Non-Drug/Device Protocol Template

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NOTES TO USERS

Who should use this template?	Anyone conducting clinical research which does **not** involve drugs or devices.
Why do you need a protocol?	The protocol is essential for study conduct, review, reporting, and interpretation.
Why use this template?	This non-drug template has been modified from the SPRIRIT (**S**tandard **P**rotocol **I**tems: **R**ecommendations for **I**nterventional **T**rials). The Spirit Statement is an international initiative that aims to improve the quality of clinical trial protocols by defining an evidence-based set of items to address in a protocol. Reference: Chan et al., (2013) SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. *BMJ 2013; 346:e7586*
How do I use this template?	There is a brief explanation under each heading stating the information that should be contained in that section. You will need to input your study specific information under each heading and remove explanatory information. As this is a template, users are remaindered that not all examples may be applicable to their study. Please contact your institution to discuss specific protocol questions.
Do I still need to complete the National Ethics Application Form (NEAF)	Yes – you must finalise your protocol prior to completing the NEAF. The NEAF is a form used by ethics committees to conduct standard review of all projects. While you need to refer to your protocol to answer most questions in the NEAF, it does not replace the need for a detailed protocol.
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PROACTIVE IN SCHOOLS PROTOCOL

Effectiveness of school group-based acceptance and commitment therapy for children with anxiety: a randomised controlled trial

Protocol Number (if applicable):1

Version: 1

Date: 04/07/2016

Author/s:
Dr Karen Hancock

Sponsor/s:
<<Insert Sponsor/s>>

CONFIDENTIAL

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

TABLE OF CONTENTS

CONTENTS

1. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
ProACTive	Treatment program for children with anxiety using acceptance and commitment therapy
ACT	Acceptance and Commitment Therapy
PARS	Paediatric Anxiety Rating Scale
SCAS	Spence Child Anxiety Scale
CALIS	Child Anxiety life interference Scale
CDI-S	Child Depression Inventory (Short)

2. STUDY SITES

2.1 STUDY LOCATION/S

[List all locations, their address & contact details this study or parts of the study will be conducted]

Site	Address	Contact Person	Phone	Email
Catholic Education Diocese of Parramatta	Victoria Rd, Parramatta	Ms Anoushka Houseman	9840 5725	ahouseman@parra.catholic.edu.au
CHW, Dept Psychological Medicine	Crnr Hainsworth and Hawkesbury Rds, Westmead	Dr Karen Hancock	98450408	Karen.hancock@health.nsw.gov.au

3. FUNDING AND RESOURCES

3.1 SOURCE/S OF FUNDING

[This section should describe how the study will be financed, but should not contain specific dollar amounts.

Internal funding from the Department of Psychological Medicine, and the Catholic Diocese of Parramatta will be used: both in-kind and monetary. Both partners will share in the costs of funding printing of therapy manuals and other material resources for group implementation. School counsellors will implement the program following training by the Department of Psychological Medicine. Staff from CHW will assist with assessments, and oversee the project. A Masters Clinical Psychology student will assist with group implementation.

4. INTRODUCTION/BACKGROUND INFORMATION

4.1 LAY SUMMARY

[All information provided in this section must be in language that can be understood by an interested, intelligent person without a scientific background. Do not use scientific jargon, abbreviations and do not include journal citations in the lay summary. This summary should include information on the aims and importance of the study as well as briefly summarizing what will happen to the participants, the time commitment required by the participants and how their safety will be ensured.]

Acceptance and Commitment Therapy (ACT) is rapidly growing in its evidence base for treating a variety of psychological disorders, but it is in an early stage of research in children. At the Children's Hospital at Westmead, Department of Psychological Medicine, we have developed and evaluated the effectiveness of an ACT program (ProACTive) for children and young people with anxiety disorders in the world's first and largest randomised controlled trial in this area. Following its initial successful implementation and evaluation in a hospital clinic setting, this project aims to evaluate the feasibility and effectiveness of a school-delivered ACT program (ProACTive) for children and young people with anxiety disorders.

The program aims to improve quality of life and to assist school students with an anxiety disorder to manage their symptoms so they don't have such a negative interference in their life. We plan to evaluate the program on a group -delivered basis in children aged 7-17 years (primary and high school versions). An RCT will be used to compare two groups (n=65 per group) who receive (1) ProACTive and 2) comparison wait list control group. Controls will be offered the program 10 weeks after recruitment and two assessments (see below) take place 10 weeks apart. The program runs 1 hour every week for 10 weeks and will be implemented by school counsellors trained in ProACTive. It involves learning skills (e.g. mindfulness, acceptance, distancing from thoughts/feelings/sensations, exposure therapy), to assist students manage their anxiety in such a way as they can get on with doing what's important and things they enjoy (i.e. leading a more rich, full and meaningful life). Parents will also be engaged in the program,

but with less involvement, undergoing psychoeducation and skills training on 2 occasions: on initiation of treatment and exposure therapy sessions.

