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Cognitive behaviour therapy for depersonalisation-derealisation disorder

Submission date
25/05/2022

Recruitment status
No longer recruiting

Registration date
05/01/2023

Overall study status
Completed

Last Edited
28/07/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Depersonalisation-Derealisation Disorder (DDD) is a distressing condition where people feel a profound sense of unreality and disconnection from the world around them. Around 1% of the population have DDD, but there has been almost no research and there is limited information about effective treatments. Cognitive Behaviour Therapy (CBT) is helpful in treating other mental health conditions and CBT has been specifically adapted for people with DDD (CBT-f-DDD). The best way to investigate whether CBT-f-DDD is helpful for people with DDD symptoms would be through a randomised controlled trial comparing two groups (those who receive CBT-f-DDD and those who do not) across a range of factors at set time periods. In this study, the researchers plan to see how feasible this research is to conduct, refine the treatment and subsequently set up a large-scale clinical trial. They have two aims: (1) to investigate the feasibility of using CBT-for-DDD in a small study where people with DDD are randomly divided into either having CBT or not, and (2) to try this within a typical NHS setting.
The researchers have previously carried out two small studies which showed that CBT-for-DDD can reduce people's symptoms of DDD, and also anxiety and depression, as well as improve their work and relationships. However, these studies did not compare those offered CBT to those who weren't, so it is not certain whether it was the CBT that helped. Also, both these studies were from the same specialist clinic and so the researchers want to know if it is possible to train general CBT therapists to deliver CBT-for-DDD so that it can be widely available in standard NHS mental health services.

Who can participate?
Patients aged 16-75 years who have current symptoms of DDD

What does the study involve?
The researchers will design a CBT-for-DDD manual and train NHS therapists in this. They will then recruit people with DDD from routine NHS services and randomly split these people into two groups where one is given CBT-f-DDD and the other group has standard care. After 6 months of treatment these groups will be compared to see if their symptoms have changed. The researchers will assess the practicalities of delivering the treatment and patients' experience so we can better design a future larger study.

What are the possible benefits and risks of participating?
Participation will allow the researchers to understand if CBT-f-DDD is an effective and acceptable treatment option for DDD and if this can be delivered easily in a typical NHS setting. Participants will be contributing to research which could inform future treatment and raise awareness around DDD. Upon completion of the study, participants will also receive £10 for their participation in the study.
This is not a high-risk study, and the researchers are not expecting there to be any harmful effects. However, they are aware that within any therapy there is the potential that discussion of past difficult events may cause some distress and that there is a potential to feel a little worse before feeling better, as discussing difficult life events could temporarily cause some negative feelings. However, all interventions will be carried out by qualified and trained NHS clinicians, and there will be opportunities to discuss any issues or concerns with the research team as well.

Where is the study run from?
Camden and Islington NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2021 to June 2024

Who is funding the study?
National Institute for Health Research (NIHR)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
314923

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 314923, Sponsor number H-1809b, CPMS 52687

Study information

Scientific Title
Cognitive behaviour therapy for depersonalisation-derealisation disorder (CBT-f-DDD): a feasibility study

Acronym
CBT-f-DDD

Study objectives
This project has four aims:
1. To fill the demonstrable gap in effective treatments for depersonalisation-derealisation disorder (DDD) by undertaking a feasibility randomised controlled trial (RCT) of cognitive behaviour therapy (CBT) for depersonalisation-derealisation disorder (CBT-f-DDD) to define the parameters to inform a future efficacy trial (RCT)
2. To disseminate specialist CBT f-DDD skills to generic NHS clinicians
3. To evaluate a manualised protocol, training workshop and clinical supervision
4. To determine whether CBT-f-DDD can be conducted within a typical NHS setting with generic CBT therapists given a brief training in DDD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/05/2022, London Bridge Research Ethics Committee (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 1048202, +44 (0)207 1048124; londonbridge.rec@hra.nhs.uk), ref: 22/LO/0318

Study design
Multicenter interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depersonalisation-Derealisation Disorder (DDD)

Interventions
Participants with symptoms meeting the clinical threshold for Depersonalisation-Derealisation Disorder (DDD) who consent to enter the study will be randomly allocated to either the Cognitive Behaviour Therapy for DDD (CBT-f-DDD) group or the standard care/treatment as usual (TAU) group. Those allocated to the CBT-f-DDD group will receive 6 months of weekly individual CBT-f-DDD sessions (min. 12 and max. 24 sessions of 1 hour each) delivered by trained NHS clinicians. Those allocated to TAU will receive the standard care they would be offered normally within the NHS service. Randomisation will take place via the sealed envelope method, and the randomisation lists have been created by an independent statistician prior to participants entering the study, to ensure an unbiased approach.

There is a 6-month recruitment period, followed by a 6-month intervention period, and a follow-up 6 months after that. The researchers assess participants at Time 0 (eligibility), Time 1 (baseline), Time 2 (post-intervention), and Time 3 (6-month follow-up from the end of intervention).

