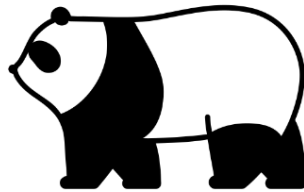


FUNDED BY

NIHR | National Institute
for Health Research

Treatment of Panic Disorder in Adolescents (PANDA Study)



INFORMATION FOR PARENTS/CARERS

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

Version 4.0 11/06/2020; 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 11-18 years

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

One of our team will go through this information with you and answer any questions you have next time you speak with us.

What you can find in this leaflet:

- | | |
|------------------|--|
| Page 2 | A brief overview of the study |
| Page 3 | Some important points about what your child's involvement will mean |
| Page 4 | Details about how we will keep your child's information safe |
| Page 5-8 | A closer look at the study and what we will ask you and your child 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 your child:

- Is between **11 and 18 years old**
- Has been diagnosed with **panic disorder**
- Has been offered treatment and we think **the treatments in this study will be helpful** to them

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

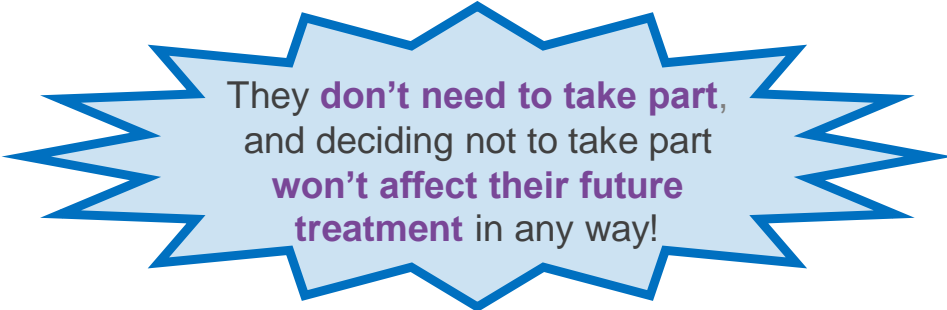
If they take part, we will ask them to:

- Fill in some questionnaires
- Attend to up to 5 treatment sessions, either face to face or by video or phone call (and 2 extra 'booster' sessions)
- Have 2 assessments (one after they 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 and parents 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

2. Committee as well as the University of Reading Ethics committee.

SOME IMPORTANT POINTS



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

- Assessments and treatment sessions will be **video or audio taped** so that we can make sure they are getting high quality therapy and that the assessments are done well.
- If they decide **not** to take part, they will be allocated to a therapist who isn't taking part in the study and they will receive all of the same support that they would usually.
- They can **stop taking part** in the treatment or meetings **at any point** in the study and this **won't affect their future treatment**.
- They can also decide that they don't want us to use some or all of the information they have given us, but **they 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.

3.

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.

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**, either in the AnDY Research Clinic or by video/telephone call. Your child will also be given **reading materials and worksheets** to complete outside sessions.

ABOUT THE THERAPY

The treatments are called Cognitive Behaviour Therapy because:

- They focus on the **thoughts** (cognitions) that people have when they are anxious
- They also focus on the **ways that they behave** when they are in a situation that makes them 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 your child and their 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 child's own pace and **they 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: your child will have an assessment about their difficulties and you will both be asked to fill in some questionnaires.



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



Your child will be randomly assigned to one of the two treatments. You will both be asked to fill in some further questionnaires



| | |
|------------------------------------|------------------------------------|
| Brief Cognitive Therapy | Graded Exposure |
| • 5 sessions | • 5 sessions |
| • Reading materials and worksheets | • Reading materials and worksheets |
| • Questionnaires at each session | • Questionnaires at each session |



Post-treatment assessment: you will both be asked to fill in questionnaires at the end of the 5 treatment sessions. Your child may also be interviewed about their experience of the study.



| | |
|--------------------------------|------------------------|
| Brief Cognitive Therapy | Graded Exposure |
| • 2 booster sessions | • 2 booster sessions |



Final assessment: 3 months after the post-treatment assessment, your child will have a final assessment and you will both be asked to fill in questionnaires.

- At the initial and final assessment sessions, your child (and you) will be asked a number of questions, and we will give you both some questionnaires to fill out **about their current difficulties**. Assessment sessions will last up to **2-3 hours**.
- The questionnaires will ask about your child's **panic attacks** and things that are related, such as **anxiety/low mood**. Their therapist will use them to make sure the treatment is helpful and relevant.
- We will also use the 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 their 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**. They will be given reading materials and worksheets to read and complete outside sessions.
- They will also be asked to have another **assessment** 3 months after they finish treatment (and after any booster sessions), so we

We will be inviting **some young people and parents/carers** to take part in up to 2 **additional meetings** before and after the treatment.

- These will involve young people talking to a researcher before treatment starts about their experience of having panic disorder, and young people and parents/carers after treatment, about what they 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 child's or your real name**, so no-one will know the quotes were from your child or 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 them will help us to do our best to make sure this treatment works well for them.
- They will work with their therapist as a team and will be in control at all times. They will **never be made to do anything** that they do not want to do.
- The treatment will be specific to your child.
- By taking part, they will help us learn about **the best ways to help others**, like them, with panic disorder.

THE DISADVANTAGES OF TAKING PART

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



- They will have to have **more assessments and questionnaires** than usual if they take part in this study. Where this involves more time than would be normal, we will reimburse them 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).
 - Where young people and parents/carers take part in interviews before and after treatment, they will be given £10 to cover the time and inconvenience for each interview.

WHAT HAPPENS NOW?

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

Then, if they want to take part:

- If they are aged 11-15 years, they need to fill out the assent form. **You will also need to sign a consent form to agree that they can take part.**
- If they are aged 16 or older, they can give consent and so they need to fill out the consent form.

We will also send a short letter to your child's GP letting them know that they are taking part.

If they don't want to take part:

- They don't have to do anything more. They will get their treatment as usual.

Deciding not to take part won't affect how they 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 child will also be getting some information about this research, so they can talk to Polly or other members of the team too.