Effectiveness

To evaluate the effectiveness of the program, participants in the treatment group and their parents/guardian will be asked to complete some standardised questionnaires and a 30 minutes structured interview: (1) prior to (ii) immediately after and (iii) 6 months after participating in the program. These questionnaires will take approximately 20 minutes to complete and will assess students' level of anxiety, depressive mod symptoms and quality of life. Controls will be assessed on the same measures on 2 occasions 10 weeks apart, prior to receiving the same program.

Feasibility

School counsellors implementing the program will be asked to complete a feasibility questionnaire evaluating the ease of implementation and usefulness of resources

The main aims are:

1) Evaluate the feasibility of implementing ProACTive in a school setting

2) Evaluate the effectiveness of delivering ProACTive in a school setting

4.2 INTRODUCTION

Childhood anxiety disorders are among the most common mental health conditions affecting youth, and they are predictive of long-term adulthood psychiatric problems (1,2). Acceptance and Commitment Therapy (ACT) is considered to be part of the “third wave” of behavioral and cognitive therapies, incorporating elements of cognitive behavioral therapy (CBT) with processes of mindfulness and acceptance (3). Despite the potential of ACT for children, the empirical base is subject to several limitations.

We recently reported on the findings of the largest RCT to date evaluating ACT for children with anxiety disorders (4,5.)The program "ProACTive" was found to be a highly effective treatment, being far superior to the wait list control group and to have similar outcomes to the gold standard cognitive behavioural therapy group. This study indicates that ACT is an empirically supported treatment option for anxious youth. Further research is required to determine whether findings generalise to other settings, such as schools, where flexibility to deal with context specific factors is required. Parents are routinely included in the treatment of their child’s anxiety disorder in clinical practice, with the assumption that parents’ involvement in their children’s treatment is beneficial for therapy (6). Evidence for the extent of that role is lacking. In our initial study parents attended all treatment sessions, whilst this is not always possible in the school setting.

With regard to school settings, there have been four studies, with only one published (7). In summary, there is some evidence to support further investigation using ACT with young people in schools, however none have focused on children with anxiety disorders and are of low scientific quality.

Following its initial successful implementation and evaluation in a hospital clinic setting at the CHW up to three months post treatment (4) and two years post treatment (5) , this project aims to evaluate the feasibility and effectiveness of a school delivered ACT program (ProACTive) for children and young people with anxiety disorders. We plan to evaluate the program on a group delivered basis in 130 children aged 7-17 years (primary and high school versions) in a 'real-world' school setting where responsiveness to context specific factors is required. An RCT will be used to compare two groups who receive (1) ProACTive and 2) comparison wait list control group. Participants in the control group will be offered the program 10 weeks after recruitment and assessment take place, undergoing an initial assessment, then 10 weeks later and then undergoing the Proactive program. It involves learning skills (e.g. mindfulness, acceptance, distancing from thoughts/feelings/sensations, exposure therapy), to assist students manage their anxiety in such a way as they can get on with doing what's important and things they enjoy (i.e. leading a more rich, full and meaningful life). Parents will also be engaged in the program but with lesser involvement than the previous clinical trial. Parents will undergo psychoeducation and skills training on 2 occasions: on initiation of treatment and exposure therapy sessions. To evaluate the effectiveness of the program, participants in the treatment group and their parents/guardian will be assessed on clinician rated and self/parent rated standardised instruments: (1) prior to (ii) immediately after and (iii) 6 months after participating in the program. School counsellors implementing the program will be asked to complete a feasibility questionnaire evaluating the ease of implementation and usefulness of resources. The research questions are: Is ProACTive 1) feasible and 2) effective in a real life school setting?. This will fill the gap in research into the effectiveness of ACT for children with anxiety disorders as well as being able to determine whether minimal parent input is feasible.

[The introduction is a very brief overview of the study (~250-500 words). The introduction should be concise but sufficient to orientate the reader to the main purpose of the study and how it will be conducted and its expected benefits. It should include details on (1) What the research question is (2) How the proposed study will fill a gap in the literature and (3) provide an understanding that this study is novel]

4.3 BACKGROUND INFORMATION

[This section should give clarity on the research question being addressed. The information should convince the reader of why the study needs to be done. The following points may be used as a guide:

Childhood anxiety disorders are increasingly being recognized as being a serious problem, and are the most common psychiatric conditions among children and young people (2). However, young people with anxiety are typically underrepresented in clinical research, and anxiety in children is often minimized by health professionals, potentially due to a common perception that in this population anxiety is developmental, transient and innocuous [8,9]. Despite this, anxiety in childhood increases the likelihood of academic and social skills difficulties as well as substance abuse, and is often enduring if untreated [10). People with serious mental illness live shorter lives, with nearly 80% of those who die before the average life expectancy of 79.5 years for men and 84 years for women do so due to physical health conditions, losing anywhere between 10 and 36 years of expected life (11).

