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Treatment of Panic Disorder in Adolescents (PANDA Study)



INFORMATION FOR YOUNG PEOPLE

Full Title: Feasibility study examining the efficacy of Brief Cognitive
Therapy for the Treatment of Panic Disorder in Adolescents

Version 2.0 08/07/2019; IRAS Project ID: 265340



University of
Reading



OVERVIEW

We are carrying out a research project to compare two talking therapies, that involve working with a therapist one-to-one, for the treatment of panic disorder in young people aged 11-17½ years

We would like to invite you to take part. In this leaflet, there is some information that we hope will help you to decide whether you would like to take part.

One of our team will go through this information with you at your next visit and answer any questions you may have.

What you can find in this leaflet:

Page 2	A brief overview of the study
Page 3	Some important points about what your involvement will mean
Page 4	Details about how we will keep your information safe
Page 5-8	A closer look at the study and what we will ask you to do
Page 9-10	The advantages and disadvantages of taking part
Page 11	What next?





A BRIEF OVERVIEW

You have been given this leaflet because you:

- Are between **11 and 17½ years old**
- Have been diagnosed with **panic disorder**
- Have been offered treatment and we think **the treatments in this study will be helpful** to you

We will be using **two forms of a talking treatment called Cognitive Behaviour Therapy (CBT)** as part of this research, but you will only have one of them. The one that you have will be decided at random.

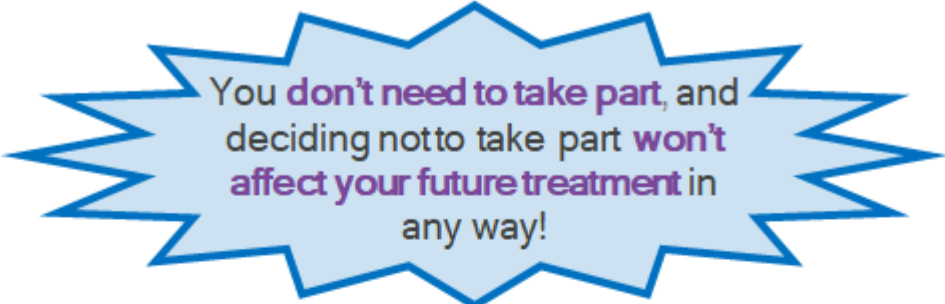
If you take part, we will ask you to:

- Fill in some questionnaires
- Come to up to 5 treatment sessions (and 2 extra 'booster' sessions)
- Have 2 assessments (one after you finish the 5 sessions and one 3 months later)
- We will also invite some young people to be interviewed about their experience of having panic disorder **before** they have treatment and some young people to tell us about their experience of the treatment and taking part in research **afterwards**.

The study was reviewed and given a favourable ethical opinion for conduct by the National Research Ethics Service (NRES) South Central - Berkshire B Committee as well as the University of Reading Ethics committee.



SOME IMPORTANT POINTS



You **don't need to take part**, and deciding not to take part **won't affect your future treatment** in any way!

- Meetings and treatment sessions will be **video or audio taped** so that we can make sure you are getting high quality therapy and that the assessments are done well.
- If you decide **not** to take part, you will be allocated to a therapist who isn't taking part in the study and you will receive all of the same support that you would usually.
- You can **stop taking part** in the treatment or meetings **at any point** in the study and this **won't affect your future treatment**.
- You can also decide that you don't want us to use some or all of the information you have given us, but **you must tell us before we start to analyse the data from the study (by 31st March 2021)**.

If you have any concerns about this research study


If you have concerns about **any** part of the study, please speak to Polly Waite, the Lead Researcher (details on page 11). If you are still unhappy and wish to complain formally, please contact our Joint Heads of School, School of Psychology & Clinical Language Sciences - Prof Carmel Houston-Price and Dr Graham Schafer. They can be contacted via email: hos-pcls@reading.ac.uk or tel: 0118 378 8523 and will arrange to meet with you to discuss your concerns.



KEEPING YOUR INFORMATION SAFE

- Each person in the study is given a **participant number**. We will use this number to label information we collect about them.
- Any information they provide online will use a **secure website**.
- We will store the information that you and your child give us on a **secure University system**.
- None of this information will be taken out of the offices where we do the research and it will not be stored on personal computers.
- Both the files and the drive on which we store these files are **password controlled** and only members of the research team have access to these passwords.
- The data collected about them will be preserved and made available in **a form in which they cannot be identified**, so that it can be consulted and re-used by others (called 'open access').

AFTER THE STUDY FINISHES

- Everyone's results will be grouped together, included in publications of scientific journals, and be presented to other researchers and clinicians.
 - We will send a leaflet explaining the main findings to everyone who took part in the study.
 - Some of the findings from the study will form part of a researcher's educational qualification.
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A CLOSER LOOK AT THE STUDY



The best treatment for panic disorder is **Cognitive Behaviour Therapy, or CBT**. CBT can be delivered in different ways, but we don't know what the best way to deliver it is.

- We are conducting a trial to **compare two different versions of CBT** which are both likely to be effective.



These are called **Brief Cognitive Therapy for Panic Disorder and Graded Exposure**

- We want to give some young people **Brief Cognitive Therapy** and some **Graded Exposure**.
- Both treatments involve **the same number of sessions** and **working with a therapist one-to-one** in the AnDY Research Clinic. You will also be given reading materials and worksheets to complete outside sessions.

