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Effectiveness of Group-Based Acceptance and Commitment Therapy in a School Setting for Children with Anxiety: A Quasi-Randomized Study

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Abstract

Background: The aim of the ProACTive in schools study was to investigate the effectiveness of an Acceptance and Commitment Therapy (ACT) group anxiety management program in a school setting in Sydney, Australia.

Methods: Following feasibility and acceptability study, the program was conducted and evaluated using quasi-randomization in 14 schools with group size ranging from 6-8 students with anxiety symptoms. There was no bias in allocation to groups, being pragmatic randomization in a "real-life" setting. Of the 98 students randomly allocated, 57 students comprised the treatment group and 41 the control group. There were 53 completer participants in the treatment group and 37 in a wait-list control group. Participants in the treatment group and their parents/guardian completed some standardized questionnaires (the Spence Child Anxiety Scale, the Child Anxiety Interference Scale) prior to, immediately after and 6 months after participating in the program. These questionnaires assessed students' level of anxiety and quality of life. Controls were assessed on the same measures on 2 occasions 10 weeks apart, prior to receiving the same program. Data were obtained for participants in the treatment group who also completed a clinical interview pre and post treatment using the Pediatric Anxiety Rating Scale (PARS), which is a composite score of child, parent and clinician anxiety ratings. Data for the 57 versus 41 were analyzed using the maximum likelihood estimation method.

Results: Results of the questionnaires demonstrated that the treatment group had significantly improved anxiety scores compared with controls on the Spence Child Anxiety Scale, and the Child Anxiety Life Interference Scale for child measures, but not for parent measures. The PARS scores showed significant reductions in anxiety symptoms from pre to post treatment. However, external validity is limited due to low sample size and lack of comparison group.

Conclusion: The findings support the utility of ProACTive treatment program for school children with anxiety.y.

Keywords: Acceptance and commitment therapy • Children • Adolescents • Schools • Anxiety • Effectiveness • Group therapy

Introduction

Childhood anxiety disorders are among the most common mental health conditions affecting children and young people [1,2]. Anxiety disorders have increased in prevalence over the past 20 years, with US data indicating an increase in diagnosis of an anxiety disorder from 5.5% in 2007 to 6.4% in 2011-2012, and 7.1% in 2015 [2]. Similar prevalence is reported in Australian data [1]. However, it is likely this data is an underestimate, for several reasons. Firstly, anxiety in children is often minimized by health professionals and parents, with misunderstanding of the difference between normal anxiety symptoms and abnormal anxiety manifestation [3]. Further, anxiety is often an internal process that may not be visible to others, especially health professionals who may only see the child once [3]. Anxiety in children also manifests in various ways, and can be misdiagnosed as ADHD, particularly if anxiety is leading to inattentiveness, distractibility, fidgetiness, and/or anger. Only 22% of adolescents who meet diagnostic criteria are diagnosed and treated by their primary care provider, which is particularly concerning given it is estimated that nearly one in three adolescents (31.9%) will meet criteria for an anxiety disorder by the age of 18 [4]. According to the 2015 Child Mind Mental Health

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Report, 80% of children with a diagnosable anxiety disorder are not receiving treatment [4].

The importance of children having accessible treatment is underscored even more with the current global COVID-10 pandemic against a background of growing climate change providing ripe conditions for a rise in anxiety disorders [5]. A narrative literature review by Fegert et al. [6] recently reported on the challenges and burden of COVID-19 on the well-being of children and adolescents. Taken together, the data from the review indicates alarming threats to mental health of children and adolescents. The consequences of anxiety in childhood include academic and social difficulties as well as substance abuse, and are often enduring if untreated, and predictive of depression [7-9]. It is the most common reason for school refusal [10]. On the positive side, there is evidence for effective psychological treatments for anxiety in children, though most have focused on Cognitive Behavioral Therapy (CBT) [11].

Acceptance and Commitment Therapy (ACT) is growing exponentially in its evidence for the treatment of anxiety disorders [12]. ACT is a therapeutic model founded on a theoretical framework called relational frame theory [13]. It is evidence based and is part of the "third wave" of behavioral and cognitive therapies [14]. This third wave involves a modified form of cognitive behavioral therapy, with ACT integrating processes of mindfulness and acceptance [14]. Although both ACT and CBT focus on thoughts, feelings and behavior, ACT does not attempt to alter the content, frequency or form of thoughts, but rather one's relationship with thoughts [14]. Instead of focusing on controlling thoughts, feelings and sensations, and symptom reduction, it focuses on enhancing quality of life (which as a side effect often results in symptom reduction).