Beyond the personal and societal cost there is a substantial economic cost in terms of health care, welfare and lost productivity. Recognition of this disorder as having a significant impact on public health has increased focus on treatments and evaluating their effectiveness. In a recent review of the best available evidence for the treatment of psychological disorders, Cognitive Behaviour Therapy (CBT) was found to be the first-line evidence-based psychosocial intervention for anxiety among adults and is currently the most empirically supported therapeutic approach for children and adolescents [12]. In part, this is a consequence of insufficient evidence for alternative interventions [12) rather than findings indicating other treatments are unsuitable. Indeed, the dearth of population-specific research in this area is highlighted by the aforementioned review, which found a complete absence of studies assessing the efficacy of CBT in the treatment of panic disorder among children and variable levels of evidence for its use in other anxiety disorders in this population [12.) Furthermore, others have found that one in four children do not benefit from CBT [13]. As such, it is important that other interventions are developed and evaluated to address this shortcoming.

Acceptance and Commitment Therapy (ACT) has sparked increased interest among clinicians and researchers in the last decade [14]. Acceptance and Commitment Therapy (ACT) is considered to be part of the "third wave" of behavioral and cognitive therapies, incorporating elements of cognitive behavioral therapy (CBT) with processes of mindfulness and acceptance (3). ACT considers the fundamental cause of psychopathology and human suffering to be the interrelationships of cognition, language and life circumstances that lead to decreased capacity to modify or continue exhibiting behaviours that are in the service of personal values [15]. ACT aims to increase psychological flexibility; 'the process of contacting the present moment fully as a conscious human being and persisting or changing behaviour in the service of chosen

values' [16]. Whereas other therapies focus on altering the content, frequency and form of private experience (thoughts, feelings and sensations), ACT works to modify the function of internal experience - such as supporting individuals to recognize thoughts for what they are, simply thoughts and not necessarily the truth -and thus reduce their bearing on behaviour [17]. ACT focuses on assisting clients to live valued meaningful lives. To do this, six core therapeutic processes organized in a 'hexaflex' model are employed, including 'acceptance,''defusion,' 'values,' 'committed action,' 'the present moment' and 'self-as-context' [17). These processes are interrelated and support each other in increasing psychological flexibility.

ACT has a growing empirical base demonstrating its efficacy for an array of problems, including the treatment of anxiety concerns among adults such as social phobia [18,19), generalized anxiety disorder [20] and mathematics anxiety [21]. Indeed, in the first known review of published ACT controlled trials up to 2005, the authors found ACT to be superior to control conditions, waitlists and treatment as usual at both post-intervention and at follow-up across a myriad of different problems from psychosis to work stress [22]. Whilst evidence for the use of ACT in adult populations with anxiety has grown, and the potential of ACT for children, the empirical base is subject to several limitations. There is currently a paucity of research examining the efficacy of ACT in children and adolescents with anxiety.

The published literature is confined to three studies involving a total of 11 participants (see 23,) which are subject to caveats including non-random treatment assignment, an absence of control or alternative treatment comparisons and questionable external validity. However, a recent review of 21 studies of ACT involving a range of presenting problems demonstrated emerging evidence for ACT in the treatment of children as young as 6 years (24).

We recently reported on the findings of the largest RCT to date evaluating ACT for children with anxiety disorders (3,4). The program "ProACTive" was found to be a highly effective treatment, with outcomes being far superior to the wait list control group and to have similar outcomes to the gold standard cognitive behavioral therapy group. This study indicates that ACT is an empirically supported treatment option for anxious youth. Being an iterative process, research firstly needs to show that it is efficacious in an RCT in a clinical setting. Further research is required to determine whether findings generalise to other settings, such as schools, where flexibility to deal with context specific factors is required. Parents are routinely included in the treatment of their child's anxiety disorder in clinical practice, with the assumption that parents' involvement in their children's treatment is beneficial for therapy (6). Evidence for the extent of that role is lacking. In our initial study parents attended all treatment sessions, whilst this is not always possible in the school setting.

With regard to school settings, there have been four studies, with only one published (7). The non-published studies were either preventative or for children without a mental health diagnosis- for example youth at risk (25), aggression (26), and prevention of stress (27,28). Livheim et al (7) 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 with anxiety disorders and are of low scientific quality.

This study fills this gap by investigating the feasibility and effectiveness of ProACTive using an RCT with an adequate sample size to test the aims. This is the next important phase of this research given it has been evaluated in a hospital clinical setting. Being able to provide ProACTive in a school environment means that it is likely to benefit a group of children and their families that may not pragmatically be able to otherwise receive such treatment. The risks of adverse effects are low- rather the children are likely to benefit from such treatment.

- Conduct a comprehensive literature search
- Critically appraise the relevant literature and discuss the current knowledge on the topic (include deficiencies). If applicable, discuss the current treatment options and the associated issues risks and benefits.
- Indicate how the research question has emerged and fits logically with the evidence detailed above.
- Explain how your study will contribute to existing research and benefit your target population.
- Discuss the importance of the topic (e.g., public health, clinical importance, community, incidence, prevalence, mortality and morbidity)

5. STUDY OBJECTIVES

5.1 RESEARCH QUESTION

[Clearly state the question the study intends to answer]

1) Can ProACTive be feasibly implemented in a school setting under real world conditions for students with anxiety disorders?

2) Is ProACTive effective in treating childhood anxiety disorders in the school setting?

5.2 PRIMARY OBJECTIVES

[The primary objective reflects the main clinically relevant goal of the study. Define the primary objective in terms of the population, intervention, comparator, and outcome that will be measured in a single clear and concise statement]

To determine the effectiveness of ACT for children with anxiety disorders in a school setting, in comparison to a wait-list control group, in terms of anxiety symptom reduction and quality of life improvement.

5.3 Secondary Objectives

[A study may or may not have secondary objectives. Secondary objectives consider outcomes of interest that may or may not be related to the primary objective. Secondary objectives may include more general non-experimental objectives e.g., to develop a registry, to collect medical history data]

To determine the feasibility of ACT for children in a school setting in treating anxiety disorders in children and young people,

5.4 Outcome Measures

[This section of the protocol must clearly state what the variables to be measured are. The primary outcome measure should reflect the clinically relevant effects of the intervention and be based on the primary objective of the trial. There should only be one primary outcome.
The secondary outcome measures are other effects to be measured in the study, these may or may not be related to the primary objective and are based on the secondary objectives.

For all the measures below children and a parent/guardian will complete respective versions. The primary outcome is clinician, child and parent rated.

Primary outcome measure: Anxiety Symptoms using the PARS: The Pediatric Anxiety Rating Scale (PARS) is a clinician-administered instrument that assesses the frequency, severity, and impairment of common pediatric anxiety disorders and has been used as a primary outcome measure in several landmark treatment trials (see below for further information). It is used to rate the severity of anxiety in children and adolescents, ages 6 to 17 years. The clinician elicits information from both the child and parent, resulting in a child, parent and clinician rating. The PARS has two sections: the symptom checklist and the severity items. The symptom checklist is used to determine the child's repertoire of symptoms during the past week. The 7-severity item is used to determine severity of symptoms and the PARS total score. The PARS has been found to have high interrater reliability, adequate test-retest reliability, and fair internal consistency. Convergent and divergent validity are satisfactory (29).

Secondary Outcomes

SCAS: The Spence Children's Anxiety Scale (30) will be used to assess child- and parent-reported anxiety symptoms. This measure contains 38 items that load on a single factor range from 0 to 114). Internal consistency and retest reliability are good. The measure distinguishes anxious and nonclinical children and has adequate convergent and discriminate validity.

CALIS: The Child Anxiety Life interference Scale (31). The CALIS is a self report measure that assesses life interference across school, family, peers/friendships, and physical health. Items are

rated on a 5-point Likert scale from not at all to all the time. There is a child (CALIS-C) and parent form, the latter having two subscales of child (CALIS-P) and family (CALIS-F) interference. Test–retest reliability has been established as moderate (r = .66–.87) and intraclass correlations (r = .38–.74) acceptable. Reliability estimates were found to be good at 0.80, and convergent validity has been established

CDI-S (32): The Child Depression Inventory (Short-Form) is a 10 item self-rated scale suitable for youths aged 7 to 17. The CDI:S was developed to provide a psychometrically sound way to quickly screen children for depressive symptoms. The CDI:S can be used when a quick screening measure is desired, when the examiner's time with the child is limited, or other similar situations. It has well established validity and reliability. CDI-S: Child Depression inventory (brief). This tool will only be used as a screening tool to indicate if severe depressive symptoms are present. Children with major depression and active suicidality will be referred to another program.

Feasibility:
We have developed a questionnaire to be completed by school counsellors online via Zoo Monkey. This survey was developed with the assistance of the CHW Service Improvement Unit, and was adapted from a feasibility questionnaire used by other colleagues in our Department evaluating the feasibility of Emotional Based Social Skills training by Michelle Wong and her team (publications under preparation). We have piloted this survey on school counsellors who have previously undergone ProACTive training and implemented the program, and the survey answered our questions as well as not being burdensome on the counsellors in terms of their time.

Treatment fidelity measures:

Treatment sessions will be audiotaped and 20% randomly selected and rated according to the Drexel treatment adherence scale that we previously used and has been use in other ACT studies (Forman et al., 2012).

Al school counsellors will undergo formal training in ProACTive , conducted by the two Chief Investigators of this study. On completion of training they will receive an accreditation certificate

Primary and secondary outcome measures may be:

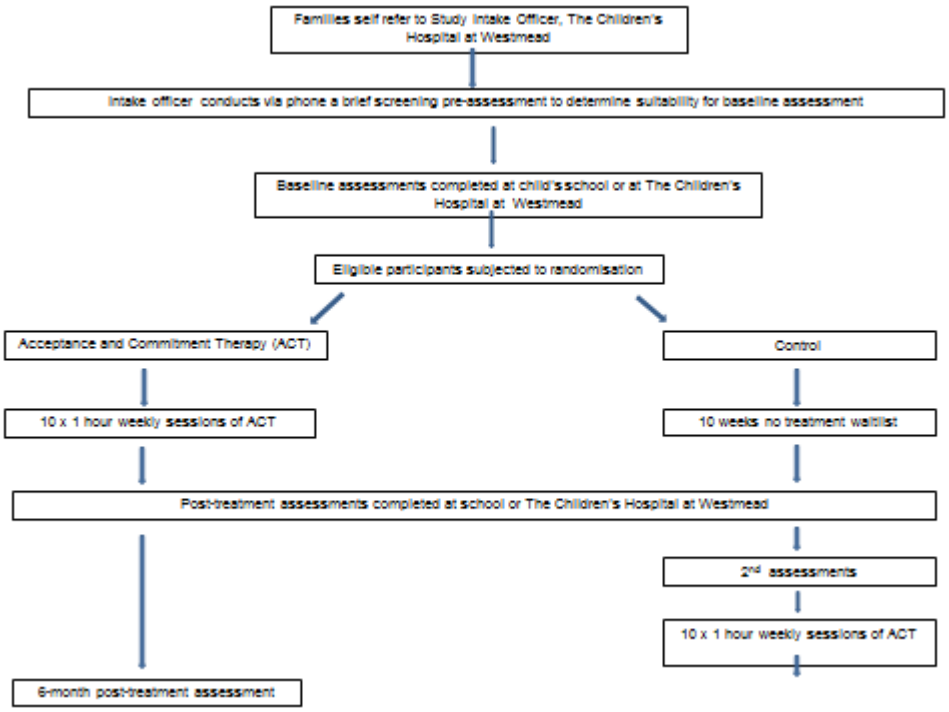
- Objective assessments (e.g. mortality rates);
- Subjective clinical assessments (e.g. validated rating scales);
- Measurements of various physiological functions (e.g. blood

- pressure);
- Anatomical or histological assessments (e.g. tumour measurements)
- Biomarkers or biochemical markers (e.g. tumour markers, liver
- function tests); or
- Pharmacokinetic tests.]

6. Study Design

6.1 Study Design Diagram

The study is a 2 by 2 factorial design. The between-subjects factor, Group, will comprise two treatment conditions (ACT, wait list control). The second repeated measures factor, Time, will be test occasion (pre and post). The wait list control group will only be assessed on the two occasions that coincide with pre and post for the treatment group (corresponding to baseline and 10 weeks post baseline for controls). However, a within subjects analysis will be conducted over 3 occasions for the treatment group, who will be assessed 6 months post treatment. Controls will not be assessed then as they will have received treatment follow 10 weeks wait listed.



[To increase readability, include a flow chart of the study design. The following are examples:]

6.2 Study Type & Design & Schedule

[The description of the study design should be capable of meeting the study objectives. A thorough description of **ALL** study procedures and assessments in a logical and sequential format]

1. Specify the type of study e.g., Cohort-study (retrospective or prospective), case-control study, cross-sectional study

   Prospective randomised controlled trial. A treatment group will be compared with a control group for changes from pre to post treatment. A within subjects analysis will occur for the treatment from post to 6 months post, as controls will not be assessed on the 3rd occasion since they will have received treatment by then.

2. Specify the basic design elements including the population to be studied (e.g., Adults aged 18-35), any risk factors present

School Children aged 7-17 years, primary diagnosis of anxiety disorder. Groups will be stratified by age (primary versus high school)

3. Specify if this study will be a single-centre or multi-centre (national or international) study.

   Single-centre, with 10 schools within the site

4. Specify how the design will achieve the aims and objective

   This is a prospective repeated measures RCT comparing a treatment group to a wait list control group. Inclusion of the control group is necessary as a comparison to assess the success of ProACTive at reducing the level of anxiety in children and adolescents who have a disorder. It is possible that the passage of time may improve symptoms, so it is necessary to compare the role of the treatment program in influencing outcomes over time.

   The program will be implemented across 10 schools so it will enable an examination of whether the program generalizes to the real world.

5. Please state what data will be collected e.g., blood tests, MRI's, genetic testing, videos, photos, questionnaires etc... For each item, specify if the data collected will be identifiable, re-identifiable or non-identifiable.

Clinician, self and parent rated psychological scales measuring anxiety and quality of life. The PARS clinical interview will be audiotaped as will treatment sessions for the purposes of treatment credibility and outcome reliability. Data will be re-identifiable in case parents contact us and request information about their participation in the study for purposes such as subsequent treatment and therapy. Therefore, we need to be able to identify the data. We also need to follow up participants up to 6 months post treatment so need to link their pre data.

Treatment sessions will be audio-taped and any identifying information removed.

6. Describe how you will collect, handle and store all types of data collected.

A trained psychologist will administer the tests. Hard copy data will be immediately stored in locked filing cabinets to which only the research team have access. Each participant will be given an identification code that can be matched in an electronic file that is password protected. Electronic data will be stored on a computer which is password protected.

7. Specify the time frame for each component of the study, this should include study visits, how long recruitment is open for and how long analysis will take etc.

There will be 10 schools involved over the 3 years of the study. Two schools at a time will be studied. For each school recruitment will be open for 4 weeks, screening and assessment will occur over 2 weeks, intervention 10 weeks, post assessment over the following week, then 6 month follow-up. This, the total approximate time frame for each school until post treatment assessment will be approximately 4 months.

	Recruitment	Screening and pre assessment	Intervention	Post
Timeframe for each school: 2 schools at a time over 5 consecutive time periods involving 10 schools	4 weeks	2 weeks	10 weeks	1 week

8. Specify if the study requires any home visits, and what the home visit policy and procedures are.

No home visits

9. Ensure you have included all information on all required contingency plans within your study outline.

This is answered throughout this proposal. See 7.1 in recruitment, and flowchart below as well as design flowchart

10. State if this protocol will be used towards a student project, and if so, state what course and degree the student will undertake.

    Psychology masters student- Master of Clinical Psychology.

11. Provide a flowchart or table specifying visits, interventions and other relevant details

Procedure for treatment group

Example procedures	Assessment/Procedure	Screening	Pre assessment (immediately following screening)	Intervention (10 weeks)	Post assessment (immediately following treatment) months post treatment	Follow up (6 months post treatment)
	Initial phone screening	x				
	Demographic Information	x				
	Informed Consent	x				
	CDI questionnaire	x				
	PARS interview		x		x	x
	SCAS questionnaire		x		x	x
	CALIS questionnaire	x	x		x	x
	Feasibility questionnaire for school counsellors				x	

Procedure for wait list control group

Example	Assessment/Procedure	Screening	Pre	Intervention	Post	Follow up (6 months post

			assessment (immediately following screening)	(10 weeks)	assessment (immediately following treatment) months post treatment	treatment)
	Initial phone screening	x				
	Demographic Information	x				
	Informed Consent	x				
	CDI questionnaire	x				
	PARS interview		x		x	
	SCAS questionnaire		x		x	
	CALIS questionnaire	x	x		x	
	Feasibility questionnaire for school counsellors				x	

6.3 Standard Care and Additional to Standard Care Procedures

[In table format LIST all procedures, assessments, and tests (e.g., CT-scans, MRI, blood tests etc…) that form part of standard care and that are additional to standard care. Include testing times, dosages and volumes where applicable]

Standard Care Procedures		
Procedure	**Time/Visit**	**Dosage/Volume**
Usual school attendance	n/a	n.a

Additional To Standard Care		
Procedure	**Time/Visit**	**Dosage/Volume**
ProACTive intervention	1 hour per visit	10 session once a week for 10 weeks

6.4 RANDOMISATION

[Include a description on how your participants will be randomised, include any software that will be used. Where applicable, a description of the type of ranomisation performed, ratio of assignment to group and stratification should be included. An explanation on the method used to conceal group allocations should be included and who will assign participants to their groups. This section should also discuss if the participants and/or investigators will be blinded to group allocations or if the study will be unblinded to the participants and/or investigators]

A computer generated series of random numbers will be used to allocate participants to treatment condition, generated using block randomisation with variable block sizes using Graphpad (***graphpad****.com/quickcalcs/randomize1.cfm)*. Students will be stratified by age (primary versus high school), as there are separate ProACTive programs tailored for these ages. Codes for the group allocation (1=Treatment group, 2=No Treatment control) will be sealed in opaque envelopes labelled with sequential ID numbers. Each eligible participant will be allocated the next available number. Once an eligible participant has been identified, they will be sequentially randomly allocated to one of two treatment groups. Codes for condition will be written onto squares of paper, which will be inserted into the relevant participant's envelopes, and then the envelopes sealed. Prior to the commencement of therapy, a designated research team member will contact a colleague in the Department of Psychological Medicine not involved in the study who will have the sealed envelopes in the order designated indicating to which condition each of the participants is assigned. That person will be blinded to the treatment condition.

6.5 STUDY METHODOLOGY

[Describe each clinical or laboratory assessment/s that will be carried out as part of this study. This should include a procedures list that details what information will be collected. If you are using standardised surveys, questionnaires or other test please attach a copy of each of these tests to the appendix of the protocol

See above for details on questionnaires- also copies attached

7. STUDY POPULATION

7.1 RECRUITMENT PROCEDURE

[Define the group in which the study will be carried out on. Explain how participants will be identified and recruited. You should make a distinction between how you will recruit control subjects compared to other groups.]

The group being studied are school children aged 7-17 years old who have a diagnosis of an anxiety disorder. Referrals will be obtained via information will be sent out via the school newsletter inviting children with anxiety problems to participate in the research. The information will outline the nature of the treatment program and how to obtain further information if interested in participating. School counsellors will have a caseload of children referred to them by teachers, parents of self referrals from children. Potential participants will also be informed of the program and its potential utility reinforced. Advertisements will also be placed around the school noticeboards. Potential participants' parents will be instructed to either phone or email the intake officer if they are interested in participating in the study. If deemed eligible, the child and parent will then be offered a face to face assessment by a psychologist. If it is apparent at referral or following an assessment that the family would receive more suitable help elsewhere, the psychologists will provide referral. Control subjects will be recruited in the same way as treatment subjects using an RCT design.

Cohort Studies: Describe sources and methods that will be employed in the identification and recruitment of potential participants e.g., clinics, referring doctors, advertisements etc…

Cross-sectional Studies: Describe the sources and methods that will be employed in the identification and recruitment of prospective participants (e.g., clinics, referring doctors, advertisements etc…) and retrospective data (e.g., medical records, registries, databases etc...)

Case-Controlled studies: Describe how controls will be identified and recruited (e.g., advertisements, letters from GP's, family members etc...), and describe how they will be matched. Describe how the study population will be identified and recruited, and then provide a justification for how bias has been avoided.

7.2 Inclusion Criteria

School children aged 7-17 years. Meet criteria for anxiety disorder as measured by at least one of the assessment outcome measures. See exclusion criteria below

[Clearly describe the study population that is required for a subject to be included in the study. The criteria may be based on factors such as age, gender, type and stage of disease, previous treatment history etc...]

7.3 Exclusion Criteria

[Provide details of participants that will be considered ineligible to participate and justify why they have been excluded. Exclusion criteria may include an inability to give informed consent, understand English, contraindications of the study treatment and/or procedures, conditions that will hinder the participant's ability to comply with the study protocol].

Exclusion criteria:
-Developmental or language delay (more than 1 year behind peers);
-Complex mental health problems such as psychosis, conduct disorder, attention deficit disorder not well controlled;
-Severely depressed and actively suicidal
-Been on antianxiety/antidepressant medication for less than 2 months
-Post traumatic stress disorder

7.4 CONSENT

[Describe if individual consent will be obtained or if a waiver of consent is required, or if no consent is required]

Informed consent will be obtained from both parent and child following the provision of an information sheet and verbal explanation of what their involvement in the study entails from the intake officer and assessor.

8. PARTICIPANT SAFETY AND WITHDRAWAL

8.1 RISK MANAGEMENT AND SAFETY

[Identify all areas where participant safety may be compromised, safety such examples may include, but are not limited to exposure to radiation and invoking psychological or physical distress. Safety considerations are not just physical, they can also be psychological, therefore, you must ensure for psychological distress you have arranged an appropriate contingency plan.]

There are no physical risks. The treatment is likely to benefit rather than cause psychological harm. There is a very low chance that some of the questions in the psychological scales may be upsetting, but if so, there is a psychologist present that they can talk to during the assessment as well as referral available to talk to a health professional. This question is answered further below in 8.2.

During the introductory section of the first treatment session for participants, and the parent introductory information session, participants and parents will be assisted to make a risk management plan to have in place for support needs should the school counsellor not be available in class time, or if after school hours. They should have a readily available list of websites (e.g., *https://www.beyondblue.org.au/get-**support**/national-help-lines-and-websites)* that can direct the person to telephone help lines, support services in their area, and websites. The safety plan should also list child's general practitioner (GP)'s contact details, and if the GP is not available, the nearest emergency department if the child's safety is at risk. Participants will also be provided with a listed of apps for self- directed use for emotional well-being (see attached). We will also provide details of local support services (e.g. WentWest ATAPS for younger children, Headspace for older children).

8.2 ADVERSE EVENT REPORTING

[If applicable, provide a description of how adverse events will be defined for your study. Include how adverse events occurring in the study subjects are to be identified and reported. Details should include the definition of a serious adverse event (SAE) and reporting timeframes.

An adverse event is defined as harm (i.e. a sustained deterioration) that is caused directly by the psychological intervention (33). Some examples of mental health adverse events include overdose, self-harm, or a suicide attempt. However, simply because an adverse event occurs during the trial does not automatically mean that the intervention caused the downturn in health. Whilst inappropriate application of a psychological intervention may be a possibility (though unlikely in this study due to the training and experience of the facilitators and the research team), it can be difficult to demonstrate causality in psychological interventions as it may be that temporary discomfort is often a necessary part of the process of psychological change part of the natural history of the mental health condition or a response to troubling life events (33). Nonetheless, subjective and objective measures will be taken so as to determine whether the adverse event is likely or not to have occurred as a result of the intervention (e.g. psychological test scores, subjective report of behavioural deterioration or negative effects on others etc).

The research team will routinely document any adverse event using an Excel spreadsheet. If an adverse event does occur, or is suspected to be one, the Research Ethics Officer will be contacted as close to the time of the adverse event occurring. If it is agreed that an adverse event has occurred, we will submit a completed electronic Adverse Event Form to the research office. It will also be documented in the Annual Progress Report.

