

# **Effectiveness of Brief and Standard School-Based** Cognitive-Behavioral Interventions for Adolescents With Anxiety: A Randomized Noninferiority Study

Bente Storm Mowatt Haugland, PhD, Ashild Tellefsen Haaland, PhD, Valborg Baste, PhD, Jon Fauskanger Bjaastad, DPsych, Asle Hoffart, PhD, Ronald M. Rapee, PhD, Solfrid Raknes, PhD, Joseph A. Himle, PhD, Elisabeth Husabø, PsyD, Gro Janne Wergeland, PhD

**Objective:** We examined the effectiveness of targeted school-based cognitive-behavioral therapy (CBT) for adolescents (12-16 years of age) with anxiety, and tested whether brief CBT was noninferior to standard duration CBT.

Method: A randomized controlled study of 313 adolescents (mean 14.0 years, SD = 0.84, 84% girls) were recruited through school health services to 10 weeks CBT group interventions. Groups of 5 to 8 adolescents were randomly allocated to brief (5 sessions, comprising 5.5 hours) or standard CBT (10 sessions, comprising 15 hours), or 10 weeks waitlist (WL). Self-reported and parent-reported youth anxiety symptoms, impairment from anxiety, depressive symptoms, and clinical severity were assessed pre- and postintervention, after WL, and at 1-year follow-up.

Results: Targeted school based CBT significantly reduced adolescents' anxiety symptoms with small to moderate effect sizes compared to WL (Cohen d = 0.34 for youth report and d = 0.53 for parent report). According to the parents, also adolescents' impairment from anxiety was significantly reduced compared to WL (d = 0.51). Pre to post changes in anxiety symptoms were small to moderate (within-group effect sizes between d = 0.41 and d = 0.410.67). Although no significant differences in effects were found between brief and standard CBT, brief CBT was not noninferior to standard CBT. Outcomes from both interventions were sustained at 1-year follow-up.

Conclusion: Targeted school-based CBT interventions reduced anxiety, impairment, and depressive symptoms in adolescents. Both brief and standard CBT demonstrated efficacy, but brief CBT was not noninferior to standard CBT. By administering school-based CBT to youths with anxiety symptoms, we may reach young people with effective interventions at an earlier phase in their lives.

Clinical trial registration information: School Based Low-intensity Cognitive Behavioral Intervention for Anxious Youth (LIST); http:// clinicalrials.gov/; NCT02279251.

Key words: anxiety, brief CBT, school interventions, targeted prevention

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argeted school-based cognitive-behavioral therapy (CBT) interventions for anxiety are intended to make effective interventions more accessible to youths with anxiety symptoms or at risk for developing anxiety disorders. These are important aims, as onset of anxiety disorders often begin early in life.<sup>2,3</sup> With a point prevalence of 6.5%<sup>4</sup> and lifetime prevalence around 30%,<sup>2,3</sup> anxiety disorders are the most prevalent mental health problems in adolescence. In addition, many adolescents report subclinical levels of anxiety.<sup>5</sup>

Anxiety disorders often follow a chronic course with significant functional impairment, 6,7 including diminished academic functioning, peer problems, and additional psychopathology. 8-10 Unfortunately, the majority of adolescents with anxiety are unidentified and do not receive help, or may endure long delays from disorder onset to accessing treatment. 11-13 A number of barriers to treatment have been identified, including lack of knowledge of mental health problems, referral procedures, stigma, costs, and travel distances. 14,15 These barriers may be reduced if effective interventions are offered in the everyday contexts of adolescents' lives. 16

Meta-analyses of targeted prevention and school-based interventions report small to moderate effects. 17-22 A meta-analysis of targeted school-based prevention for anxiety showed a small mean effect of Hedges g = .22, 1 whereas a meta-analysis of targeted prevention for anxiety symptom, not limited to the school setting, showed an average effect size of Cohen d = 0.32.<sup>21</sup> Shortcomings have been identified in previous school-based anxiety prevention studies, such as failure to report attendance and completion rates, lack of treatment integrity evaluation, and limited long-term follow-up.<sup>1,22</sup> Thus, school-based targeted prevention studies with improved methodological rigor are warranted.

The majority of preventive CBT interventions for youths with anxiety comprise 8 to 12 sessions. 1,17 Schools are faced with numerous demands, and extracurricular programs targeting anxiety compete with other activities on the school agenda. Standard CBT programs may be lengthy and costly, 23 partly explaining why school-based interventions often show low implementation rates.<sup>24</sup> "Brief CBT" has been defined as having sessions reduced by at least 50% compared to standard treatment.<sup>25</sup> Brief-CBT may fit better with the school setting than standard CBT, and may concur with the limited resources often found in school health services. Brief CBT, if found effective, might improve the dissemination of school-based interventions for anxiety. Thus, reducing number and duration of sessions may be an approach to improve access to school-based CBT.

There is limited knowledge about the effects of brief compared to standard CBT, with little research examining the optimal dose needed to have an impact on youth anxiety. Hence, it is not known whether youths with mild to moderate anxiety may prefer and benefit from briefer interventions. A previous review identified seven clinical studies on brief CBT for youths with anxiety disorders.<sup>25</sup> The mean number of sessions was 5.9 (SD = 3.2), comprising 6.4 (SD = 3.3) hours of therapy. Brief CBT was found to be effective compared to wait list and attention control, both posttreatment and at 1-year follow-up, and comparable in effect to standard CBT. However, most of the studies were intensive CBT, targeting specific phobia, and with few studies on other anxiety disorders.<sup>25</sup> Another meta-analysis, including 55 clinical studies of youths with anxiety disorders, report association between treatment duration and effect.<sup>26</sup> Whereas treatments of less than 4 hours yielded nonsignificant effects, 5 or more sessions showed small to moderate effects, and 9 or more sessions showed moderate to large effects.<sup>26</sup>

No previous studies have compared the effectiveness of school-based interventions for anxiety with differing intensity (ie, hours and number of sessions). Authors of meta-analyses examining anxiety prevention have concluded that the number of sessions does not moderate the effectiveness of interventions. However, most school-based programs fall into the narrow range of 8 to 12 sessions and are not

considered brief CBT. Given the inconsistent findings in clinical studies and lack of studies on brief CBT in school-based interventions, the question of the efficacy of brief CBT remains important to address.

The aims of the present study were as follows: (1) to examine the effect of targeted school–based CBT in adolescents with anxiety symptoms; (2) to compare the effectiveness of two CBT interventions of different intensity; and (3) to examine whether effects of school-based interventions are maintained at 1-year follow-up. The main research hypotheses were as follows: (1) targeted school-based CBT interventions are effective in reducing anxiety in adolescents; (2) brief CBT is noninferior to standard CBT; and (3) outcomes are maintained at 1-year follow-up.

#### **METHOD**

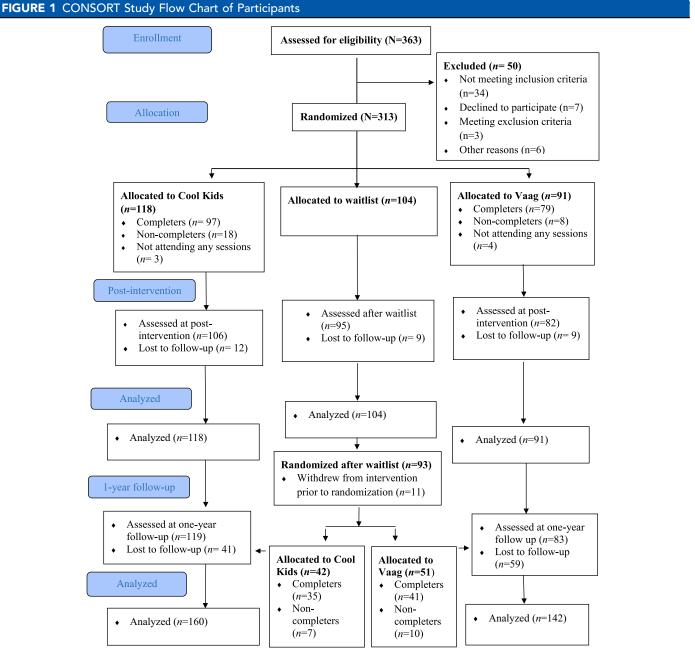
# Study Design

This was a randomized controlled trial (RCT) recruiting adolescents to 10-week, school-based CBT group interventions (brief or standard CBT) or to 10-week delayed-access wait list (WL). Immediately following the WL, participants were randomized to either brief or standard CBT. Assessments were conducted pre- and post-intervention, post-WL, and at 1-year follow-up.

#### **Participants**

Eligible participants were 363 adolescents aged 12 to 16 years from 18 junior high schools (17 public schools and 1 private school) recruited between October 2014 and November 2016. The schools, located in different regions of Norway, represented both rural and urban areas. Adolescents were invited if either self-reported or parentreported youth anxiety symptoms were ≥25 on the Spence Children's Anxiety Scale (SCAS),<sup>27</sup> with some interference in daily life (a score of  $\geq 1$  on first question on Child Anxiety Life Interference Scale). 28 The adolescent and at least one parent had to understand Norwegian. Exclusion criteria were as follows: problems following group rules; disruptive behavior; or learning problems causing difficulties following a manualized group program, assessed by group leaders based on information from adolescents, parents, and teachers. Three adolescents were excluded. The final sample comprised 313 adolescents (mean 14.00 years, SD= 0.84, 84% girls). Figure 1 provides the CONSORT flow chart for the study, and Table 1 lists sample characteristics.

At each school, sequences of five to eight adolescents were recruited to groups. Each group was randomly assigned to brief (Vaag [Norwegian word meaning "dare" or



Note: Figure is for study comparing brief (Vaag) and standard-length (Cool Kids) school-based cognitive-behavioral interventions and waitlist for adolescents with anxiety

"venture"]; n=91), or standard CBT (Cool Kids; n=118), or WL (n=104). There were no baseline differences among the three conditions with regard to demographic or symptom measures (ie, sex, ethnicity, family structure, social class, internalizing symptoms, or impairment from anxiety). However, a minor difference in age between intervention groups and WL was found (mean difference 0.27 years, p < .01). This was considered to have no clinical significance and was not given further attention.

A detailed description of the study protocol has been published by Haugland *et al.*<sup>29</sup> The study was approved by the Regional Committees for Medical and Health Research Ethics (approval no. 2013/2331).

# Recruitment and Randomization

Participant were recruited through multiple formats. Adolescents and/or parents were informed about the study at routine meetings with school nurses. Group leaders met

symptoms. Please note color figures are available online.

**TABLE 1** Baseline Characteristics of Included Participants

|                                      | CBT vs. WL         |            |               |            | Vaag vs. Cool Kids |            |                   |            |
|--------------------------------------|--------------------|------------|---------------|------------|--------------------|------------|-------------------|------------|
|                                      | <b>CBT n = 209</b> |            | WL n = 104    |            | Vaag n = 142       |            | Cool Kids n = 160 |            |
| Variable                             | Mean (SD)          | n (%)      | Mean (SD)     | n (%)      | Mean (SD)          | n (%)      | Mean (SD)         | n (%)      |
| Age, y <sup>a,b</sup>                | 14.08 (0.85)       |            | 13.81 (0.78)  |            | 13.91 (0.86)       |            | 14.04 (0.81)      |            |
| Sex <sup>c</sup>                     |                    |            |               |            |                    |            |                   |            |
| Female                               |                    | 174 (83.3) |               | 89 (85.6)  |                    | 120 (84.5) |                   | 135 (84.4) |
| Male                                 |                    | 35 (16.7)  |               | 15 (14.4)  |                    | 22 (15.5)  |                   | 25 (15.6)  |
| Ethnicity <sup>c</sup>               |                    |            |               |            |                    |            |                   |            |
| Norwegian <sup>d</sup>               |                    | 200 (95.7) |               | 101 (97.1) |                    | 136 (95.8) |                   | 156 (97.5) |
| Family structure <sup>c,e</sup>      |                    |            |               |            |                    |            |                   |            |
| Two-parent families                  |                    | 162 (78.8) |               | 84 (80.8)  |                    | 111 (78.2) |                   | 127 (79,9) |
| Single-parent families               |                    | 46 (22.1)  |               | 20 (19.2)  |                    | 31 (21.8)  |                   | 32 (20.1)  |
| Social class <sup>c</sup>            |                    |            |               |            |                    |            |                   |            |
| High                                 |                    | 56 (26.9)  |               | 27 (26.0)  |                    | 41 (28.9)  |                   | 39 (24.5)  |
| Medium                               |                    | 131 (63.0) |               | 66 (63.5)  |                    | 89 (62.7)  |                   | 100 (62.9) |
| Low                                  |                    | 32 (10.1)  |               | 11 (10.6)  |                    | 12 (8.5)   |                   | 20 (12.6)  |
| Anxiety symptoms <sup>b</sup>        |                    |            |               |            |                    |            |                   |            |
| SCAS-a                               | 44.36 (16.57)      |            | 41.56 (16.13) |            | 42.02 (17.20)      |            | 42.65 (16.94)     |            |
| SCAS-p                               | 33.08 (13.09)      |            | 31.25 (12.22) |            | 31.31 (13.47)      |            | 31.62 (13.24)     |            |
| Impairment from anxiety <sup>b</sup> |                    |            |               |            |                    |            |                   |            |
| CALIS-a                              | 12.84 (7.66)       |            | 11.04 (6.49)  |            | 11.36 (7.20)       |            | 12.65 (7.79)      |            |
| CALIS-p                              | 15.09 (6.41)       |            | 14.14 (6.35)  |            | 14.03 (6.61)       |            | 14.75 (6.38)      |            |
| Depressive symptoms <sup>b</sup>     |                    |            |               |            |                    |            |                   |            |
| SMFQ-a                               | 11.95 (6.94)       |            | 10.54 (6.49)  |            | 11.20 (7.02)       |            | 11.79 (7.20)      |            |
| SMFQ-p                               | 12.81 (6.40)       |            | 12.03 (6.64)  |            | 10.73 (6.67)       |            | 11.51 (6.36)      |            |
| Clinical Global Impression           |                    |            |               |            |                    |            |                   |            |
| CGI-S                                | 4.37 (0.88)        |            | 4.3 (0.84)    |            | 4.31 (0.83)        |            | 4.36 (0.89)       |            |