ACT's primary aim is to increase a person's psychological flexibility (the ability to be fully in the present moment and to engage or persist in behavior that reflects our values) in order to live valued meaningful lives [14]. To do this, six core therapeutic processes organized in a 'hexaflex' model are

employed, including 'acceptance,' 'defusion' (distancing or unhooking from difficult thoughts, feelings or sensations) 'values,'(knowing what matters) 'committed action,' (taking action to do and be what matters)'the present moment'(mindfulness) and 'self-as-context' (observing self) [14]. These processes are interrelated and support each other in increasing psychological flexibility [14]. ACT is a highly interactive therapy, using imagery, metaphors, and short experiential exercises including mindfulness. Focusing on values provides an over-arching framework to guide the intervention.

Despite the rapid growth of Acceptance and Commitment Therapy (ACT) in its evidence base for treating a variety of psychological disorders, it is in an early stage of research in children. It is possible some of the reluctance to focus on children was due to the perception that children may find it difficult to relate to concepts and language in the ACT model (e.g. values and self as context). On the other hand, the use of metaphors and experiential approaches in ACT may be particularly suited to children, as they have less preconceived notions, think less literally than adults and may readily grasp abstract concepts through experience [15]. The past few years has seen a growth in both adaptations of ACT programs for children, and the number of studies in children investigating the effectiveness of ACT for a variety of childhood problems [16]. However, the majority are pilot or case studies, reflective of the newness of this research.

A systematic review of the application of ACT with children and young people published by Swain et al. [17] identified 202 empirical papers in the literature. Although there were several limitations identified in most studies, 21 met their inclusion criteria for further analysis. The overall findings were highly encouraging, particularly for depressive symptoms, tic-related disorders, high-risk sexualized behavior, and stress for young people. This review found that the published literature specific to evaluating ACT for anxiety in children entailed only three studies totaling 11 participants. All had limitations of non-random treatment assignment, an absence of control or alternative treatment comparisons and lacking generalizability.

A more recent meta-analysis conducted by Fang and Ding [16] focused on Randomized Controlled Trials (RCTs) from 2009-2018 evaluating the efficacy of ACT for childhood problems (predominantly anxiety and depression). The review examined 14 RCTS on ACT for children (totaling 1186 children). The review found that ACT had a significant effect on reducing children's' symptoms including depression, anxiety and behavioral problems. It outperformed conventional therapy except for traditional CBT. There was no difference between ACT and treatment as usual or traditional CBT in terms of quality of life and well-being of children, but ACT outperformed the untreated group. It is not surprising that ACT did not outperform CBT given the large sample sizes that would be needed to detect the small effect size differences likely when comparing ACT and CBT.

Included in Fang and Ding's [16] review was the world's first and largest RCT to date evaluating ACT for children with anxiety disorders, led by the first author of the current study [18,19]. In developing ProACTive [20], Hancock et al. incorporated all six processes of the ACT model, making them accessible to children. The study found ProACTive to be a highly effective treatment, being far superior to the wait list control group and to have similar outcomes to the gold standard CBT group. This study provides support for ACT being an empirically supported treatment option for children and young people with anxiety disorders.

Regarding the evaluation of mental health programs in school settings, several studies have been conducted, though most are preventative and most are CBT-based [21]. Two RCTs examined the effectiveness of "Cool Kids"[®], a child anxiety CBT program, administered as a school-based, early intervention program [22,23]. Mifsud and Rapee [22] demonstrated a significant reduction in anxiety symptoms relative to a wait-list control group in children from an economically disadvantaged area (n=91, 8-11 years). The McCloone et al study (n=152, 7-12 years) [23] failed to find group differences on child-and teacher-reported child anxiety symptoms. More recently an adolescent CBT program "Chilled" (originally developed by Hudson et al. [24] was evaluated using an RCT in a school setting of 313 adolescents comparing brief and longer versions [25]. Results were favorable for both, including significantly

reduced anxiety, life interference and depressive mood symptoms.

Turning to ACT in school settings, there have been four ACT studies of effectiveness, with only one published [26]. The non-published studies were either preventative or for children without a mental health diagnosis-for example youth at risk, aggression, and prevention of stress. Livheim et al. [26] conducted a pilot study on adolescents with problems with depressive and stress symptoms and found positive results with the ACT program. However, there were many methodological problems with this study, including small sample size, limiting generalizability. In summary, there is some evidence to support further investigation using ACT with young people in schools, however none have focused on children specifically with anxiety and are of low scientific quality.

Following its initial successful implementation and evaluation in a hospital clinic setting [18,19] the current study adapted ProACTive to application in schools. It is vital that clinical research be further translated to real life settings to determine whether findings are generalizable. Schools are a real life setting that requires treatments to be flexible and responsive to context specific factors (e.g. changes to timetabling). In addition, parents are not easily available in schools to be included in the treatment of their child's anxiety disorder in contrast with what routinely occurs in clinical practice. However, the assumption of routinely including parents is grounded in the belief that parents' involvement in their children's treatment is beneficial for therapy, but evidence for the extent of that role is lacking [27]. In Hancock et al. [18] study, parents attended all treatment sessions, but this is not possible within the current study. This study has the potential to fill a gap in treatment, enabling a group of children and their families to receive a treatment that may not pragmatically be able to otherwise access. In addition to providing easy access to treatment, school programs provide a path to more specialized services and community care, and reduction of stigma associated with treatment. The significance is underscored even more in our current COVID-19-situation, considering associated mental health risks will disproportionately hit children and adolescents who are already disadvantaged and marginalized, particularly economically [7].

A pilot investigation of the feasibility and effectiveness of a school-delivered group ProACTive program was recently completed and found to be feasible and acceptable, with 16 students piloting the program and showing positive results [28]. Following feasibility testing, some minor adjustments were made to the program, including shortening/simplifying some activities, increasing the detail in parent correspondence *via* notes, and recording webinars for parents to view at any time as an alternative to attending parent information sessions live twice in the program. Further detail on the adjustments can be found in Hancock et al. [29].

Objective of the study: The objective of this study was to determine whether ACT might be another empirically supported treatment option in a school setting for anxious children. To achieve this aim, a quasi-randomized design was used comparing group-based ACT (ProACTive) to a Wait List Control (WLC) group in terms of and quality of life improvement anxiety symptom reduction. Inclusion of the control group was used to assess the success of ProACTive at reducing the level of anxiety in children and adolescents. It is possible that the passage of time or maturation may improve symptoms, so it is necessary to compare the role of the treatment program in influencing outcomes over time. It was hypothesized that ProACTive would be superior to WLC in outcomes.

Methodology

Study design

Figure 1 shows the CONSORT flow diagram of the study outlining the progress of the phases (enrolment, intervention allocation, follow-up, and data analysis).

This is a quasi RCT (i.e. using a method of allocation that is not truly random) with 14 groups of 6-8 students (7-18 years) with anxiety symptoms allocated to a school-based ACT intervention (ProACTive) and a delayed

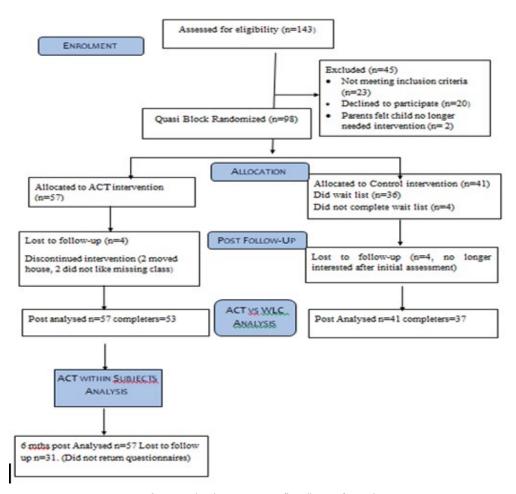


Figure 1. Showing CONSORT flow diagram for study.

access control condition. Participants allocated to the ProACTive intervention started after a group had been assembled and randomized (randomization procedure explained below). The waitlist group was randomized in groups and received the same treatment program 10 weeks post initial assessment. Based on previous research, ProACTive is expected to be efficacious [18], therefore, we considered it unethical to withhold the intervention for the waitlist group for an extended period. A within subjects analysis was conducted for the treatment group from post to 6 months post. Controls were not assessed on the 3rd occasion since they had received treatment by then. However, case study data is reported for a subset of the controls who desired post-treatment assessment, reported using an ABA design.

The study also adopted an adaptive trial design, whereby modifications could be made during its conduct with the purpose of increasing the probability of success of the study procedure or the intervention. This is a reasonable approach given ACT is at such an early stage of investigation in children at schools, and this study was interested in determining if the program was adaptable to the school context.

Although an RCT was planned, the design was adapted to a quasi RCT due to logistical issues in implementing the program, discussed below.

Study site

This is a single-center design, with 10 schools within the Sydney schools' site. There were 16 groups in total for the study and the first two being analyzed as part of the pilot study [28]. Hence 14 groups from 10 schools were analyzed for this study, enabling a comparison of whether the program generalizes across different school settings, but not across sociodemographic areas.

Randomization procedure

Initially the groups were randomized with a computer-generated list of random numbers to allocate school as the unit of randomization using "Graph

pad" [29]. However, pragmatic difficulties occurred as discussed below, with two schools not being able to facilitate the groups within the timeline of group allocated. For the four schools that had high referral numbers and more than one group, participants were block randomized to one of two groups (ProACTive treatment versus wait list control). A computer-generated series of random numbers was used to allocate participants to treatment condition, generated using block randomization with variable block sizes. Blocks were generated by using a permuted block design (using a sequence of blocks to achieve balance in design in which each block contains a prespecified number of treatment assignments in random order) using Graph pad. A member of the research team not involved in treatment carried out the block randomization procedure. Participants were allocated according to their order in the list of names, which were ordered according to the timeframe of providing consent. Participants were assessed by researchers masked to the treatment condition with both parties informed of group allocation after assessment.

As discussed, six of the ten schools had capacity for conducting one group in the timing of the study, with four running between two and three groups. It was not always possible to organize assessments and group commencement time in line with random allocation. This was due to group facilitators only being available to facilitate at certain times, or the school term having conflicting activities or timetabling that impeded assessments. Also, it was not possible to achieve the timing required for the WLC group for two schools that were only able to conduct one group. For ethical reasons we did not wish to withhold treatment so they were allocated to treatment rather than wait listed. However, there was no bias in allocating students or schools to groups. As well, the study ended sooner than anticipated as some research staff were no longer available to work on the project (due to resources, illness or school transfer). The final groups planned would have been WLC to equalize numbers but this did not eventuate.

Power analysis

Power analysis for a repeated measures ANOVA with 2 groups was conducted in G'Power [30] to determine a sufficient sample size using an alpha of 0.05, a power of 0.80, and a medium effect size (f=0.25). Based on the aforementioned assumptions, the desired sample size is 82. Our sample of 98 would was powered to allow a medium but not small effect size.

Participants

There were 98 participants initially enrolled, allocated and assessed but who did not complete treatment/post assessment (57 ProACTive, 41 WLC), with 90 completing the program (53 ProACTive, 37 WLC). Groups were stratified by age (primary versus high school) but only two high school groups were conducted during the trial (one in each group) due to less demand. Initial age comparisons indicated no differences in outcomes for age [primary versus high school, SPENCE child F(1,50)=0.04, p=0.84)]. There were no significant differences between the ProACTive and WLC groups in terms of demographic factors (age t=1.78, df=98) and gender (x²=0.0051, p=0.94). All participants lived in the same socioeconomic area (moderately advantaged). Exclusion criteria were as follows: non-English speaker, complex mental health problems (e.g. psychotic symptoms, major depression primary disorder) disruptive behavior; or learning problems causing difficulties following a manualized group program, assessed by group leaders based on information from children, parents, and teachers. The Child Depression Inventory [30] was used to screen for depression, with severe symptoms including suicidal ideation being exclusion criteria (only the case for one child in this study).

Demographics

As seen in Table 1, the total group consisted of 55% females, and a mean age of 10.3 years (SD=1.6). Of the 57 ProACTive group children, 31 (54%) were female and 26 (46%) were male, with a mean age of 10.4 years (range 7-15 years, SD=1.7). Of the 41 control group children, 22 (54%) were female and 19 (46%) were male, with a mean age of 9.8 years (range 8-14 yrs, SD=2).

The schools were Catholic systemic Western Sydney schools, and classed as a moderate socioeconomic advantaged group using the "My SchoolTM" [31] Index of Community Socio-Educational Advantage as discussed in Hancock et al [28]. Children were eligible if they met criteria for anxiety according to the either the Spence Child Anxiety Scale (SCAS) (either total score or one sub scale of the SCAS), child or parent scores or the Pediatric Anxiety Rating Scale (PARS). Liberal inclusion criteria regarding anxiety symptoms was used to increase external validity of the study.

Four school counselors (also registered psychologists) nominated themselves to participate. They completed formal training in ProACTive and had an average of 5.3 years (range 3-9 years) experience as a school counsellor.

Ethics

Consent was sought from school counsellors, school principals, Catholic Education Office Diocese of Parramatta, and parents for all children involved. The study had ethics approval from the Human Research Ethics Committee at

the Children's Hospital at Westmead Human Ethics Committee.

Recruitment

As discussed in Hancock et al. [28] participants were recruited via school newsletters, school counsellors' caseloads and school noticeboards. If deemed eligible, the child was then offered a face to face assessment and parent a telephone assessment by a psychologist. If it was apparent at referral or following an assessment that the family would receive more suitable help elsewhere, the psychologists provided referral. Recruitment of the WLC group followed the same procedure as the ProACTive group.

Participants in the treatment group and their parents/guardian completed some standardized questionnaires (i) prior to (ii) immediately after and (iii) 6 months after participating in the program. These questionnaires took approximately 20-30 minutes to complete and assess students' level of anxiety, depressive mood symptoms and quality of life.

Some participants completed a clinical interview as well, with results presented below.

Outcome measures

The outcome measures are described briefly below. Further detail can be found in the feasibility study [27].

Primary: The Spence Children's Anxiety Scale (SCAS) was used to assess child-and parent-reported anxiety symptoms [32]. This 38 item measure (score 0-114) has good reliability and validity [31].

Secondary: The Child Anxiety Life Interference Scale (CALIS) [32]. The CALIS is a self-report measure that assesses life interference across school, family, peers/friendships, and physical health. It has demonstrated good reliability and validity, with further details in Hancock et al. [28].

The Pediatric Anxiety Rating Scale (PARS) [33] is a clinician-administered instrument that assesses the frequency, severity, and impairment of common pediatric anxiety disorders with well-established validity and reliability [34]. It is used to rate the severity of anxiety in children and adolescents, ages 6 to 17 years. Further information on the validity and reliability of this scale is discussed in Hancock et al [28]. Unfortunately, the use of the PARS ceased halfway through the study because the interview was too burdensome for participants. As well we had reduced staff members during the study and resources were unavailable to replace them, so there was only adequate resource allocation for participants to compete the questionnaires. Also, if ProACTive in schools were to be used beyond this study, outcome measures that school counsellors could use that did not add unnecessary time burden was an important consideration [35]. Given this study was about the applicability of ProACTive in schools, we needed outcome measures that were feasible. Thus data is presented in this study for 35 ProACTive group participants pre and 19 post-treatment (Figure 2).

Treatment integrity

ProACTive group (n=57)	Wait list control group (n=41)	Total group	
31 (54%)	22 (54%)	54 (55%)	
x =10.4 (SD 1.7)	x =9.8 (SD 1.2)	x =10.3 (SD=1.6	
50 (88%)	36 (88%)	86 (88%)	
Ethnicity(n)			
38 (67%)	29 (70%)	67 (68%)	
13 (22%)	11 (27%)	24 (24%)	
3 (5%)	0	3 (3%)	
2 (4%)	1 (2%)	3 (3%)	
1 (2%)	0	1 (1%)	
57 (100%)	41 (100%)	98 (100%)	
	$31 (54\%)$ $\overline{x} = 10.4 (SD 1.7)$ 50 (88%) Ethnicity(n) 38 (67%) 13 (22%) 3 (5%) 2 (4%) 1 (2%)	$31 (54\%)$ $22 (54\%)$ $\overline{x} = 10.4 (SD 1.7)$ $\overline{x} = 9.8 (SD 1.2)$ $50 (88\%)$ $36 (88\%)$ Ethnicity(n) $29 (70\%)$ $13 (22\%)$ $11 (27\%)$ $3 (5\%)$ 0 $2 (4\%)$ $1 (2\%)$ $1 (2\%)$ 0	

Table 1. Showing demographics of the treatment and control groups.

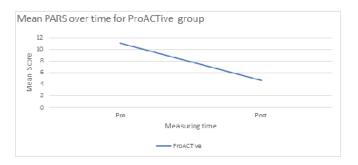


Figure 2. Showing mean PARS score from pre to post for ProACTive group (n=19).

A therapist adherence scale (available from the authors) was used as per our previous RCT [18]. A rater not involved in the therapy evaluated, on a session-by session basis, the extent to which therapy components described in the treatment manual were implemented effectively, based on guidelines and specific examples of objective observable descriptions of the therapist's demonstration of the skills. Adherence to the protocol (i.e., treatment-specific skills and activities) ratings were performed on 20 (10%) randomly selected video recording sessions (ensuring all ten sessions were rated at least once), on a scale ranging from 1 (ineffective) to 5 (extremely effective). Ratings of 4 (reasonably effective) or 5 were considered "within protocol." Overall, the therapists were found to adhere to the treatment protocol. The average adherence rating was 4.5 (range 4.2-5). Therapist competence scale scores were measured using a validated subscale of an ACT/CBT adherence and competence tool [36]. This scale investigated factors such as "knowledge of treatment," "skill in delivering treatment," "relationship with client," and "overall performance." At the end of each recording, mean ratings on scale items represented the therapist competence for that session, as per Hancock et al. [18]. Results indicated very good therapist competence, with an average of 4.6 (range 4-5) out of 5.