Updated 31/01/2023:
There is an 11-month recruitment period, followed by a 6-month intervention period, and a follow-up 3 months after that. The researchers assess participants at Time 0 (eligibility), Time 1 (baseline), Time 2 (post-intervention), and Time 3 (3-month follow-up from the end of intervention).

Intervention Type
Other

Primary outcome(s)
The primary outcomes relate to the feasibility and acceptability measures (see below). The researchers will use a traffic light system to establish the success of the trial based on each measure.
1. Recruitment/eligibility data: collected throughout the recruitment period (6-month window, includes Time 0 and Time 1)
2. Participant attrition rates: collected throughout participant journey (12 months), and reviewed at each timepoint (Time 0-3)
3. Therapist attrition rates and reasons for withdrawing throughout the study: collected throughout the recruitment and intervention period (Time 0-2)
4. Resources needed to complete CBT-f-DDD:
4.1. Length of time required for RAs to complete assessments and collect and analyse data (from research assistant time sheets - collected at each time point, Time 0-3, throughout the study), CBT attendance rates (from electronic patient records - Time 1-2), and the amount and nature of supervision required (from Co-PI supervision notes - Time 1-2)
4.2. A minimum of 12 sessions and a maximum of 24 weekly sessions are established for the 6-month window, allowing for 50% attendance rates (Time 1-2, 6 months)
5. Therapist adherence to CBT-f-DDD (fidelity) (Time 1-2): Records of session content, participants' engagement with CBT-f-DDD, and homework tasks completed (all from therapist post-session checklists). A random sample of 10% of audio-recorded therapy sessions will be evaluated using standardised CBT protocols for adherence to the CBT model as well as an adapted CBT-f-DDD checklist
6. Participant acceptability (Time 2 and 3):
6.1. Acceptability of assessment procedures and measures (Time 2 and 3)
6.2. Acceptability of CBT-f-DDD including aspects of the treatment found helpful and unhelpful, perceived impact of the intervention, and satisfaction with the intervention and therapists (from

thematic analysis of the qualitative interviews [Time 3]; and as measured by items on the end-of-treatment questionnaire “CBT-f-DDD brief outcomes and experiences questionnaire” [Time 2])

Key secondary outcome(s))
1. Health data and demographics: Health economic outcomes measured using the Client Service Receipt Inventory (CSRI) at Time 0, 2 and 3
2. Clinical data:
2.1. Depersonalisation-Derealisation Disorder measured using the Cambridge Depersonalization Scale (CDS) at Time 0-3
2.2. Dissociation measured using the Dissociative Experiences Scale (DES) at Time 0-3
2.3. Depression measured using Patient Health Questionnaire (PHQ)-9 at Time 0-3
2.4. Anxiety measured using Generalised Anxiety Disorder Assessment (GAD-7) at Time 0-3
2.5. Co-morbidity measured using Clinical Interview Schedule - Revised (CIS-R) at Time 0 and 3
2.6. Functioning measured using the Work and Social Adjustment scale (WASA) at Time 0-3
2.7. Global rating of change question (i.e., “do you feel better?”) at Time 2
2.8. Quality of life measured using EQ-5D-5L at Time 0, 2 and 3
2.9. Clinical characteristics including the age of onset of DDD, duration, co-morbid diagnoses, previous treatments for DDD, type and dosage of current medication; measured using semi-structured interview of DDD experiences (Time 0-3) and CSRI (Time 0, 2 and 3)

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Aged 16-75 years
2. Have current symptoms of DDD meeting Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnostic criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
1. People having previously had CBT specifically for DDD
2. Where there are co-morbid current diagnoses of:
2.1. Psychosis spectrum disorder
2.2. Substance dependence

2.3. Intellectual disability
2.4. Cognitive impairment due to head injury or organic disorder
2.5. Post-traumatic stress disorder (PTSD)
3. Participants lacking the capacity to consent to take part in the study
4. Insufficient proficiency in the English language to engage in CBT
5. Requiring special communication needs arrangements.
6. People who are not registered with a GP
7. Those with depersonalisation and/or derealisation symptoms which score below clinical severity (i.e., a total score of 0-2) in response to the diagnostic questions
8. Participants involved in other research studies involving mental or physical health research (including drug trials)

Date of first enrolment
13/05/2022

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Camden and Islington NHS Foundation Trust
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
Trust Headquarters Block B2
St Ann's Hospital
St Ann's Road
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N15 3TH

Sponsor information

Organisation
Camden and Islington NHS Foundation Trust

ROR
https://ror.org/03ekq2173

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

Individual participant data (IPD) sharing plan
Access to the final study dataset will be limited to the minimum number of individuals necessary for quality control, audit, and analysis, which will be members of the research team only and members of the Research Steering committee and Independent Data Monitoring and Ethics Committee. However, access will also be permitted to site investigators if a formal request describing their plans is approved by the steering group. Given these data could have potential for identification of participants the final study dataset will not be available to others beyond the immediate research team and committees. However, the details of the statistical analysis and the analysis of transcripts will be made more widely available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/08/2024	12/08/2024	Yes	No

Basic results			28/07/2025	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 6.4	27/10/2022	31/01/2023	No	No
Protocol file	version 6.5	20/02/2023	21/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes