CON-EXT Study

INFORMATION SHEET

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GU Ref No:	2025/078

Why is the research being conducted?

Anxiety disorders are the earliest emerging, most common and debilitating mental illnesses, yet 40 to 45% of anxious children do not respond to best-practice psychological treatment, cognitive-behavioural therapy (CBT). Our team, and others, have found retrospectively that anxious people who respond to CBT exhibit normal pre-treatment markers of fear conditioning and extinction (CON-EXT), the mechanisms underlying change in CBT. By integrating key tenets from basic science and applied clinical research over two decades of collaborative experimental and translational research, and consumer and clinician feedback, we have developed a novel CON-EXT Predictive Marker Task to identify anxious children at the individual patient level who exhibit CON-EXT predictive markers of CBT response, i.e., Marker (+), and those who do not i.e., Marker (-). The next and most stringent test of the CONEXT Predictive Marker Task is to conduct a Phase II trial to examine prospectively whether CON-EXT Marker (+) anxious children respond to CBT, whereas CON-EXT Marker (-) anxious children do not, and secondarily, whether the CON-EXT Predictive Marker Task is feasible and acceptable to clinicians and consumers. The findings will position the CON-EXT Predictive Marker Task with the necessary evidence-base to support partnership projects to examine its implementation into clinical practice and mental health services to ensure that the right anxious children receive CBT.

All children will receive the Take Action Program which is evidence-based cognitive behavioural therapy. Take Action includes 10 sessions with children and a 1-month

booster session and 6 parent sessions. Sessions 1-4 focus on psychoeducation, relaxation strategies and cognitive therapy. Within-session exposure therapy is conducted from sessions 5-10 using individualised exposure hierarchies. Between-session exposure activities are completed at home.

The research is approved by the Griffith University Human Research Ethics Committee (GU Ref No: 2025/078). All members of the research team are international experts who hold PhD's in relevant fields, (clinical, developmental, neuroscience and health economics). The team have been conducting large-scale clinical treatment research for anxious youth for more than 20 years.

What you will be asked to do

If you agree to participate in the study, we will contact you via phone and interview you and your child, using well-established diagnostic assessments of anxiety in youth. The diagnostic interview is a type of clinical interview and will tell us what type and how severe your child's anxiety is at each assessment. The interview will take approximately 40-60 minutes, and the questionnaires take approximately 30 minutes to complete. In addition to the diagnostic interview and questionnaires, your child will complete the CON-EXT task in your home or at the Griffith University clinic, (e.g., Gold Coast or Nathan campus), in which they will be attached to a data collecting device to measure their skin conductance response. This will involve attaching disposable electrodes to the palm or fingers of the non-dominant hand, the electrodes are stickers that attach to the skin, they are passive sensors that record responses, and no electrical current will be emitted from the electrodes. Your child will be presented with a series of shapes via computer screen, and a tone at 82 dB for 1 second will be presented via headphones. The task requires the child to identify which shape is associated with the tone. After each presentation, they will be asked to complete a rating scale that asks about your reaction to the stimuli during the task. They will also be asked to complete a questionnaire that asks about feelings of anxiety. Participation in this study will require approximately 30 minutes.

Children will then receive treatment either in person with a clinician from our team at Griffith University or at home with a clinician from our team at Griffith University via teleconference. All children will receive the Take Action Program.

After treatment we will contact you again to complete another diagnostic interview and questionnaires. This will occur again at 1-month after the treatment. This will help us to assess the long-term outcomes for the treatments. All phone calls will be audio-taped to document that our interviewers and researchers carefully follow the research protocol

and will then be erased after they have been checked. In sum, the information collected from questionnaires, computer tasks, and interviews will help us determine how much progress your child makes as a result of treatment. Any child who continues to meet criteria for an anxiety disorder after participation in this study will be given referral options for further care.

The basis by which participants will be selected or screened

To assess your child's eligibility for the treatment the following determines eligibility to participate: (a) children 7-12 years old; (b) meets criteria for a principal DSM-5 anxiety disorder, (c) parent/carer consent for child to cease concurrent psychotherapy (if relevant), (d) parent/carer consent for child to stabilise medication (if relevant) at the same dose for 12 weeks prior to baseline diagnostic assessment. If your child is receiving other treatment, you will need to discuss this with your clinician before agreeing to cease treatment and participate in this study. If your child does cease other treatment to participate in this study, it is recommended that parents obtain a letter from the treating clinician/s to confirm that they have discussed the specific requirements of the study with the treating clinician/s, before ceasing their current psychotherapy and/or stabilising any medication (if applicable).

Your child will not be eligible to participate if: a) non-anxiety diagnosis is their main problem, b) your child has a pervasive developmental disorder or intellectual disorder, c) your child has impairments that prevent computer use e.g. vision impairment or hearing impairment, and d) your child has had prior CBT treatment. If your child has a depressive or disruptive behaviour disorder that is not as severe as the anxiety disorder, they will be able to participate. We will discuss these matters with you during an initial telephone call to assess eligibility and provide referral options in cases where children are not eligible.

The expected benefits of the research

Results of this study will help us determine the effectiveness and clinical utility of the CON-EXT Predictive Marker Task and targeted CBT for children with anxiety disorders. Such a development would allow us to share this information with other mental health professionals and to assist them in working with other families. Although no guarantee of treatment outcome can be provided to you, these treatments may benefit your child. Feedback will be provided after each assessment time- point and families will be contacted at the end of the study and offered the opportunity to receive a summary of the study findings in simple, easy to follow terms. Parents can also request via email to have a plain language summary of the overall research report at the end of the project.

Risks to you or your child

Participation in this study does not pose any foreseeable risks to children or adults. During CBT treatment, participants may be asked to approach stimuli (e.g. a dog, heights, birthday party, and other situations) that may have made them anxious in the past, however approaching these and other stimuli and situations are important for overcoming anxiety. Children will also answer some questions about anxiety or other feelings that could make them feel uncomfortable. However, many children complete these questionnaires and anxiety, and distress is rare, if this does occur, the therapists will help the child and parent handle this distress with techniques such as slow breathing, relaxation and positive thoughts. Moreover, children do not have to answer any questions or discuss any topics that make them feel uneasy nor will they ever be asked to do anything they are not prepared to do. Children may feel fatigued during the interview and treatment session however they are advised that they are free to take breaks at any time, this is discussed with parents before commencement of interview and treatment.

For the CON-EXT task, there are also no foreseeable risk to your child's health. The tone presented through the headphones might be considered as unpleasant; however, it is safe for human hearing. The study will be conducted in accordance with standard safety procedures.

Confidentiality

All data from this study will be kept confidential. Numerical codes only will be used for identifying data and no personal identifying details will be stored with the responses collected from children. The data collected from this research will be reported in general terms only and will not involve identifying information about children who participated. All information collected will be stored for fifteen years after the end of this study. Information will be stored on a password protected computer at Griffith University, with access limited to the research team only. After this time, all data and other information will be destroyed. The results of this research may be presented at conferences or published in academic journals, but only in a format that is aggregated across individuals. You or your child will not be identified in any results that are presented or published.

Consent to share data

It is important for advancing knowledge and improving our ability to provide effective

treatment to children with anxiety to share or reuse participant de-identified data in future research. Your consent for the future use of your child's data is voluntary, and your decision to consent to the use of your child's data does not affect your child's ability to participate in this study.

Participation is voluntary

Your child's and your own participation in this study is voluntary and neither you nor your child is under any obligation to consent to participate in this study. Non-participation will not involve any penalty and will not affect you or your child's standing at Griffith University. If you choose to allow your child to participate, he or she may discontinue participation at any time without penalty or without providing an explanation. As the parent you would just need to inform the team that you would like to stop participation, and we will ensure no further contact.

Questions / further information

For additional information you can contact Prof Allison Waters as per the details provided on the beginning of this information sheet or the Project Coordinator on phone 07 3735 3351.

If you should experience distress as a result of participation in this study, please contact the project coordinator on the above number to direct you to recommended services. Otherwise, please call *Lifeline* on 13 11 14 or *Beyond Blue* on 1300 224 636.

The ethical conduct of this research

Griffith University conducts research in accordance with the *National Statement on Ethical Conduct in Human Research*. If you have any concerns or complaints about the ethical conduct of the research project (GU ref no: 2025/078) you should contact the Senior Manager, Research Ethics and Integrity on 3735 4375 or research-ethics@griffith.edu.au.

Feedback

Feedback to you will be provided after each assessment time-point, that is: 3 months follow up and 6 months follow up.

Privacy Statement

The conduct of this research involves the collection, access, storage and/or use of your

identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes, including publishing openly (e.g. in an open access repository). However, your anonymity will at all times be safeguarded. For further information consult the University's Privacy Plan at http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan or telephone (07) 3735 4375.