**Note**: a = adolescent; CALIS = Child Anxiety Life Interference Scale; CBT = cognitive-behavioral therapy; CGI-S = Clinical Global Impression—Severity; p = parent; SCAS = Spence Children Anxiety Scale; SMFQ = Short Mood and Feeling Questionnaire; WL = wait list.

with teachers to consult on how to identify and to recruit adolescents with anxiety symptoms. The study was featured in local media. Furthermore, adolescents scoring above mean on the SCAS at a school survey of anxiety<sup>29</sup> were informed about the study. Thus, both self-referral and referral from others were endorsed.

Eligible adolescents and their parent(s) met with the group leader. Informed written consent was obtained from each youth and a parent, followed by baseline assessments and evaluation of inclusion and exclusion criteria.

Three schools recruited a limited number of participants. Adolescents from these schools were included in groups at nearby schools, resulting in 15 randomization sites. The randomization procedure was determined prior to

inclusion and according to a computer-generated random-digit procedure, with groups equally randomized to each of the three conditions at each school. Randomization was concealed and administered by an administrative employee. A total of 52 intervention groups were completed (including adolescents re-randomized after WL), comprising 142 adolescents allocated to Vaag and 160 adolescents allocated to CK.

## Interventions and Group Leaders

Vaag. Vaag<sup>30</sup> is a 5-session CBT group program developed for this study, with weekly sessions of 45 to 90 minutes (total 5.5 hours) over the first 4 weeks, followed by a final session 5 weeks later. Session 2 is a joint youth—parent session. Included in Vaag is a self-help material.<sup>31</sup>

<sup>&</sup>lt;sup>a</sup>Except for age between CBT and WL groups (p < .01), no significant differences were found after Bonferroni correction.

<sup>&</sup>lt;sup>b</sup>Independent-sample t test.

<sup>&</sup>lt;sup>c</sup>Pearson  $\chi$ 2 test.

<sup>&</sup>lt;sup>d</sup>Norwegian ethnicity defined as 1 or both parents born in Norway.

<sup>&</sup>lt;sup>e</sup>Determined by occupation of the highest-ranking parent, in accordance with the Registrar General Social Class coding scheme and categorized as high, medium, and low.

Cool Kids. Cool Kids (CK) is a 10-session CBT program for youth anxiety (total 15 hours plus two 90-minute parents-only sessions). In the present study, the adolescent group-based, school version of CK was applied.<sup>32</sup> Adolescents attended weekly 90-minute sessions. The program comprises separate workbooks for adolescents and parents. CK has previously shown efficacy in treatment of youths with anxiety disorders<sup>33</sup> and, as indicated, school-based prevention.<sup>34</sup>

Both Vaag and CK comprise basic CBT principles for anxiety, for example, cognitive restructuring and exposure tasks. For both programs, between-session exposure is encouraged, given as homework assignments from session 3 onward. In Vaag, during the 5 weeks between sessions 4 and 5, participants perform exposure tasks on their own, assisted by two 5- to 10-minute telephone calls or text messages from group leaders. Thus, an important difference between the programs is the amount of therapist contact during the last 5 weeks. The youths reported on how often they performed exposure tasks between sessions (0 = not atall, 3 = every day). No difference in exposure training was reported between programs for sessions 3 and 4. However, compared to CK (n = 140, mean = 1.16, SD = 0.73), youths in Vaag (n = 100, mean = 1.37, SD = 0.80) reported doing exposure tasks more frequently the last 5 weeks [t (238) = 2.12, p = .035]. Further comparison of the content and structure of the programs is available in Table S1, available online.

Each Vaag and CK group was administered by two group leaders, recruited either from community services (school nurses, n=21; community psychologists, n=5; family therapist, n=1) or from Child and Adolescent Mental Health Services (CAMHS) (n=5, eg, social workers). Thus, group leaders were mainly school personnel (ie, school nurses) or mental health workers participating in the study as part of their regular job.

Group leaders were 93.8 % women (mean age = 43.2 years, SD 0 =8.09, range 32–62), had an average of 6.7 years of experience working with youths (SD = 6.74, range 0–27 years), and 83.9% had no prior CBT training. Each administered 1 to 8 groups (mean = 3.3 groups; SD = 1.8).

Group leaders received a 4-day skills-training workshop focusing on basic CBT principles for anxiety, both program manuals, and assessment procedures. During the inclusion period, group leaders also attended 2 additional 2-day workshops. A total of 75.0% of the group leaders administered both Vaag and CK.

# Implementation

The interventions were administered at school, during school hours. A team of researchers and local coordinators

monitored the implementation. To ensure cross-site consistency, two annual face-to-face meetings were held for researchers, coordinators, and group leaders. The research team was available via telephone between meetings, and local coordinators kept close contact with the group leaders. Regular supervision was provided by experienced CBT therapists (n = 10), with 3 to 4.5 hours of supervision for each Vaag group and 6 to 10.5 hours for each CK group, primarily administered face-to-face. To ensure high-quality supervision across sites and programs, instructions on duration, structure, and content of supervision were developed. Supervision was monitored by checklists completed by supervisors after each session.

#### Assessments

Questionnaires were completed electronically by adolescents (a) and parents (p), preintervention, postintervention, post-WL, and at follow-up. Parent reports consisted mainly of mothers' ratings (90.4%). Fathers' ratings were used when mothers' ratings were not available.