5.





ABOUT THE THERAPY

The treatments are called Cognitive Behaviour Therapy because:

- They focus on the **thoughts** (cognitions) that you have when you're anxious
- They also focus on the **ways that you behave** when you're in a situation that makes you feel anxious.

Research has shown that helping people to deal with their fearful thoughts and try out different ways of behaving in frightening situations is a great way of building confidence and helping us overcome our fears.

There are different ways that you and your therapist could try to deal with fearful thoughts and look at changing behaviours.

The therapies in this trial use **different ways** of tackling these problems.

This is always done at your own pace and **you are always in control**. Both treatments work well but **we don't know which works best**



WHAT WE WILL ASK YOU TO DO

Initial assessment: you will have an assessment about your difficulties and you (and your parent/carer) will be asked to fill in some questionnaires.



If eligible, you will be invited to take part in the study. You may also be interviewed about your experience of having panic disorder.



You will be randomly assigned to one of the two treatments. You (and your parent/carer) will be asked to fill in some further questionnaires



Brief Cognitive Therapy <ul style="list-style-type: none">• 5 sessions• Reading materials and worksheets• Questionnaires at each session	Graded Exposure <ul style="list-style-type: none">• 5 sessions• Reading materials and worksheets• Questionnaires at each session
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Post-treatment assessment: you (and your parent/carer) will be asked to fill in questionnaires at the end of the 5 treatment sessions. You may also be interviewed about your experience of the study.



Brief Cognitive Therapy <ul style="list-style-type: none">• 2 booster sessions	Graded Exposure <ul style="list-style-type: none">• 2 booster sessions
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Final assessment: 3 months after the post-treatment assessment, you will have a final assessment and you (and your parent/carer) will be asked to fill in questionnaires.

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- At the initial and final assessment sessions, you and your parent/carer (where possible) will be asked a number of questions, and we will give you both some questionnaires to fill out **about your current difficulties**. Assessment sessions will last up to **2-3 hours**.
 - The questionnaires will ask about your **panic attacks** and things that are related, such as **anxiety/low mood**. Your therapist will use them to make sure the treatment is helpful and relevant to you.
 - We will also use your questionnaire data to help us understand whether these processes are specific to panic disorder in order to further adapt and develop our treatments (by comparing your responses to those of young people without panic disorder).
 - **The regular treatment sessions** will happen mainly weekly and will last between **30 and 90 minutes**. You will be given reading materials and worksheets to read and complete outside sessions.
 - You will also be asked to have another **assessment** 3 months after you finish treatment (and after any booster sessions), so we can check how you are getting on.

We will be inviting **some of you** to take part in **2 additional meetings** before and after the treatment.

- These will involve talking to a researcher before treatment starts about the experience of having panic disorder, and after treatment, about what you thought of the treatment and taking part in a research study.
- We will record these interviews so that we **can be accurate** and learn more about the treatments.
- When we write up our research, we will **include some quotes** from the meetings so that people know the important things that were said. **We won't use your real name**, so people won't know that the quotes were from you.



ADVANTAGES OF TAKING PART



We have good reason to think that both treatments will be helpful for most young people but **we don't know which is best**. That's why we are doing this research.

- All of the questions that we will ask you will help us to do our best to make sure this treatment works well for you.
- You will work with your therapist as a team and will be in control at all times. You will **never be made to do anything** that you do not want to do.
- The treatment will be specific to you.
- By taking part, you will help us learn about **the best ways to help others**, like you, with panic disorder.

THE DISADVANTAGES OF TAKING PART

- As with all forms of talking therapies, you may be asked to **discuss some thoughts and feelings that might make you feel upset**. However, these are similar to the questions you would be asked in treatment, even if you were not taking part in the research, and are an important part of treatment. You can always decide what you would like to discuss in therapy.



- You will have to have **more assessments and questionnaires** than usual if you take part in this study. Where this involves more time than would be normal, we will reimburse you for this.
 - Each family will get £10 to cover the extra time completing questionnaires before and after treatment and £20 for the assessment 3 months after finishing treatment (as this involves a clinical interview as well).
 - If you take part in interviews before and after treatment, you will be given £10 to cover the time and inconvenience for each interview.

WHAT HAPPENS NOW?

We will ask you some questions to check you are eligible to take part. You won't be able to take part if you have already had either type of CBT for panic disorder, or if you have certain other difficulties.

Then, if you want to take part:

- If you are aged 11-15 years, fill out the assent form. Your **parent/carer will also need to sign a consent form to agree that you can take part**.
- If you are aged 16 or older, fill out the consent form.

We will also send a short letter to your GP letting them know that you are taking part.

If you don't want to take part:

- You don't have to do anything more! You will get your treatment as usual.

Deciding not to take part won't affect how you are looked after in any way!!

QUESTIONS?

If you have any questions or worries about anything to do with this research study, **please speak to the team member who is going through this leaflet with you.**

Or you can email or telephone the lead researcher

Polly Waite
 Email: p.l.waite@reading.ac.uk
 Telephone: 0118 378 5534



Your parent/carer will also be getting some information about this research, so you can talk to them too.