NEW RESEARCH

Internet-Based Cognitive–Behavioral Therapy Intervention Master Your Worries With Telephone Coaching for Anxious Finnish Children Aged 10-13 Years: A Population-Based Randomized Controlled Trial

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Objective: No previous studies have evaluated the efficacy of Internet-based cognitive–behavioral therapy (ICBT) among children below age 13 years screened at the population level. This study was an open, 2 parallel–group randomized controlled trial (RCT), stratified by sex, that compared ICBT with telephone coaching vs an educational control.

Method: Altogether 465 children (mean age = 11.5 years, SD = 1.0 years, 71.4% girls) were randomly allocated to ICBT or psychoeducation. The 10-week ICBT included weekly digital material and exercises and weekly telephone calls. Assessments comprised child and parent reports on anxiety (Screen for Child Anxiety Related Emotional Disorders questionnaire [SCARED]), impacts of anxiety, quality of life, comorbidity, and parental mental health assessed at baseline and at 6-month follow-up.

Results: The ICBT group yielded significantly higher improvement in primary outcomes (SCARED total scores) when compared with control group in the child reports ($p = .04$, Cohen $d = 0.17$) but not in the parent reports ($p = .41$, $d = 0.03$). The ICBT group had significantly higher improvement in several secondary measures of outcome, including child-reported SCARED generalized anxiety ($p = .047$, $d = 0.09$), separation anxiety ($p = .004$, $d = 0.40$), social anxiety ($p = .007$, $d = 0.27$), the parent-reported Strengths and Difficulties Questionnaire total score ($p = .002$, $d = 0.22$), emotional difficulties ($p = .02$, $d = 0.20$), hyperactivity ($p = .003$, $d = 0.19$), and quality of life ($p = .02$, $d = 0.16$).

Conclusion: When children were screened at the population level for anxiety and enrolled in this RCT study of ICBT combined with telephone guidance, they showed efficacy in improving anxiety and quality of life. These findings are encouraging when developing early population-based intervention strategies for childhood anxiety.

Clinical Trial Registration Information: A Randomized Controlled Study of Digitalized Cognitive-behavioral Intervention for Childhood Anxiety; https://clinicaltrials.gov/study/NCT03310489

Key words: children; anxiety; ICBT; RCT

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Anxiety disorders are the most common psychiatric disorders among school-aged children,[1] affecting 6.5% of all children and adolescents globally.[2] Untreated anxiety in childhood predicts not only anxiety but also depression, substance abuse, suicidality, and other psychiatric comorbidities in adulthood.[3,4] This highlights the need to identify and to provide evidence-based early interventions for childhood anxiety. The most studied evidence-based treatment of childhood anxiety disorders is cognitive–behavioral therapy (CBT).[5,6] Most children with anxiety disorders do not receive face-to-face evidence-based treatment[7,8] because of a lack of trained professionals, long waiting lists, stigma, or logistical reasons. Guided Internet-based cognitive–behavioral therapy (ICBT) programs provide solutions to these treatment barriers. Child anxiety is often not recognized by adults, which poses an important clinical challenge.[7]

According to a recent meta-analysis including participants under 18 years of age, approximately 40% of those with anxiety disorders were in remission after receiving ICBT, compared to 10% in control conditions.[9] In an early phase of ICBT development, programs included combined Internet-based material and face-to-face meetings.[10,11] To our knowledge, only 3 randomized controlled trials have

evaluated fully computerized ICBT assisted by remote guidance for anxiety among children 7 to 13 years of age, one in Australia[12] and 2 in Sweden.[13,14] The length of these programs was 10 to 12 weeks, and the guidance included written feedback (e-mails, text messages) and, in 2 of these studies,[12,13] 2 or 3 telephone calls. Among preschool-aged children, the Australian Brave-Online parent training program has been evaluated with a randomized controlled trial (RCT) among children aged 3 to 6 years of age.[15] In addition, RCT studies by Spence *et al.*[16,17] and Nordh *et al.*[18] included both children and adolescents up to 18 years of age and assessed the efficacy of ICBT, the latter focusing on social anxiety. Previous ICBT studies have generally shown a reduction in clinician-rated anxiety symptoms, whereas results for child- and parent-rated anxiety have been inconsistent. The sample sizes for all of the previous ICBT RCT studies including children have ranged from 52 to 131 participants.

There are several limitations in previous RCT research on using ICBT among children. The results of the studies including both children and adolescents are not fully generalizable to children because of differences in cognitive skills and differences in parental roles in treatment. Most importantly, recruitment in the studies focusing on children has been based on either clinical samples[11] or media advertisement,[13] or a combination of these.[10,12,14-18] There are no existing RCT studies examining the effect of ICBT on children with anxiety screened at the population level. The present study is based on a large sample of children 10 to 13 years of age who were screened from school health check-ups. Contrary to studies based on clinical samples or cohorts recruited from media advertisements, using population-based screening increases the recognition of anxiety, thus offering treatment possibilities for children whose parents are not aware of their problems.

The primary objective of this RCT study is to evaluate the efficacy of the Master Your Worries program when compared with an educational control group between baseline and 6 months after randomization. Our hypothesis was that the intervention would have superior results compared to the education control. We also aimed to explore what type(s) of anxiety problems showed the most effective treatment response.

METHOD

The study is an open, 2 parallel–group RCT, stratified by sex, that compares ICBT combined with telephone coaching vs a digital educational control (EC) providing psychoeducation on childhood anxiety. Both groups additionally received treatment as usual (TAU). Detailed information on the study methods has been previously published.[19]

Participants

Participants were children 10 to 13 years of age, in grades 4 to 6, who attended comprehensive school in 6 study sites in Finland, as described in detail in a previous publication on the protocol.[19] The inclusion criteria were that the child (1) was 10 to 13 years of age, (2) had access to the Internet, (3) was fluent in Finnish or Swedish, and (4) had scored at least 22 points in the 41-item SCARED questionnaire. Participants were excluded if they (1) had a visual or hearing impairment that hindered their use of the program, (2) had an intellectual disability, (3) had been diagnosed with autism spectrum disorder, (4) had suicidal intentions or a severe mental health disorder, (5) were in ongoing psychotherapy or therapy due to start within about 6 months, (6) had anxiety medication that was started or changed in any way during the last 2 months, (7) had been involved with child protection services regarding child custody or abuse investigations, or (8) had a parent with a severe psychiatric or somatic disease or any other factor that would hinder their active participation. Screening took place between August 2017 and January 2020.

Description of the Master Your Worries ICBT Program

The program was developed by a multidisciplinary study group. It is based on the components that have been most commonly applied in well-established studies on the efficacy of ICBT for various anxiety disorders.[20]

The program consists of 9 themes and includes separate digital material for the child and the parent. The material in the digital platform includes text, pictures, educational audio clips and animations. Two animated video bloggers were created to perform as experts by experience. The program is supported by weekly coaching calls. No face-to-face contact or video calls are included.

Table 1 presents an overview of each theme; the program is described in detail in the protocol paper.[19] The first theme of the program is psychoeducation about anxiety; themes 2 to 5 focus on anxiety management skills; themes 6 to 8 focus on gradual exposure; and the last theme, theme 9, is making a long-term plan to prevent setbacks. The families receive a booster call approximately 1 month after finishing the program, and they can use the Web-based material for 2 years. The parent's material includes psychoeducation about anxiety and parenting skills to encourage the child. The child's material is adapted to their developmental level and reading skills. During the highly structured coaching calls,

TABLE 1 Content of the Program Master Your Worries

Theme	Content	CBT component
Introduction	Intervention and tools, motivating, creating working alliance	Psychoeducation
Theme 1. Learn to know anxiety	Information about anxiety, fears, and CBT model	Psychoeducation
Theme 2. Deep breathing	Breathing techniques, introducing exposure	Anxiety-mastering skills, gradual exposure
Theme 3. Encouraging thinking	Recognize and change negative thoughts, parents' modeling behavior	Cognitive restructuring, gradual exposure
Theme 4. Relaxation	Learning how to relax, positive parenting	Anxiety-mastering skills, gradual exposure
Theme 5. Safe place	Learning to use imaginary techniques	Anxiety-mastering skills, gradual exposure
Theme 6. Anxiety ladders	Setting stepwise goals and creating exposure hierarchy, role playing	Gradual exposure
Theme 7. Learn by practicing	Practicing in real life	Gradual exposure
Theme 8. Master your anxiety	Summary of the child's skills and parent's skills	Gradual exposure
Theme 9. Long-term plan	Choosing workable anxiety- mastering skills, creating a future plan	Preventing setbacks
Booster phone call	Follow-up on skill practicing	Reinforcing skills

Note: *CBT = cognitive–behavioral therapy.*

both parent and child are present. The child receives home assignments from the digital platform and receives feedback from the coach in the phone call. As reported previously, the average time spent on the webpage per family per theme, including both child and parental material, has been 127 minutes, and weekly coaching calls last on average 32 minutes (SD = 8 minutes, range = 4-58 minutes).[21] The median total amount of time that the children spent on the webpage materials was 654 minutes (interquartile range [IQR] = 362-1,107). The corresponding median total amount of time for parents was 174 minutes (IQR = 100-266).

Educational Control

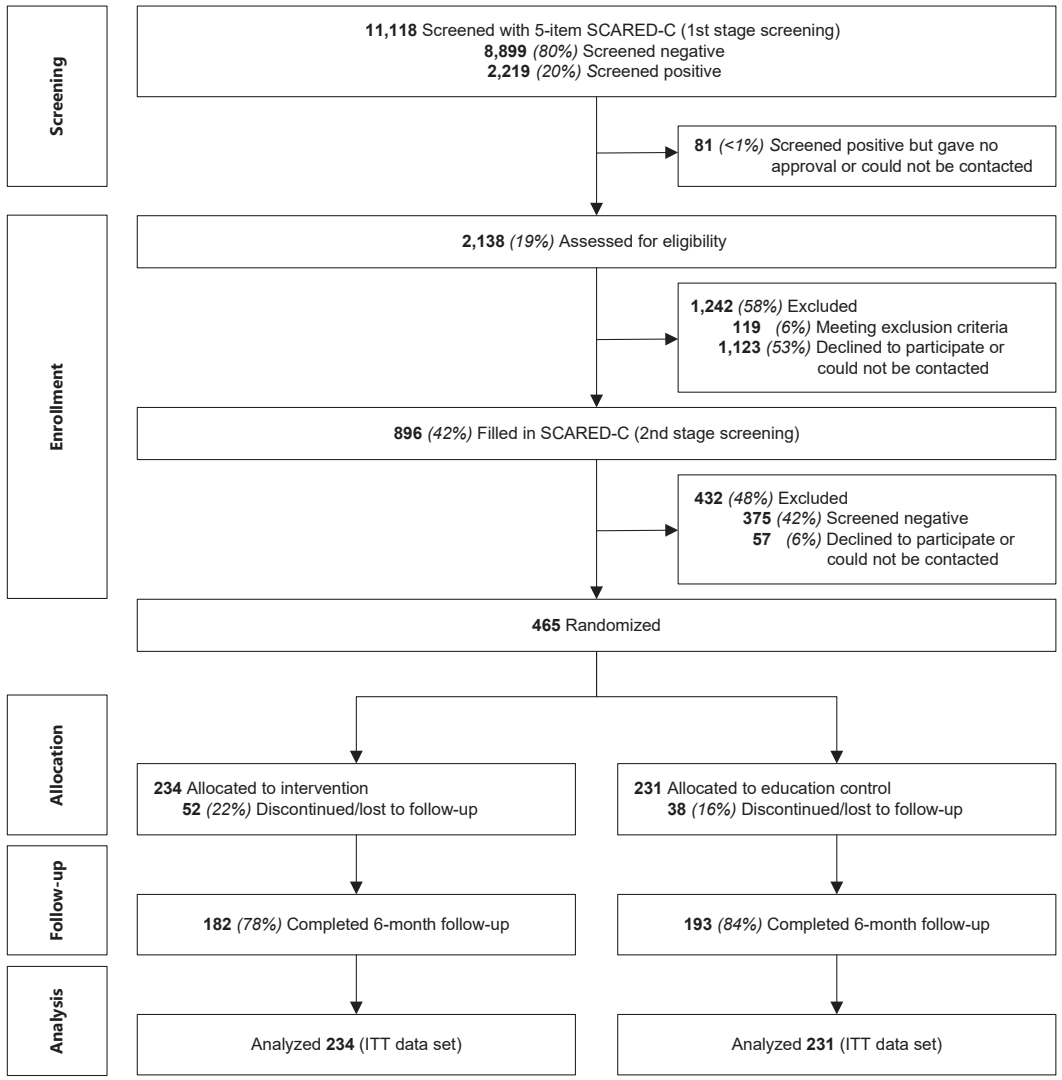
In this study, after the randomization, the families who had been allocated to the control group received an automated e-mail with a link directing them to the psychoeducational material on the platform. The materials were created separately for children and parents. Psychoeducation materials included 15 PowerPoint pages worth of material for parents and 8 pages for children. Both child and parent content included psychoeducation on anxiety, anxiety as an emotion and part of normal development, etiology of anxiety disorders, and recognizing anxiety symptoms and excessive anxiety. In addition, the child's content included information on healthy lifestyle habits and help seeking, and the parent's content included material on how to encourage, motivate, and support the child and manage parental well-being. The material did not include any CBT techniques, and the control group did not receive any phone coaching.