Primary Outcomes. Primary outcomes were changes in both youth and parent ratings of anxiety symptoms and related impairment observed at postintervention, post-WL, and follow-up. Youth anxiety was assessed by the SCAS-a/p,  $^{27,34}$  comprising 38 items. SCAS has sound psychometric properties.  $^{27,35-37}$  Good to excellent internal consistency was found in the current study, applying Cronbach's alpha ( $\alpha$ ) (youths  $\alpha = 0.91$ , mothers  $\alpha = 0.89$ , fathers  $\alpha = 0.87$ ). Impairment from anxiety was assessed by the Child Anxiety Life Interference Scale (CALIS-a/p), a nine-item scale covering interference from anxiety across home, social life, school and activities. CALIS has demonstrated satisfactory psychometric properties. Adequate to good internal consistency was found in the current sample (youths  $\alpha = 0.86$ , mothers  $\alpha = 0.79$ , fathers  $\alpha = 0.84$ ).

Secondary Outcomes. Secondary outcomes were depressive symptoms measured by the Short Moods and Feelings Questionnaire (SMFQ-a/p), <sup>38</sup> a 13-item scale with good psychometric properties. <sup>38-40</sup> Good to excellent internal consistency was found in the current sample (youths  $\alpha = 0.91$ , mothers  $\alpha = 0.81$ , fathers  $\alpha = 0.84$ ). A joint semistructured clinical interview (15–30 minutes) with adolescent and parent(s) was administered by group leaders at preand postintervention and post-WL. Based on this, group leaders rated the overall severity of the adolescents' anxiety symptoms using the Clinical Global Impression scale—Severity (CGI-S). <sup>41</sup> CGI-S is scored on a seven-point scale (with lower ratings indicating less severe anxiety). All

interviews were videotaped. Three expert scorers, blinded to the group leaders ratings, rated CGI-S for 20% of the interviews, randomly selected and stratified by condition, time, schools, and groups. Agreement between expert scorers and group leaders across CGI-S ratings was acceptable, with an average agreement intraclass correlation coefficient [ICC] (2.1) = 0.73.

Client satisfaction (CS-a/p) was rated on a nine-item scale developed for this study (eg, "I would recommend this program to a friend with similar problems"). Items were scored on a 5-point scale (1 = totally disagree, 5 = totally agree), and averaged to a total score, with higher ratings indicating more satisfaction.

# Treatment Integrity

All group sessions were videotaped (except out-of-office exposure exercises).

Independent raters scored treatment integrity, rating 2 sessions from each group, sessions 3 and 4 in Vaag and sessions 6 and 7 in CK. These sessions were of the same duration and comparable content across programs. Group leaders did not know which sessions would be rated. Rating was done with the Competence and Adherence Scale for Cognitive-Behavioral Therapy (CAS-CBT),  $^{42}$  an 11-item instrument covering adherence (0 = none to 6 = thorough) and competence (0 = poor skillsto 6 = excellent skills). Treatment differentiation was assessed by a 3-item measure indicating whether materials from 1 program was applied in the other (eg, selfhelp material in Vaag or realistic thinking schema in CK). Coding was done by 7 clinical psychologists/psychiatrist (66.7% women; mean age = 48.7 years, range = 31-66 years) trained in CBT for anxiety. Satisfactory agreement was found between expert scorers (developers of CAS-CBT) and the remaining scorers for adherence: [ICC (2,1) = 0.63] and competence [ICC(2,1) = 0.69. Adherence and competence scores for each group (mean of the 2 rated sessions) ranged from  $3.17 \text{ to } 5.75 \text{ (mean} = 4.41, SD} = 0.56) \text{ for adherence}$ and 2.75 to 5.88 (mean = 4.18, SD = 0.66) for competence. Differentiation between programs was excellent (mean = 0, SD = 0).

# Data Analysis

Targeted prevention for anxiety symptoms in youths have been found to have an average effect size of 0.32 (Cohen d). We expected a slightly larger effect size (d = 0.40), because the standard intervention applied previously has shown moderate to large effects when delivered as targeted school prevention or treatment. <sup>33,34</sup> Power calculations to obtain a small to moderate effect size of 0.40 between

conditions, with 2 repeated measurements, with an assumed correlation of 0.6, yielded a required total sample size of 294 participants (power = 0.80,  $\alpha$  = 0.05). With an assumed attrition of 10%, a recruitment goal of 323 participants was established.

Baseline differences were analyzed by t tests (continuous variables) and  $\chi^2$  tests (categorical variables). Mean difference in client satisfaction was tested with a t test.

Linear mixed effect models (LMMs) were used to analyze differences in change from pre- to post-intervention (CBT), and pre- to post-WL, between CBT and WL. To account for dependency within schools and intervention groups, intervention groups and schools were used as random intercepts in addition to individual. Furthermore, the model included intervention (Vaag/CK), time (pre- and postintervention/post-WL) and an interaction term between intervention and time as a fixed effect. Separate analysis was conducted for each outcome variable. For groups re-randomized to Vaag or CK after WL and included in analyses comparing brief versus standard CBT, post-WL scores were used as pre-intervention scores.

Noninferiority. Tests to evaluate whether Vaag was noninferior to CK were performed on the primary outcome variables. For each primary outcome, a noninferiority limit was determined. If the upper limit of a 95% CI for the mean difference in change in pre to post score in SCAS-a/p between Vaag and CK was less than 1.4, then Vaag could be deemed noninferior to CK on the SCAS scale. For CALIS-a/p, the noninferiority bound was set to 0.7. The rationale for calculation of noninferiority bounds is given in the study protocol.<sup>29</sup> Furthermore, to conclude that Vaag was noninferior to CK, three of four primary outcome measures had to be declared noninferior. LMM with intervention groups, schools, and individual as random intercepts, and intervention, time, and an interaction term between intervention and time as fixed effect, were applied to estimate mean differences in the noninferiority tests.

Superiority analyses including 1-year follow-up for primary and secondary outcomes between Vaag and CK were conducted using LMM. The model was similar to the previous model, except that three time points were included. Estimated means, standard errors, and *p* values for differences between changes in Vaag and CK from pre- to postintervention and from preintervention to follow-up are presented.

Within-group and between-group effect sizes (Cohen *d*) were calculated based on estimated means from LMM analyses and pooled pre-SD.

Because of multiple testing regarding outcome measures, significance level was set to 0.01, with a corresponding 99% CI.

## Missing Data

Missing data were examined by the missing value analysis in SPSS 25 (SPSS/IBM Statistics, Chicago, IL) and handled by full information maximum likelihood missing data methodology (FIML) in STATA (15.1) (StataCorp, College Station, TX). Missing data originated mainly from participants who were lost to assessment postintervention (n = 21; 10.0%), after WL (n = 9; 9.5%), and at 1-year follow-up (n = 100; 33.1%). The Little MCAR test indicated that missing data for outcome measures occurred completely at random at postintervention (p = .09) and at 1-year followup (p = .053). However, higher adolescent and parent response rates were found at follow-up for those completing CK (74.4%) compared to Vaag (58.5%). Adolescents lost to follow-up reported higher anxiety (p = .04) and higher levels of parent-reported depressive symptoms (p = .01) at postintervention. These findings support the use of FIML, also for the follow-up assessments, based on an assumption of missing at random for these measures.<sup>44</sup>

Sensitivity analyses were conducted, including only those participants who completed the interventions. Furthermore, separate analyses were performed excluding adolescents who received other treatments for anxiety during the interventions, during WL, or during follow-up. These analyses were performed with corresponding LMM as for the main analyses.

