A Randomized Controlled Trial of a Cognitive Behavior Therapy Program for Children with Clinical Anxiety Symptoms

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Abstract: High anxiety and anxiety disorders are among the most prevalent mental health problems in children and lead to significant interference with children’s daily functioning. Most empirical evaluations of treatment come from English-language countries. The aim of the present study was to evaluate and replicate the effectiveness of a cognitive-behavioral intervention program to manage anxiety in children among children from Greece. Forty-one children–parent(s) dyads participated in the study. Children were 9–12 years old, with clinically elevated symptoms of anxiety, and they were assigned to either the standard group treatment (cognitive behavior therapy (CBT)) or to a waitlist group (WL). Both children and their parents in the CBT group reported statistically significant reductions in children’s anxiety symptoms at post-intervention and at the 6-month follow-up. A significant reduction was also found in life interference due to anxiety according to both child and parent reports. In contrast, no significant changes in anxiety symptoms or life interference were reported among the WL. The current results support the effectiveness of a CBT program for anxious children from a non-clinic, non-school setting in Greece.

Keywords: child; parent; anxiety; CBT treatment

1. Introduction

Anxiety disorders are the most prevalent form of mental disorder in childhood and adolescence, with an estimated prevalence in youth (3–17 years old) of 7.2% [1]. Anxiety disorders in childhood are associated with considerable distress and impairment. Due to their prevalence and chronicity [2], they are a leading cause of disability worldwide [3]. Hence, evidence-based treatments for youth anxiety disorders are of utmost necessity.

Manualized treatments for the management of broad, non-specific anxiety disorders among youth have been developed since the 1990s [4]. Empirically validated treatments for anxious youth primarily follow the principles of cognitive behavior therapy (CBT) [5]. While most manualized treatment packages combine several components of CBT, evidence suggests that exposure-based intervention is associated with the strongest and most consistent effects [6,7]. The efficacy of CBT for anxious youth has been demonstrated across multiple trials based on different forms of delivery and formats. Overall, at the end of treatment, around 60% of treatment completers are remitted from their primary disorder, and symptom-based measures show moderate to large effect size reductions [7–10]. While most evaluations have compared CBT against waitlist controls, a number of studies have demonstrated positive effects in comparison to other active treatments [11]. Positive outcomes from CBT have been (a) demonstrated across diverse youth characteristics (e.g., age range and ethnicities); (b) demonstrated by therapists with varying levels of training; (c) delivered in diverse formats ranging from individual and group to parent/teacher group to phone/Internet/e-mail; and (d) evaluated in a number of different settings, including outpatient clinics, home- or hospital-based treatment, in schools, and online [7,9].
There is good evidence that CBT has demonstrated good acceptability and efficacy for the management of pediatric migraine [12] and other chronic and recurrent pain in children and adolescents [13].

Among the well-studied, manualized CBT protocols for anxious youth is the Cool Kids set of programs [14,15]. Cool Kids is a structured program that follows the basic principles of CBT, is primarily centered around systematic exposure to threat cues, and teaches children, adolescents, and their parents effective ways of coping with anxiety [14,16]. A number of clinical trials have supported the efficacy of the Cool Kids program. At the end of treatment, around 31% to 69% of youth are remitted from their presenting disorder and 16–25% from all anxiety disorders [17–20]. Follow-up assessments, ranging from 6 months [16] to 6 years [21] post-treatment, support the maintenance of treatment gains, with up to 75% of youth being remitted by 12 months [22]. Improvements are also demonstrated in both related difficulties such as depression and in associated constructs such as life interference and negative cognitions. Mychailyszyn [15] reviewed and meta-analyzed the available research (16 studies, N = 1579) on the family of studies belonging to the Cool Kids Program. Analyses indicated superior improvement for youth receiving the Cool Kids intervention compared with controls according to both child and parent reports of anxiety. Mychailyszyn concluded that the Cool Kids program holds considerable promise and, in the contemporary context of evidence-based practice, should be considered a program with strong empirical support.

The Cool Kids program was developed in Australia; thus, the majority of empirical evaluations have come from that country. A considerably smaller number of clinical trials have demonstrated the efficacy of Cool Kids when used outside of Australia, including Denmark [23–26], Turkey [27], and Norway [28]. For an internationally utilized program, this lack of cross-cultural evaluation remains a limitation.

