like a lot of the responsibility is being lifted from my shoulders because I know the information that the parent has read is good quality, accessible and I can check that they understood it." (01C) "That's what I love about the Co-CAT—so I can go on, so I might go on the day before to have a quick look." (08C) "It's easy to like track the progress with the questionnaires that they filled in and see how the scores are changing each week, so that was good. (10C) "You can build that rapport, the same way that we would anyway…and actually having check-ins with parents, 20 minutes is still enough to catch up and check in." (05C)	OSI plus therapist support is perceived to have a relative advantage over other approaches in terms of therapists' time and resources.
Some therapists were champions for the approach, voluntarily taking a particular interest in OSI plus therapist support and its adoption in the local service.	"I really, really really hope that OSI sticks around and that as a Trust we do sign up to it and that we can use it because it is like being given almost the key to the magical Kingdom that you are shown this whole other world…like Willy Wonka's Chocolate Factory and everything is brilliant and marvellous, and then go back to the way it was before…I think I would be a bit gutted to be fair." (01C) "I'm like guys it's great. You know, it's brilliant, we have to sign up for this. We need it. We need it to do well and to be rolled out across the country." (05C)	The active recruitment of champions could help spread knowledge about OSI plus therapist support and enthusiasm for the approach, and facilitate embedding it into services.
Based on small numbers of cases (therapists had only delivered OSI plus therapist support to between one and four parents), therapists expressed some ideas around who OSI plus therapist support might or might not work for; in their experience, it appeared to be acceptable to parents from multiethnic communities and those who might experience difficulties in reading or with the English language; they felt OSI plus therapist support might be less successful if children were older, had high levels of anxiety and avoidance, or were unable to articulate their worries; they also felt there were some instances where parents did not have capacity to engage in the programme and required more support.	"Something they brought up consistently is just how easy it was to understand in terms of the language. And it was easy to sort of digest information and also they had the option to have someone to narrate the text, and that was a useful function for them." (02C) "Yeah, I think for the younger ones, yes, I think it's definitely got its place for the younger ones." (23C) "As much as Mum can try and ask those questions she would say like sometimes, he just won't answer the questions, or he'll shut down when she tries to talk to him." (10C) "My sense is that I'm not sure, it works for children who aren't at school…I'm not sure if it works if the child isn't in situations where they're experiencing all their anxiety." (20C) "One of her comments was when we had the assessment was that she didn't want to be her child's therapist…then mum was a bit reluctant to start with anyway, then a few weeks in she said, oh it's too parent led. I'm gonna try something else." (23C) "I think it would really depend on the parent, so I think some parents are more suited to it than others, and some parents need that hour if you know what I mean. It can be like a therapy session for them. And some parents are that busy they just don't need, the time, just don't need you taking up the time, just need the skills…I would definitely just kinda wait and decide after I met the parents." (29C)	Therapists' initial impressions are that OSI plus therapist support appears to be acceptable to parents from multiethnic communities and those who may experience difficulties in reading or with the English language. There are initial impressions that OSI plus therapist support may be less suited to some families. Further evidence is required to determine to whom might or might not benefit from OSI plus therapist support and therefore who it should be offered. Once evidence becomes available, this should be communicated to therapists in services so that decisions are made based on the evidence.
Although they recognised the positives in using OSI plus therapist support, some therapists described preferences for, or perceived benefits in, delivering sessions in-person rather than via OSI plus therapist support. This appeared to be particularly the case for therapists who had not had professional training or were within the first year of being qualified.	"I don't mind doing online interventions, but face to face is still definitely my preference 'cause I think it's just so much easier to build that rapport and engage with someone and see how they're presenting like in front of you." (10C) "With the treatment as usual [delivering parent-led CBT in a group], it's—I probably get more out of them ones as well, I probably learn more myself, as a, as a practitioner." (29C) "I'd like to give them all the information and then get them to read the additional materials, for just, to aid more understanding. So, I'd probably talk through the anxious thoughts, the physical changes, the anxious behaviours, and then just give that [OSI plus therapist support] as additional knowledge." (08C)	Within services, there is likely to be variability in therapists' interest, motivation, values or beliefs, learning opportunities, skills and knowledge, and access to support or supervision to deliver OSI plus therapist support. If OSI plus therapist support is to be delivered by a range of therapists within services, these factors will need to be assessed and addressed via a range of strategies.

Co-CAT=Child Anxiety Treatment in the context of COVID-19. OSI=Online Support and Intervention. Parent participants are identified as P and clinician participants are labelled as C.

Table 3: **Parents' (n=11) and therapists' (n=10) experiences regarding the acceptability of OSI plus therapist support from the qualitative interviews**

therapist support once), therapists were somewhat more comfortable delivering their usual treatment. It was also not surprising, given that OSI was provided as part of a time-limited research trial, that therapists were somewhat uncertain that they would use it again in the future; however, overall satisfaction was high. There were no serious adverse events or adverse events that were considered to relate directly to the intervention. The qualitative interviews indicated high levels of acceptability for OSI in terms of usability (for parents and therapists), effort, time, and perceived outcomes.

Therapist training in OSI plus therapist support was highly pragmatic, given the COVID-19 pandemic context, which brings both advantages and disadvantages. On the one hand, the results are particularly encouraging given the minimal training and support that therapists were given in this new online intervention. On the other hand, even better outcomes might be achieved with more substantial initial training and ongoing support and supervision. Future studies are warranted to explore the level of training required to optimise treatment outcomes. This trial included children with a broad range of anxiety problems; future studies should also explore whether outcomes differed by anxiety subtype.

We had minimal exclusion criteria for the trial and we did not require a formal diagnosis of an anxiety disorder, as this is rarely done in clinical settings.[41] An established autism diagnosis was an exclusion criteria, but many children in this age group will have not yet had a formal assessment and it is possible some participants might have received a diagnosis had this been assessed. Indeed, 15% of the children in our sample had a recognised special educational need, 32% of whom had difficulties with communicating and interacting, and 32% had difficulties with sensory or physical needs.

This study had various limitations, including that the researchers who collected data were not blind to treatment arm due to some differences in the therapist-reported data that was collected between arms. We used participant-reported outcomes, as is typical in routine practice, and we prioritised parent report as some of the outcome measures have not been validated with children as young as 5 years and in line with recent guidance.[40] This choice of reported outcome brings risk of bias from the parent, but we were encouraged that the same pattern of results was found across parent and child report measures and most of our child self-report measures somewhat favoured OSI plus therapist support, despite children not having direct therapist contact. This evaluation was conducted in a large number of routine child mental health services by a large and varied group of therapists as part of their routine caseloads. This is a strength in terms of learning about real-world implementation and no doubt contributed to this trial having a relatively diverse sample in terms of family income and parent education, but it also brings challenges associated with the demands on busy clinical teams. Given that all participating clinicians were taking part in this trial as part of their routine clinical work, there was a limit to how much information we could collect on the nature of the interventions delivered and the integrity of delivery of particular treatment models. It is possible that the COVID-19 pandemic context might have compromised delivery of treatment as usual, with the majority of contacts occurring remotely, however clinicians reported high satisfaction with their 'as usual' approach and were highly likely to continue to work in the same way beyond the trial. Clinical teams were responsible for identifying potential families for the study and we were therefore unable to obtain detailed information about families who did not participate. As such, we do not know whether the relatively low ethnic diversity among participants and therapists reflects the broader characteristics of participating clinical teams or reflects a bias in who was willing or able to participate in the trial. We relied on clinical teams to deliver the treatments in a timely manner and to report on the treatment provided, but other pressures, such as high staff turnover, presented considerable challenges; only 79% of families enrolled into the trial started treatment within 12 weeks of randomisation, and 13% did not receive any treatment within 26 weeks. However, a range of sensitivity analyses provided consistent results, which adds confidence in the robustness of the results. More participants started treatment within 12 weeks of randomisation in the OSI plus therapist support arm than the treatment as usual arm, and the families receiving OSI plus therapist support attended more sessions. This better engagement in treatment might partly explain the better overall trial retention in the OSI plus therapist support arm than in the treatment as usual arm, which leads to the need for caution in interpreting results, particularly in the per-protocol analyses. Encouragingly, most baseline demographic and clinical variables were not associated with trial attrition. The exception was that fewer participants with missing data were partnered or cohabiting, probably reflecting the fact that participating in the trial might have been particularly burdensome for single parents, as supported by the qualitative interviews. Finally, although overall the primary economic analyses results (cost-utility analyses, which are those more likely to inform policy making) indicated that OSI plus therapist support is likely to be cost effective under several scenarios, these analyses need to be considered with caution, due to their sensitivity to the underlying values sets used for deriving QALYs, and the large uncertainty surrounding the cost-effectiveness estimates (see appendix pp 184–87 for a full discussion of the health economics results).