# **RESULTS**

#### Sample characteristics

Mean scores on self-reported (43.43, SD = 16.46) and parent-reported (32.48, SD = 12.83) youth anxiety (SCAS a/p) for the total sample, were in the clinical range, or slightly below ratings of clinical samples. 35,36 Scores on impairment (CALIS-a/p) were comparable to clinical samples 45,46 for the adolescents' ratings (mean 12.24, SD = 7.42) and less impaired than clinical samples for the parent ratings (mean 14.78, SD = 6.40). Mean depressive symptoms were above cut-off for high scorers on SMFQ-a/p, 47 according to both adolescents (mean 11.48, SD= 6.82) and parents (mean 12.56, SD = 6.48). Clinical ratings of global severity of anxiety (CGI-S) at baseline showed mean severity above moderate level (4.34, SD = 0.87). According to the adolescents, 29 (9.5%) had been in contact with CAMHS once a month or more frequently during the year before inclusion. According to adolescents and parents, 31 (9.9%) of the participants received other treatments (ie, anxiety medication or meetings at CAMHS

once a month or more frequently) during the interventions, 7 (6.7%) during WL, and 58 (18.5%) during follow-up.

#### Attrition

Of those randomized to CBT, 7 youths (2.3%) did not attend any sessions. Eleven youths withdrew post-WL and before re-randomization to CBT. Among those randomized to CBT, 83.4% (n = 252) were defined as completers (attending  $\geq$ 7 sessions of CK or  $\geq$ 4 sessions of Vaag). There was no difference in retention between interventions (p = .68). Post hoc comparisons of completers versus noncompleters showed no baseline differences on participants' age, sex, social class, family structure, clinical severity (CGI-S), anxiety (SCAS-a/p), depressive symptoms (SMFQ-a/p), or youth-reported impairment (CALIS-a). However, a difference was found on parent-reported baseline impairment (CALIS-p), which was higher for noncompleters (p = .01).

#### **CBT Versus WL**

Primary Outcomes. The CBT group (initially randomized to Vaag or CK) decreased significantly more than the WL from pre- to postintervention for SCAS-a/p, with betweengroup effect sizes (Cohen d) of 0.34 (p=.001) and 0.53 (p<.001) for adolescent and parent ratings, respectively. Furthermore, parent-rating of youth impairment from anxiety improved significantly more for the CBT condition compared to WL (d=0.51, p<.001) (Figure 2, and see Table S2, available online, for mean difference in change and CIs).

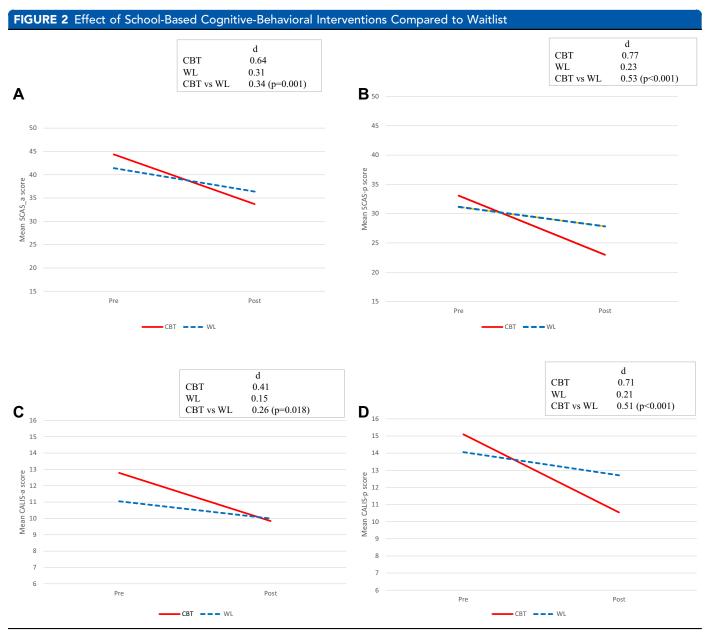
## Secondary Outcomes

Parent-rating of youth depressive symptoms decreased significantly more in the CBT-group compared to WL group (d=0.30, p=.006). Also, clinical global severity decreased more (d=1.03, p<.001) from pre to post in the CBT condition compared to the WL.

Sensitivity analyses, including completer analyses and analyses excluding adolescents receiving other treatments (during interventions, or WL) gave similar results when comparing CBT and WL.

# Noninferiority Tests Between Brief and Standard CBT on Primary Outcomes

The sample used for the noninferiority tests also included those reallocated to Vaag and CK after WL (n = 302). The difference in mean reduction (pre- to postintervention) in SCAS-a between Vaag (7.1 points) and CK (10.5 points) was 3.37 (99% CI = -0.12 to 6.85). As the upper limit of the CI included the noninferior bound 1.4, Vaag was *not* 



Note: (A) Youth-reported anxiety symptoms; (B) parent-reported youth anxiety symptoms. (C) Youth-reported impairment; (D) parent-reported youth impairment. (E) Youth-reported depressive symptoms; (F) parent-reported youth depressive symptoms. (G) Clinical severity of anxiety. a = adolescent; CALIS = Child Anxiety Life Interference Scale; CBT = cognitive-behavioral therapy, CGI-S = Clinical Global Impression—Severity; p = parent; SCAS = Spence Children Anxiety Scale; SMFQ = Short Mood and Feeling Questionnaire; WL = wait list. Please note color figures are available online.

noninferior to CK with respect to SCAS-a scores. Also, for the other primary outcomes (SCAS-p and CALIS-a/p) Vaag was not noninferior to CK (Figure 3). Additional analyses were performed with less strict bounds based on an assumed effect size of 0.2 between Vaag and CK. With this adjustment, only one (CALIS-p) of the four primary measures indicated noninferiority, confirming that brief CBT could not be deemed noninferior to standard CBT. Sensitivity analyses (completer analyses and analyses

excluding those receiving other treatments) gave similar results.

#### Brief Versus Standard CBT Over Time

Primary and Secondary Outcomes. Estimated means, difference in change, effect sizes, and *p* values of SCAS-a/p, CALIS-a/p, and SMFQ-a/p for pre- and postintervention and follow-up, and pre and post CGI-S for Vaag and CK, are presented in Table 2. In general, within-group effect



sizes were larger for CK compared to Vaag. However, no significant difference was found between Vaag and CK with regard to effects on any of the primary or secondary measures (Table 2).

