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Feasibility study examining the efficacy of brief cognitive therapy for the treatment of panic disorder in adolescents (PANDA)

Submission date
27/09/2019

Recruitment status
No longer recruiting

Registration date
05/12/2019

Overall study status
Completed

Last Edited
31/01/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People who have panic disorder experience repeated, unexpected panic attacks, which involve intense physical sensations, e.g., increased heart rate, breathlessness and dizziness. Typically, these sensations are misinterpreted as being dangerous and as a result the person avoids activities or situations that may bring on the sensations. Around 0.5-1% of adolescents meet diagnostic criteria for panic disorder and it is a disabling condition, associated with adverse long-term outcomes. Despite this, adolescents with panic disorder have typically been excluded from treatment trials of children and young people with anxiety disorders, and there is limited current guidance for NHS Child and Adolescent Mental Health Services (CAMHS) as to how adolescents with panic disorder should be treated. Cognitive Therapy (CT) has been shown to be highly effective for adults with panic disorder, even in a brief format with self-study modules. Key aspects of the CT model apply to adolescents.

This feasibility study will provide the groundwork for a future definitive trial to investigate the effectiveness of brief CT for panic disorder in adolescents compared to standard care (graded exposure)

Who can participate?
Patients aged 11 – 18 years diagnosed with panic disorder

What does the study involve?
After an initial assessment at the AnDY Research Clinic at the University of Reading, adolescents with panic disorder will have 5 sessions (and up to 2 boosters) of either brief CT or graded exposure. Both treatments involve working one-to-one with a therapist. Young people will be assessed post-treatment and at 3-month follow-up. Adolescent outcomes, expectations and experiences and health economic factors will be assessed.

A second study will examine how adolescents with panic disorder think and behave in panic-related situations to determine whether these processes are specific to this particular anxiety disorder, to then further adapt and develop the treatment for focused use with adolescents.

This will involve comparing their responses on self-report measures to those of adolescents with other anxiety disorders and non-anxious adolescents.

What are the possible benefits and risks of participating?
Benefits: Participants taking part in the feasibility study will all receive treatment from clinicians who are receiving training and supervision that goes beyond what therapists ordinarily receive in routine clinical practice. We anticipate that this will benefit the young people and their families.
Risks: Assessments will involve discussing potentially distressing thoughts and feelings that may cause a degree of distress or discomfort for some children and parents. The voluntary nature of all assessments will be emphasised to young people and their parents/carers and study researchers will be on the alert for families who appear unduly distressed and will notify senior members of the study team immediately

Where is the study run from?
AnDY Research Unit, Unversity of Reading, UK

When is the study starting and how long is it expected to run for?
October 2019 to April 2023

Who is funding the study?
National Institute for Health Research, UK

Who is the main contact?
Dr Polly Waite (scientific), p.waite@reading.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Polly Waite

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
265340

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS: 265340; CPMS: 42363

Study information

Scientific Title
Feasibility study examining the efficacy of brief cognitive therapy for the treatment of panic disorder in adolescents

Acronym
PANDA

Study objectives
Is a full randomised control trial comparing brief cognitive therapy to an existing cognitive behavioural treatment (graded exposure) for adolescents with panic disorder feasible?
Do adolescents with panic disorder show significantly higher levels of (i) bodily sensations (ii) panic cognitions, (iii) safety behaviours, and (iv) avoidance, compared to adolescents with other anxiety disorders and non-anxious adolescents?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/06/2019, NHS HRA South Central - Berkshire B (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0) 207 104 8310; nrescommittee.southcentral-berkshireb@nhs.net), ref: 19/CRB/2888

Study design
Cross-sectional randomised controlled intervention feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Panic Disorder

Interventions
The main research is a feasibility study to determine whether a full RCT to establish the effectiveness and cost-effectiveness of brief cognitive therapy and an existing cognitive behavioural treatment (graded exposure) for adolescent panic disorder will be possible.

Adolescents (aged 11-17.5) will be recruited to the study, whose primary presenting problem is panic disorder, and they will be randomised in a 1:1 ratio, randomisation stratified by baseline panic disorder severity, to receive either brief cognitive therapy or graded exposure. We will aim to recruit 48 adolescents (24 in each group) but will accept a minimum of 30 participants (15 in each group). This sample size is considered to be sufficient to provide an estimate of variation in outcomes (on continuous variables) on which to power the definitive trial, if indicated. It is also considered sufficient to indicate if any adverse events or significant deterioration is likely to occur, as well as to examine recruitment and drop-out rates, and treatment integrity. Clinicians within the AnDY Research Clinic will be suitably trained in delivering both treatment arms.

Both treatments involve 5 face to face sessions (and up to 2 booster sessions) with a therapist and involve parents/carers and school staff as appropriate. Brief cognitive therapy involves self-study modules and the main focus in sessions is experiential exercises in which bodily sensations and safety behaviours are manipulated to demonstrate their adverse effects. Graded exposure involves creating a hierarchy of feared situations and the young person is encouraged to enter situations in order to learn that anxiety goes down over time.

Symptoms and diagnoses of panic disorder and common co-morbid disorders and overall functioning will be assessed before treatment, as part of a routine assessment used in the Clinic. Participants in both treatment arms will take part in a post-treatment assessment and 3-month follow-up assessment, including adolescent- and parent- report questionnaire measures. A further diagnostic assessment will also be conducted at the 3-month follow-up assessment. Young people will also complete questionnaires before/during each therapy session to monitor progress and inform treatment delivery. Health economic questionnaire measures will also be administered at each assessment time point. A subgroup of adolescents will be invited to take part in qualitative interviews before and after treatment to explore their experience of having panic disorder and of their experience of the treatment and the trial procedures.

A second study examining cognitive processes in adolescents (aged 11-17.5) with panic disorder will be carried out to determine whether these processes are specific to this particular anxiety disorder in order to further adapt and develop the treatment for focused use with adolescents. This study will recruit 3 groups of adolescents (Group 1: Adolescents with a primary diagnosis of panic disorder; Group 2: Adolescents with an anxiety disorder that does not include panic disorder; Group 3: Non-anxious adolescents). Group 1 have the same inclusion and exclusion criteria as the feasibility study. It is likely that the majority, if not all, will be taking part in the feasibility study (and therefore their baseline measures will be used for this study). Group 2 will be recruited from the AnDY Research Clinic following their initial assessment and comprise adolescents without panic disorder and with another anxiety disorder as their primary problem. Group 3 will be recruited from community settings (e.g., schools, youth groups) and to take part, they must score below the clinical cut-off on a measure of anxiety and depression.

The 3 groups of adolescents will complete questionnaire measures of cognitive and behaviours that are associated with the cognitive model for panic disorder in adults to investigate whether adolescents with panic disorder show significantly higher levels of bodily sensations, panic cognitions, safety behaviours and avoidance, compared to adolescents with other anxiety disorders and non-anxious adolescents. Groups 2 and 3 will be reimbursed for their time

Intervention Type
Other

Primary outcome measure
Feasibility of a definitive RCT on the basis of acceptability of the treatments and trial procedures, recruitment rates, rate of treatment drop out, and retention to research assessments 12-weeks after the start of treatment.
The specific outcome measures are:
1. Young person's panic disorder symptoms and interference in daily life measured using Panic Disorder Severity Scale for Children and Adolescents and the Child Anxiety Interference Scale
2. Young person's diagnostic status, quality of life and health resource use measured using the Anxiety Disorders Interview Schedule (ADIS-C/P), The Clinical Global Impression Scale - Improvement, Outcome Rating Scale, EQ-5D (5L), Child Health Utility 9D and Client Services Receipt Inventory (CSRI)
3. Acceptability of the treatments and trial procedures measured using the Experience of Service Questionnaire and qualitative interviews
4. Rate of recruitment, drop-out, and retention to post-treatment and 3-month follow-up assessments using patient records
5. Therapist treatment adherence measured using the Therapy Content Checklist
6. Treatment credibility measured using the Treatment Credibility and Expectation of Improvement Questionnaire
7. Adverse events measured using patient records