Screening and Recruitment

The flow chart for the study is presented in Figure 1.

To ensure the persistence of each child's anxiety symptoms, screening was conducted at 2 stages: at the first stage, by screening in school health care with a short 5-item version, and at the second stage, by screening with the whole 41-item version of the SCARED. At the first screening stage, during the annual health check-up at school, children completed a short screening instrument that included 5 items from the 41-item SCARED child report.[22,23] The selection of items was based on a Finnish epidemiological study,[24] and the statements that were chosen had the highest sensitivity for predicting possible anxiety disorder based on the SCARED total score of $\geq$25.[23] The short screening scale included 1 item from each of the 5 SCARED subscales: general anxiety (I am nervous), separation anxiety (I get scared if I sleep away from home), panic disorder (when I get frightened, I feel dizzy), school phobia (I am scared to go to school), and social anxiety (I feel nervous when I am going to any place where there will be people that I do not know well). These items were scored 0 ("not true or hardly ever true"), 1 ("somewhat true or sometimes true"), and 2 ("very true or often true"). A total score of 3 or more points, or 2 points on any of the 5 items, was used as a cut-off. In this Finnish epidemiological study with 342 schoolchildren 11 to 13 years of age, the 5-item screening scale and the 41-item SCARED child report results were highly correlated (r = 0.77, $p < 0.001$). The sensitivity and specificity of the 5-item scale when compared to the 41-item SCARED as

FIGURE 1 CONSORT Flow Diagram



predicting possible anxiety disorder were 67% and 96%, respectively.

Before the health check-up, the parents received information about the study digitally and then provided their informed consent. The children provided written informed assent during the healthcare check-up and were informed about the study by the school nurse.

If the child screened positive for anxiety according to the short screening scale, the study team conducted a recruitment call to the families who had given permission. They were informed about the study protocol and were offered the chance to have an eligibility assessment.

After informed consent and assent were obtained, the children filled in the 41-item SCARED report on a secure website. If they scored at least 22 points, their parents proceeded to the digital baseline assessment. The cut-off score was selected to be in line with the preventive focus of the study, based on data from an earlier epidemiological study conducted in our research center.[24]

Measures

Primary Outcomes. The primary outcome measure was the Screen for Child Anxiety Related Emotional Disorders questionnaire (SCARED-C/P),[22,23] either the child or parent version, which screens the child's anxiety symptoms during the last 3 months. The SCARED scale includes 41 items consisting of 5 subscales, which screen for 4 specific anxiety disorders (panic disorder [13 items], generalized anxiety disorder [9 items], separation anxiety disorder [8 items], and social anxiety disorder [7 items]), as well as a

subscale for school phobia (4 items), which is not classified as an anxiety disorder. The items are scored on a scale of 0 to 2 (0 = "not true or hardly ever true"; 1 = "somewhat true or sometimes true"; and 2 = "very true or often true"). The maximum total score is 82. In a Finnish study,[24] the internal consistency for the Finnish SCARED was $\alpha = 0.92$ for the child report and $\alpha = 0.90$ for the parent report, and the interrater agreement of child and parent SCARED total scores was 0.37.

Secondary Outcomes. To evaluate the presence of any anxiety disorder, children and parents were interviewed with the Development and Well-Being Assessment (DAWBA) via telephone at baseline.[25]

Some secondary outcomes included both child and parental measures. The measures including both reports were as follows: (1) the SCARED-C/P subscales (general anxiety, separation anxiety, panic disorder, school phobia, and social anxiety); (2) the 27-item Child Anxiety Impact Scale (CAIS-C/P), which assesses the effect of anxiety on the daily functioning of the child[26]; and (3) the 24-item Revised Children Quality of Life Questionnaire (Kid-Kindl-C/P), which measures health-related quality of life.[27]

One secondary outcome included only a child report: the 27-item Child Depression Inventory (CDI), which measures the presence of depression symptoms in children.[28]

Two secondary outcomes included only parent reports: (1) the Strengths and Difficulties Questionnaire (SDQ),[29,30] which assesses child psychopathology and includes total scores and subscores for conduct problems, hyperactivity, emotional difficulties, peer problems, and prosocial behavior; and (2) the 21-item Depression Anxiety Stress Scale Short Form (DASS-21),[31] which assesses parental depression, anxiety, and stress symptoms.

