**Project Protocol**

1. **Title**

Cognitive behaviour therapy for autistic children: Exploring mechanisms of change

**1.1 Project team roles & responsibilities**

Rachel completed her Master of Science (Psychology) at the University of Auckland, obtaining First Class Honours in her experimental research on pre-training simple discriminations to facilitate the acquisition of conditional discriminations in an animal population. Since then, Rachel became a registered psychologist (AHPRA No. PSY0000976955) and Board Certified Behaviour Analyst (BACB CN 1-09-5275), now with over 15 years’ experience in clinical practice. She is the founder and Clinical Director of Caterpillar Clinic, a private psychology practice located in Cairns, FNQ, which provides psychological services to typically developing and autistic children aged 2-18 years. She is adept in the administration of diagnostic assessments and screeners for children and parents and has access to diagnostic and physical (e.g., rooms, iPads) resources to be used for the proposed research.

Rachel will be responsible for compiling the documentation and resources required for the proposed study (e.g., consent forms, flyers, participant information sheets, intake forms etc etc), identifying the likely participant pool, training research assistants, administering key measures, program delivery, data collection and analysis.

Principal supervisor, Adrian Kelly, is Associate Professor of Clinical Psychology and Academic Lead (Postgraduate Research) in the QUT School of Psychology and Counselling. He is an Investigator within the Centre for Inclusive Education, and Co-Director of the Child Adversity Research Program. Adrian has an internationally recognised track record in research on child and adolescent pathways into health and educational risk.

Professor Marilyn Campbell is associate supervisor. Marilyn’s research expertise is in anxiety disorders in children and adolescents and in bullying. She also researches in mental health issues for young people involving web-based counselling and promoting resilience in intellectually disabled children and adults.

Both supervisors have extensive, well recognised and highly regarded experience in applied research involving vulnerable children groups, including autistic children. Adrian and Marilyn have excellent clinical experience to assist in the practicalities of conducting a quantitative research program that involves providing in-person group treatment. Both supervisors will be overseeing and approving documentation to be provided to potential participants, providing guidance regarding administration of measures, consulting and providing supervision around intervention delivery, and assisting with data analysis.

1. **Background information**
	1. **Project outline**

The proposed study will deliver an existing validated and empirically supported Cognitive Behaviour Therapy (CBT) program, *Exploring Feelings - Anxiety,* for anxious young autistic children. The program will be slightly extended based on the results for an earlier study (see UHREC project approval number 5350), by way of the inclusion of two additional sessions specifically focused on social skills. A within-subjects design with repeated measures will be used to evaluate changes in levels of anxiety across the delivery of the program. Delivery of pre- and post-intervention assessments along with session-by-session measures will allows the researchers to explore (a) changes in anxiety levels from before to after intervention delivery, and (b) if any changes that do occur are more likely at certain timepoints of the intervention, pointing towards particular components of the intervention as being more helpful than others.

* 1. **Introduction/background information**

Autism (also referred to as Autism Spectrum Disorder, or ASD) is a disorder that manifests across multiple domains of daily function, affects a significant portion of the population, and incurs negative impacts on an individual’s present and future outcomes, family relationships, and the public health system. Anxiety disorders are common comorbid mental health conditions amongst autistic children, with up to 40% of autistic children meeting criteria for at least one anxiety disorder. Autistic children often experience anxiety in different ways from their neurotypical peers (i.e., children without neurodevelopmental disorders such as autism or ADHD), including anxiety around routine, novelty and restricted interests, unusual specific fears, social fearfulness, performance anxiety and compulsive/ritualistic behaviour. Co-occurring anxiety can cause acute distress for autistic children, amplify the core symptoms of autism and trigger behavioural difficulties including tantrums, meltdowns, aggression and self-injury. Given the high rates of anxiety amongst autistic children, the development and testing of effective treatments for anxious autistic children is an important public health issue.

 Attention and investigation into factors that impair and/or enhance outcomes for autistic children is an important area of ongoing research. Delivering interventions that are tailored to the unique and specific needs of autistic children are likely to have better outcomes. Optimising intervention programs for this population can have many benefits, including removing unnecessary components and focusing on the aspects of intervention that help the child more efficiently and effectively, possibly reducing the amount of time therapeutic intervention is required.

Cognitive Behaviour Therapy (CBT) is an effective anxiety treatment for autistic children under certain conditions, particularly when parents are involved in treatment, sessions are provided over an extended period, and content is adapted to suit the age of the child. Core components of CBT for anxious children typically involve psychoeducation about the nature of anxiety (e.g., normalising the experience of anxiety, differentiating helpful versus unhelpful forms of anxiety, identifying cognitive behavioural and physiological components of anxiety etc), cognitive strategies (e.g., learning to identify and challenge unhelpful anxious thoughts or comments), and behavioural strategies (e.g., graded exposure to feared situations using a fear hierarchy, exposure and response prevention strategies, and behavioural experiments to test catastrophic and anxious predictions). CBT adaptations for autistic children sometimes have a reduced focus on cognitively oriented intervention components and a greater focus on teaching practical skills, which may be understandable given the challenge for autistic children with metacognition.

The researchers of the proposed study have recently completed an initial study exploring the relationships between anxiety, theory of mind (ToM) skills and social behaviour for autistic and non-autistic children aged 6-10 years (see UHREC project approval number 5350). Preliminary results show no significant differences in levels of anxiety reported for each group, but key differences between autistic and non-autistic children on measures of parent-rated ToM skills and social behaviour, with autistic children having more challenges with ToM and more severe levels of social difficulties. Although ToM difficulties and social challenges appear more prevalent for anxious autistic children, previous interventions targeting ToM skills for autistic children have not generalised well to real-life settings (Baron-Cohen et al., 2013), suggesting ToM training not to be a useful or viable standalone intervention. However, studies employing social skill interventions have been found to have positive effects on both social skill application and levels of anxiety (e.g., Hill et al., 2017).

Given the heightened prevalence of cooccurring mental health conditions and high service needs among autistic children, interventions that simultaneously address multiple-treatment targets would be time- and cost-effective, reducing burden on the autism community (Factor et al., 2022). It may be that by targeting both anxiety and social skills in a single intervention, anxiety symptoms will lessen, and social behaviour improved for young autistic children. Positive findings could lead towards development of more efficient treatment programs that achieve positive effects across multiple areas of clinical need.

The study of mechanisms of therapeutic change (i.e., why therapy works) is needed for improving clinical practice (Kazdin & Nock, 2003). Little is known about mechanisms of change in CBT for anxious children (Hudson, 2005). It has been proposed that treatment would be more effective when all three components of the emotional response are targeted (i.e., cognitive, behavioural, physiological; Davis & Ollendick, 2005), however it is possible that if one component (e.g., behavioural, such as social skills) is targeted in briefer more cost-effective treatments, then this might bring change across subjective fear, cognitive, *and* physiological arousal (Hudson, 2005). By employing a research design that measures any change on a session-by-session basis, researchers may be able to pinpoint when and why change is most likely to occur, to obtain information to inform development of more efficient yet effective treatment programs for young anxious autistic children.

* 1. **Rationale/justification**

Anxiety is highly prevalent amongst autistic children and results in substantial social challenges, which can increase as children get older in contrast to the decreasing pattern of anxiety symptoms often displayed in typically developing children (Sebastian et al., 2009). Mental health problems and social impairments predict significant negative outcomes across the lifespan for autistic individuals (Mason et al., 2019). Providing early intervention for anxious autistic children is a key preventative public health matter.

The frequent overlap of autism and anxiety suggests that an intervention that targets social skills specifically for those with autistic and social anxiety symptoms is not only warranted, but necessary (Factor et al., 2022). The current literature supports group-based CBT with family involvement as an effective anxiety treatment for anxious autistic children (Hillman et al., 2020; Sukhodolsky et al., 2013). CBT primarily focuses on relationships between unhelpful cognitive processes, physiological responses, and behavioural responses to reduce anxiety. It is proposed that adding additional social skills training to an empirically supported anxiety management CBT program would improve both anxiety and social behaviour for autistic children. Currently, interventions targeting multiple outcomes (i.e., social behaviour improvement and anxiety reduction) occur less frequently in the current literature despite the apparent relation between the two.

The proposed study will use an existing empirically supported CBT program for autistic children, plus include two additional sessions on social skills, The program selected, *Exploring Feelings* (Attwood, 2004) is an Australian-designed CBT program specifically for autistic children as a treatment for anxiety disorders. *Exploring Feelings* was intended for autistic children between the ages of 9 and 13 years but allows for adaptation to be more suitable for younger children. The program primarily focuses on psychoeducation around anxiety, positive emotions, creating a ‘toolbox’ (physical, relaxation and social strategies) to use when anxious, identification of physical feelings of anxiety, improving social and emotional knowledge, and cognitive strategies to address negative thoughts. The program has been previously evaluated with a significant reduction in key measures found at follow-up (e.g., Clarke et al., 2017; McConachie et al., 2014).

Teaching social skills to autistic children can vary substantially dependent by modality (direct instruction, peer modelling, video-based training etc) and type of skills to be targeted (e.g., initiating social interactions, play skills such as sharing, turn-taking, conversation skills, negotiating and compromising, problem solving etc) (Wolstencroft et al., 2018). Considering the method (direct instruction) and format (group) of the current study, components of a recent study with autistic children (i.e., Dekker et al., 2019) will be replicated. Noting that only two sessions have been allocated, topics of focus in the proposed study will include asking something to someone, asking to participate, discussing with someone, playing a social game, and saying no. These skills will be taught by direct instruction, role modelling, practising in peers, group and instructor feedback.

Frequent evaluation on a session-by-session basis of the proposed program to be delivered in addition to pre/post assessment measures may allow additional understanding of which components of the program are the most/least effective, which is important to our understanding of the effective components of multi-component CBT programs. Identifying key components of the intervention may allow for CBT programs to be adjusted to be more efficient yet retain treatment efficacy.

The proposed Study aims to expand on existing literature by evaluating if (a) autistic children’s anxiety and/or social behaviour will improve after completing the *Exploring Feelings* CBT program with the inclusion of two social skills sessions, and (b) to regularly track participant’s progress to determine if symptom change correlates with particular aspects of the program.

There are several benefits to the proposed research, including but not limited to:

* Providing a known efficacious treatment program at no cost to anxious autistic children and their parents. *The Exploring Feelings program will be delivered in its entirety prior to the additional social skills session. It is anticipated that anxiety will improve based on the existing literature associated with this program.*
* Potentially improving an existing treatment program to be a more effective treatment option for autistic children.
* Developing a better understanding of what contributes to therapeutic changes for this population by evaluating child- and parent-reports on program components considered to have been the most/least helpful.
* Personal development of research skills for the researcher and any clinical staff assisting in both studies.
1. **Study objectives**
	1. **Research questions / hypotheses**

The key questions to be addressed by the proposed research is:

* Will the *Exploring Feelings* program reduce anxiety for young anxious autistic children? It is expected that the program will show positive effects for autistic children’s anxiety (i.e., reduce anxiety symptoms).
* Will the addition of social skills sessions further reduce anxiety and/or increase social behaviour skills for young anxious autistic children? It is anticipated that anxiety will further reduce and social behaviour skills increase after completion of two sessions targeting social skills.
* What aspects of the program may be correlated with the greatest reduction in anxiety? It is expected that, in line with existing literature, practical/behavioural components of the intervention to be more helpful than cognitive strategies.
* What do autistic children and their parents consider to be the most helpful components of an exposure-focused CBT program? Similar to above, it is expected that children and parents will report practical/behavioural components of the intervention to be more helpful than other components.
	1. **Research aims**

The proposed research has the following aims:

1. To evaluate the overall effectiveness of a group cognitive behaviour treatment program targeting anxiety for autistic children using an evidence-based program and including two additional sessions targeting social skills; and
2. To determine which component(s) of the treatment program may correlate with changes in reported anxiety based on child- and parent-reports.
3. **Outcome measures**

Initial assessment of autism symptoms and cognitive levels will be conducted to ensure participants meet inclusion criteria for the study. All participants must meet criteria for Autism Spectrum Disorder as per Diagnostic and Statistical Manual of Mental Disorders Fifth Edition Text Revised (DSM-V-TR; APA, 2022) and be within a normative range of intelligence as assessed by the Weschler Children’s Intelligence Scale Australian and New Zealand Version Fifth Edition (WISC-V A&NZ; Wechsler, 2016).

*There may be some children who participated in Study one who completed inclusion measures at that time (i.e., ADOS-2 or SCQ and WISC-V). If they apply for inclusion in Study two, those assessment measures will not be readministered as they are considered stable within the timeframe between Study one and Study two.*

Subsequent assessments will be used to participant inclusion criteria is met and to obtain measures of anxiety and program evaluation. A summary of the measures to be used and format of delivery is provided in Tables 4 and 5 under 8.2 Schedules of measure/duration (pages 20 and 21).

***Inclusion Measures***

*Autism Assessment*

Assessment of autism will be conducted by two of three methods: (1) parent report on the Study’s intake form, and (2) administration of the ADOS-2 or (3) administration of the Social Communication Questionnaire (SCQ).

* *Autism Diagnostic Observation Schedule Second Edition (ADOS-2)*

Autism symptoms will be assessed using the Autism Diagnostic Observation Schedule Second Edition (ADOS-2; Lord et al., 2012). This measure is a semi-structured standardised assessment tool that consists of five modules, with the module used selected based upon the individuals’ level of expressive language, chronological age, and appropriateness of assessment materials (Kamp-Becker et al., 2018). For each module, between 29 and 41 behavioural aspects must be coded, with a selection of these codings forming the algorithm used to ascertain diagnostic cut-offs (i.e., total cut-off score for autism = 9; autism spectrum = 7). For most coding decisions, ratings range from 0 (= that the abnormality specified is absent) through 2 or 3 (= the abnormality specified is definitely present).

Administration of the ADOS-2 is approximately 60 minutes, with the examiner and child together in a minimally furnished room with only assessment materials present. There are two Modules to be used in the current study – Module 2 and Module 3 (see Table 1 for module content). Selection of a module is based on the age and language abilities of the participants, with Module 3 likely to be used for the majority of assessments. There are several activities from Module 2 that occur in Module 3 (see Table 1). The assessment is interactive, play-based, and relatively informal in that the opportunity for response and engagement is provided but how the participant responds and engages is dependent on their level of social skills and language abilities. Most children generally report an enjoyment of the assessment as many of the components are considered ‘fun’.

The lead researcher currently completes autism assessments in professional practice. The ADOS-2 assessment kit is accessible to the researcher through Caterpillar Clinic, a private psychology clinic located in Cairns, FNQ. Response booklets are available for purchase through the Australian Council for Educational Research (ACER). The researcher completed ADOS-2 training through Monash University in 2018 and has completed many administrations of the ADOS-2 in clinical practice. All administrations of the ADOS-2 during the proposed study will be completed by the lead researcher.

**Table 1**

*Observation/Coding Components of the ADOS-2 Modules 2 and 3*

|  |  |  |  |
| --- | --- | --- | --- |
| Task | Module 2 | Module 3 | Description |
| Construction Task | X | X | Putting identical pieces of a puzzles into a set outline |
| Response to Name | X |  | Eye contact or orientation to name being called |
| Make-Believe Play | X | X | Playing with a variety of toys and evaluating creativity and imagination |
| Joint Interactive Play | X | X | The assessor joining in with Make-Believe Play |
| Conversation | X | X | Talking about topics of interest or current events. |
| Response to Joint Attention | X |  | Seeing if the child follows the examiner’s gaze to an object |
| Demonstration Task | X | X | Giving a description of a daily activity (e.g., brushing teeth) and using gestures |
| Description of a Picture | X | X | Shown a picture of a family eating at a table and being asked to describe it |
| Telling a Story from a Book | X | X | Being asked to tell the story ‘Tuesday’ using the book as guide |
| Cartoons |  | X | Describing a series of cartoon pictures showing  |
| Free Play | X |  | Withdrawal of attention from examiner, child able to freely play with range of toys provided |
| Birthday Party | X |  | Engaging in a play sequence where a birthday party is held for a baby (doll) |
| Snack | X |  | Pretzels, chocolate chip cookies and drink provided |
| Anticipated Routine with Objects | X |  | Blowing up and letting a balloon go |
| Bubble Play | X |  | Blowing bubbles |
| Emotions |  | X | Asking set questions about feelings of happiness, being scared, anxious, angry, sadness, and relaxed |
| Social Difficulties and Annoyances |  | X | Asking set questions about problems getting along with others, finding others annoying, or others finding you annoying |
| Break |  | X | Withdrawal of attention from examiner, able to play with games and toys provided |
| Friends, Relationships and Marriage |  | X | Set questions about friends, relationships, future plans |
| Loneliness |  | X | Set questions about feeling lonely, if others may be lonely, what actions may take |
| Creating a Story |  | X | Creating a brief story using an array of items (e.g., toy car, popsicle stick, mini glasses, playing card, piece of string etc). |

* *Social Communication Questionnaire (SCQ)*

The Social Communication Questionnaire (SCQ; Rutter et al., 2003) is widely used as a screener for entry into research studies on autism (Centre for Autism Research; CARS; 2020). The instrument helps evaluate communication skills and functioning in children who may have autism and is completed by a parent or caregiver in less than 10 minutes without supervision. The questionnaire is comprised of 40 yes-or-no questions. The SCQ has shown strong discrimination between between autism and non-autism cases (sensitivity 0.90, specificity 0.86) (Chandler et al., 2007).

This assessment will be administered in person by the lead researcher with the parent/legal guardian. The SCQ is currently available to the researcher through Pearson Clinical Assessment. Administration time is approximately 10 minutes and responses are autoscored with a cut-off level of 15 applied.

*Wechsler Intelligence Scale for Children – Australian and New Zealand Standardised Fifth Edition (WISC-VA&NZ)*

Cognitive level will be measured using the Wechsler Intelligence Scale for Children – Australian and New Zealand Standardised Fifth Edition (WISC-VA&NZ; Wechsler, 2016).  The WISC-VA&NZ is composed of 10 primary subtests that can be clustered into composite quotients for five indices (i.e., Visual Spatial skills, Fluid Reasoning, Verbal Comprehension, Working Memory and Processing Speed), however only the first seven subtests are used to calculate the Full-Scale Intelligence Quotient (FSIQ).

The WISC-V assessment has been used in multiple studies with autistic children (Caemmerer et al., 2018; Kuenzel et al., 2021; Sutton et al., 2021) and is the most common cognitive assessment for children in clinical and educational settings in Australia. The WISC-V is currently available to the lead researcher through Caterpillar Clinic, with administration conducted by using hardcopy booklets for administration and Q-Interactive software for scoring. Administration time is approximately 45 minutes (likely to be less as only core subtests will be administered) and results are autoscored through the software once raw scores are entered by the researcher.

The list of subtests to be completed by participants is provided in Table 2.

**Table 2**

*Subtests of WISC-VA&NZ to be administered in proposed study*

|  |  |  |
| --- | --- | --- |
| Subtest | Associated Index | Description |
| Block Design\* | Visual Spatial | Matching 3D blocks to a model or picture shown  |
| Similarities\* | Verbal Comprehension | Associating underlying concept between two words |
| Matrix Reasoning\* | Fluid Reasoning | Identifying the underlying concept to sequence of pictures shown |
| Digit Span\* | Working Memory | Recalling numbers in forward, backward, and numerical order |
| Coding\* | Processing Speed | Drawing an object associated with a number in the set time |
| Vocabulary\* | Verbal Comprehension | Giving descriptions or definitions of target words |
| Figure Weights\* | Fluid Reasoning | Using quantitative abilities to match various objects shown on scales |
| Visual Puzzles | Visual Spatial | Working out which three pictures (puzzle pieces) comprise a target picture |
| Picture Span | Working Memory | Recalling pictures shown in set order |
| Symbol Search | Processing Speed | Marking designated symbols in the set time |

*\*Core subtests to inform FSIQ*

The WISCA&NZ is completed in a room containing a desk, chairs, and assessment items. Parents remain in attendance with the caveat that they do not actively participate in any way.

***Primary Measures***

*Spence Children’s Anxiety Scale (SCAS) – Parent and Child Version*

Anxiety will be measured using the Spence Children’s Anxiety Scale (Parent and Child versions; SCAS-P and SCAS-C; Spence, 1998). The SCAS-P is a 38-item measure and the SCAS-C a 44-item measure, both rated on a 4-point Likert-type ranging from 0 (never) to 3 (always). The SCAS provides a Total Anxiety score, as well as scores associated with anxiety disorders listed in the DSM-V-TR (i.e., Separation Anxiety, Physical Injury Fears, Social Phobia, Generalised Anxiety Disorder, Obsessive Compulsive, and Panic/Agoraphobia).

The SCAS is favoured due to the higher proportion of items related to observable behaviour, which has been found to increase parent-child agreement (e.g., Blakeley-Smith et al., 2012; Ooi et al., 2016) and useful for autistic populations where younger children may be more likely to have difficulties verbalising their internal experiences (Carruthers et al., 2020). The SCAS-P and SCAS-C are freely available for use. Copies of the SCAS-P and SCAS-C are provided as Appendix A and B respectively.

The SCAS-P is a self-report measure that does not involve the parent asking the child any questions. The questions are intended for the parent and their response. A link to access the questionnaire is sent to the parents by email, a paper version can be provided, or the measure can be administered in person. Standard instructions included with the SCAS-P are: ‘Below is a list of items that describe children. For each item please tap a response that best describes your child. Please answer all the items.’ The statements given (e.g., ‘My child worries about things’) and options available (Never/Sometimes/Often/Always) are considered with the capabilities of most typically-functioning adults.

*Anxiety Scale for Children – Autism Spectrum Disorder (ASC-ASD) – Parent and Child Version*

The Anxiety Scale for Children- ASD (ASC-ASD©; Rodgers et al., 2016) is a 24 item self-report anxiety questionnaire, with four sub-scales: Separation Anxiety (SA), Uncertainty (U), Performance Anxiety (PA) and Anxious Arousal (AA). It was designed for use with young autistic children aged between 8-16 years however has been used in studies with autistic aged 6-14 years (e.g., Adams et al., 2020). Severity is rated on a four-point scale ranging from 0 (never) to 3 (always).

The scale has good validity, reliability, and internal consistency and is highly correlated with the Screen for Child Anxiety Related Emotional Disorders and the Spence Child Anxiety Scale (den Houting et al., 2018; Rodgers et al., 2016), both of which are robust measures of anxiety in the general population. Although there is similarity with several questions between the SCAS-P/C and ASC-ASD, having fewer questions in the ASC-ASD allows for repeated administrations with less participant burden. In the Adams et al (2020) study, internal consistency for the total sample was identified as good to excellent for all subscales based on Cronbach’s alpha: Anxious Arousalα= 0.85, Separation Anxietyα= 0.81, Performance Anxiety α= 0.84, and Uncertainty α= 0.88. Copies of the ASD-ASD (Parent) and ASC-ASD (Child) are included as Appendices D and E respectively.

*Social Responsiveness Scale Second Edition (SRS-2)*

Autism symptoms and social behaviours will also be assessed using the Social Responsiveness Scale Second Edition (SRS-2; Constantino & Gruber, 2012). The SRS-2 consists of 65 items rated on a 4-point scale from 1 (not true) to 4 (almost always true) by the respondent (parent or legal guardian) based on the child’s behaviour over the past 6 months. It yields raw scores and gender-based T-scores, with T-scores of 60 through 75 being in the “mild to moderate” range for ASD and T-scores of 76 or higher in the “severe” range. A total SRS raw score of 75 or higher differentiates best between children with and without a clinical diagnosis of autism (Constantino & Gruber, 2012).

This assessment can be delivered electronically to the parent/legal guardian via email and is currently available to the researcher through Pearson Clinical Assessment. Administration time is approximately 15 minutes and autoscored.

The SRS-2 is a self-report measure that does not involve the parent asking the child any questions. The questions are intended for the parent and their personal response based on their interactions with the child participant. A link to access the questionnaire is sent to the parent by email, a paper version can be provided, or the measure can be administered in person. Standard instructions included with the assessment are: ‘For each question, please circle the number that best describes this child’s behaviour over the past 6 months’. The ratings available are Not True (1)/Sometimes True (2)/Often True (3)/Almost Always True (4). Responding to the questionnaire is considered within the capabilities of most typically-functioning adults.

*Coping Self-Efficacy Scale*

Coping self-efficacy is considered a key determinant of one’s ability to successfully manage stressful situations and emotions. Greater levels of coping self-efficacy is theoretically linked with more effective anxiety management, i.e., the more one believes in one’s ability to cope in a situation, the less anxiety one may experience in that situation. Coping self-efficacy will be measured using a modified version of the Coping Self-Efficacy Scale (CSES; Chesney et al., 2006). The CSES is a 26-item self-report measure, scored on an 11-point Likert scale ranging from 0 (*cannot do at all*) to 10 (*certain can do*), of the child’s confidence and parent’s view of their child’s ability to respond adaptively to stressful events. Higher scores are indicative of greater confidence. The CSES has shown strong psychometric properties including good reliability (α=0.79–0.92) and concurrent validity (Chesney et al., 2006). Alpha coefficients in previous studies using the CSES have ranged from 0.95 to 0.97 across two time points for children’s reports (Mackay et al., 2017). Similar to Mackay et al. (2017), the current study has adapted the CSES to suit young autistic children by using more literal language and by providing explanatory statements with some statements (e.g., for ‘Talk to yourself in a way that is positive and helpful’, including ‘This means to say nice things to yourself that makes you feel better’) (see Appendix C).

***Parent- and Child-report Measures of Program Content***

*Child Outcome Rating Scale (CORS)*

The Child Outcome Rating Scale (CORS; Duncan et al., 2006), based upon the original Outcome Rating Scale (ORS; Duncal et al., 2003) is a brief and highly accessible self-report measure of young people’s psychosocial functioning used extensively by mental health professionals around the world (Casey et al., 2020). It was originally developed for use with children aged 6-12 years (Duncan et al., 2006). Respondents answer the four questions using a visual analogue scale (VAS) (see Appendix F). The internal consistency for the overall CORS is good, with a Cronbach’s alpha of 0.81. Moderate negative correlation has been found particularly with emotional problems (*r* = 0.54) and positive correlation with self-esteem (*r* = 0.49).

*Child Group Session Rating Scale / Parent Session Rating Scale*

The Session Rating Scale (SRS) and derivatives, including the Child Group Sessions Rating Scale (CGSRS) and Parent Session Rating Scale (PSRS) are self-report measures used to evaluate four key measures of treatment: (1) the relationship between the clinician and participant, (2) the focus on relevant goals, (3) the way in which the session was administered, and (4) overall rating of the session. The structure of each SRS is based on a brief VAS (see Appendix G and H). Internal consistency of SRS versions has ranged from α 0.72 – 0.97. Test-retest reliability has ranged from r = 0.54 – 0.88 (Murphy et al., 2020).

*Client Satisfaction Questionnaire (CSQ-8)*

The Client Satisfaction Questionnaire (CSQ-8) is a self-report statement of satisfaction with health and human services (Larsen et al., 1979). It comprises of eight items on a four-point Likert scale with a total maximum score of 32. Higher scores indicate higher satisfaction. Internal consistency on the CSQ-8 is reported as Cronbach’s alpha 0.92-0.93. The questionnaire was extended in the current study to obtain further information regarding specific elements of treatment that participants felt were most or least helpful (see Appendix I).

**6. Study details**

**6.1 Study design**

The proposed study was previously submitted as a randomised control trial (RCT). However, due to the remaining timeframe of the lead researcher’s PhD candidature to complete the study and the known difficulties with recruiting a very specific clinical group of participants (i.e., anxious autistic children) in a regional location, the study will be changed to a within-group repeated measures design.

The current study will use a quantitative research design where information will be obtained from participants (children and parents) through administration of a range of validated and reliable psychometric assessments. All participants meeting inclusion criteria for the study (i.e., autistic, aged 6-10 years, Elevated or Clinical Total Anxiety) will be allocated to a treatment group. Three groups will be run each week. Treatment groups will comprise of 5-6 participants and differ only by the day/time of program administration (i.e., three groups running each week but on different days and/or different times). All treatment groups will receive the same program (*Exploring Feelings* – see details below, page 15), with all sessions provided in the same order. See Figure 1 below (page 16) for details on program administration and timeline.

**6.2 Locale**

Participants will attend Caterpillar Clinic to complete in-person measures required for both studies, which is providing the location for the proposed research. Caterpillar Clinic is a private child psychology practice located in Cairns, Far North Queensland. Each room is furnished in a child- and family-friendly manner. Two rooms will be allocated for QUT participants and sign posted as such during the course of the study. It is likely that the program and parent sessions will be delivered out of the Clinic’s standard office hours (i.e., after 5 p.m. or on Saturdays) so as not to provide any impact to the Clinic’s operations nor confuse research participants with Clinic attendees, and not to interfere with children’s schooling or parent’s work schedules. It is acknowledged that specifying these session times may limit the availability of some participants, however, it is hoped that offering three choices of session times across a week (i.e., one mid-week time, a morning and afternoon time on Saturdays) will allow for attendance around school/work/recreation activities and allow for recruitment of sufficient participant numbers.

**6.3 Intervention program**

The treatment program to be used will be the *Exploring Feelings* program (Attwood, 2004), which was originally created for children aged 9–13 years (Sofronoff et al., 2005; Sofronoff et al., 2007). The *Exploring Feelings* program (Attwood, 2004) has been evaluated in several studies. McConachie and colleagues (McConachie et al., 2014) investigated the adaptability and feasibility of the program with autistic children aged 9-13 years. Thirty-two children were randomised to immediate or delayed therapy, with child and parent groups run in parallel for seven weekly sessions. At end point, both parents and children in the immediate therapy group were more likely to report a reduction in anxiety symptoms.

In a school-based study, thirty-five autistic children aged 11-14 years and elevated anxiety were randomly assigned to six sessions of the *Exploring Feelings* program or a wait-list control group. The intervention (compared to wait-list control) group showed positive change for parent, teacher and self-reported anxiety symptoms (Luxford et al., 2017).

The *Exploring Feelings* program will be delivered across six 1.5 hour sessions (noted as week’s 1-6; see Table 3 for session outline, page 15), with parents and children in separate yet concurrent groups, each with two group leaders. Group leaders will be a paired combination of the lead researcher, and volunteer research assistants pooled from generally registered psychologists and provisional psychologists who are interested in assisting with the Study (see section below, 8.4 Data collection/gathering techniques, page 22).

Children will be taught to confront negative cognitions regarding maladaptive emotional judgements through the weekly introduction of new tools or coping strategies, which are added to the ‘Emotional Toolbox’. At the end of each session, children will be provided with ‘project work’ to be completed before the next session. Project work is comprised of tasks that the child is to do outside of sessions that relates the session content, such as collecting ideas from family members or friends about ‘tools’ they use to help manage anxiety, or physically putting together a ‘toolbox’ of items that the child identifies would be helpful to them to manage their anxiety in other settings (e.g., school, home). Completion of project work is encouraged but incomplete project work does not preclude children from ongoing participation. Parents will receive psychoeducation about autism and emotion regulation while observing the tools being taught to the children by group leaders (Hassenfeldt et al., 2015). Parents will be encouraged to support their child with project tasks.

The *Exploring Feelings: Cognitive Behaviour Therapy to Manage Anxiety* program are available for public purchase, are currently owned in digital format by the researcher, and are available for loan in hard-copy format from Caterpillar Clinic.

**Table 3**

*Session Overview of the Exploring Feelings Program*

Session Number Content of Session and Central Themes

1. Introduction of participants; Being happy; Feeling relaxed; Explanation of the project (things to be happy about, happiness diary, pleasures book, relaxation pictures, cue cards, feeling anxious list). *Strengths and talents, Being Happy, Feeling Relaxed.*
2. Review main points session 1; Discuss project work; Why we feel anxious; Heroes who become anxious; A time when I have felt anxious; An emotional toolbox to fix the feeling; Session 2 project. *Heroes who become anxious, A time when I have felt anxious, An emotional took box (physical tools), An emotional toolbox (relaxation tools)*
3. Review main points in session 2; Discuss project work; An emotional toolbox part 2; Session 3 project. *Social Tools, Thinking Tools, Other Tools, Inappropriate Tools.*
4. Review main points in session 3; Discuss each person’s emotional toolbox and how have been used since last session; Thermometer activity. *Practice using the Toolbox.*
5. Review main points in session 4; Discuss thermometer’s and review strategies; Social Stories; Antidote to poisonous thoughts; Social story project. *Antidote to poisonous thoughts.*
6. Review key points from session 5; Discuss each person’s Social Story and antidotes to poisonous thoughts; Sharing Strategies. *Sharing Strategies.*
7. Social skills I – Conversation skills including asking something to someone, asking to participate, discussing with someone.
8. Social skills II – Playing a social game, saying no.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Two additional social skills sessions will be provided at the conclusion of the *Exploring Feelings* program. These sessions will explicitly target asking something to someone, asking to participate, discussing with someone, playing a social game, and saying no.

**Figure 1**

*Flowchart of Study two – Enrolment to Final Analysis of Data*

Recruitment via advertising to psychology clinics, GP clinics, disability providers, etc

**Consent and assessment for eligibility**

* ADOS-2 and WISC-VA&NZ administrations
* SCAS-P/C (1/4)

Excluded

* Not meeting study criteria
* Declined to participate
* Other

Allocated to group based on preferred session day/time

Group 1 / 2 / 3 (*n* = 15)

**Pre-intervention assessments administered (week 0):**

* SRS-2
* CSES
* SCAS-C
* ASC-ASD (P/C)

CBT Program

* Concurrent child and parent sessions
* 1.5-hours per week for 8 weeks (weeks 1-9)
* Three groups of five participants (Groups 1, 2, 3)
* Weekly administration of the ASC-ASD, CORS, CGSRS and PSRS

**Post-intervention assessments administered (week 9):**

* SCAS-C/P
* SRS-2
* CSES
* ASC-ASD (P/C)
* CSQ-8 (P/C)
1. **Study population**
	1. **Participants (who, how many)**

A sample of approximately 15-20 autistic children (6 to 10 years-old) will be recruited for inclusion in the study upon approval from the UHREC. To be eligible for the study, participants must have had an ADOS-2 or SCQ administered and exceed the cut-off level for autism (Level 1) by scoring guidelines, fall within a normative range of intelligence (FSIQ = 100 ± 15) as determined by the WISC-V(A&NZ), and have elevated levels of anxiety as determined by the SCAS-P or SCAS-C.

As mentioned previously, participants of Study one who reside locally and indicated interest in obtaining information on Study two will be provided with the relevant Participant Information Sheet. Those participants will not be required to undergo a second ADOS-2 and WISC-V assessment as earlier results would be considered valid given the assessment was conducted by the same researcher within a 12-month period.

* 1. **Inclusions and exclusion criteria**

Inclusion criteria for Study two are:

1. Aged between 6:0 and 10:11 years; AND
2. Consent provided by parent/legal guardian and assent by child; AND
3. Elevated or Clinical Total anxiety, as determined by the SCAS-P/C; AND
4. Average intelligence (VCI or FSIQ = 100±15) as determined by the WISC-VA&NZ at time of intake or during Study one; AND
5. Criteria for autism to be met through parent report and administration of the ADOS-2 or SCQ at time of intake or during Study one.

Exclusion criteria for Study one are:

1. Inclusion criteria not met; OR
2. Consent not provided by the parent or child; OR
3. Unable to attend in-person for assessment measures or ongoing participation (commit to weekly sessions).

**Recruitment strategies, timeframe (as required in addition to that outlined in your ethics application)**

Previous participants of Study one who indicated an interest in future study participation will be approached in the first instance if they remain within the required age limit. In addition, participants will be recruited by marketing to families of young children by placing flyers (see Appendix J) in waiting and session rooms at Caterpillar Clinic, providing these to other psychology practices in Cairns, through the researcher’s social media platforms, as well as through direct contact to local medical practitioners who review children with suspected or confirmed anxiety, and advertising to local disability support agencies who support autistic children. The local newspaper (Cairns Post) will be contacted to inform them of the Study and if they might be interested in promoting this, as well as a local children’s magazine (Pakmag). It will be for the child’s parent to contact the researcher to register interest in participation of the Study – there will be no direct approaches to parents and/or children.

Direct marketing to GP’s and paediatricians will occur by way of email/information sheet (Appendix J and K) outlining the study components and intended outcomes and requesting this information be shared with families who have anxious children in the specified age-range. A similar approach will be used with disability support providers located in Cairns (e.g., Autism Queensland, the Benevolent Society) with information sent to key personnel with a request for dissemination to the target participant group.

It is expected that all intake assessments will be completed across 4 weeks, with up to five children and their parents attending the study’s location each week for approximately one hour duration, commencing April 2023. Assessments will be scored as administered. The intervention program will commence in Term 2 (May 2023) for all participants and conclude by July 2023. Data analysis will occur throughout the study, with the full data set of the intervention study anticipated to be available from August 2023.

* 1. **Consent approach/es**

As per the National Statement on Ethical Conduct in Human Research (2007), research involving children and young people raises particular ethical concerns about:

* their capacity to understand what the research entails, and therefore whether their consent to participate is sufficient for their participation;
* their possible coercion by parents, peers, researchers or others to participate in research; and
* conflicting values and interests of parents and children.

Due to the age of participants, written parent/legal guardian consent will be required and assent from the participating child sought. Parents/legal guardians and children will be provided with a Participant Information Sheet (see Appendix L and M) and consent form (see Appendix N and O). Parents are also indicating their consent for participation in the study. The child’s information sheet and consent form is modified to use ‘child-friendly’ language appropriate to their age and level of comprehension. Consent will be obtained prior to the administration of any initial screeners (e.g., SCAS-P/C) or assessments (e.g., ADOS-2, WISC-V). Consent forms will be scanned and saved to QUT’s secure U: drive for data storage and hard-copies retained for the minimum 15 year requirement.

It is recognised that there may be pre-existing relationships between some participants and the researcher or between participants and others involved in facilitating or implementing the research (see National Statement on Ethical Conduct in Human Research, 2007; Chapter 4:3 – *People in dependent or unequal relationships*). It is understood that these relationships may compromise the voluntary character of participants’ decisions. Every endeavour is being made to separate the Study from Clinic processes, so that the Clinic is essentially only the provider of a physical location and resources (see Appendix P). To ensure that participants are engaging in the research willingly and without perception or impression that this unduly benefits the researcher or the Clinic, it will be made exceptionally clear that participation in the study/s are completely separate to any clinical engagement with the Clinic, and one does not relate to the other (i.e., participating in the research does not relate to access to clinical services, and vice versa). Withdrawing from the research does not impact current or future attendance to the Clinic for clinical services nor does participating in the research guarantee access to Clinical services. No preference or advantage is given to children who currently or have previously accessed the Clinic for appointment times or group allocations.

Participant records will be maintained and stored through separate systems/facilities from the Clinic’s. There is no overlap and no access to Clinic records afforded for research purposes (see further details under 8.4 Data collection/gathering techniques, page 22). All appointments scheduled to complete assessments will be done outside of Clinic processes, i.e., directly with the investigator, using her QUT email account and personal mobile phone for scheduling appointments to complete assessments.

* 1. **Participant withdrawal**

Participants can withdraw at any time from the study. Participants will be asked if information collected about them up to the point of withdrawal can continue to be used in the Study or if they wish all their information to be removed (see Appendix Q).

1. **Procedures**
	1. **Screening of participants**

Initial screening of participants will occur to determine if age (6- to 10-years) and anxiety (elevated) requirements are met. If this requirement is not met, they will be thanked for their time and no further progression will take place. If the initial requirements for Study two are met, participants will progress to completing cognitive and autism assessments (if needed) to ensure they have a normative range of cognition and meet autism criteria.

In any case where ‘unexpected’ results are found during administration of assessments to determine Study inclusion (e.g., if the child falls outside a normative range of cognition, or who does not meet criteria for ASD on the ADOS-2 or SRS-2), the parent would be contacted post-assessment by the investigator and outcome measures discussed. This would not be a formal consultation, but rather general discussion on results from the assessment measures. There is no cost to the parent for this contact as the Study sits outside the Clinic’s services.

The follow-up consultation for unexpected results would comprise of reviewing the results obtained and discussing what this meant, i.e., if below a score of 85 on the WISC-V, then this may indicate some difficulties with cognitive processes although not necessarily indicative of an intellectual impairment. Full acknowledgement would be provided on how this may have been unanticipated/unexpected for the parent and may be quite a shock or surprise to them. That it would be understandable if they had more questions or needed more clarification around the meaning of the results. And it would be recommended for them to possibly reach out to family and/or close friends if needing that form of support. They may also wish to speak to the child’s school/teacher to see if they may have more information on the child’s behaviours in that setting that could be helpful for the parent to know.

Options will be provided for further assessment/investigation if this is what the parent is interested in doing. A list of providers involved in intellectual and/or autism assessment will be provided along with information on the process for intellectual and/or autism assessment in Queensland (e.g., attendance to GP, referral to paediatrician, formal assessment by autism or neurodevelopmental specialists, diagnostic outcome, confirmation by paediatrician or multi-disciplinary team of speech pathologist, occupational therapist, and/or psychologist etc). Whilst the researcher is an experienced psychologist and adept with micro-counselling, and these would absolutely be provided during the conversation, it would be maintained that ongoing services and support were outside the provisions of the Study.

* 1. **Schedule of measurements/duration**

**Table 4**

*Study two intake measures, method of delivery and time to administer*

|  |  |  |  |
| --- | --- | --- | --- |
| Measures | Delivery Method | Primary Outcome Measures | Administration Time |
| ADOS-2 | Direct (child) | Autism symptoms | 45 minutes\* |
| WISC-V (A&NZ) | Direct (child) | Cognitive assessment | 45 minutes\* |
| SCAS-P | Parent report | Anxiety symptoms | 15 minutes |
| *Total Time* |  |  | *90 minutes (child)**15 minutes (parent)* |
|  |  |  |  |

\*Only administered if not previously completed in Study one

**Table 5**

*Study two pre-treatment, post-session, and post-treatment measures*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Measures | Delivery Method | Primary Outcome Measures | Frequency (Session) | Administration Time |
| SCAS-C | Direct (child) | Anxiety symptoms | Pre (0)/post (8) treatment | 10 minutes |
| SRS-2 | Parent report | Social behaviour | Pre (0)/post (8) treatment | 20 minutes |
| CSES | Direct (child)Parent report | Coping self-efficacy rating | Pre (0)/post (8) treatment | 15 minutes |
| ASC-ASD | Direct (child)Parent report | Anxiety symptoms | Weekly (1-8) | 5 minutes |
| CORS | Direct (child) | Rating of how well child is doing that week | Weekly (1-8) | <5 minutes |
| CGSRS | Direct (child) | How good the child found the group session | Weekly (1-8) | <5 minutes |
| PSRS | Parent report | Usefulness of session | Weekly (1-8) | <5 minutes |
| CSQ-8 | Direct (child)Parent report | Treatment satisfaction/Most and least helpful treatment components | Post-treatment (8) | 10 minutes |

* 1. **Participant follow-up**

Parents will indicate on the Participant Intake Form (see Appendix R) if they would like feedback on their child’s result and/or the overall results of Study two. If indicated/requested, basic feedback will be provided to parents via a set template (see Appendix S) after intake measures are completed. Feedback will include information on cognitive level (i.e., Below Average/Average/Above Average), autism criteria (i.e., Criteria Met/Not Met), anxiety (i.e., Clinical/Elevated/Average) and social behaviour levels (i.e., Normal/Mild/Moderate/Severe). Parents will have the opportunity to discuss any concerns at any time with the lead researcher, however no advice regarding application of a diagnosis nor clinical intervention will be provided. Parents will be referred to medical pathways (e.g., GP or paediatrician) for further review if needed.

See also comments in section 8.1 Participant Screening above regarding handling of unexpected results/outcomes.

* 1. **Data collection/gathering techniques**

All measures pertaining to study inclusion and outcomes will be administered, scored, and interpreted by the lead researcher. However, assistance will be required to deliver the program outlined and assistance will be obtained by additional registered psychologists currently employed at Caterpillar Clinic, or provisional psychologists (also referred to as ‘interns’) currently completing their AHPRA 4+2 internship (meaning they have completed an Honours degree in psychology and are currently completing two-year postgraduate practical training) to obtain registration as a general psychologist *if they are willing and able to do this*. This is completely voluntary for the registered and provisional psychologists and not a requirement of their employment at the Clinic. Participation as research assistants is at everyone’s discretion – they will be invited to participate if willing but entirely able to decline without any impact to their employment or provisional registration requirements. All interns can meet their requirements for general registration outside of the Study. However, the Study presents an opportunity for interns to gain more experience in program delivery which they might deem valuable to their training. It also allows interns an opportunity for understanding the research process, which could be interesting for them if looking to take up research opportunities at some point in the future. They will learn how research and Clinic processes are separated and develop their understanding of the need for this, which could be useful in their career.

* 1. **Impact of and response to missing data e.g., extrapolation; participant withdrawal**

There is the possibility that data will not be completed by parents and/or participants will not be brought to scheduled appointments. In the case of parents not completing online assessments within a reasonable timeframe (e.g., one week), phone contact will be made to follow up and ensure the email was received and if there was any confusion about assessment content. A further week will then be allowed for completion before additional follow-up is scheduled. At this time (two weeks from issue), contact would again be made to enquire if there were any barriers to participation. Offer would be made for in-person completion using paper-copy with the examiner. If this was declined, the parent would be thanked and excused from ongoing involvement in the study. Any information obtained at that time would be included in the study’s results where possible, unless requested for removal by the parent.

A similar process would be employed for non-attendance to in-person appointments. A text message reminder would be issued prior to the initial appointment, and if non-attendance occurred, follow-up would occur by phone call on the same day. If the appointment was rescheduled and subsequently non-attended, the parent would be thanked and excused from ongoing involvement in the study. Any data obtained prior to this will be retained for study inclusion (if relevant), unless specified for removal by the parent at which time data management processes would be applied (see Section 9).

Outcomes will be examined first using intention-to-treat analysis, followed by treatment completer analyses. It is common practice to provide results of those who complete the trial as well as those who have missing data as a result of dropping out (Luby et al., 2012; Meiser‐Stedman et al., 2017; Wood et al., 2009). Participants who have completed a minimum of six (of eight) sessions will be designated as treatment completers.

* 1. **Safety and adverse effects/events**

There are no aspects to Study two that entail risk from the physical environment resulting in physical harm, in any components of completion of the assessments outlined, nor of participation in the weekly intervention sessions. There is no evidence that any of the measures used in this study produce adverse emotional consequences for children. There is some evidence that the measures used in this study can be helpful in generating insight/discussion. All participants are reassured that there are no ‘right’ or ‘wrong’ answers other than when completing the WISC-V, when they are advised that ‘some things will be easy for you and some things might be more difficult, but that’s OK, just try your best’.

The primary risk to participants is emotional wellbeing, given all children eligible for participation will have atypical levels of anxiety. However, studies have shown that anxiety can be decreased prior to engagement in tasks such as tests or assessment in a variety of ways, including deep-breathing (e.g., Khng, 2017), mindful colouring (e.g., Carsley et al., 2015), or writing about the worries (e.g., Ramirez & Beilock, 2011).

All participants will be monitored for signs of excessive anxiety, and if present, intervention will be provided by way of giving reassurance and positive feedback, offering a break, engaging briefly in another preferred task, seeing a parent, or bringing them into the room if needed, or ending the session earlier if needed. A Subjective Unit of Distress (SUDS) scale (see Appendix T) can be used to aid regular check-ins to ensure the child remains within a manageable range of anxiety.

All attempts will be made to ensure children are comfortable and at ease with participating in the research during both assessment and intervention components. This will include a friendly welcome to all children upon arrival, initial time to develop some rapport with each child (e.g., asking them about possible interests and enjoyable activities), including a brief overview of the reason and content of their attendance (e.g., ‘You’ve been brought here today to help us learn a bit more about children who might get worried about things … We really appreciate you coming in … We’ll be doing some activities together like putting blocks together and looking at pictures … some things might be easy for you and some things more tricky but that’s OK, just try your best.’ Also, to advise children ‘[Parent/carer] will be here throughout and you can see them at any time. If you need a break for the toilet or something to eat or drink, you can do that whenever you need to, just let me know. Or if you just need a break for any reason, that’s fine too, just tell me ‘I need a break’ and we’ll stop for a few minutes.’

The Participant Information Sheet (see Appendix L) provides contact numbers for QUT’s psychology clinic that is available for research participants, as well as Lifeline and the Kids Helpline if additional support is needed. Parents can also be given referral information for seeing their GP or paediatrician and accessing independent psychological support.

There is also minimal risk regarding economic harm, due to the requirement to attend in person for child-based assessments, and the minimal costs that may be associated with driving and taking time from the parent and child’s regular schedule. The study is located in a central location in Cairns, with free parking, so travel costs would be considered minimal. Appointments will be scheduled to best suit the parent/child, with sessions tied to existing appointments, made before/after school, or on Saturdays if needed.

QUT’s policy relating to Child Protection (A/8.11) apply and will be adhered to. That is, all members of the University community have a responsibility to respond to a disclosure or suspicion of harm to a child by following QUT reporting processes and other mandatory reporting obligations where applicable. The University’s Child Protection Coordinator is the principal point of contact for child protection matters and is responsible for facilitating processes for responding to and reporting suspicions of harm to a child or young person. QUT’s policy and procedures will be followed in any instance of abuse disclosure.

Further, the researchers are all trained in the Clinic’s procedures, legal and ethical guidelines regarding disclosure or revelation of child abuse. Steps taken in these matters may include:

1. Providing immediate support to the child/parent
2. Reasserting limits to confidentiality
3. Determining immediate risk and risk mitigation
4. Determining reporting protocol (online, phone call, 000)
5. Provision of resources to parent (i.e., relevant services pertinent to disclosure, which may range from GP attendance, Child Safety involvement, TRUE Relationships, Cairns Regional Domestic Violence Service, private counselling services etc).
6. **Statistical plan**
	1. **Sample size determination and power**

A power analysis indicated that the minimum sample size to yield a statistical power of at least 0.8 with an alpha of 0.05 and a medium effect size (f = 0.5) is 13 (GPower 3.1; Cohen, 1988).

* 1. **Data analysis and statistical methods**

Measurements will be administered at nine timepoints (see Table 6): (Timepoint 0) during administration of pre-intervention assessment measures; (Timepoints 1-8) at the end of each session completed, and after completion of treatment (Timepoint 8). The purpose of the staggered timepoints is to a) evaluate for treatment versus no treatment effects from the first to final timepoint to determine decreases in anxiety occur as anticipated, and b) obtain evaluations of the program immediately post-session to capture information pertinent to each particular session.

 To evaluate treatment effects from pre- to post-treatment for each of the outcome measures, a series of repeated measures ANOVAs will be performed on the full data set (i.e., all data combined from all weekly groups). Where significant time effects are found, simple contrasts will be conducted to assess between which time points the significant difference lays (e.g., 1 to 2, 1 to 3, 2 to 5 etc). For condition × time interactions, mean change scores will be used to calculate effect sizes, with effect sizes of 0.2, 0.5, and 0.8 (Cohen, 2013) corresponding to small, medium, and large effect sizes, respectively. Analyses will be performed with SPSS 25.0 (Version 25.0. Armonk, NY: IBM Corp, 2017) software. Statistical tests will be two-tailed with a significance level of p < 0.05.

1. **Data management and record keeping**

The research data collected in the course of the Study will be ‘standalone’. All information will come from parents and children during completion of the Study via the Participant Intake Form and measures. The Clinic’s own database and client records will not be accessed at any time for purposes related to the proposed Study.

The research will be conducted in Cairns, FNQ, which necessitates provision and interim storage of assessment materials to be completed locally. In line with the Australian Code for the Responsible Conduct of Research, the QUT Management of research data policy (D/2.8) and the QUT Records management policy (F/6.1), the following undertakings are in place for the proposed research:

* 1. **Confidentially and privacy (including linkages)**

Data collected during the Study of the study will be stored according to Queensland State Archives University Sector Retention and Disposal Schedule and the Australian Code of the Responsible Conduct of Research (2018). QUT’s Research Data Storage Service will be used to store all research data. Data can be entered securely and accessed remotely (i.e., in Cairns/off campus) with permissions granted on a folder-level basis.

Participant’s involvement and outcomes from the research study remains confidential and will not be shared with anyone outside the research team. Any research assistants employed as Clinic staff are subject to the Clinic's confidentiality requirements and directions under APS Code of Ethics.

All appointments scheduled to complete assessments will be done outside of Clinic processes, i.e., directly with the investigator, QUT Outlook for scheduling appointments to complete assessments.

* 1. **Data security (including how will you store)**

QUT guidelines regarding data collection and storage will always be followed, with consultation to the faculty’s representative in the Space, Assets and Logistics team made where required for advice on storage options and best practice.

Two data sets will be created. The first will contain participant demographics as provided from the Participant Intake Form, along with an allocated participant ID code. This is individually identifiable information. The second set will only contain the participant ID code and raw data obtained from the measures completed. When the children are interviewed, their participant ID numbers will be recorded on data sheets, with no recording of names or other identifiable information. However, this information can be re-identified from matching to the first data set with the unique identifier allocated.

Both data sets are securely stored through QUT’s RMSS with access only available to the investigator and supervisors. All data will be entered by the investigator.

Non-digital research data (e.g., consent forms, ADOS-2 booklets, WISC-V response booklets) will be stored on site at Caterpillar Clinic in a locked filing cabinet. For assessment measures, raw data will be uploaded into the requisite spreadsheet saved to QUT’s U: drive. In line with QUT’s Records governance policy (F/6.1, specifically section 6.1.7), permanent records that are created or received in hardcopy format must be maintained in their original format for the entire retention period as set out in the University Sector Retention and Disposal Schedule. The retention period for consent forms (section 601.2/C111) is 15 years, whilst assessment/supporting documentation is five years for parent participants (section 601.2/C115) and until 31 December 2028 for child participants (GRDS Disposal Authorisation 1559). Storage will be by way of QUT’s secure record storage facility.

Data from measures obtained in digital-only format (i.e., for measures sent by email link and completed online) will be obtained through the associated service provider (e.g., Novopsych for the SCAS-P/C, WPS for the SRS-2) and uploaded to QUT’s secure U: drive. This occurs by the results being provided to the researcher in PDF report-form. Whilst online assessments adhere to strict privacy and security protocols, including high level 256-bit encryption that meets Australian Privacy Principles (Australian Privacy Act 1988) and the European General Data Protection Regulation (GDPR), only non-identifiable information will be entered into each database to ensure participant information will remain confidential. Only the participant’s identifying code, gender and date of birth will be entered for online administrations.

Videos taken during ADOS-2 administrations will be obtained via iPad and saved to the device only. The device remains onsite at Caterpillar Clinic in a locked office when not in use and is not taken offsite. In line with QUT’s Record governance policy (F/6.1 specifically section 6.1.6), electronic records must be captured in either the corporate electronic recordkeeping system, QRecords, or in another corporate business system. For this project, QRecords will be used. Immediately after videos are captured, they will be uploaded to QRecords as an MP4 file and retained for the minimum storage period (i.e., until 31 December 2028 for child participants). Once ensuring the video has been uploaded in its entirety to QRecords, it will be deleted from the device.

* 1. **Training**

Some research tasks (e.g., group leaders of the CBT intervention) may be completed by research assistants, which was explained in section 8.4 (page 22).

Research assistants (whether provisional or registered psychologists) aiding in the provision of the intervention program will undergo training to ensure consistency of program administration. The training will comprise of three key areas:

1. Providing an overview of the research project and obtaining consent from potential participants
2. Administration of the *Exploring Feelings* program and additional social skills sessions
3. Knowledge on and behaviours associated with child-based group programs (e.g., friendly and helpful demeanour, effective behaviour management techniques for group-programs, thorough theoretical knowledge of anxiety and CBT etc).
	1. **Record retention**

All participant information will be entered into the requisite spreadsheet (participant information, raw data) or converted to digital format (e.g., PDF or video files) and saved to QUT’s secure U: drive. Access to participant records (restricted to the investigator and supervisors) will remain current indefinitely, to meet record retention requirements under the University Sector Retention and Disposal Schedule (i.e., 15 years for consent forms, five years for research data), however as the proposed study involves a vulnerable population, records must be retained until 31 December 2028 (GRDS Disposal Authorisation 1559). At the conclusion of the study, hard-copy documents will be safely transported by the lead researcher to Brisbane to be stored at QUT’s record storage facility.

* 1. **Secondary use (including providing access, disclosing)**

QUT requires staff and students to share research data and primary materials as appropriate, during the course of the research, at publication and at completion. As such, the de-identified data set collected during the proposed research will be made available for any subsequent research and evaluation. Participants will be informed of this during the process of obtaining consent.

1. **Resources**

Key resources needed for the completion of the study include physical location, assessment questionnaires and kits, recording devices (for the ADOS-2 administration – helpful but not critical), program manuals and items for use during program delivery (as indicated by the program manuals). Most are currently available to the researcher in the quantity required through Caterpillar Clinic, however any additional items will be loaned/hired/purchased with HDR research funding available to cover research expenses. There is no additional funding or in-kind support currently secured nor being sought.

1. **Results, outcomes and future plans**

Feedback on individual participants can be provided to parents/guardians via the Feedback Form provided in Appendix S. An overview of overall study results will be compiled and provided to participants who indicate or request this at any time during the Study.

As the study forms part of a PhD by publication plan, the study will be written up and submitted for journal publication. Publishing both a trial protocol and results of the study is planned.

Project closure processes will take place at the conclusion of the proposed Study. This will include ensuring all research data is converted to standard, interchangeable and long-lasting formats for long-term storage and access. QUT’s RDSS has designated archive storage for the retention of research data from complete projects. A best practice guide by the Inter-University Consortium for Political and Social Science is available through QUT to provide guidance on data preservation, including archiving files and closure practices. QUT’s eResearch Office and project supervisors will be fully consulted to ensure all data archiving and project closure requirements are met.

**References**

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**List of Appendices (Saved/Provided Separately to Protocol)**

Appendix A Spence Children’s Anxiety Scale Parent Version (SCAS-P)

Appendix BSpence Children’s Anxiety Scale Child Version (SCAS-C)

Appendix C1 Coping Self-Efficacy Scale (CSES) – Parent Version

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