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Cognitive Behavioural Therapy for psychosis (CBTp) in acute mental health inpatient settings

Submission date
18/02/2021

Recruitment status
No longer recruiting

Registration date
18/02/2021

Overall study status
Completed

Last Edited
12/08/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Psychosis is a mental health problem that includes experiences such as hearing voices, feeling paranoid, and seeing things that are not there. Psychosis is one of the most distressing mental health problems and has been identified as one of the top 25 causes of worldwide disability. When people go to a mental health hospital for help with their experiences of psychosis, they tend to be very distressed, and can often be a risk to themselves (due to self-harming or wanting to end their own life) or even to other people. Stays in hospitals are very expensive for the NHS, and both inpatients and hospital staff say they are a missed opportunity as current treatment mainly relies on medication. They would like hospital wards to also provide talking therapies that have a chance of changing the long-term outlook for people with psychosis.
This study will be based on a type of talking therapy called Cognitive Behavioural Therapy for psychosis (CBTp) which is well developed for use in the community over longer periods of up to a year. CBTp has been used over shorter periods in inpatient settings but no research has been conducted to specifically adapt it to this setting. The study will be adapting CBTp so that it can be used during a hospital stay and will investigate whether patients and staff find it acceptable and feasible.

Who can participate?
Service users of acute mental health inpatient care over the age of 18 who have a diagnosis or symptoms of schizophrenia or psychosis.

What does this study involve?
A small research study will be conducted to see if CBTp is feasible to run in the hospital setting and acceptable to participants and staff. Participants will be recruited for this study and will be randomly allocated to one of two groups (to either receive therapy or not), with an equal chance of being in either group (like tossing a coin). Participants and researchers will not have a choice in the treatment given. The therapy will be conducted during participants' hospital stay. Participants will be asked to complete questionnaires and will be interviewed about their experience of the therapy and taking part in the study. Therapists will also be interviewed to see how they experienced the training, delivering the therapy, and taking part in the study.

What are the benefits and risks of participating?
Taking part in this research will help develop a new talking therapy for inpatients experiencing psychosis. Participants may find it an enjoyable experience being involved in such work. It is possible that talking about personal experiences could sometimes lead to feeling upset.

Where is the study run from?
The study is a collaboration with University College London (UK) and North East London NHS Foundation Trust (UK)

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

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

Who is the main contact?
Dr Lisa Wood, l.wood@ucl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
272043

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44582

Study information

Scientific Title
Crisis-focused Cognitive Behavioural Therapy for psychosis (CBTp) in inpatient settings (the CRISIS study): a feasibility randomised controlled trial

Acronym
CRISIS

Study objectives
Conducting a randomised controlled trial of a crisis-focused CBTp intervention adapted for an ethnically diverse acute mental health inpatient population will be feasible, suitable, safe, and acceptable to service users and therapists.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/04/2020, London – City and East NHS Research Ethics Committee (**Currently being held remotely via Teleconference/ZOOM** Henry VIII Committee Room, St Bartholomew's Hospital, North Wing, EC1A 7BE; +44 (0)207 104 8171; cityandeast.rec@hra.nhs.uk), ref: 20/LO /0137/AM01

Study design
Single-centre individually-randomized controlled feasibility study with an embedded qualitative component

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute mental health inpatient service users experiencing psychosis

Interventions
Participants will be randomly allocated to either Treatment as Usual (TAU) or CBTp plus TAU in a 1:1 ratio. The randomisation will be undertaken using www.sealedenvelope.com. Participant numbers will be entered into the sealed-envelope website by someone independent from the trial after the research assistant has completed the baseline assessment. Allocations will be emailed to the PI who will then contact the therapists to commence therapy with the service users assigned to the intervention arm and inform participants of their allocation.

1. Crisis-focused CBTp intervention. This intervention will be delivered by psychological therapists working in the acute inpatient services. All therapists are clinical psychologists or counselling psychologists registered with the UK Health and Care Professions Council (HCPC),

with experience of delivering CBTp in inpatient settings. The majority of sessions will be delivered in a private and quiet room on the inpatient ward or outside or off the ward if the service user has the appropriate leave, with some sessions being delivered in community settings or remotely (e.g. via phone or video conferencing technology) if the participant is discharged.

The crisis-focused CBTp intervention is underpinned by a modularised CBTp protocol that aims to deliver approximately six to eight sessions of therapy to participants. The protocol outlines seven modules including: engagement, assessment and identifying priorities; formulation of the crisis; stabilisation and safety; coping, self-management and problem solving; crisis plans and crisis cards; change strategy work focusing on crisis appraisals and safety behaviours; and discharge, relapse planning and recovery toolkits. The first two components (engagement, assessment and identifying priorities, and formulating the crisis) are essential components of the intervention and the remaining ones are flexibly chosen based on the collaboratively chosen service user priorities. The number of sessions will be determined by the collaborative priorities set by the service user and therapist and length of admission, and therefore more or fewer sessions can be offered. The therapy will also include at least one follow-up sessions post-discharge to ensure support through the discharge process. The intervention will also include strategies to involve the individual's network (e.g. family sessions, and formulation sharing with the multi-disciplinary team).

The therapists delivering the CBTp intervention will receive a training package which involves watching pre-recorded therapy videos (https://www.psychosisresearch.com/cbt-phase-1/), and two days training specifically focusing on crisis-focused CBTp. The training, delivered by the study team and a service user with lived experience of therapy and inpatient care, includes an introduction to the crisis-focused CBTp model, making culturally appropriate adaptations, undertaking a crisis-focused assessment, and developing a crisis-focused formulation, and utilising brief crisis-focused intervention strategies. It includes a combination of didactic teaching, role plays, reflective exercises, and group discussion. Therapists will also have access to weekly 90 min group supervision whilst delivering the intervention.

All therapy sessions will be audio-recorded if the participant consents. 10% of sessions will be rated on the Cognitive Therapy Rating Scale to ensure adherence to the CBT model. Some adaptations to the application of the fidelity scale will be made, taking into account that the therapy is being delivered as a brief intervention and with people in an acute mental health inpatient population, which may make some of the fidelity items harder to achieve. For example, the agenda may only be brief and only include a single agenda item, specific thoughts or cognitions may not always be identifiable, and only a simple formulation may be possible (making basic links between thoughts, feelings and behaviours).

2. Treatment as usual (TAU): This will be the routine care that participants receive within the acute inpatient setting. This includes multi-disciplinary care from mental health nurses, nursing assistants, psychiatrists, pharmacists, occupational therapists and psychologists. TAU will include access to routinely delivered psychosocial intervention, this can include structured psychological therapies delivered by clinical or counselling psychologists, and brief interventions delivered by appropriately trained nurses or occupational therapists. The NHS study site employs a maximum of 0.5 Whole Time Equivalent (WTE) of qualified psychologist (clinical or counselling) input and 0.8 WTE of assistant psychologist input per 20 acute care beds. The trial therapists also work in treatment as usual however recruitment will not be conducted on the ward in which they are offering treatment as usual so it is extremely unlikely study participants will be offered therapy from the trial therapists. They will also not use any of the therapy resources in treatment as usual.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility measured using the following collected between baseline and 6 months:
1. Individual patient data collected on a pre-developed sheet adhering to CONSORT guidelines including patient eligibility status, number of referrals received by ward staff, the willingness of participants to consent, the willingness of participants to be randomised, and attrition
2. Therapy-specific data including the number of sessions attended, therapy resources used, mode of therapy, location of therapy sessions, number of sessions conducted prior to and post-discharge, time and duration of sessions, quantity of homework completed, and any serious adverse events
3. Patient outcome measure completion

