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Guided self-help CBT for voices

Submission date	Recruitment status	[X] Prospectively registered
20/09/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
28/09/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/10/2024	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Psychosis is a severe form of mental health condition. People with a diagnosis of psychosis may experience distress associated with delusional beliefs and hearing voices. The National Institute for Health & Care Excellence (NICE) recommend Cognitive Behaviour Therapy for psychosis (CBTp) as one of the best treatments for people with a diagnosis of psychosis. But only 26% of people with a diagnosis of psychosis have the chance to receive this talking therapy. CBTp is scarce because it can take a long time to deliver and needs to be delivered by highly trained therapists. We have adapted CBTp in several ways to make it less resource intensive. Firstly, we have targeted CBTp at only one of the problems commonly associated with psychosis – hearing voices. Secondly, this targeted approach has enabled us to reduce the number of sessions over which the therapy is conducted (from the recommended minimum of 16 sessions, down to 10 sessions). Finally, we have structured the therapy in the form of a workbook to enable briefly trained therapists to guide people through the therapy. Our therapy is called Guided self-help CBT for distressing voices (also known as the GiVE intervention). Our briefly trained therapists are called Assistant Psychologists. They have a degree in psychology and usually work in NHS Mental Health Services under the supervision of highly trained therapists. We want to see if our GiVE intervention is helpful for people with a diagnosis of psychosis who are distressed by hearing voices, when delivered by Assistant Psychologists.
We have successfully completed a smaller version of this study. The lessons that we learnt from the smaller version have helped us to design this larger study.
Our research aims to give more people with a diagnosis of psychosis the chance to receive a helpful talking therapy.

Who can participate?
Patients aged 18 years and older, with a diagnosis of psychosis and currently experiencing voice-hearing.

What does the study involve?
We will include 130 people with a diagnosis of psychosis in our study:
• 65 people will be offered the GiVE intervention over 10 sessions, delivered by an Assistant Psychologist
• 65 people will continue to receive the usual support and treatments offered by their mental

health team
Our findings will tell us if the GiVE intervention is helpful to people with a diagnosis of psychosis who are distressed by hearing voices, when delivered by Assistant Psychologists.

What are the possible benefits and risks of participating?
We hope that the CBT will be helpful, but we can't guarantee this. The information we find out from this research will help provide helpful information about whether CBT delivered by briefly trained therapists is helpful for people who hear distressing voices. This will help mental health services to make decisions about what therapies should be provided for people who hear voices.

Talking about experiences of hearing voices can be helpful, though it can also sometimes feel difficult or distressing. The therapists will be trained in helping people with distressing voices and would help you to cope with any temporary increases in distress, should this occur. The therapists will be supervised by experienced Clinical Psychologists. You would also be free to access help from your care team, should you wish, and to drop out of the therapy if you wished.

Where is the study run from?
Sussex Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2022 to October 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Prof Mark Hayward, mark.hayward@spft.nhs.uk

Study website
https://www.sussexpartnership.nhs.uk/sussex-voices-clinic

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
312765

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52684, Grant Codes: NIHR203241, IRAS 312765

Study information

Scientific Title
Increasing access to CBT for psychosis patients: a randomized controlled trial evaluating brief, targeted CBT for distressing voices delivered by Assistant Psychologists

Acronym
GiVE3

Study objectives
In comparison to usual care, is the GiVE intervention effective at treating distressing voices when delivered to psychosis patients by briefly trained Assistant Psychologists?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/06/2022, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 207 104 8233; preston.rec@hra.nhs.uk), ref: 22/NW/0118

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Psychosis - schizophrenia

Interventions
Participants will be randomly allocated to one of two groups and receive either the GiVE intervention (and Treatment-As-Usual) or Treatment-As-Usual alone

GiVE intervention - is described in our published workbook and will consist of 10 one-hour sessions over a 16-week period, delivered by Assistant Psychologists in NHS clinics, participants' own homes or other community locations as preferred and appropriate. Where participants express a preference for the intervention to be delivered remotely (by videocall or phone), this preference will be honoured. GiVE is a psychological intervention that targets the mechanisms that have been empirically found to maintain voice-related distress - negative beliefs about voices, negative beliefs about self and negative relating. After the introductory sessions (including a focus upon coping), the intervention will cover three core modules: (1) beliefs about the self, (2) beliefs about voices and (3) relationships. Modules (1) and (2) draw upon psychoeducation and cognitive behavioural strategies to help participants to reevaluate the accuracy of their negative or unhelpful beliefs related to the self and voices. Module (3) additionally involves work on how to relate to others and voices more assertively.
Participants will be provided with a copy of the workbook and companion self-help book and will be 'guided' through the structured content of the workbook by an Assistant Psychologist – with encouragement to complete between session exercises in the workbook and to read relevant chapters of the self-help book. Consistent with the previous recommendations from Experts-By-Experience, we will recruit Assistant Psychologists who have some experience of working as an Assistant Psychologist with patients with complex needs. The Assistant Psychologists will receive a brief 3-day training in the delivery of the GiVE intervention facilitated by the Chief Investigator. The training will include one introductory day (covering the experience of distressing voices and CBT principles) and two days on the GiVE intervention (covering the content of the workbook) and will be delivered to all Assistant Psychologists at the same time. Two Assistant Psychologists will offer the GiVE intervention at each site. The Assistant Psychologists will be offered weekly clinical supervision by the Site Leads, including both 1:1 supervision at site and group supervision at both site and remotely across sites. Participants in the GiVE arm will continue to receive treatment as usual throughout their participation in the study.

Treatment as usual (TAU) - will be delivered according to national and local service protocols and guidelines and mainly consist of antipsychotic medication and support and monitoring from the local clinical team, with individual and family psychological therapies offered occasionally. Any variation across sites will be measured by the service use data within the Health Economic Analysis and captured by including site (a stratification factor) in the statistical model.

Intervention Type
Behavioural

Primary outcome measure
Psychotic Symptoms Rating Scale – Auditory Hallucinations (PSYRATS-AH) – voice-related distress will be measured by the 5-item 'distress' subscale at screening/eligibility, 16 weeks and 28 weeks.

Secondary outcome measures
Timepoints: screening/eligibility (-t1), baseline (-t2), 16 weeks post-randomization (16 weeks) and 28 weeks post-randomization (28 weeks).
1. Secondary (clinical) outcome: Psychotic Symptoms Rating Scale – Auditory Hallucinations (PSYRATS-AH) – the attribution, loudness and frequency of voices will be measured at -t1, 16 weeks and 28 weeks.
2. Secondary (clinical) outcome: Hospital Anxiety and Depression Scale (HADS) – anxiety and depression will be measured at -t2, 16 weeks and 28 weeks.
3. Secondary (clinical) outcome: CHoice of Outcome In Cbt for psychosEs (CHOICE) – recovery will be measured at -t2, 16 weeks and 28 weeks.
4. Secondary (mechanism) outcome: The Brief Core Schema Scale (BCSS) - self scale - the degree of positive and negative beliefs about self will be measured -t2, 16 weeks and 28 weeks.
5. Secondary (mechanism) outcome: Approve – Voices - the styles of relating to voices will be measured at -t2, 16 weeks and 28 weeks.
6. Secondary (mechanism) outcome: Approve – Social - the styles of relating to other people will be measured at -t2, 16 weeks and 28 weeks.
7. Secondary (mechanism) outcome: Beliefs about voices questionnaire - revised (BAVQ-R) – the 14-item version of this measure will capture 'persecutory beliefs' and 'benevolent beliefs' at -t2, 16 weeks and 28 weeks.
8. Secondary (clinical) outcome: Revised Green Paranoid Thoughts Scale (R-GPTS) – will measure paranoid delusions at -t2, 16 weeks and 28 weeks.
9. Health economic measure: Client Service Receipt Inventory (CSRI-UK) - will be used to collect information on service utilization, income, accommodation, and other cost-related variables at -t2, 16 weeks and 28 weeks.
10. Health economic measure: EQ-5D-5L - will be used as a measure of health-related quality of life relevant to a wide range of health conditions and treatments at -t2, 16 weeks and 28 weeks.
11. Health economic measure: SF-12 v2 – will capture information about functional health and well-being from the patient's point of view at -t2, 16 weeks and 28 weeks.

Overall study start date
30/04/2022

Completion date
29/10/2024

Eligibility

Key inclusion criteria
1. In contact with Secondary Care Mental Health Services (under the care of a mental health team in one of the recruiting Trusts)
2. Have a clinician-reported diagnosis of psychosis
3. Aged 18 yeras or over
4. Willing to provide written, informed consent
5. Experiencing current voice-hearing; this will be operationalised by participants having a score of at least 1 on item 1 ('Frequently') on the Psychotic Symptoms Rating Scale - Auditory Hallucinations Scale (PSYRATS-AH) at the time of consent – indicating that the participant has

experienced at least one episode of voice-hearing in the past week
6. Scoring 3 or 4 (rated on a 0–4 scale) on either the intensity of distress item or the amount of distress item on PSYRATS-AH at the time of consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 130; UK Sample Size: 130

Total final enrolment
135

Key exclusion criteria
1. Established organic cause for distressing voices
2. Primary diagnosis of substance misuse
3. Currently detained in hospital under a section of the Mental Health Act
4. Having completed a full course (minimum of 16 hours) of CBTp for psychotic symptoms during the past year
5. Immediate and serious risk to self or others (assessed at the point of referral/eligibility review).

Date of first enrolment
01/10/2022

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road

Worthing
United Kingdom
BN13 3EP

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

Sponsor details
Trust HQ
Swandean
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United Kingdom
BN13 3EP
+44 3003040088
ResearchGovernance@sussexpartnership.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.sussexpartnership.nhs.uk/

ROR

https://ror.org/05fmrjg27

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Findings will be written up and submitted for open-access publication in high-impact academic journals. Four peer reviewed papers are planned:
1. The trial protocol will be submitted for publication in Trials (or a similar open access journal) before the completion of recruitment
2. A paper reporting on the main findings from the study will be submitted to Lancet Psychiatry (or a similar journal)
3. A paper reporting on the health economics will be submitted for publication in Social Science and Medicine (or a similar journal)
4. A paper reporting on the implementation model will be submitted for publication in Implementation Science (or a similar journal)

Intention to publish date
01/10/2025

Individual participant data (IPD) sharing plan
An anonymised dataset will be deposited within the University of Sussex Research Repository to facilitate open access for other researchers. The reuse and sharing of anonymised data will be made explicit to participants on the study consent form. Identifiable information will not be shared with anyone outside of the research team.

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 1.0	18/10/2021	27/09/2022	No	Yes
HRA research summary			28/06/2023	No	No
Protocol article		15/09/2023	18/09/2023	Yes	No
Statistical Analysis Plan	version 1.0	20/08/2024	20/08/2024	No	No