NHMRC HREC: 2019/146

Improving Access to Treatment for Children with Anxiety Disorders

INFORMATION SHEET

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Why is the research being conducted?

You are invited to participate in a nationwide study funded by the National Health and Medical Research Council that will determine how well a computer-delivered treatment designed to help children control their attention improves and reduces children's anxiety compared to another computer-delivered treatment based on cognitive-behavioural therapy. Anxiety is defined as feelings of nervousness, worry and fear that is usually brought on by seeing or experiencing certain triggers or events, and/or by the expectation that this is too frightening or difficult to cope with. Anxiety can be helpful when dealing with new challenges and novel situations. However, if it occurs too often or too strongly, it can lead to children not coping in many situations. 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 two treatment conditions and determine if they are as effective as each other in alleviating children's anxiety disorders.

One of the treatments is called Positive Search Training (PST), a treatment that is based on scientific findings about how children direct their attention to different stimuli that trigger anxiety. This treatment is delivered on a computer at home and takes about 30 minutes to complete each session. Children will complete 12 sessions over 3 weeks. The treatment has been shown to "work" because it helps children learn to control the focus of their attention on positive and calm stimuli in the environment which in turn helps to reduce anxiety.

The other treatment is called Cognitive Behavioural Therapy (CBT), a treatment that is based on scientific findings about how children think and behave in response to different triggers of anxiety. The treatment is delivered on a computer at home and takes 20 – 60 minutes to compete each session. Children will complete 10 sessions over 10 weeks, and parents will complete 6 sessions during the 10 weeks. The treatment has been shown to "work" as it helps children to think differently and approach stimuli in the environment which in turn helps to reduce anxiety.

The research is approved by the Griffith University Human Research Ethics Committee (GU Ref No: 2019/146). All members of the research team are international experts who hold PhD's in relevant fields, (clinical, developmental, neuroscience and health economics). Mrs Ryan is the project co-ordinator and holds an undergraduate degree in psychology with honours. 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 a computer task on your home computer in which they will see angry, happy and neutral facial expressions and press a key on the keyboard for the location of an asterisk probe. This task helps us assess children's responses to various types of emotional stimuli.

To accomplish the scientific goals of this project, your child will be randomly assigned into one of two treatment conditions that are delivered via computer at home. One treatment condition is called positive search training (PST), this will take 30 minutes to complete, 4 times a week over 3 weeks in your home on a computer, laptop or tablet. It involves your child viewing a wide variety of pictures (such as growling dogs, angry faces and thunderstorms), and learning to focus their attention on the good and calm pictures among them (such as happy children, playful animals and healthy food). PST also includes games, verbalisations and animations so it is interactive for children. The pictures used in PST are no more fear provoking then pictures or images the children see and hear about on the television or part of their everyday life.

The other treatment condition is called cognitive behavioural training (CBT). Children complete 10 sessions (one per week) and parents complete 6 sessions over 10 weeks. The sessions are 20 - 60 mins in duration, and include a variety of interactive games, quizzes and animations. In addition to the content in the computer program, children completing this treatment will be asked to face their fears as homework tasks by approaching stimuli that they fear e.g., a dog; heights; a birthday party. These stimuli and events are no more fear provoking than those children see and engage in as part of

everyday life. Parent sessions include psychoeducation about anxiety in children and how they can assist their child in overcoming anxiety.

Both treatment conditions are accompanied with instructions and phone calls to assist with set up and children's progress will be monitored by therapists or project staff who will email and consult with you throughout the treatment phase.

At the end of three weeks, we will call to complete another diagnostic interview and questionnaires, and your child will again complete the computer task. This will occur again at 6 months and 12 months after the treatment. This is to help us 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, 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.

Risks to you or your child

Participation in this study does not pose any foreseeable risks to children or adults. Participants will 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. 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.

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. Computer records will be password protected and hard copy data will be stored in a locked filing cabinet in the School of Applied Psychology, Griffith University for a period of 5 years and will then 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.

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 Kathy Ryan, Project Coordinator on k.ryan@griffith.edu.au or 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* (2007). If potential participants have any concerns or complaints about the ethical conduct of the research project they should contact the Manager, Research Ethics on 3735 4375 or **research-ethics@griffith.edu.au**.

Feedback

Feedback to you will be provided after each assessment time-point, that is; three weeks after treatment begins, 6 months follow up and 12 months follow up.

Privacy Statement

The conduct of this research involves the collection, access 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. 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.