This trial presents compelling clinical evidence and promising cost-effectiveness evidence that digitally augmented psychological therapies with therapist support can increase efficiencies in and access to child mental health services without compromising patient outcomes. Efforts are now needed to take full advantage of the opportunity that digitally augmented psychological treatments can bring to drive a step change in children's mental health services, learning from successful examples of digital implementation elsewhere in health services.[49]

Contributors

CC took overall responsibility for all aspects of the study. PW led on the qualitative aspects, LMY on statistical analyses, and MV on health economics. CC, LT, PW, MV, VR, CH, and LMY contributed to conceptualisation, funding acquisition, and methodology. LT, SG, SH,

LR, EW, EB, and FK contributed to methodology, investigation, data collection, and project administration. JvS contributed to data curation. LMY, NW, SM, VH, FK, PW, MV, JP, and SY contributed to formal analysis and visualisation. All authors contributed to writing, reviewing, and editing. JvS, NW, SM, VH, MV, SY, JP, and LM directly accessed and verified the underlying data reported in the manuscript. All authors have full access to all the data in the study and accept final responsibility to submit for publication.

Declaration of interests

CC is the author of a book for parents that is used in many of the participating clinical teams to augment treatment as usual for child anxiety problems and receives royalties from sales. CC and CH are developers of the OSI platform. They do not receive any personal financial benefits from the use of OSI. All other authors declare no competing interests.

Data sharing

Deidentified individual participant data, a data dictionary, and the analysis code will be made available on an open access data repository accompanied by the study protocol and the statistical analysis plan as soon as possible after publication; for more information contact the corresponding author.

Acknowledgments

This study was funded by a Department for Health and Social Care–United Kingdom Research and Innovation Research Grant (managed by the Medical Research Council; COV0375), National Institute of Health and Care (NIHR) Research Policy Research Programme (PRP NIHR204435), Oxford and Thames Valley NIHR Applied Research Collaboration, Oxford Health NIHR Biomedical Research Centre. CC and MV also receive funding from the NIHR Oxford Health Biomedical Research Centre and the NIHR Applied Research Collaboration Oxford and Thames Valley. The views expressed are those of the author and not necessarily those of the NHS, NIHR, or the Department of Health and Social Care. We are extremely grateful to our Trial Steering Committee and Patient and Public Involvement representatives who provided invaluable support throughout the trial. We also thank Zoe Ryan and Abi Thomson for research support, Eve Merriam and En-Nien Tu for systematic review support, and Ana Gibertoni Cruz for helping with medication classifications. We would like to express huge gratitude to all the participating families and therapists that contributed to the study, as well as the Trust Research and Development teams and Clinical Research Networks that supported recruitment.

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