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Effectiveness of focused CBT for panic disorder

Submission date
15/01/2024

Recruitment status
No longer recruiting

Registration date
23/01/2024

Overall study status
Completed

Last Edited
28/10/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Panic disorder is often treated in NHS talking therapies services by psychological well-being practitioners (PWPs). There is a need to improve recovery rates for panic disorder in local NHS talking therapies. Therefore, the primary aim of this study is to improve the recovery rates for panic disorder in two local NHS talking therapy services by delivering training to PWPs in a treatment called 'Focused Cognitive Behavioural Therapy (CBT)' and to see if this treatment is more effective or not than the current psychological treatment for panic disorder. In addition, research has shown that panic disorder is often maintained by behaviours known as 'safety-seeking behaviours' and reducing or stopping these behaviours can help with treatment. These behaviours aim to help someone with panic disorder stop a catastrophic event from happening. For example, someone with panic disorder may sense that their heart rate has increased, believing this indicates a heart attack is occurring, therefore to stop this from happening they will engage in a safety-seeking behaviour such as asking for help. However, some research has suggested that these safety-seeking behaviours are not bad and can help someone with panic disorder during psychological treatment. Also, no research has examined the impact of 'approach supporting behaviours' which are behaviours that can help someone confront their fears. Therefore, another aim is to investigate, if there is a difference between focused CBT and the current treatment of panic disorder in NHS Talking therapies, that may explain this. Could the use of approach-supporting behaviours and reducing/stopping safety-seeking behaviours explain any differences between the treatments?

Who can participate?
Individuals who are 18+ years of age, of any sex and where panic disorder with or without agoraphobia is the main problem.

What does the study involve?
People with panic disorder at the NHS talking therapies service are asked if they would like to take part in the study. If so, they will be randomly placed into either the 'focused CBT' treatment or the current treatment provided for panic disorder at the NHS talking therapies services. Participants will then receive the treatment they have been randomly allocated to. The symptoms and severity of the participant's panic, depression, anxiety and the participant's daily functioning are measured before they start treatment, during each treatment session and at the end of treatment. Safety-seeking behaviours and approach-supporting behaviours are measured before treatment begins, mid-way through treatment and at the end of treatment.

What are the possible benefits and risks of participating?
Taking part could help improve the current psychological treatment for panic disorder with or without agoraphobia in two local NHS Talking Therapies services. In addition, it would also mean participants will obtain psychological treatment for panic disorder with or without agoraphobia which may help with their difficulties with panic.

The research team do not anticipate any risk associated with taking part.

Where is the study run from?
The University of Oxford.

When is the study starting and how long is it expected to run for?
November 2023 to December 2024

Who is funding the study?
Oxford Health NHS Foundation Trust. This research is part of the main contact's (Saarim Aslam) Doctorate in Clinical Psychology Thesis, at the University of Oxford.

Who is the main contact?
1. Saarim Aslam, saarim.aslam@stx.ox.ac.uk
2. Professor Paul Salkovskis, paul.salkovskis@hmc.ox.ac.uk

Contact information

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333071

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 333071

Study information

Scientific Title
Evaluating the effectiveness of a focused CBT training for panic disorder with or without agoraphobia

Study objectives
1. Individuals with panic disorder with or without agoraphobia who receive focused CBT treatment delivered by trained PWPs will show a greater reduction in panic symptom severity compared to those who receive the current step 2 psychological treatment for panic disorder with or without agoraphobia.

2. Individuals with panic disorder with or without agoraphobia who receive focused CBT treatment from trained PWPs will show a greater reduction in anxiety and depression and will show an improvement in daily functioning compared to those individuals who receive the current step 2 psychological treatment for panic disorder with or without agoraphobia.

Exploratory aim: If differences in panic symptom severity occur between those receiving focused CBT and the current step 2 psychological treatment for panic disorder, what mechanisms could underlie this difference?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/12/2023, South West - Cornwall & Plymouth Research Ethics Committee (Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8079; cornwallandplymouth.rec@hra.nhs.uk), ref: 23/SW/0151

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community, Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Panic disorder with or without agoraphobia

Interventions
1. Focused CBT: This will involve six sessions, delivered by Qualified Psychological Wellbeing Practitioners (PWPs). Participants randomly allocated to this treatment will receive workbook modules to complete which will introduce each session's topic. They will be required to complete the workbook modules before each session as these workbooks will be used by the PWPs with the participants during the treatment sessions. The workbook modules and treatment sessions will use cognitive behavioural therapy (CBT) techniques to help participants with their panic symptoms.

2. Treatment as usual has two different treatments which are currently provided by the NHS Talking Therapies Services taking part. These are (i) Guided Self Help (GSH) and (ii) computerised CBT (cCBT). GSH involves a consultation with a PWP followed by six treatment sessions whereby the participant will be guided through different skills and techniques to help with the panic symptoms and difficulties. cCBT is delivered on an online platform which involves seven modules teaching participants skills to help with their panic symptoms and involves online reviews by a PWP.

Random allocation: Participants will be randomly allocated to either focused CBT or treatment as usual. Randomisation is being stratified by site and using blocked randomisation. The tool used will be an online randomisation tool such as ‘Sealed Envelope’. If participants are randomly allocated to treatment as usual, they will follow normal NHS Talking Therapies service procedures for allocation to either cCBT or GSH which involves a discussion of these options with the participant and an agreement between the participant and clinician of which is the most suitable option for them.

Administration: Focused CBT is administered face-to-face or online via MS Teams. Both cCBT and GSH are administered either face to face, online via MS Teams or by telephone. This is based on participant preference and clinical need.

Intervention Type
Behavioural

Primary outcome measure
Panic symptom severity measured using the Panic Disorder Severity Scale (PDSS) at pre-treatment, each treatment session and the end of treatment

Secondary outcome measures
1. Depression measured using the Patient Health Questionnaire (PHQ-9) at pre-treatment, each treatment session and the end of treatment
2. Anxiety measured using Generalised Anxiety Disorder Assessment (GAD-7) at pre-treatment, each treatment session and the end of treatment
3. Daily functioning measuring using the Work and Social Adjustment Scale (WSAS) at pre-treatment, each treatment session and the end of treatment
4. Safety-seeking and approach-supporting behaviours measured using the Panic Safety Seeking and Approach Supporting Behaviours Questionnaire (P-SSASBQ) at pre-, mid and the end of treatment (this is to help answer an exploratory aim).

Overall study start date
06/11/2023

Completion date

31/12/2024

Eligibility

Key inclusion criteria
1. Age 18+ (no upper age limit)
2. English speaking and able to complete questionnaires and workbooks in English
3. Any gender
4. The presence of recurrent panic attacks whereby some are unexpected
5. Panic disorder with or without agoraphobia is the main problem as identified in the problem descriptor

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
46

Total final enrolment
72

Key exclusion criteria
1. Panic is not the primary difficulty
2. Individuals who cannot consent
3. Those with long-term conditions
4. Involvement in another research project
5. Risk/safeguarding cannot be managed
6. Substance/alcohol use that would impact therapy and individuals unwilling to work to reduce this use
7. Inability to access materials, for example, technology barriers

Date of first enrolment
29/01/2024

Date of final enrolment
08/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Health NHS Foundation Trust
Warneford Hospital
Warneford Lane
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
https://www.oxfordhealth.nhs.uk/

ROR
https://ror.org/04c8bjx39

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Oxford Health NHS Foundation Trust

Alternative Name(s)
OxfordHealthNHS, Oxford Health NHS (UK), Oxford Health NHS FT, OHFT

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

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

Intention to publish date
03/02/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the detailed level of information gathered.

IPD sharing plan summary
Not expected to be made available