Key secondary outcome(s))
1. Experiences of psychosis measured using the Positive and Negative Syndrome Scale (PANSS) completed by trained research assistants during a semi-structured clinical interview at baseline, 2, and 6 months. The PANSS is a 7-item sub-scale and participants can score from 1 (absent) to 7 (extreme) on each item.
2. Depression measured using the Beck Depression Inventory brief 7-item measure (BDI-7) completed by participant self-report (with assistance from the researcher) at baseline, 2, and 6 months. Participants can score from 0 (not present) to 3 (indicating severe) on each item (symptoms of sadness, pessimism, past failure, loss of pleasure, self-dislike, self-criticism, and suicidal thoughts) and have a total score of 21.
3. Hopelessness measured using the short-form of the Beck Hopelessness Scale (BHS) completed by participant self-report (with assistance from the researcher) at baseline, 2, and 6 months. The BHS is a recently developed 9-item version of the scale validated for psychiatric inpatients to include items 2, 6, 11, 12, 14, 16, 17, 18 and 20 from the original scale. Participants can score 0 (not present) or 1 (present) on each item ("My future seems dark to me" and "I have great faith in the future").
4. Personal recovery measured using the 15-item Process of Recovery Questionnaire (QPR) completed by participant self-report (with assistance from the researcher) at baseline, 2, and 6 months. Participants can score from 0 (disagree strongly) to 4 (agree strongly) on each item ("I feel better about myself" and "I feel that my life has a purpose"), and score a total a maximum of 40 on the scale.
5. Anxiety measured using the Generalised Anxiety Disorder 7-item (GAD-7) measure completed by participant self-report (with assistance from the researcher) at baseline, 2, and 6 months. Participants can score from 0 (not at all) to 3 (nearly every day) on each item.
6. Subjective experiences of crisis in psychosis measured using a newly developed measure by the study team completed by participant self-report (with assistance from the researcher) at baseline, 2, and 6 months. This is a 23 item measure which includes statements such as "I have been feeling very strong distressing emotions" and "I feel able to live my life in line with my morals and values" with scores of between 1 (not at all) to 5 (all of the time) on each item.
7. Quality of life measured using the Recovering Quality of Life (REQOL-10) completed by participant self-report (with assistance from the researcher) at baseline, 2, and 6 months. Participants can score from 0 to 4 on each of 10-items (e.g. "I felt lonely" and "I felt happy").
8. Service use measured using an adapted version of the "generic UK mental health" version of the Client Service Receipt Inventory (CSRI), adapted to reflect the local care pathways in the recruitment site, completed through participant self-report and information from clinical notes at baseline, 2, and 6 months

9. Functioning measured using the Global Assessment of Functioning (GAF) measure completed by the clinician or researcher at at baseline, 2, and 6 months. GAF scores range from 1 (in some danger of hurting self or others) to 100 (absent or minimal symptoms).
10. Severity of participant mental health difficulties measured using the Threshold Assessment Grid (TAG) completed by the clinician or researcher at baseline, 2, and 6 months. The TAG has seven domains measuring three areas of safety, risk and needs, and disabilities and participants can receive a score from 0 (none) to 4 (very severe) on each domain, which are analysed individually and as a total score.
11. Hospitalisation, the total number of days in hospital and number of admissions measured from participant clinical records at baseline, 2, 6, and 12 months
12. Relapse, the total days under the care of acute mental health services (including inpatient wards, crisis home treatment, psychiatric liaison, and acute crisis and assessment teams) and number of episodes measured from participant clinical records at baseline, 2, 6, and 12 months
13. Number of serious incidents and adverse events, including those of harm to self and others measured from participant clinical records at baseline, 2, 6, and 12 months

Completion date
01/10/2023

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Meet criteria for a schizophrenia-spectrum diagnosis (schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, or psychotic disorder not otherwise specified) or meet criteria for an Early Intervention Service (EIS) for treatment of psychosis to allow for diagnostic uncertainty
3. Able to give informed consent and have the capacity to consent to participation in the study
4. Currently receiving care from an acute psychiatric inpatient team

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
52

Key exclusion criteria

1. Non-English speakers (due to translation costs and difficulty of producing valid translations of the research instruments and intervention
2. Acquired brain injury or substance misuse judged to be the acute cause of the psychotic experiences
3. Already undertaking a structured psychological intervention delivered by a psychologist or trained therapist at the time of study

Date of first enrolment
18/02/2021

Date of final enrolment
18/02/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North East London NHS Foundation Trust
Goodmayes Hospital
Ilford
United Kingdom
IG3 8XJ

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

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
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/07/2025	12/08/2025	Yes	No
Protocol article		10/09/2022	12/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Patient's experiences	01/08/2024	02/08/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes