Personalised Anxiety Treatment for Children (PATCH)

INFORMATION SHEET

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Why is the research being conducted?

Anxiety disorders are the most common class of mental disorders in Australia with approximately one in seven people experiencing an anxiety disorder in any 12-month period. These disorders have been shown to significantly impair individual functioning and reduce overall quality of life. It is therefore important to fully understand the processes that contribute to the development of anxiety to help us develop better treatments. You are invited to participate in a nationwide study funded by the Wellcome Trust that will determine how treatment based on cognitive- behavioral therapy can be tailor-made for children. This is based on their responses to a task (CON-EXT) that assesses their responses to threat and safety cues and provides information about their threat sensitivity, positive valence, and cognitive control systems. This information can then help us to personalize, or tailor, their treatment to their individual response systems. For many children and their parents, anxiety can be highly disruptive and prevent children from doing things that other children their age can do. This project will examine how effective it is to tailor treatment based on children's responses systems compared to regular treatment in alleviating their anxiety.

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

Children receiving personalized treatment will receive Take Action and depending on their responses on the CON-EXT task may also receive either Positive Search Training (PST) or Cognitive Control Training (CCT). PST is treatment is based on scientific findings about how children direct their attention to different stimuli that trigger anxiety and is designed to activate the positive valence system. It is a computer-based task that will be conducted at the beginning of each Take Action session, children learn to find and focus on positive targets and use catch phrases and jingles to facilitate attention to positive stimuli and approach motivation.

CCT is designed to help children keep their attention on target stimuli and avoid moving their attention and anxiety to other stimuli. It is designed to improve cognitive control. It is a computer tak that will be conducted at the beginning of each Take Action session and involves keeping attention on target stimuli and verbalization strategies to narrow and maintain attention.

The research is approved by the Griffith University Human Research Ethics Committee (GU Ref No: 2025/077). 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 devise 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 task 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. If they are in the regular treatment condition, they will receive the Take Action Program and if they are in the personalized treatment condition, they will receive Take Action Program and may also receive PST and CCT depending on their responses to the CON-EXT task.

After treatment we will contact you again to complete another diagnostic interview and questionnaires. This will occur again at six months 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) child is 7- 12 years of age, b) meets criteria for an anxiety disorder, c) willingness to cease concurrent psychotherapy (if applicable), d) willingness to stabilise medication (if applicable) at the same dose for 12 weeks prior to 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 or PST 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 may help us determine whether these treatments are effective 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. Participants may view a number of emotional faces (i.e., angry, happy) and other picture scenes (e.g., growling dogs, sharks, plane crash; smiling puppies, happy children, household objects, rain clouds, thunderstorms) which they will see on the computer if they complete the PST treatment. However, these pictures are no more fear provoking than pictures and images children see and hear about on television or as part of their daily lives and learning to control attention is important for overcoming anxiety. In the CBT treatment, participants will 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 email cadrp@griffith.edu.au.

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: 2025/077) 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: post-treatment 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.