Secondary outcome measures
At post-treatment and 3-month follow up:
1. Bodily sensations measured using the Body Sensations Questionnaire
2. Panic cognitions measured using the Agoraphobia Cognitions Questionnaire
3. Safety behaviours measured using Safety Behaviours Questionnaire
4. Avoidance measured using the Mobility Inventory

Overall study start date
01/01/2019

Completion date
30/04/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/09/2021:
1. Aged 11-18 years at assessment
2. A DSM-5 diagnosis of panic disorder that has been identified as the primary or secondary presenting disorder
3. At least one panic attack in the month prior to assessment

4. No psychotropic medication use or alternatively, willingness to be withdrawn from medication before the start of the trial under the supervision of the young person's GP (a minimum 6-week drug-free period for SSRIs and a 2-day drug free period for benzodiazepines will be required before the young person can start trial treatment) and agreement not to start medication during the trial
5. If the young person has a co-morbid medical condition (such as asthma, epilepsy or cardiovascular disease), the young person's GP must have been consulted and given the opinion that this will not interfere with treatment delivery
6. Willingness to engage in the treatment
7. Willingness to accept random allocation

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Previous inclusion criteria as of 24/08/2021:
1. Aged 11 - 17.5 years at assessment
2. A DSM-5 diagnosis of panic disorder that has been identified as the primary or secondary presenting disorder
3. At least one panic attack in the month prior to assessment
4. No psychotropic medication use or alternatively, willingness to be withdrawn from medication before the start of the trial under the supervision of the young person's GP (a minimum 6-week drug-free period for SSRIs and a 2-day drug free period for benzodiazepines will be required before the young person can start trial treatment) and agreement not to start medication during the trial
5. If the young person has a co-morbid medical condition (such as asthma, epilepsy or cardiovascular disease), the young person's GP must have been consulted and given the opinion that this will not interfere with treatment delivery
6. Willingness to engage in the treatment
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5. If the young person has a co-morbid medical condition (such as asthma, epilepsy or cardiovascular disease), the young person's GP must have been consulted and given the opinion that this will not interfere with treatment delivery
6. Willingness to engage in the treatment
7. Willingness to accept random allocation

Participant type(s)
Patient

Age group

Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
48

Total final enrolment
34

Key exclusion criteria
1. A current primary disorder other than panic disorder (such as another anxiety disorder or major depressive disorder (MDD)), identified through a diagnostic assessment at baseline
2. Co-morbid conditions that are likely to interfere with treatment delivery; such as an established autistic spectrum disorder, learning disabilities, suicidal intent, or recurrent or potentially life-limiting self-harm (i.e. current frequency of at least once per week or self-harm that requires medical attention)
3. Having been identified by social services as currently 'at risk' due to, for example, child protection concerns
4. Currently receiving a psychological intervention or have received previous treatment with cognitive therapy or graded exposure therapy for panic disorder

Date of first enrolment
17/10/2019

Date of final enrolment
17/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
AnDY Research Unit
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Sponsor type
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ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/08/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Anonymised datasets containing quantitative data will be stored in the university of reading research data archive (https://researchdata.reading.ac.uk) on completion of the study. data can be accessed by registered users who have agreed to the terms and conditions of the archive. written consent from participants to make the data available in this way was obtained.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2	08/08/2019	05/12/2019	No	Yes
Protocol (preprint)		30/09/2021	17/11/2021	No	No
Protocol article		03/03/2022	31/01/2025	Yes	No