The aim of the current study was to evaluate the efficacy of the Cool Kids program for anxiety amongst children in a country outside Australia, in this case, Greece. Efficacy was determined on the basis of both children’s and parents’ reports and evaluating both symptoms of, and interference from, anxiety. Based on the extensive evidence base from Australia and the smaller evidence base from other countries, it was hypothesized that CBT would be superior to a waitlist control condition for both anxiety symptoms and life interference. Further, we predicted that the therapeutic gains would be maintained at least 6 months following intervention with effects comparable with the effects observed in similar RCTs.

2. Materials and Methods

A parallel-group trial design was used in the present study with a “no treatment” concurrent control. The allocation ratio was 1:1.

2.1. Participants

Participants included 41 anxious children and their parents. Inclusion criteria for children were an age range of 9–12 years (mean (M) age = 10.43; standard deviation (S.D.) = 1.02; 23 (56%) female) and a score above the pre-determined cut-off score on a measure of anxiety symptoms (see below). Cut-off scores were retrieved from the official website of the Spence Children’s Anxiety Scale (SCAS) [29]. The exclusion criterion was a child’s score below the previously mentioned cut-off score. Participants who did not complete the questionnaires or who did not have the parent’s consent were also excluded from the study. No specific inclusion or exclusion criteria were applied for parents. Children were recruited from 28 elementary schools (4th-, 5th-, and 6th-grade students) located in the city of Thessaloniki in Greece, where questionnaires were distributed to 1123 children and their families. Forty-one children with clinically elevated anxiety symptoms were included in the study (Figure 1). Twenty-one children were randomly allocated to the treatment group, while the remaining twenty children were allocated to a waitlist group. Meta-analysis has shown controlled effect sizes of around Cohen’s $d = 1$ on continuous
measures of child anxiety symptoms [8]. Hence, a sample of 34 participants (17 per group) was required to provide a power of 0.8 with an alpha = 0.5 [30].

Figure 1. Flow chart of participants through the study. Note: FU = follow-up.

2.2. Measures
2.2.1. Child Self-Report Measures

The Spence Children’s Anxiety Scale (SCAS) [31] is a self-report measure of anxiety symptoms designed for children and adolescents in the general population and contains 38 items reflecting characteristics of anxiety disorders (plus 6 filler items). Items factor into six subscales: Panic Disorder and Agoraphobia (PDA), Separation Anxiety Disorder (SAD), Social Phobia (SP), Physical Injury Fears (PIF), Obsessive-Compulsive Disorder (OCD), and Generalized Anxiety Disorder (GAD). Each item is rated on a 4-point scale from 0 (never) to 3 (always).
The measure was previously translated into Greek, and an additional item, “Fear of elevators”, was added [32]. The Greek translation has shown good psychometric properties [32]. Internal consistency for the total (39-item) scale in the current sample was $\alpha = 0.90$.

The State-Trait Anxiety Inventory for Children (STAIC) [33] is a self-report questionnaire that assesses how children experience their anxiety in everyday life, reflecting either state or trait anxiety. In the present study, we used only the STAIC-Trait scale. The Trait Scale (STAIC-T) consists of 20 items and examines a stable tendency to experience anxiety. Each item is rated on a 3-point frequency scale: very often (3), sometimes (2), and hardly ever (1). Hence, scores range from 20 to 60. The Greek translation of the STAIC-T scale has demonstrated excellent internal consistency ($\alpha = 0.80$) and test–retest reliability coefficient ($r = 0.81$) [34]. In the present sample, internal consistency was $\alpha = 0.81$.

The Child Anxiety Life Interference Scale (CALIS) [35] assesses interference from symptoms of anxiety on a child’s life, including home, school, and social activities. The child version of the CALIS contains 10 items rated on a 5-point scale from (0) not at all to (4) a great deal. The original version of the CALIS-C demonstrated good internal consistency (0.84), strong test–retest reliability (0.72), and moderate to strong convergent validity (ranging between 0.57 and 0.78) [35]. In the present sample, internal consistency for the total scale was $\alpha = 0.89$.

2.2.2. Parent-Report Measures

The Spence Children’s Anxiety Scale for Parents (SCAS-P) [36] contains 38 items and, as in the child’s version, is intended to measure symptoms of six subtypes of anxiety disorders. Items are rated on a 4-point scale from 0 (never) to 3 (always). The original version of SCAS-P demonstrated good internal consistency (0.89) for the total scale [36]. Internal consistency in the current sample was $\alpha = 0.89$.

The Child Anxiety Life Interference Scale-parent version (CALIS-P) [35] assesses the interference that anxiety has on a child’s life and that of their parents. CALIS-P has 16 items rated on a 5-point scale from (0) “not at all” to (4) “a great deal”. It measures the impact that anxiety has in various areas of life (e.g., home, school, social life, activities, relationships in family, work, personal stress, and leisure time). CALIS-P has two subscales: (a) interference in the child’s life (a1) Outside-Home Interference and (a2) At-Home Interference and (b) interference in the parents’ life. The scores for all items relevant to interference in the child’s and parent’s life are combined to yield total scores. The CALIS-P demonstrates good internal consistency ($\alpha’s$ between 0.75 and 0.90), moderate to high test–retest reliability ($r$-values between 0.66 and 0.91), and significant inter-rater reliability ($r$-values between 0.37 and 0.74 [35]). For the current sample, internal consistency for the total score was $\alpha = 0.95$.

The Achenbach System of Empirically Based Assessment (ASEBA) [37,38] is a commonly used parent measure to assess child behavioral, emotional, and social problems and adaptive functioning. It includes 113 items, and parents are asked to evaluate whether the behavior is not true (0) for their child, somewhat or sometimes true (1), or very true or often true (2), now or during the past six months. Questions are associated with problems on a syndrome scale in eight different categories: anxious/depressed, withdrawn/depressed, somatic complaints, social problems, thought problems, attention problems, rule-breaking behavior, and aggressive behavior. The ASEBA contains two empirically derived (i.e., through factor analysis) broadband scales representing internalizing and externalizing problems. This organizational structure makes the ASEBA an attractive measure to use in screening and diagnostic assessment protocols. The psychometric properties of this scale, as well as of the Greek version, have been well established, and the measure is widely used internationally [38]. Ratings higher than 20 for externalizing and internalizing behaviors and ratings higher than 7 for anxiety/depression subscale are considered clinically significant (93rd percentile). The scores in ASEBA were not used as a criterion for the selection of the participants.
2.3. Procedures

Ethics approval was granted for this study by the “Research Ethics and Deontology Committee” of the University of Macedonia. The study also had the approval of the corresponding Section of Pedagogical Institute/Greek Ministry of Education, Research and Religious Affairs. The initial request for approval included 28 schools selected from a list of all primary schools in Thessaloniki in Greece. The list was available from the Pedagogical Institute/Greek Ministry of Education, Research and Religious Affairs. Firstly, the schools were distributed in three groups by municipality. In proportion to the size of each group, the schools were selected by simple randomization. After the approval, fifteen schools were selected with the process described above. From the 15 schools, the researchers visited 9 schools after the consent of the school principal.

Questionnaires were distributed to 1123 children and their families, and informed written consent was asked from parents. Only 431 (38.4%) children with their parents completed the questionnaires. Children that reported high anxiety symptoms in the self-reported SCAS questionnaire (at least one standard deviation above the mean score of the present sample) were invited to participate in the intervention study. From this initial sample, 53 (14.1%) children presented clinically elevated anxiety symptoms, but forty-one (9.5%) of them had their parents’ consent and were selected for the program. Unstructured clinical interviews were conducted with parents of candidate families in order to assess the significance of their child’s anxiety and issues related to the attendance of the program. The aim of the interviews was to collect data about specific issues (e.g., if the children were already in treatment for their anxiety or possible obstacles for attending the program). Following assessment, families were allocated either to the intervention or the waitlist group. The first author used a schedule from a random number generator to assign families to CBT or waitlist (WL) groups. Each newly accepted child was simply allocated to the next condition on the schedule.

The intervention lasted 13–14 weeks. Two sessions were arranged every second week, and there was a one-week break in compliance with school vacations. Consequently, the second measurements in both groups took place after 13–14 weeks. All the participants from the CBT group completed the intervention program and the 2nd measurement. Two child–parent(s) dyads did not respond to the call for the 6-month follow-up. Concerning the control group, during the 2nd measurement, there were missing data from 1 child–parent(s) dyad and one parent. No data were available from the 6-month follow-up measurement because the response rate was very low, despite the recurrent contacts and reminders.

2.4. Treatment and Waitlist Conditions

Children and their parents who met the inclusion criteria participated in therapy. Treatment groups were led by the first author, a clinically experienced psychologist who was also accredited by EABCT. The therapist also attended an accredited two-day Cool Kids training course. Treatments were conducted in groups of 5–9 children, in ten, two-hour, mostly weekly, sessions according to the original protocol.

Children and their families allocated to the waitlist condition were a non-active group that received no intervention.