Questions about family demographics asked about family structure, languages spoken by the family, parental occupation, education, employment status, and family income. There were also questions regarding any psychotropic medications that the child had been prescribed, and about contact with mental health professionals (including school psychologists, school counsellors, and professionals in psychiatric clinics [psychiatrist, psychologist, psychiatric nurse, or psychotherapist]) during the last 6 months.

Secondary outcome measures are described in detail in the eMeasures in Supplement 1, available online.

Ethics

The study has been registered at ClinicalTrials.gov (NCT03310489, initially released September 30, 2017) and has been approved by the research ethics board of the Hospital District of Southwest Finland (ETMK:67/1801/2017, approved June 20, 2017) as well as by local authorities.

Statistical Analysis

The sample size of the study was calculated with the 2-sample t test assuming equal variance for the SCARED total Score. With 147 subjects in both treatment groups, we expected to detect a mean difference of 3.0 (SD 8.5) between the intervention and education control groups, with an 85% power and using a 2-sided significance level of .05. Allowing for 30% attrition over time in both groups, we required a minimum of 210 participants randomized to each group. Two separate randomization sequences were generated according to sex with a 1:1 ratio for the intervention vs the education control group, using a computerized random permuted block sequence generator, SAS V.9.4. Concealed block sizes were used to ensure that the researcher team members were blinded. A sequential, double-envelope system, labeled and color coded according to sex, was used to conceal the individual placements. As each boy or girl entered the study, the next envelope for that sex was selected, their allocated group was recorded, and they were advised by e-mail. The study statistician created the randomization code using only letters A and B for the 2 groups. She stayed blinded to the treatment groups until the randomization expert opened the coding after blinded primary analyses at the end of the study.

The randomization expert was responsible for the technical randomization process and the envelopes. Neither the statistician nor the randomization expert was directly involved in conducting the study.

All demographic and baseline variables were presented with summary statistics for intervention and education control groups separately. Frequencies and percentages were calculated for categorical variables. Means and standard deviations were calculated for continuous variables. The Pearson χ^2 test or Fisher exact test was used to explore differences in categorical variables at baseline between the children and parents in the intervention and in the education control group. Student t tests were used to explore differences in continuous variables between the groups at baseline.

The primary outcome measures are the total scores from the child and parent versions of the SCARED questionnaire, each version comprising 41 items. These were collected before randomization (baseline) and 6 months after randomization (follow-up). We analyzed the SCARED total scores with linear mixed models for repeated

measurements adjusting for the stratifying factor sex. There were no baseline differences in the primary and secondary outcome variables. All analyses were performed separately for the children and parents, and we used all available data according to the intention-to-treat (ITT) principle. The participating children/parents were included as a random effect to generalize the results beyond our study sample.[32] As the 2 primary outcomes are both single measurements, that is, the SCARED total scores for children and for parents, there was no need for adjustment of p values due to multiple tests. The secondary outcome measures were analyzed using the same modeling approach as for the primary outcome measures. The Cohen d was calculated as a measure of effect size for the difference in primary and secondary variables between the 2 groups, to complement the statistical testing.

We conducted a subgroup analysis, which included stratified analyses based on the possibility of children's anxiety disorders using DAWBA. A 2-sided p value of less than .05 was considered statistically significant. PROC MIXED in SAS (version 9.4) was used in all statistical analyses.

RESULTS

The Consolidated Standards of Reporting Trials (CONSORT) flow diagram for this study is shown in Figure 1. A total of 11,118 children were screened with a short, 5-item version of the SCARED-C. Of these, 2,219 (20.0%) met the screening criteria, whereas 8,899 (80.0%) were excluded because they did not meet the screening criteria. In 81 cases (<1.0%), a child was screened positive, but either the parents or the child did not give approval or could not be contacted for recruitment because of missing contact information. Of the 2,138 children who fulfilled the screening criteria and could be contacted, 119 (5.6%) met exclusion criteria, and 1,123 (52.5%) declined or did not proceed to fulfill the 41-item SCARED in the platform. Of the 896 children who filled in the 41-item SCARED, 375 (41.9%) screened negative (SCARED <22) and 57 (6.4%) declined to participate or could not be contacted. Finally, a total of 465 children were randomized into 2 groups: 234 to the intervention group and 231 to the EC group. The overall response rate in the RCT was 80.6% (n = 375). The dropout/discontinuation rate was fairly similar in the intervention group and EC group (22.5% vs 16.5%, $p = .12$).

Table 2 gives the demographic and diagnostic characteristics of the intervention group and the EC group. Of the children randomized, 332 (71.4%) were female. When the intervention and control groups were compared, there was no significant difference in age, sex, family structure, parental education, employment, or economic difficulties. Based on pooled information from parent and child DAWBA diagnostic interviews, 77.4% of the children in the intervention group and 78.2% of the children in the control group met the diagnostic criteria for at least 1 anxiety disorder. Of the participants, 20 (4.3%) used some type of psychotropic medication, and 29 participants (12.4%) in the intervention group and 31 (13.4%) in the education control group had met with a professional in specialized psychiatric services (a psychiatric nurse, psychotherapist, psychologist, or psychiatrist) during the last 6 months at baseline. Table S1, available online, shows the correlations between parent and child reports of SCARED total scores (primary outcomes) and subscores at baseline. The child–parent correlation of the SCARED total was 0.43, and subscale correlations varied from 0.43 to 0.62.

Table 3 shows the child-reported mean scores of the primary and secondary outcomes at baseline and the 6-month follow-up in both groups, and the change in primary and secondary outcomes based on the children's version of the survey when the intervention group was compared with the control group. There was significant improvement in both groups between baseline and the 6-month follow-up in the child-reported child psychopathology mean difference for SCARED in the intervention group 11.2 (9.6 to 12.8) and EC group 8.9 (7.3 to 10.4) and for CDI 3.1 (2.1 to 4.2) and 2.4 (1.4 to 3.4), respectively; daily functioning 7.7 (5.8 to 9.5) and 6.1 (4.3 to 7.8) respectively; and quality of life −5.0 (−6.7 to −3.3) and −4.2 (−5.9 to −2.6), respectively.

In the RCT comparison, the child-reported SCARED total score reflected significantly greater improvements for the intervention group than for the EC group between baseline and the 6-month follow-up ($p = .042$, $d = 0.17$). Secondary outcomes showing significantly higher improvement in the intervention group included SCARED general anxiety ($p = .047$, $d = 0.09$), separation anxiety ($p = .004$, $d = 0.40$), and social anxiety ($p = .007$, $d = 0.27$).

Table 4 shows the parent-reported mean scores of the primary and secondary outcomes at baseline and the 6-month follow-up in both groups, and the change in primary and secondary outcomes based on the parent version of the survey when the intervention group was compared with the control group. There was significant improvement between baseline and the 6-month follow-up in parent-reported child psychopathology (both SCARED and SDQ), daily functioning, and quality of life, and in parent depression, anxiety, and stress in both groups.

In the RCT comparison, no statistically significant differences were seen between the groups in the parent-reported

TABLE 2 Demographic Characteristics of Intervention and Education Control Groups

Baseline variable	Intervention (n = 234)	Education control (n = 231)	p
Child characteristics			
Sex, n (%)			
Girls	167 (71.4)	165 (71.4)	
Boys	67 (28.6)	66 (28.6)	.99
Age, y, mean (SD)	11.5 (1.0)	11.4 (0.9)	42
Use of psychotrophic medication			
Any psychotrophic medication	8 (3.4)	12 (5.2)	.37
SSRI medication	0 (0.0)	0 (0.0)	>.99
ADHD medication	7 (3.0)	11 (4.8)	.35
Antipsychotic medication	1 (0.4)	1 (0.4)	>.99
Contacted a professional in specialized psychiatric services during the last 6 mo, n (%)			
Psychiatric nurse	6 (2.6)	4 (1.7)	.75
Psychotherapist	0	5 (2.2)	.03
Psychologist	17 (7.3)	18 (7.4)	.86
Psychiatrist	6 (2.6)	4 (1.7)	.75
DAWBA			
Any anxiety disorder[a]	178 (77.4)	179 (78.2)	
No anxiety disorder	52 (22.6)	50 (21.8)	.84
Diagnostic subgroups			
Separation anxiety disorder[a]	77 (33.5)	67 (29.3)	
No separation anxiety disorder	153 (66.5)	162 (70.7)	.33
Social phobia[b]	73 (31.9)	71 (31.0)	
No social phobia	156 (68.1)	158 (69.0)	.84
Specific phobia[a]	125 (54.4)	144 (62.9)	
No specific phobia	105 (45.7)	85 (37.1)	.06
Generalized anxiety[b]	114 (49.8)	101 (44.1)	
No generalized anxiety	115 (50.2)	128 (55.9)	.22
Panic disorder[a]	22 (9.6)	24 (10.5)	
No panic disorder	208 (90.4)	205 (89.5)	.74
Parent/family characteristics			
Responder, n (%)			
Biological mother	212 (90.6)	209 (90.5)	
Biological father	20 (8.5)	19 (8.2)	
Other[c]	2 (0.9)	3 (1.3)	.96
Age, y, mean (SD)			
Mother	41.9 (5.2)	42.1 (5.1)	.68
Father	43.8 (6.7)	44.6 (6.4)	.27
Family structure, n (%)			
Two biological parents	145 (62.0)	148 (64.1)	
Non-nuclear family	89 (38.0)	83 (35.9)	.64
No. of siblings			
No siblings	15 (6.4)	17 (7.4)	
One sibling or more	219 (93.6)	214 (92.6)	.69
Native language, n (%)			
Finnish	228 (97.4)	217 (93.9)	
Swedish	4 (1.7)	9 (3.9)	
Other[d]	2 (0.9)	5 (2.2)	.21
Parental education, n (%)			
Secondary education or lower	85 (36.3)	79 (34.2)	

(continued)

TABLE 2 Continued

Baseline variable	Intervention (n = 234)	Education control (n = 231)	*p*
Higher education level	149 (63.7)	152 (65.8)	.63
Parental employment, n (%)			
Fully employed	183 (78.2)	170 (73.6)	
Part-time employed or unemployed	51 (21.8)	61 (26.4)	.24
Family income, n (%)			
No economic difficulties	139 (59.4)	153 (66.2)	
Mild or severe economic difficulties	95 (40.6)	78 (33.8)	.13

Note: ADHD = attention-deficit/hyperactivity disorder; DAWBA = Development and Well-Being Assessment; SSRI = selective serotonin reuptake inhibitor.
[a]*Six missing.*
[b]*Seven missing.*
[c]*For example, step-parent, foster parent.*
[d]*The most common other native language in the sample was Estonian (2 speakers). Speakers of Greek, Hungarian, Italian, Russian, and Turkish were also represented in the sample.*

SCARED total scores ($p = .41$) or the SCARED subscales. However, several secondary outcome measures showed higher improvement in the intervention group including the SDQ total ($p = .002$, $d = 0.22$), emotional difficulties ($p = .02$, $d = 0.20$) and hyperactivity ($p = .003$, $d = 0.19$) scores, and the KINDL total ($p = .02$, $d = 0.16$) scores.

In the additional analysis shown in Table S2, available online, we stratified the whole sample to those who fulfilled or did not fulfill the diagnostic criteria for any anxiety disorder in the DAWBA parent or child interview at baseline. Altogether, 357 children (77.8%) had at least 1 anxiety disorder, whereas 102 (22.2%) did not fulfill the diagnostic criteria for any of the anxiety disorders. When we compared the results of the child SCARED scores between the intervention and EC groups, we found that among children with an anxiety disorder diagnosis at baseline, there was a significantly higher improvement in separation anxiety ($p = .001$, $d = 0.43$) and social anxiety ($p = .004$, $d = 0.32$) subscale scores in the intervention group, whereas results in the SCARED total score were close to significant ($p = .076$). However, among children who did not fulfill the diagnostic criteria, there was no significant difference in improvement between the 2 groups.

DISCUSSION

This study is the first RCT of an ICBT intervention for anxiety using a population-based screening procedure among school-aged children. Almost 80% of the children who were screened and took part in the study met the diagnostic criteria for at least 1 anxiety disorder. Only 20 participants (4.3%) used any psychotropic medication, and 60 (12.9%) had contacted specialized psychiatric services during the last 6 months at baseline. This highlights the prevalence of untreated anxiety among school-aged children.

The findings are important in planning low-threshold early interventions and in service planning for children with anxiety. The ICBT intervention group and the EC control group showed significant improvement in both the parent and child reports between baseline and the 6-month follow-up in most measures related to child anxiety, other psychopathology, daily functioning level, and quality of life. Parents reported significant improvement in their own well-being. When the intervention group was compared with the control group, there was a significantly higher improvement in child-reported anxiety, especially in generalized anxiety, social anxiety, and separation anxiety. In the parent ratings, we did not observe significant improvement in anxiety based on the SCARED-P when the intervention and EC groups were compared. However, the parents reported significant improvements in some other indicators for child mental health, such as SDQ total scores, emotional symptoms (assessing mostly anxiety), hyperactivity, and quality of life, when the intervention group was compared with the EC. Future studies are needed to determine whether the improvement in the intervention group resulted from the Internet sessions or the telephone calls (or the combination), or from the length and intensity of the program. This information could be used to provide patients with more personalized program content, for example, changing the frequency of telephone calls in relation to the family's needs.

Our findings differ from previous ICBT RCTs focusing on childhood anxiety. In our study, there was significantly more improvement in the intervention group in child-reported anxiety in the SCARED total score and the generalized anxiety, separation anxiety, and social anxiety

TABLE 3 Child-Reported SCARED, CDI, CAIS, and KINDL Mean Scores at Baseline and 6 Months After Randomization by Treatment Groups and Treatment Comparisons

	Intervention				Education control				Comparison		
	Baseline	6 mo	Baseline to 6 mo		Baseline	6 mo	Baseline to 6 mo		Intervention vs education control		
Variable	Mean[a] (SE)	Mean[a] (SE)	Mean (95% CI)	*p*	Mean[a] (SE)	Mean[a] (SE)	Mean (95% CI)	*p*	Mean[a,b] (95% CI)	*p*	Effect size
Primary outcome											
SCARED total	33.5 (0.6)	22.3 (0.9)	11.2 (9.6-12.8)	<.001	33.3 (0.7)	24.5 (0.8)	8.9 (7.3-10.4)	<.001	2.3 (0.09-4.6)	.042*	0.17
Secondary outcomes											
SCARED subscores											
Panic disorder	7.2 (0.3)	5.0 (0.3)	2.2 (1.6-2.8)	<.001	7.0 (0.3)	4.4 (0.3)	2.6 (2.0-3.2)	<.001	−0.4 (−1.3 to 0.4)	.33	0.13
General anxiety	9.3 (0.2)	6.3 (0.3)	3.1 (2.5-3.6)	<.001	9.0 (0.2)	6.7 (0.3)	2.3 (1.8-2.8)	<.001	0.8 (0.01-1.6)	.047*	0.09
Separation anxiety	7.0 (0.2)	3.8 (0.2)	3.2 (2.7-3.6)	<.001	7.3 (0.2)	5.0 (0.2)	2.3 (1.8-2.7)	<.001	0.9 (0.3-1.5)	.004**	0.40
Social anxiety	7.6 (0.2)	5.7 (0.3)	1.9 (1.5-2.4)	<.001	7.8 (0.2)	6.7 (0.2)	1.1 (0.6-1.5)	<.001	0.8 (0.2-1.5)	.007**	0.27
School phobia	2.4 (0.1)	1.5 (0.1)	0.8 (0.6-1.1)	<.001	2.3 (0.1)	1.6 (0.1)	0.6 (0.4-0.9)	<.001	0.2 (−0.1 to 0.5)	.22	0.07
CDI total	12.2 (0.6)	9.1 (0.6)	3.1 (2.1-4.2)	<.001	12.2 (0.6)	9.8 (0.6)	2.4 (1.4-3.4)	<.001	1.6 (−0.95 to 4.1)	.22	0.06
CAIS Total	19.1 (0.8)	11.5 (0.9)	7.7 (5.8-9.5)	<.001	20.1 (0.8)	14.0 (0.8)	6.1 (4.3-7.8)	<.001	0.7 (−0.7 to 2.2)	0.33	0.04
KINDL Total	63.1 (0.8)	68.1 (1.0)	−5.0 (−6.7 to −3.3)	<.001	62.7 (0.8)	67.0 (0.9)	−4.2 (−5.9 to −2.6)	<.001	−0.8 (−3.1 to 1.5)	.51	0.03

Note: *CAIS = Child Anxiety Impact Scale; CDI = Child Depression Inventory; KINDL = 24-item Revised Children Quality of Life Questionnaire; SCARED = Screen for Child Anxiety Related Emotional Disorders.*

[a]*Least-squares means.*

[b]*Adjusted with sex of the child.*

*p < .05; **p < .01; ***p < .001.

TABLE 4 Parent-Reported SCARED, CAIS, KINDL, SDQ, and DASS-21 Mean Scores at Baseline and 6 Months After Randomization by Treatment Groups and Treatment Comparisons