8.3 Handling of Withdrawals

[Participants may withdraw from the study for the following reasons: participant has chosen to withdraw from the study, protocol violation, or participant has experienced an adverse event. Describe the procedures to be followed when a participant is withdrawn from the study. This should include what happens to all collected data (e.g., blood samples, scans, photos, etc…) that have already been collected, if the participant needs to have any follow-up, all administrative requirements to withdraw a subject to ensure their information isn't inappropriately used after their withdrawal from the study].

If a participant chooses to withdraw, their hard copy and electronic data will be locked and stored with the rest of the data for the study. This ethics proposal seeks approval only for data to be used for this study and not beyond the study date end. As per the participant information sheet, participants are informed that their current and future care at school or at the CHW will not be affected in any way due to their withdrawal.

8.4 Replacements

[Describe if withdrawn participants will be replaced in the study and if not, describe what impact this will have on the statistical significance of the sample size for the study]

Withdrawn participants will be replaced with participants meeting selection criteria. All participants will be randomised, but if it happens that there is an imbalance in the group numbers for treatment versus controls (e.g. due to withdrawals or the randomization process), adaptive randomisation will be used to maintain balance.

Statistical Methods

8.5 Sample Size Estimation & Justification

[Specify the estimated sample size and justify how this sample size will ensure that your study numbers will reach statistical significance]

The estimated sample size is 130 (65 per group, including completers). As discussed in the next question this is based on a power calculation using 2 tailed t-tests to compare the treatment versus control group, for an effect size of 0.5 and power of 80%, which would require 64 participants per group. Our previous study obtained a large effect size when comparing outcomes of the treatment group versus control group, and the current study is powered to detect a medium effect size or larger.

8.6 Power Calculations

[Describe and detail how the power calculations were obtained.]

This study is powered using 2 tailed t-tests on the primary outcome measure (PARS) which is a continuous variable, to compare the treatment versus control group, for an effect size of 0.5 and power of 80%, which would require 64 participants per group. A 1 standard deviation difference would represent a clinical cut-off between normal and abnormal scores.

8.7 Statistical Methods To Be Undertaken

[Describe the statistical methods that will be undertaken for this study. It is recommended this section is written in collaboration with a statistician.]

The main statistical analyses will be a series of mixed model analyses. The first factor, Group, will have two levels (ACT versus Controls). The second factor, Time, is a within subjects, repeated measures factor. Two sets of linear mixed model analyses will be conducted examining the following outcomes: (1) Anxiety: PARS, SCAS (2) Quality of Life: CALIS. The linear mixed model approach has been selected as it allows for inter-participant and intra-participant variance as well as the inclusion of participants with missing data, whilst maintaining power. Post-hoc tests will be used to compare groups at each time point and to compare changes over time within each group. The same design used for this study was used by Wuthrich et al (34), and they used a mixed model approach. We also used this approach for our initial RCT (4).

Descriptive statistics will be used to score school counselor ratings of feasibility questions, rated on a 5 point Likert scale (see attached).

Storage of Blood and Tissue Samples

8.8 Details of where samples will be stored, and the type of consent for future use of samples

[Describe what samples are taken, how long you will store each sample, where you will store the sample and state if any samples will be used for genetic testing. Finally describe if samples will be entered into a biobank, and if consent from participants will be for this research project only, for future projects related to this, or if participants have given unspecified consent.]

This study will only store psychological test scores that will be de-identified.

9. Data Security & Handling

9.1 Details of where records will be kept & How long will they be stored

[List the location/s where records will be held. If there are multiple locations, list the exact data to be held at each location. All records for non drug trials should be kept for a minimum of 7 years post study closure, if your study contains a CTN device, then records must be kept for a minimum of 15 years.]

Participant records will be stored in locked files in the researcher's office at the CHW, Dept Psychological Medicine, where only the research team has access.The information will be retained for a period of 15 years post study closure, as per the Australian Code for Responsible Conduct of Research. Data on electronic files will be stored on the researchers' password protected computer.

9.2 Confidentiality and Security

[Describe how confidentiality of all study data will be ensured via security mechanisms in place.]

Data will be de-identified; with participant will be given a research code. However, data will be re-identifiable using a password protected excel file matching the participants' name and demographics to their ID code. All hard copy data will be stored in locked files in the researcher's office, with the research team being the only people with access to the locked files.

Back-up data will be stored on a portable hard disc that will be kept in locked filing cabinets when not in use. Any files that have a password-protected facility (e.g. word, excel) will have a password known only by the research team.

9.3 Ancillary data

[Describe how where and for how long you will store data such as videos, photographs and images, also describe how confidentiality will be ensured].

The PARS clinical interview and treatment sessions will be audio recorded and Mp4s transferred to a hard drive which will be kept in locked files where the hard copy questionnaire

data for each participant is stored. Data will be stored for 15 years after the study has been completed.

10. APPENDIX

[Attach any questionnaires, functional and/or cognitive tests, surveys, telephone scripts, advertisements, photographs of devices etc….].

List of Attachments included:

Document Name	Version Number	Date (e.g., 18 January 2012)
PARS	1	
SCAS		
CALIS		
CDI-short		
Feasibility questionnaire		
Screening tool		
Advertisement		

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