Treatment Condition—Description of the Cool Kids Program

Cool Kids is a structured CBT program designed for children from 7 to 17 years old that aims to teach them how to manage their anxiety. It is theoretically grounded in the cognitive-behavioral approach. Cool Kids is derived from the Coping Koala program [39], which was a modified version of Coping Cat [40]. Standard treatment with Cool Kids consists of ten sessions and includes the below core components:

(a) Psychoeducation for anxiety and its principal components. Children learn to recognize and rate their feelings.
(b) Thought recognition and realistic thinking. Children learn to identify their anxious and unhelpful thoughts and evaluate them realistically based on available evidence.
(c) Parent training. Parents learn how to interact with their anxious child in positive ways, manage anxious responding, and differentiate anxious from oppositional behavior.

(d) Gradual exposure to threat cues. Children and their parents design gradual stepladders to help them face cues that elicit threat expectations and, through repeated practice, build non-threat associations.

(e) Coping skills such as assertiveness training, building confidence, and problem solving.

### 2.5. Statistical Procedures

The statistical software SPSS-19 was used for data analysis. Two-way repeated-measures ANOVA was used to compare the mean differences between the two groups, over two time points, across the examined variables. One-way repeated-measures ANOVA was used to compare the scores over pre–post and 6-month follow-up measurements for the CBT group. Computation of effect sizes was used to detect the strength of the observed differences. The Reliable Change Index (RCI) [41] was estimated to evaluate whether the observed changes over time were clinically meaningful.

### 3. Results

#### 3.1. Pretreatment Ratings and Comparisons

Means and standard deviations from children’s and parents’ reports on the two conditions (CBT, WL) in all scales and subscales are presented in Table 1. ASEBA scales were administered only to parents in the CBT group.

| Table 1. Demographic and clinical reports/diagnostic characteristics. |
|----------------------------------------------------------|
| **Children**                                              |
| CBT (n = 21)     | Waitlist (n = 20) | CBT (n = 21) | Waitlist (n = 20) |
| Males:          |
| 8              | 10             | 2            | 2              |
| Females:        |
| 13             | 10             | 18           | 16             |
| Both parents:   |
| 3              | 7              | 3            | 2              |
| 4th Grade:      |
| 3              | 7              | 18           | 16             |
| 5th Grade:      |
| 12             | 4              | 18           | 16             |
| 6th Grade:      |
| 6              | 9              | 2            | 2              |
| Age of father:  |
| M (SD) 45.21 (4.93) | M (SD) 45.94 (5.90) |
| Age of mother:  |
| M (SD) 41.29 (3.72) | M (SD) 40.76 (5.09) |
| SA:            |
| 7.38 (3.49) | 9.40 (4.47) | 6.38 (4.18) | 5.90 (4.60) |
| SP:            |
| 9.90 (3.36) | 10.25 (3.44) | 7.23 (3.43) | 6.80 (4.27) |
| OC:            |
| 8.48 (3.39) | 10.45 (4.02) | 3.43 (2.84) | 2.90 (2.53) |
| PD:            |
| 8.00 (4.53) | 9.25 (5.27) | 3.81 (3.57) | 3.35 (4.11) |
| PIF:           |
| 7.67 (2.80) | 6.70 (3.26) | 6.57 (3.52) | 5.10 (2.43) |
| GAD:           |
| 8.61 (2.98) | 9.10 (3.12) | 6.43 (3.14) | 5.45 (3.17) |
| SCAS_total:    |
| 50.05 (11.91) | 55.15 (15.26) | 33.86 (15.7) | 29.50 (15.96) |
| STAIC-T:       |
| 39.00 (6.63) | 37.95 (6.57) | 37.95 (6.57) | 37.95 (6.57) |
| CALIS-P, parents: |
| –              | –              | 9.10 (7.02) | 6.94 (7.78) |
| CALIS-P, children: |
| –              | –              | 13.38 (9.25) | 8.95 (7.98) |
| Internal ASEBA:                                      |
| 11.86 (5.64) | 16.80 (10.08) | 22.48 (15.39) | 14.94 (13.95) |
| External ASEBA:                                     |
| 9.10 (6.55)  | 11.05 (7.15)  | 11.05 (7.15) | 11.05 (7.15) |
| Anxiety/Depression:                                |
| 8.71 (4.14) | 6.94 (7.78) | 6.94 (7.78) | 6.94 (7.78) |