Data analysis

To determine whether the hypothesis that the ProACTive group would have improved outcomes over time compared with the WLC group, the maximum likelihood estimation (MLE) method was used [37]. The Wald test was used. Essentially, this test determines how many standard errors separate the null value and the maximum likelihood estimate [38]. It computes the estimate of the population parameter value that is the best fit to the observed data [37].

Missing data

Data were analyzed for participants with both pre-and posttreatment measures. For these analyses, there were at least 10 percent data missing for all outcome measures averaged over pre, post and 6 months post. Analyses were repeated using available data and multiple imputation procedures (MIP) for addressing missing data due to attrition. Results were similar. Data are presented for the 98 participants, with missing data post treatment handled using MIP.

As discussed above, considerable data was missing for the PARS due to the decision to cease using this measure half-way through the study. There was not enough data for between group comparisons, so t-tests were performed for the ProACTive group available data pre to post.

Results

Figures 2-5 show mean scores over time, with Table 2 showing means and standard deviations for each group over time.

Spence Child Anxiety Questionnaire (SCAS)

Child self-report: Analysis of Maximum Likelihood estimates was conducted comparing post-intervention scores between ProACTive groups and controls, adjusted for baseline score. Figure 3 shows a reduction in SCAS scores from pre to post treatment. There was strong evidence statistically that mean SCAS scores in children were lower in the ProACTive treatment group

than in controls (difference in means 8.4, 95% CI: 2.9-13.9, p<0.01). Mean post-treatment scores also decreased with baseline scores (0.80 per unit baseline score, 95% CI: 0.65-0.95, p<0.0001).

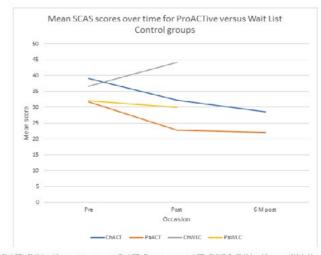
Analysis of within subjects changes over time indicate the ProACTive group maintained their improvements at the 6 month follow up with no evidence of difference in means from post to 6 months (difference in means -1.05 CI: -7.5-5.4, p=0.75=ns).

Parent report: Although Figure 4 shows a reduction in SCAS parent scores from pre to post treatment, there was statistically no evidence that mean Parent SCAS scores were lower in the ProACTive treatment group than in controls (difference in means 2.2, 95% CI: 0.35-4.8, p=0.09). Mean post-treatment scores decreased with baseline scores (1.00 per unit baseline score, 95% CI:0.9-1.1, p<0.0001).

Within subjects analysis of the ProACTive group up to 6 months time indicated no evidence of difference in means from post to the 6 month follow up (difference in means-1.6, 95%CI -6.1-2.9, p=0.5).

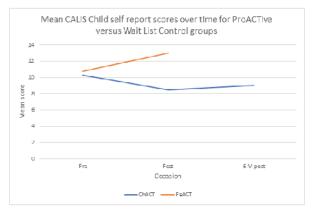
The Child Anxiety Life Interference Scale (CALIS)

Child report: Figure 4 shows a reduction in scores from pre to post CALIS scores. Analysis demonstrated evidence that mean CALIS scores in children were lower in the ProACTivegroup than in controls (difference in means 2.8, 95% CI: 0.005-5.69, p<.05). Mean post-treatment scores also decreased with baseline scores (0.74 per unit baseline score, 95%CI: 0.51-0.97, p<0.0001).



ChACT=Child self.report treatment. RaACT=Parent report ACT. ChWLC=Child self.report Walt list control. PalVLC=Parent report Walt list control

Figure 3. Showing mean SCAS scores over time for ProACTive versus wait list control groups.



ChACT-Child self report treatment, FraACT-Parent report ACT, ChWLC-Child self report Wait list control, FaWLC-Parent report Wait list control

Figure 4. Showing mean CALIS child self-report scores over time for ProACTive versus wait list control groups. Within subjects analysis of the ProACTive group up to 6 months time indicated no evidence of difference in means from post to the 6 month follow up (difference in means 0.49, 95%CI-3.4-4.4, p=0.8).