	Intervention				Education control				Intervention vs education control		
	Baseline	6 mo	Baseline to 6 mo		Baseline	6 mo	Baseline to 6 mo				
Outcome measure	Mean[a] (SE)	Mean[a] (SE)	Mean (95% CI)	*p*	Mean[a] (SE)	Mean[a] (SE)	Mean (95% CI)	*p*	Mean[a,b] (95% CI)	*p*	Effect size
Primary outcome											
SCARED total	23.9 (0.7)	18.1 (0.8)	5.8 (4.4, 7.1)	<.001	22.8 (0.7)	17.8 (0.8)	5.0 (3.6, 6.3)	<.001	0.8 (−1.1, 2.7)	.41	0.03
Secondary outcomes											
SCARED subscores											
Panic disorder	3.5 (0.2)	2.9 (0.3)	0.6 (0.1, 1.0)	.02	3.1 (0.2)	2.7 (0.3)	0.5 (−0.01, 0.9)	<.001	0.1 (−0.5, 0.8)	.73	0.05
General anxiety	7.6 (0.3)	5.9 (0.3)	1.7 (1.3, 2.2)	<.001	7.2 (0.3)	5.7 (0.3)	1.5 (1.0, 1.9)	<.001	0.3 (−0.4, 1.0)	.41	0.05
Separation anxiety	5.0 (0.2)	3.2 (0.2)	1.8 (1.4, 2.2)	<.001	4.9 (0.2)	3.4 (0.2)	1.5 (1.1, 1.9)	<.001	0.3 (−0.2, 0.8)	.28	0.06
Social anxiety	5.7 (0.3)	4.7 (0.3)	1.0 (0.6, 1.4)	<.001	5.7 (0.3)	4.7 (0.3)	1.0 (0.6, 1.3)	<.001	0.03 (−0.5, 0.6)	.91	0.0
School phobia	2.0 (0.1)	1.4 (0.1)	0.7 (0.4, 0.8)	<.001	1.9 (0.1)	1.3 (0.1)	0.5 (0.3, 0.7)	<.001	0.1 (−0.2, 0.4)	.48	0.06
CAIS total	14.7 (0.6)	9.5 (0.7)	5.1 (3.9, 6.4)	<.001	14.4 (0.6)	10.6 (0.6)	3.8 (2.6, 5.0)	<.001	1.3 (−0.4, 3.0)	.12	0.12
KINDL total	68.3 (0.7)	72.6 (0.8)	−4.3 (−5.7, −2.9)	<.001	69.1 (0.8)	71.0 (0.8)	−1.9 (−3.2, −0.5)	.008	−2.4 (−4.4, −0.5)	.02*	0.16
SDQ											
total	12.0 (0.4)	9.3 (0.4)	2.7 (2.1, 3.3)	<.001	11.4 (0.4)	9.9 (0.4)	1.4 (0.9, 2.0)	<.001	1.3 (0.5, 2.1)	.002**	0.22
Emotional	3.4 (0.1)	2.0 (0.1)	1.4 (1.1, 1.6)	<.001	3.2 (0.1)	2.3 (0.1)	0.9 (0.6, 1.2)	<.001	0.4 (0.06, 0.8)	.02*	0.20
Conduct	2.3 (0.1)	2.0 (0.1)	0.3 (0.1, 0.5)	.002	2.2 (0.1)	1.9 (0.1)	0.3 (0.07, 0.4)	<.001	0.05 (−0.2, 0.3)	.73	0.0
Hyperactivity	3.7 (0.2)	3.1 (0.2)	0.6 (0.4, 0.8)	<.001	3.4 (0.2)	3.3 (0.2)	0.1 (−0.10, 0.33)	<.001	0.5 (0.2, 0.8)	.003**	0.19
Peer	2.6 (0.1)	2.2 (0.1)	0.4 (0.2, 0.6)	<.001	2.6 (0.1)	2.4 (0.1)	0.2 (−0.04, 0.4)	<.001	0.2 (−0.08, 0.5)	.15	0.11
Prosocial	7.3 (0.1)	7.2 (0.1)	0.1 (−0.1, 0.3)	<.001	7.3 (0.1)	7.1 (0.1)	0.2 (−0.04, 0.4)	<.001	−0.05 (−0.4, 0.2)	.73	0.03
DASS-21											
total	16.0 (1.0)	14.6 (1.0)	1.4 (−0.3, 3.0)	<.001	14.2 (1.0)	14.5 (1.0)	−0.3 (−1.9, 1.3)	<.001	1.6 (−0.7, 4.0)	.16	0.0
Depression	4.6 (0.4)	4.1 (0.4)	0.5 (−0.2, 1.3)	<.001	4.2 (0.4)	4.0 (0.4)	0.2 (−0.5, 0.9)	<.001	0.4 (−0.6, 1.4)	.48	0.02
Anxiety	3.0 (0.3)	2.5 (0.3)	0.5 (−0.1, 1.0)	<.001	2.5 (0.3)	2.3 (0.3)	0.1 (−0.4, 0.7)	<.001	0.3 (−0.5, 1.1)	.43	0.01
Stress	8.4 (0.4)	8.0 (0.5)	0.3 (−0.4, 1.1)	<.001	7.6 (0.4)	8.2 (0.5)	−0.6 (−1.3, 0.15)	<.001	0.9 (−0.2, 2.0)	.09	0.03

Note: *CAIS = Child Anxiety Impact Scale; CDI = Child Depression Inventory; DASS-21 = 21-item Depression Anxiety and Stress Scale Short Form; KINDL = 24-item Revised Children Quality of Life Questionnaire; SDQ = Strengths and Difficulties Questionnaire.*

[a]*Least-squares means.*

[b]*Adjusted for sex of the child.*

*p < .05; **p < .01; ***p < .001.

subscales, but not in the respective parent SCARED scales. This is in contrast with previous ICBT RCT studies involving children, none of which have shown statistically significant changes in child-reported anxiety. Contrary to our results, previous studies focusing on children have reported small to modest improvements in parent-reported child anxiety symptom scale scores in the intervention group when compared to the control group.[12-14] Although 2 of the previous studies[12,13] compared ICBT to a waitlist, a study by Jolstedt *et al.*[14] used Internet-delivered child-directed play as the control intervention, and found significant improvement in both groups. When comparing the 2 groups, greater improvement in the ICBT group was found only for clinician-assessed indicators and parent-reported anxiety symptoms. However, we found significant between-group treatment effect on parent-reported emotional symptoms, hyperactivity, and total psychosocial problems score based on the SDQ. Our finding that parent-rated quality of life among children got better in the ICBT group when compared to the control group is in line with findings by Vigerland *et al.*[13] There are several possible explanations for the differences observed between our study and previous reports. Because the present study was based on a population screening, and cases were identified based on child reports, many parents were not aware of their child's anxiety before they entered the study. Presumably, they learned, in both study groups, to recognize their child's anxiety based on robust psychoeducation, which might have increased their ratings of the children's anxiety symptoms at the follow-up. As symptoms that are externally observable (ie, behavioral manifestations of anxiety) can be noticed by the parents, in order to recognize covert anxiety symptoms, communication between child and parent, and parental insight into the child's thoughts and feelings, are crucial.[33,34] Contrary to our study, previous studies used an anxiety disorder as the inclusion criterion and were based on clinical samples or media recruitment, meaning that parents were well aware of their child's anxiety and were actively seeking help. It has also been shown that diagnostic interviewers tend to weigh parental reports over child self-report.[35] An alternative explanation is that because anxiety is often heritable, parents with personal anxiety problems may be less likely to interpret their child's anxiety as abnormal and search for help.[36] Earlier studies as well used another symptom scale (ie, the Spence Children's Anxiety Scale),[37] child- and parent-report, did not offer treatment including CBT elements for the control group, and included also younger children than we did. Among adolescents, both child- and parent-reported anxiety symptoms significantly decreased in the computerized CBT treatment group when compared to the waitlist.[38]

The question of which informant should be prioritized is crucial when identifying children with anxiety. In the present study, the correlations between parent and child reports of anxiety problems were moderate ($r = 0.43$-0.59) to strong ($r = 0.62$ for separation anxiety). It is known that anxiety disorders easily go unnoticed. A meta-analytic estimation was that only one-third of children with an anxiety disorder receive treatment.[39] Population-based screening and gathering information from multiple sources enable the discovery of internalizing symptoms and secondary prevention. In the present study, 52% of families of the screen-positive children refused to participate or could not be contacted. In an intervention targeting the parents of children with behavioral problems, the respective number was only 37%.[40] This difference could reflect the dissimilarities in the experienced impediment by parents in regard to internalizing and externalizing problems of the child.

The effect sizes seen in this study are low, reaching a Cohen *d* of 0.4 at the highest. The effect sizes in previous ICBT trials based on clinical samples have been higher. When interpreting these findings, it is important to note that, in the present study, significant changes in most of the symptom categories were seen in both groups. Among children with a diagnosed anxiety disorder, there were statistically significant differences in results between the intervention and educational control groups, whereas among children with no anxiety disorder, no significant differences were found. Children without an anxiety disorder diagnosis gained the same benefit from the psychoeducation as from the intervention. In a meta-analysis on psychotherapy of childhood anxiety disorders,[41] CBT was superior to TAU as well as to active comparators that did not include any elements of CBT, whereas 2 studies that used psychoeducation comparable to information given in CBT as the control condition showed that psychoeducation was as effective as CBT.[42,43] In these previous 2 studies, psychoeducation included consecutive face-to-face sessions, whereas in our study, psychoeducation was given as digitalized material. Still, there was significant improvement in the educational control group, and a difference between the intervention and control groups was seen for more severe anxiety. This highlights the benefits and adequacy of simple psychoeducation for parents and children with less severe anxiety. It is also possible that the thorough assessment that all families underwent at baseline could lead into decreased anxiety levels in both study groups, and that it was particularly beneficial among children with less severe symptoms. The systematic assessment provided in RCTs may enhance parents' awareness of their child's emotional state and thus alter their own behavior toward the child. Another explanation for the beneficial effect of the assessment may be that the child feels

more heard and understood.[44] Still another possible reason for the low effect size was that our sample was screened from the general population, and the level of problems among participants was less severe than in clinical samples, indicating that there was less room for improvement.

Some methodologic constraints should be noted. First, clinical observations or teacher ratings would have been helpful to validate the reported changes. Second, we unfortunately did not collect diagnostic interviews at follow-up from both the intervention and the control groups. Third, those who refused participation or could not be contacted could have had anxiety, and this may have had an impact on the results, which limits the generalizability of the findings. Fourth, no data were collected on time spent on the webpage by the education control group. Fifth, the RCT study inclusion criteria included sufficient competence to understand the content in Finnish or Swedish, which are the official languages in Finland. However, based on the Nordic welfare state model, Finnish schools and health care emphasize equity. In the future, when the intervention is implemented in a real-world context, the purpose is to further develop inclusiveness of any minority groups having access to the intervention.

The present study is unique in that it used population-based screening to detect children's anxiety problems, provided psychoeducation for all screened families, and provided ICBT with telephone coaching for an RCT intervention group.

The study shows that, when children's problems were identified by using repetitive assessments on anxiety and when they were offered either psychoeducation alone (EC) or psychoeducation as a part of the intervention, there was a significant improvement in all types of anxiety, other psychiatric problems, and quality of life. The intervention showed efficacy, specifically for child reports of generalized, social, and separation anxiety. We have previously reported achieving rather high completion rates and high treatment satisfaction, and motivation to complete the whole program was associated with more severe anxiety.[21] Importantly, it was the children who fulfilled diagnostic criteria for anxiety who benefited most from the intervention. This may indicate that identifying children with anxiety symptoms and providing parents low-threshold psychoeducation may have enormous benefits for families. However, providing guided digitalized ICBT intervention is most beneficial for those who fulfill the anxiety disorder criteria. Overall, the findings indicate that the first strategy should be early identification of anxiety symptoms and providing psychoeducation for parents and children. Those who fulfill anxiety disorder criteria will likely benefit from a guided ICBT intervention.

CRediT authorship contribution statement

Andre Sourander: Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Funding acquisition, Conceptualization. **Tarja Korpilahti-Leino:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Conceptualization. **Katri Kaajalaakso:** Writing – review & editing, Writing – original draft, Visualization, Data curation, Validation. **Terja Ristkari:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Conceptualization. **Susanna Hinkka-Yli-Salomäki:** Writing – review & editing, Visualization, Validation, Methodology, Formal analysis, Data curation, Conceptualization. **Tiia Ståhlberg:** Writing – review & editing. **Terhi Luntamo:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization.

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Hinkka-Yli-Salomäki, PhLic, served as the statistical expert for this research.

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