| **Parents**                                            |
|----------------------------------------------------------|
| CBT (n = 21)     | Waitlist (n = 20) | CBT (n = 21) | Waitlist (n = 20) |
| Males:          |
| 8              | 10             | 2            | 2              |
| Females:        |
| 13             | 10             | 18           | 16             |
| Both parents:   |
| 3              | 7              | 3            | 2              |
| M (SD)          |
| 9.40 (4.47) | 6.38 (4.18) | 5.90 (4.60) | 5.90 (4.60) |
| 10.25 (3.44) | 7.23 (3.43) | 6.80 (4.27) | 6.80 (4.27) |
| 10.45 (4.02) | 3.43 (2.84) | 2.90 (2.53) | 2.90 (2.53) |
| 9.25 (5.27) | 3.81 (3.57) | 3.35 (4.11) | 3.35 (4.11) |
| 6.70 (3.26) | 6.57 (3.52) | 5.10 (2.43) | 5.10 (2.43) |
| 9.10 (3.12) | 6.43 (3.14) | 5.45 (3.17) | 5.45 (3.17) |
| 55.15 (15.26) | 33.86 (15.7) | 29.50 (15.96) | 25.90 (15.86) |
| 39.00 (6.63) | 37.95 (6.57) | 37.95 (6.57) | 37.95 (6.57) |
| 9.10 (7.02) | 6.94 (7.78) | 6.94 (7.78) | 6.94 (7.78) |
| 13.38 (9.25) | 8.95 (7.98) | 8.95 (7.98) | 8.95 (7.98) |
| 11.86 (5.64) | 16.80 (10.08) | 22.48 (15.39) | 14.94 (13.95) |
| 9.10 (6.55)  | 11.05 (7.15)  | 11.05 (7.15) | 11.05 (7.15) |
| 8.71 (4.14) | 6.94 (7.78) | 6.94 (7.78) | 6.94 (7.78) |

M: mean; SD: standard deviation; SA: separation anxiety; SP: social phobia; OC: obsessive-compulsive; PD: panic disorder; PIF: physical injury fears; GAD: generalized anxiety disorder; SCAS-C, total: Spence Children’s Anxiety Scale-Child version; STAIC-T: trait anxiety; CALIS-P, parents: Child Anxiety Life Interference Scale on parents’ life; CALIS-P, child: Child Anxiety Life Interference Scale on child’s life; CALIS-P, total: Child Anxiety Life Interference Scale reported by parents.

#### 3.2. Children

The results of the two-way repeated-measures ANOVA revealed a significant main effect of time and also a significant main effect of group on children’s self-reports on the SCAS (F(1,38) = 26.16, p = 0.00, ηp2 = 0.41, and F(1,38) = 17.65, p = 0.00, ηp2 = 0.32). A significant group-by-time interaction was also detected (F(1,38) = 9.61, p = 0.00, ηp2 = 0.20).
Partial eta squared indicated large effects. Pairwise comparisons using a Bonferroni correction showed a significant main mean difference from baseline to post-treatment for the CBT group (Mean Difference = 23.62, Std Error = 3.97, \( p = 0.00 \)). Comparisons for the WL group were non-significant (Mean Difference = 5.79, Std Error = 4.17, \( p = 0.17 \)).

On the self-report measure of children’s trait anxiety (STAIC-T), there were significant main effects of time and group, as well as a significant interaction (\( F(1,37) = 16.08, p = 0.00, \eta^2_p = 0.30; F(1,37) = 10.67, p = 0.00, \eta^2_p = 0.22, \) and \( F(1,37) = 7.97, p = 0.00, \eta^2_p = 18 \)). Pairwise comparisons showed a significant mean difference from pre- to post-treatment for the CBT group but not the WL (CBT: Mean Difference = 10.00, Std Error = 2.04, \( p = 0.00 \); WL: Mean Difference = 1.74, Std Error = 2.10, \( p = 0.41 \)).

Concerning the child’s report of anxiety’s interference in the child’s life (CALIS), ANOVA yielded significant main effects of time and group but a non-significant interaction (\( F(1,38) = 18.70, p = 0.00, \eta^2_p = 0.33; F(1,38) = 9.52, p = 0.00, \eta^2_p = 0.20 \) for the main effects, and \( F(1,38) = 0.29, p = 0.60, \eta^2_p = 0.01 \) for the interaction). Descriptive data are presented in Table 2.

### Table 2. Pre- and post-measures for CBT and WL groups for children and parents.

| Pre-Measures in Children | Post-Measures in Children |
|--------------------------|---------------------------|
|                         | CBT Group | Waitlist Group | CBT Group | Waitlist Group |
| SCAS_total               | M (SD)    | M (SD)         | M (SD)    | M (SD)         |
| 50.05 (11.91)            | 56.15 (14.98) | 26.42 (13.28) | 50.36 (17.57) |
| STAIC-T                  | 38.90 (6.78) | 37.73 (6.68) | 48.90 (6.49) | 39.47 (7.31) |
| CALIS_total              | 11.86 (5.62) | 17.26 (10.13) | 5.42 (4.34) | 12.26 (8.97) |

| Pre-Measures in Parents | Post-Measures in Parents |
|-------------------------|--------------------------|
|                         | CBT Group | Waitlist Group | CBT Group | Waitlist Group |
| SCAS-P_total            | M (SD)    | M (SD)         | M (SD)    | M (SD)         |
| 33.85 (15.70)           | 30.63 (15.55) | 20.90 (9.67) | 31.00 (14.07) |
| CALIS-P_parents’ life   | 9.37 (7.11) | 8.13 (8.00) | 4.84 (4.69) | 8.73 (7.37) |
| CALIS-P_child’s life    | 13.11 (9.57) | 9.00 (7.93) | 5.78 (4.44) | 8.93 (8.00) |
| CALIS-P_total           | 22.44 (15.98) | 15.15 (14.14) | 10.05 (8.15) | 17.92 (11.94) |

M: mean, SD: standard deviation, SCAS-C_total: Spence Children’s Anxiety Scale-Child version, STAIC-T: trait anxiety, CALIS_total: Child Anxiety Life Interference Scale, SCAS-P_total: Spence Children’s Anxiety Scale-Parent version, CALIS-P_parent: Child Anxiety Life Interference Scale on parents’ life, CALIS-P_child: Child Anxiety Life Interference Scale on child’s life, CALIS-P_total: Child Anxiety Life Interference Scale reported by parents.

One-way repeated-measures ANOVA was conducted to investigate change over three time points (pre–post and 6-month follow-up) for the CBT group across all the variables. In all analyses, the main effect of time was significant with notable decreases in anxiety symptoms and life interference, as indicated by lower scores in SCAS, STAIC, and CALIS (\( F(2,32) = 39.32, p = 0.00, \eta^2_p = 0.711; F(2,30) = 16.45, p = 0.00, \eta^2_p = 0.52, \) and \( F(2,32) = 18.36, p = 0.00, \eta^2_p = 0.53 \)). Statistically significant differences were detected between pre- and post-measures and pre- and 6-month follow-up for all the examined variables. Comparing post- with follow-up measures, although there was a stable decrease, the differences were non-significant (Mean Difference = 6.65, Std Error = 2.56, \( p = 0.06 \) for SCAS, Mean Difference = 2.25, Std Error = 2.03, \( p = 0.85 \) for STAIC, and Mean Difference = 1.59, Std Error = 0.94, \( p = 0.33 \) for CALIS). Descriptive data are presented in Table 3.
Table 3. Descriptive statistics for pre–post and 6-month FU for CBT groups for children.

|                    | Pre-Measures | Post-Measures | 6-Month FU |
|--------------------|--------------|---------------|------------|
|                    | M (SD)       | M (SD)        | M (SD)     |
| SCAS_total         | 50.76 (12.80)| 24.41 (11.51) | 17.76 (7.74)|
| STAIC-T            | 39.18 (7.04) | 49.25 (6.66)  | 51.50 (4.56)|
| CALIS_total        | 11.65 (5.60) | 4.88 (3.80)   | 3.29 (2.34)|

M: mean, SD: standard deviation, SCAS-C_total: Spence Children’s Anxiety Scale-Child version, STAIC-T: trait anxiety, CALIS_total: Child Anxiety Life Interference Scale.

3.3. Parents

According to parents’ reports of the child’s anxiety (SCAS-P), the results of the two-way repeated-measures ANOVA revealed a significant main effect of time and a significant group-by-time interaction (time: F(1,38) = 8.70, p = 0.00, η_p^2 = 0.19; group: F(1,38) = 0.80, p = 0.38, η_p^2 = 0.02, and interaction: F(1,38) = 9.75, p = 0.00, η_p^2 = 0.20). Pairwise comparisons with a Bonferroni correction showed a significant mean difference (pre–post) for the CBT group from pre- to post-treatment, but not for WL (CBT: Mean Difference = 12.95, Std Error = 2.94, p = 0.00; WL: Mean Difference = 0.37, Std Error = 3.09, p = 0.91).

Concerning anxiety’s interference in daily life (CALIS-P_TOTAL), the results revealed a significant main effect of time and significant interaction between group and time (F(1,29) = 4.85, p = 0.03, η_p^2 = 0.14, and F(1,29) = 12.04, p = 0.00, η_p^2 = 0.29, respectively) but a non-significant main effect of group (F(1,29) = 0.00, p = 0.95, η_p^2 = 0.00). Pairwise comparisons with a Bonferroni correction showed a significant mean difference between pre- and post-treatment measures only for the CBT group (CBT: Mean Difference = 12.39, Std Error = 2.83, p = 0.00; WL: Mean Difference = 2.78, Std Error = 3.33, p = 0.41). Interference of the child’s anxiety in the parents’ life showed non-significant main effects of time (F(1,32) = 2.52, p = 0.12, η_p^2 = 0.07 for time, and F(1,32) = 0.44 p = 0.51, η_p^2 = 0.01 for group) but a statistically significant group-by-time interaction (F(1,32) = 4.29, p = 0.04, η_p^2 = 0.12). Pairwise comparisons showed a significant mean difference from pre- to post-treatment for the CBT group but not the WL (CBT: Mean Difference = 4.53, Std Error = 1.65, p = 0.01; WL: Mean Difference = 0.60, Std Error = 1.85, p = 0.75). Concerning interference of anxiety in child’s life results indicated main effects of time (F(1,31) = 5.47, p = 0.03, η_p^2 = 0.15) but not for group (F(1,31) = 0.05, p = 0.88, η_p^2 = 0.00) and a significant interaction (F(1,31) = 5.27, p = 0.30, η_p^2 = 0.16). Pairwise comparison yielded a significant mean difference from pre- to post-treatment for the CBT group but not the WL (CBT: Mean Difference = 7.33, Std Error = 2.13, p = 0.00; WL: Mean Difference = 0.07, Std Error = 2.34, p = 0.10). Descriptive data are presented in Table 2.

3.4. Treatment Success and Failure

The above treatment outcomes are based on the statistical comparisons between pre- and post-treatment measurements. However, statistical comparisons are not always indicative of a meaningful change in psychotherapy. Therefore, we focused on what constitutes treatment success.

The Reliable Change Index (RCI) was calculated to estimate the clinical significance of the change over time [41]. The term “treatment success” in the present study was used for those who at post-treatment the SCAS total score presented an RCI less than −1.96. Therefore, when calculating the difference between pre-test and post-test divided by the standard error of difference for each individual of both groups, it was identified that 14 out of 21 (66.7%) children in the CBT group presented clinically significant change, compared against 6 out of 20 (31.6%) in the WL.

4. Discussion

The aim of the current study was to examine the efficacy of a manualized CBT group treatment for anxious children, Cool Kids, in a non-Anglo-Celtic population. Results showed significant decreases in symptoms of anxiety and life interference among a sam-
ple of Greek children aged 9 to 12 years. Positive results at the end of treatment were maintained up to six months following treatment.

Large and significant reductions in the children’s symptoms of anxiety were reported by both the child and parent. According to the children, these reductions remained at least six months following intervention. These results among Greek children are consistent with findings from prior studies of the Cool Kids program in other countries [15,17,18,20,23–26,28] and with findings from several reviews and meta-analyses that support the efficacy of CBT [7,10,11,15]. They are also in congruence with other studies that support the efficacy of the program in a non-clinical setting [26], reinforcing the transportability of CBT to the community, even the slight outperformance of the clinical setting. Moreover, the current study adds to growing evidence for the cross-cultural effectiveness of the Cool Kids program compared with the waitlist [23–27]. The improvement reported by parents indicates that parents are in a position to identify, acknowledge, and report improvements in their child’s anxiety that are evident after a CBT program. It is well known that assessment of anxiety in children is rather controversial and complicated and also that children tend to report more frequent anxiety symptoms than their parents [42,43]. By using multiple respondents, the current finding represents a more detailed and accurate investigation of the treatment effect of the Cool Kids program [18,23].

Children and parents in our study reported significant anxiety life interference. This is in line with other studies, supporting that anxiety interferes in many areas of a child’s daily routine [5,44]. At post-treatment, children of both groups reported a significant reduction in life interference. Unexpectedly, the reported reduction was similar for both groups, so it cannot be attributed to treatment. On the other hand, parents in the CBT group presented significantly lower anxiety impact. Concerning children’s reports, descriptive data showed that children in the WL group presented unusually high interference at baseline, which noted a significant reduction at post-measures. This finding disproves the initial hypothesis and also contradicts the findings of other intervention studies, where a significant reduction in life interference was associated with improvement of a child’s anxiety after successful treatment [23,26,35]. Even if there is no clear explanation for this finding, it may be attributed to age effects and the inconsistency of young children’s reports. Although there are studies that did not support age differences [35], some others showed that age was associated with interference in different areas of life. For example, older youth experienced higher interference in social life compared to younger youth that reported greater interference in family and school life [38]. We also speculate that another reason for the null finding may be that families in WL were informed that their child presented elevated anxiety. This may result in more supportive parenting, which is beneficial in the early course of anxiety [45]. Overall, this finding remains puzzling, and issues such as cultural interpretations of impairment and family relationships, as well as consistency of young children reports, need further investigation.

The post-treatment reduction in interference reported by parents of the CBT group replicates findings from other studies [23,24,26] and confirms that treatment addressing anxiety may positively contribute to a significant improvement in the whole family’s daily life, promising greater long-term gains [44]. Moreover, it seems that parents in Greece can detect how their child functions and are in a good position to notice changes and improvements, indicating that CALIS (child and parent versions) seems to have sufficient sensitivity to treatment change according to parents’ reports [35]. The areas that showed lower impact at post-treatment were parent relationship, friends outside school, schoolwork, sports participation, and daily activities concerning the child’s life. In relation to a parent’s life partner relationship, career, activities without the child, and parental stress presented significantly lower impact. Prior studies supported that anxiety-related symptoms interfere with functioning across various areas [2,46–48].

Interference of childhood anxiety in the family’s daily life is a very important issue because it significantly increases the likelihood that a parent will perceive a problem
and seek professional help [49–52]. Interference also may affect treatment choices and efficacy [53].

Concerning treatment success, two out of three children (66.7%) in the CBT group had a positive response in treatment. After treatment, their anxiety levels were lower than two standard deviations from the initial mean score. The corresponding percentage for the children of the waitlist group was 31.6%. Such a result is in line with other studies, supporting that the percentage of children who attended a CBT program is much greater than the percentage of children in the WL group [54,55]. We should note that our percent should not be confused with the percentage of remission rates reported in other studies because we examined only clinically elevated symptoms of anxiety. However, the RCI confirms a significant reduction in anxiety symptoms, supporting a reliable improvement.

A major limitation of the present study was that children in our study were assessed only for elevated anxiety symptoms and formal diagnoses were not made. As a result, some children in the study may have met the criteria for a formal anxiety disorder, but others might have been sub-clinical. Interestingly, in the current sample, only one of the children had previously been referred for assessment and management of their anxiety. This is not an unexpected finding, as data have shown that only a small minority of young people with anxiety disorders in the community ever seek help for their disorder [56]. Consistent with this result, a previous study that selected young people high on anxious symptoms from a school population found that only 2% had previously received professional help [57]. Nonetheless, it is possible that the small proportion of children in the current sample who had received prior help indicates the sub-clinical nature of the sample. The limitation, therefore, is that it is not clear whether the current results would generalize to a clinical population.

The small sample is another limitation of the current study. Demonstrated effects of the treatment were large and, therefore, the current sample was sufficient to detect these effects. However, future replication with a larger sample would be of value. Finally, the use of a waitlist control, rather than an active control condition, limits the strength of the conclusions that can be drawn. Replication of these results with a comparison condition that controls not only the passage of time but also for non-specific therapeutic factors would allow far stronger conclusions about the active components of treatment.

Despite these limitations, the main strength of the study is that this is the first clinical trial for treatment of child anxiety conducted in Greece. Use of Anglo-centric treatment programs is widespread and often implemented without empirical evidence supporting their use across diverse cultures. The Cool Kids program has now been shown to successfully reduce anxiety in Scandinavian countries [23,25,28] and Turkey [27]. The current result extends evidence for its cross-cultural relevance to a different European ethnic group. Hence, the results contribute to evidence for the cultural generalizability of treatments for child anxiety.

Despite the limitations of our research design, our study adds to and extends existing evidence for the Cool Kids program as an efficacious treatment for childhood anxiety [16,17,23]. As the above results are based on a small sample, it would be desirable to replicate our findings in a larger sample. Finally, considering that we know little about the effectiveness of Cool Kids compared with other active treatments, future research projects should focus on this. Replicating these effects across a broader range of non-Western countries would also be of benefit.

5. Conclusions

In summary, the current study demonstrates that a ten-session cognitive-behavioral group treatment program can be effective in the management of distressing anxiety symptoms in children. Furthermore, these treatment gains are maintained for six months after an effective intervention.
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