Parent report for child: Figure 5 shows CALIS parent for child scores over time. CALIS scores (parent perceived interference of anxiety in child's quality of life) did not support a difference in the ProACTtive treatment group versus controls (difference in means 0.2, 95% CI: 1.6-2.1 p=ns). Mean post-treatment scores decreased with baseline scores (0.87 per unit baseline score, 95%CI: .72-1.01, p<0.0001). Within subjects analysis of the ProACTive group up to 6 months time indicated no evidence of difference in means from post to the 6 month follow up (difference in means -1.3, 95%CI-3.5-0.9, p=0.25).

Parent report for self: Similar results were found for CALIS parent-forself-scores (Figure 6), with no evidence for a difference in the ProACTive treatment group versus controls (difference in means 0.3, 95% CI: -1.32-1.94 p=ns). Mean post-treatment scores decreased with baseline scores (0.91 per unit baseline score, 95%CI: .79-1.04, p<0.0001). Within subjects analysis of the ProACTive group up to 6 months' time indicated no evidence of difference in means from post to the 6 month follow up (difference in means 0.1, 95%CI--1.2-0.67, p=0.88).

The Pediatric Anxiety Rating Scale (PARS)

As there was only adequate data available to conduct inferential statistics for the ProACTive group for 35 participants and of those only 19 post-scores available, a paired t-test was performed to determine whether there were significant differences within the ProACTive group from pre to post treatment. PARS composite scores indicated a significant improvement from pre to post treatment (t=-3.77, p<0.001, df=18, mean pre 11.11 vs. post 4.74, n=19).

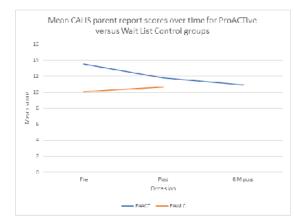
Discussion

This quasi RCT aimed to determine whether there was empirical evidence for a school-based targeted ACT program for children with anxiety symptoms. Anxiety symptoms and interference with life showed statistically significant

Table 2. Showing means and standard deviations of Outcome Measures for ACT versus wait list control groups using imputed data. ACT n=57, WLC n=41 for all measures except PARS (ACT=35). Standard deviations are in parentheses.

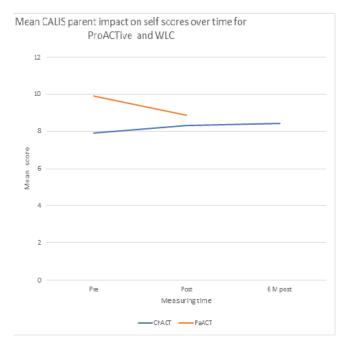
Measure and Condition (ACT n=57, WLC=41)	Pre-trt	Post-trt	6-mths post
PARS Composite			
ACT	11.11 (4.4)	4.74 (4.9)	-
WLC	-	-	-
SPENCE			
Child			
ACT	39.0 (17.7)	32.3 (18.6)	28.5 (20.2)
WLC	36.6 (18.6)	44.1 (20.7)	-
Parent			
ACT	31.7 (12.8)	22.8 (11.3)	22.1 (15.5)
WLC	32.1 (14.8)	29.9 (8.3)	-
CALIS			
Child self			
ACT	10.3 (4.9)	8.5 (7.2)	9.0 (7.7)
WLC	10.8 (7.3)	13.0 (8.2)	-
Parent for Child			
ACT	13.5 (6.1)	11.8 (6.8)	10.9 (7.1)
WLC	10.1 (6.1)	10.7 (5.1)	-
Parent for Self			
ACT	7.9 (5.9)	8.3 (5.5)	8.4 (7.2)
WLC	9.9 (6.8)	1.9 (6.2)	-
WLC	9.9 (6.8)		-

Note: N inadequate as was ceased halfway through study



ChACT=Child self_report treatment, EsACT=Parent report ACT, ChWLC=Child self_report Wait list control, PsWLC=Parent report Wait list control

Figure 5. Showing mean CALIS parent report scores over time for ProACTive versus wait list control groups.



ChACT=Child self- report treatment group, PaACT=Parent report treatment group

Figure 6. Showing mean CALIS parent impact on self-scores over time for ProACTive and wait list control groups.

improvements for child reports but not parent. Parents and children disagreed somewhat on level of the child's anxiety and impairment at baseline for the main outcomes measures (SPENCE), with parents under-rating severity compared with child ratings.

However, all measures showed an improvement in scores over time for the ProACTive group. Although statistically there was no improvement in SCAS scores from parents' perspectives, an inspection of the means indicated there were improvements of almost 9 points (28%) for the ProACTive group, but only 2 points (7%) for the WLC. These improvements for the ProACTive group maintained and slightly further improved at the 6-month follow up. Normative data for the SCAS indicate that a 0.5 standard deviation above the mean indicates elevated responses [34], so a reduction in this sample of 9 corresponds to an improvement. From a clinical perspective, mean pre-scores from parent perceptions were in the milder range overall so it is not realistic to expect clinically meaningful changes. It is possible that a larger sample size may have increased power to detect significance; however, the sample was not a clinical population. The finding that parent and child ratings of child anxiety severity using the SCAS were incongruent is common in studies of child anxiety [23-25]. The presence of internalizing symptoms rather than externalizing symptoms may reduce the level of parent-child agreement on psychological symptoms. Assessment of changes in internal emotional symptoms and cognitions that are not directly observable by parents may be difficult to accurately report. The finding of significant improvements as reported by children but not parents might suggest that although children are doing better, adults have not noticed any improvement in functioning or reduction in distress. It would be interesting to investigate in future research whether greater involvement in the program would increase parents' observations and provide potentially more accurate data.

We did attempt to incorporate clinical and multiple observers interview data to the questionnaire data, but it became pragmatically difficult in a real-life setting with limited resources and the need to minimize participant burden. However, the analyses of available data support the findings of the SCAS for the ProACTive group, with significant reductions in anxiety symptoms that reflect improvements of around 30%. According to Johnco et al. [39] this is a positive treatment response. However, results should be interpreted with caution since a compassion group was not available for this measure and only 60% of pre scores and a third post were obtained.

There was an 18% reduction in life interference scores for the CALIS Child report for the ProACTive group, and 13% for child as perceived by parent, but little change for the impact on parents' quality of life. These changes are not clinically meaningful as group mean scores were mild at baseline.

This study did have a number of methodological issues that limit the conclusions that can be drawn, including the relatively small sample size and the quasi-randomization process. Although the randomization method led to unequal numbers of participants in each condition, importantly, baseline differences between conditions were not statistically different. Further, the pragmatic randomization meant there was no bias in allocation to groups, with logistical factors in a "real-life" setting being barriers to complete true randomization.

The study was also limited in that participants were from Catholic systemic schools within a medium to high socio-economic status region. It would be of interest to evaluate the program across the socio-economic spectrum as well as obtaining more specifications on the ethnicity of the sample. It would also be useful to investigate ProACTive further in a high school setting, since only two groups were high-school based. Further limitations were the absence of external independent evaluation of the participants/symptoms and impairment, and no teacher reports of classroom behavior. In addition, we did not collect data on treatment credibility for participants or parents. Although our feasibility study found high satisfaction for the program, the current study could be strengthened by obtaining more qualitative data on outcomes and perceptions of the program. Anecdotally, we found that interest in enrolments in the program grew as the study progressed via word of mouth. However, further research needs to quantify this being the case rather than an increase in students with anxiety symptoms (the study was not conducted during COVID-19).

Strengths of our study include a wait list control group that helps to rule out passage of time, maturation, and spontaneous remission as explanations for improvements over time. Further our sample size, although relatively small, was adequate to detect medium effect sizes. In addition, the use of a previously empirically evaluated program in a clinical setting for children in ACT, as well as a feasibility and acceptability pilot study prior to the RCT lend credibility to the program and study.

It is recommended that future research focus on determining whether a briefer form of the intervention in schools is effective in treating children's' anxiety symptoms. Although Haugland et al. [24] found differences between brief and standard CBT were nonsignificant, brief CBT was not noninferior to standard CBT. However, participants were less satisfied. If further research found briefer versions were effective, this would potentially improve ease of applicability within schools as well as cost effectiveness. Another variant to explore is whether a briefer form but with additional parent sessions and/or

Conclusion

In summary, the study demonstrated the value of a school-based intervention in reducing symptoms of anxiety in school-age children. In particular, the intervention reached children who would otherwise most likely not have accessed services and received treatment. Identification and intervention with children within the school setting may help to reduce some barriers to treatment for children living in the community. It may provide a conduit for schools and health services. It is a potentially cost-effective treatment that is particularly timely give the current COVID-19 pandemic when mental health issues and economic costs are burgeoning. The relevance of ACT with its emphasis on acceptance and present-moment focus is all the more relevant in this current time of uncertainty.

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