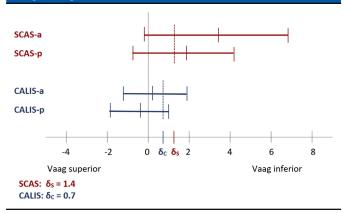
For anxiety and depressive symptoms, as well as for impairment, effects were maintained at 1-year follow-up, with no differences in effects between the programs.

Sensitivity analyses, including completer analyses and analyses excluding adolescents receiving other treatments (during interventions or at follow-up) gave similar results when comparing Vaag and CK on primary outcomes across informants at postintervention and follow-up.

## Client Satisfaction

Mean scores on the client satisfaction scale were high, 3.67 (range 1.1–5.0; SD = 0.90) for adolescents (n = 252) and 3.80 (range 1.4–5.0; SD = 0.76) for parents (n = 251), indicating positive evaluations of the interventions. Adolescents reported somewhat higher mean satisfaction (p = .048) for CK (3.77, SD = 0.86)

**FIGURE 3** Noninferiority Test of Brief Versus Standard-Length Cognitive-Behavioral Interventions



**Note:** Estimated mean differences with 95% CI, between Vaag (brief) and Cool Kids (standard length) in reduction on primary outcomes pre- to postintervention. Noninferior bound for SCAS  $\delta_S=1.4$  and for CALIS  $\delta_C=0.7$ . a= adolescent; CALIS = Child Anxiety Life Interference Scale; p= parent; SCAS = Spence Children Anxiety Scale. Please note color figures are available online.

compared to Vaag (3.55, SD = 0.94). However, parent satisfaction did not differ significantly (p = .07) between interventions.

## **DISCUSSION**

Effectiveness of school-based targeted prevention for adolescents with anxiety symptoms was demonstrated. Effects of CBT was found for adolescent and parent-reported youth anxiety and parent-reported youth depression, as well as parent-reported impairment from anxiety. Parents and adolescents disagreed somewhat on level of youth anxiety and impairment at baseline, an informant discrepancy commonly found in youth mental health research.<sup>48</sup> However, regarding anxiety symptoms, positive effects of CBT were found for both parent and youth reports. Both brief and standard CBT reduced anxiety, impairment, and depressive symptoms, with within-group effect sizes pre- to postintervention ranging from small to large, depending on program, informant, and measure. Furthermore, outcomes were maintained or even improved at 1-year follow-up. Anxiety levels from both youths' and parents' perspectives, as well as parent-reported anxiety-related impairment, changed significantly from pre- to postintervention compared to WL, indicating robust effects of the interventions. These findings support previous studies demonstrating efficacy of targeted school-based prevention for anxious youths. 1,22

The small number of decliners (2.3%), limited number of noncompleters (14.2%), and positive youth and parent client satisfaction indicate that both interventions were acceptable. Furthermore, adequate

treatment integrity scores indicate that it is feasible to train and supervise school staff (ie, school nurses) and health personnel to deliver CBT. The study also show the possibility of implementing mental health interventions at schools and during school hours. These are promising results, as large-scale dissemination of school-based interventions may be more sustainable when interventions are delivered by school staff, at schools, and during school hours.

Comparing the effect of brief versus standard school-based CBT is a novel contribution of the present study. Although differences between brief and standard CBT were nonsignificant, brief CBT was *not* noninferior to standard CBT. To ensure that we were not too conservative in estimating the noninferiority bounds, less strict bounds were tested, resulting in the same conclusion, namely, that brief CBT could not replace standard CBT.

A previous meta-analysis of clinical studies show that CBT programs with less than 9 hours of therapist contact are less efficacious. Our results extend these findings by demonstrating that also in targeted CBT preventive interventions, efficacy may vary with duration of programs. A possible explanation may be that the brief intervention (5.5 hours) did not provide sufficient time for individual tailoring of cognitive restructuring and exposure exercises.

However, it is worth noting that the effects between the brief and the standard program were not significant. Perhaps more minor reductions in duration, with a brief intervention of about 8 to 10 hours, could prove to be noninferior to the standard 15-hour program evaluated in this study. Considering the advantages of brief school interventions (eg, lower costs, less absence from school hours) and the efficacy of the brief program demonstrated in the present study, targeted prevention with brief CBT should be evaluated further.

The lower satisfaction with brief CBT and the larger number of participants lost to 1-year follow-up may indicate less engagement among youths in brief CBT. Furthermore, group leaders may have more time to connect with youths during the longer program. These might be explanations for the somewhat better outcomes of the standard program.

On the other hand, higher frequency of self-reported between-session exposure tasks in the brief CBT intervention during the last 5 weeks suggests that less contact with group leaders may stimulate youths to take more responsibility for their own exposure training.

Long-term effects are particularly important in prevention research. <sup>17</sup> The 1-year follow-up assessment showed

**TABLE 2** Estimated Means of Adolescent- and Parent-Reported Outcomes After Brief or Standard School-Based Targeted Prevention

|                    | n       | Vaag         | Cool Kids    | Cohen d              | Difference in Change Between<br>Vaag and Cool Kids |                 |                |
|--------------------|---------|--------------|--------------|----------------------|--|-----------------|----------------|
| Measure            | Vaag/CK | Mean (SE)    | Mean (SE)    | Vaag/CK <sup>a</sup> | Mean   | 99% CI          | p <sup>b</sup> |
| Primary outcomes   |         |              |              |                      |  |                 |                |
| SCAS-a             |         |              |              |                      |  |                 |                |
| Pre                | 141/159 | 42.00 (1.60) | 42.46 (1.51) |                      |  |                 |                |
| Post               | 121/136 | 35.02 (1.66) | 32.01 (1.57) | 0.41/0.62            | 3.47   | -0.99 to 7.93   | .045           |
| FU                 | 72/117  | 33.34 (1.88) | 29.04 (1.62) | 0.50/0.79            | 4.77   | -0.35 to 9.89   | .016           |
| SCAS-p             |         |              |              |                      |  |                 |                |
| Pre                | 140/159 | 31.43 (1.18) | 31.32 (1.11) |                      |  |                 |                |
| Post               | 115/137 | 24.24 (1.23) | 22.43 (1.15) | 0.53/0.67            | 1.70   | -1.68 to $5.08$ | .194           |
| FU                 | 82/118  | 20.58 (1.34) | 19.47 (1.19) | 0.81/0.90            | 0.99   | -2.72 to 4.71   | .491           |
| CALIS-a            |         |              |              |                      |  |                 |                |
| Pre                | 114/159 | 11.40 (0.80) | 12.45 (0.77) |                      |  |                 |                |
| Post               | 121/133 | 9.23 (0.83)  | 9.92 (0.79)  | 0.30/0.32            | 0.37   | -1.78 to 2.51   | .659           |
| FU                 | 72/119  | 9.06 (0.93)  | 9.14 (0.81)  | 0.32/0.42            | 0.98   | -1.47 to $3.42$ | .304           |
| CALIS-p            |         |              |              |                      |  |                 |                |
| Pre                | 140/159 | 14.06 (0.67) | 14.57 (0.64) |                      |  |                 |                |
| Post               | 115/138 | 10.04 (0.70) | 11.05 (0.66) | 0.61/0.55            | -0.50  | -2.40 to $1.40$ | .499           |
| FU                 | 83/119  | 9.06 (0.76)  | 9.16 (0.68)  | 0.76/0.85            | 0.41   | -1.68 to 2.49   | .616           |
| Secondary outcomes |         |              |              |                      |  |                 |                |
| SMFQ-a             |         |              |              |                      |  |                 |                |
| Pre                | 140/159 | 11.22 (0.73) | 11.60 (0.70) |                      |  |                 |                |
| Post               | 120/133 | 10.06 (0.76) | 9.55 (0.73)  | 0.17/0.28            | 0.89   | -1.15 to 2.93   | .260           |
| FU                 | 72/119  | 9.93 (0.85)  | 9.38 (0.74)  | 0.18/0.31            | 0.93   | -1.40 to $3.25$ | .305           |
| SMFQ-p             |         |              |              |                      |  |                 |                |
| Pre                | 140/159 | 10.66 (0.54) | 11.48 (0.51) |                      |  |                 |                |
| Post               | 115/138 | 6.30 (0.58)  | 6.06 (0.53)  | 0.65/0.85            | 1.05   | -0.79 to 2.90   | .140           |
| FU                 | 82/119  | 5.28 (0.64)  | 5.09 (0.55)  | 0.81/1.00            | 1.00   | -1.02 to $3.03$ | .201           |
| CGI-S              |         |              |              |                      |  |                 |                |
| Pre                | 139/156 | 4.33 (0.12)  | 4.26 (0.12)  |                      |  |                 |                |
| Post               | 114/128 | 3.44 (0.13)  | 3.31 (0.12)  | 1.03/1.06            | 0.50   | -0.29 to 0.43   | .620           |

**Note**: Estimated means from linear mixed models. Differences between interventions by mean difference in change in Cls, effects sizes, and p values. a = Adolescent; CALIS = Child Anxiety Life Interference Anxiety Life Interference Scale; CGI-S = Clinical Global Impression—Severity; CK = Cool Kids; FU = follow-up; p = parent; SCAS = Spence Children Anxiety Scale; SE = standard error; SMFQ = Short Mood and Feeling Questionnaire

that gains were sustained regrading anxiety, depressive symptoms, and impairment. However, because of the lack of a control group, no causal inferences can be drawn regarding these long-term effects.

In the present study, effort was made to secure high implementation quality. It was considered crucial to involve local leaders for continuous support for the interventions to be prioritized alongside other school activities. The effects of the interventions need to be considered within this context. We cannot assume that interventions

would achieve similar effects without comparable levels of training, supervision, and leader support. 49

Our inclusion criteria allowed admission of youths with moderate levels of anxiety. The actual sample, however, revealed mean levels of anxiety, impairment, and depressive symptoms comparable to those in clinical samples. <sup>28,36,47</sup> This was consistent with group leaders' baseline scores of the adolescents as "moderate" to "markedly ill" (CGI-S). Also, parents reported high levels of impairment and depressive symptoms among the

<sup>&</sup>lt;sup>a</sup>Within-group effect size (Cohen d) pre- to postintervention, and preintervention to 1-year follow up.

<sup>&</sup>lt;sup>b</sup>p Value for differences in change between Vaag and Cool Kids from pre- to postintervention, and from preintervention to 1-year follow-up.

adolescents.<sup>36</sup> Despite this, less than 10% of the sample reported frequent contact with CAMHS the year before inclusion. Thus, school-based interventions seem to reach a group of youths in need of help, who do not receive treatment elsewhere.

Among the strengths of the study are psychometrically sound measures. Additional strengths address limitations present in many previous school-based studies on youth anxiety, such as reporting completion rates, assessing impairment, including independent ratings of adherence and competence, and inclusion of follow-up data. Finally, liberal inclusion criteria, delivery of interventions at schools and during school hours, as well as adolescents recruited through school health services, suggest high external validity of the findings.

The study also has limitations. Diagnostic evaluation was not included, making it impossible to know the "true preventive effects" of the interventions, that is, the ability to prevent anxiety disorders among participants. <sup>21</sup> Limitations include a potential bias related to the clinical severity ratings, which were completed by the group leaders who also delivered the interventions. Further limitations were the absence of external independent evaluation of the youths' symptoms and impairment, and no teacher reports of classroom behavior. Finally, as randomization did not occur at the school level, a risk of contamination across conditions was present.

Even though key CBT principles and skills were the same in both programs, we compared two programs differing not only in length but, to some degree, also in content (eg, concepts used to describe cognitive restructuring). This may make it difficult to determine whether the slightly different efficacy is due to the content or to the duration of the interventions.

No cost—benefit analysis was included. Such analyses are important to assist school personnel and policy makers in determining the best balance of decisions about what interventions to implement.

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We need to reach adolescents who struggle with anxiety at an earlier time in their lives. The present study indicates that this may be achieved through school-based targeted CBT interventions.

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Drs. Haugland, Baste, Bjaastad, Raknes, and Husabø, are with the Regional Centre for Child and Youth Mental Health and Child Welfare, Norwegian Research Center, NORCE, Bergen, Norway. Dr. Haugland is also with the University of Bergen, Norway. Dr. Haaland is with Sorlandet Hospital Hr. Kristiansand, Norway. Dr. Bjaastad is also with the Division of Psychiatry, Stavanger University Hospital, Stavanger, Norway. Dr. Hoffart is with the Research Institute, Modum Bad Psychiatric Centre, Vikersund, Norway, and the University of Oslo, Oslo, Norway. Dr. Rapee is with the Centre for Emotional Health, Macquarie University, Sydney, Australia. Dr. Himle is with the University of Michigan, Ann Arbor, and the School of Social Work, University of Michigan, Ann Arbor. Dr. Husabø and Wergeland are with the Faculty of Medicine, University of Bergen, Bergen, Norway. Dr. Wergland is also with the Division of Psychiatry, Haukeland University Hospital, Bergen, Norway.

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Correspondence to Bente Storm Mowatt Haugland, PhD, University of Bergen Department of Clinical Psychology, Christiesgt 12, Bergen, 5036, Norway; e-mail: bente.haugland@uib.no

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TABLE S1 Overview of the Two Cognitive-Behavioral Interventions

|                           |                             | COOL KID                  | S (School Version)  | VAAG      |                             |                           |  |  |  |
|---------------------------|-----------------------------|---------------------------|---|-----------|-----------------------------|---------------------------|--|--|--|
| Session<br>1 <sup>a</sup> | Participants<br>Adolescents | <b>Duration</b><br>90 min | Content Psychoeducation. Anxiety, linking thoughts and feelings. Setting goals. Homework assignment   | Session 1 | Participants<br>Adolescents | <b>Duration</b><br>45 min | Content Psychoeducation. Anxiety, linking situations, thoughts and feelings. Setting goals. Homework assignment  |  |  |
| 2                         | Adolescents                 | 90 min                    | Cognitive restructuring. Principles and application of exposure hierarchies (stepladders). Homework assignment  | 2         | Adolescents and parents     | 60 min                    | Using self-help material to link situations, feelings and thoughts. Cognitive restructuring. Identifying avoidance. Helpful parenting. Homework assignment |  |  |
| 3                         | Adolescents                 | 90 min                    | Cognitive restructuring. Principles and application of exposure hierarchies (stepladders). Homework assignment  | 3         | Adolescents                 | 90 min                    | In-session exposure and behavioral experiments. Training plans. Homework assignment  |  |  |
| 4                         | Adolescents                 | 90 min                    | Exposure hierarchy. Regulating anxiety by surfing emotions and worries.  Homework assignment  | 4         | Adolescents                 | 90 min                    | In-session exposure and behavioral experiments. Training plans. Homework assignment  |  |  |
| 5ª                        | Adolescents                 | 90 min                    | Reviewing and revising exposure hierarchies (individual sessions 15-20 min)   |           |                             |                           |  |  |  |
| 6                         | Adolescents                 | 90 min                    | Simplifying cognitive restructuring. In-<br>session exposure and behavioral<br>experiments. Homework assignment   |           | Adolescents                 | 5-10 min × 2              | Two telephone calls or text-messages,<br>supporting the adolescents to follow<br>the training plan   |  |  |
| 7                         | Adolescents                 | 90 min                    | In-session exposure and behavioral experiments. Homework assignment   |           |                             |                           |  |  |  |
| 8                         | Adolescents                 | 90 min                    | In-session exposure and behavioral experiments. Additional skills if needed to facilitate progress (e.g. problem solving, assertiveness). Homework assignment |           |                             |                           |  |  |  |
| 9                         | Adolescents                 | 90 min                    | Troubleshooting exposure. In-session exposure. Homework assignment  |           |                             |                           |  |  |  |
| 10                        | Adolescents                 | 90 min                    | Reviewing goals. Positive and negative coping strategies. Future plans. Celebration.  | 5         | Adolescents                 | 45 min                    | Review of progress so far. Future plans. Mutual support  |  |  |

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SCHOOL-BASED CBT FOR YOUTH ANXIETY

Note: <sup>a</sup>Two psychoeducational parent sessions, each 90 minutes; the first was between sessions 1 and 3, and the second was after session 5.

**TABLE S2** Estimated Means for Adolescent- and Parent-Reported Outcomes for School-Based Targeted Prevention Compared to Waitlist

|              |          | n       | СВТ          | WL           | Cohend              | Differe | ence in Change Betwe<br>and CBT | en WL          |
|--------------|----------|---------|--------------|--------------|---------------------|---------|---------------------------------|----------------|
| Measure      |          | CBT/WL  | Mean (SE)    | Mean (SE)    | CBT/WL <sup>a</sup> | Mean    | 99% CI                          | p <sup>b</sup> |
| Primary out  | comes    |         |              |              |                     |         |                                 | -              |
| SCAS-a       | Pre      | 209/103 | 44.36 (1.29) | 41.41 (1.83) |                     |         |                                 |                |
|              | Post     | 188/95  | 33.69 (1.33) | 36.39 (1.86) | 0.64/0.31           | -5.6    | -10.19 to $-1.13$               | .001           |
| SCAS-p       | Pre      | 209/101 | 33.08 (0.87) | 31.16 (1.24) |                     |         |                                 |                |
|              | Post     | 181/94  | 22.98 (0.90) | 27.87 (1.27) | 0.77/0.23           | -5.51   | -9.92 to $-3.60$                | <.001          |
| CALIS-a      | Pre      | 209/104 | 12.79 (0.72) | 11.05 (0.89) |                     |         |                                 |                |
|              | Post     | 187/95  | 9.84 (0.73)  | 10.00 (0.91) | 0.41/0.15           | -1.89   | -3.95 to 0.16                   | .018           |
| CALIS-p      | Pre      | 209/101 | 15.10 (0.56) | 14.06 (0.73) |                     |         |                                 |                |
|              | Post     | 182/94  | 10.54 (0.57) | 12.71 (0.74) | 0.71/0.21           | -4.73   | -4.97 to $-1.46$                | <.001          |
| Secondary of | outcomes |         |              |              |                     |         |                                 |                |
| SMFQ-a       | Pre      | 209/104 | 11.85 (0.62) | 10.52 (0.79) |                     |         |                                 |                |
|              | Post     | 187/94  | 9.94 (0.64)  | 10.16 (0.80) | 0.28/0.06           | -2.07   | -3.47 to $0.38$                 | .039           |
| SMFQ-p       | Pre      | 209/101 | 12.97 (0.46) | 11.98 (0.62) |                     |         |                                 |                |
|              | Post     | 182/94  | 6.18 (0.48)  | 7.34 (0.64)  | 1.03/0.70           | -2.72   | -3.82 to $-0.11$                | .006           |
| CGI-S        | Pre      | 203/99  | 4.36 (0.09)  | 4.29 (0.12)  |                     |         |                                 |                |
|              | Post     | 168/92  | 3.40 (0.10)  | 4.22 (0.12)  | 1.09/0.08           | -7.17   | -1.21 to $-0.57$                | <.001          |

Note: Estimated means from linear mixed models. Differences between intervention and waitlist by mean difference in change, Cls, effects sizes and p values. a = Adolescent; CALIS = Child Anxiety Life Interference Scale; CBT = cognitive-behavioral therapy; CGI-S = Clinical Global Impression-Severity; p = parent; SCAS = Spence Children Anxiety Scale; SMFQ = Short Mood and Feeling Questionnaire; WL = waitlist.

<sup>&</sup>quot;Within-group effect size (Cohen' d): changes in CBT and WL from pre- to postintervention and from preintervention to postwaitlist.

<sup>&</sup>lt;sup>b</sup>p Value for differences in change between CBT and WL from pre- to postintervention and from preintervention to postwaitlist.