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Talking With Voices

Submission date	Recruitment status	[X] Prospectively registered
11/12/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
15/12/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/10/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Schizophrenia, a form of psychosis, is a considerable challenge for the NHS which is estimated to cost the UK £11.8 billion a year. One of the main symptoms of schizophrenia is hearing voices that others do not hear. Drugs are currently the main treatment and some patients are offered a talking therapy known as cognitive behavioural therapy (CBT). However, not everyone finds these approaches helpful. It is also known that negative life events, like childhood abuse, significantly increase the risk of developing symptoms of schizophrenia. This means there is a need for safe, effective treatments that can support people with this diagnosis to cope with the emotional impact of trauma. Hearing voices that no one else can hear is one symptom of schizophrenia that is strongly linked with traumatic events (for example, what the voices say can often reflect real-life negative experiences). This research will test a therapy for supporting people who hear distressing voices called Talking With Voices (TwV). It involves a therapist 'speaking' to the voice by asking it questions. The voice-hearer then listens to the responses and repeats them out loud to the therapist. Over time the therapist learns more about the voice(s) to support the voice(s) and voice-hearer to develop a more peaceful, positive relationship. It is hoped that TwV could eventually help people feel more in control and less distressed by their voices. However, while there are strong theoretical grounds for believing that this would be the case, there is currently no evidence for using TwV within the NHS and it is unclear if it would be feasible to run a large clinical trial or what sort of questions would need to be asked to know whether it had been successful. This study aims to conduct a small trial to discover whether a larger study could be run in the future. That definitive study (https://www.isrctn.com /ISRCTN15897915; TwV II) is now ongoing to investigate whether TwV is helpful for a broader group of people who hear negative voices and not just those with schizophrenia. Particular attention will be paid to the effects on recovery, whether the voices go away and their impact on the person's life. This will help to work out whether TwV can help and, if so, how. The study will help to understand if certain experiences focussed on in therapy can help people to cope with their distressing voices, and whether this is as a result of these targeted mechanisms, as well as other beneficial outcomes in the lives of vulnerable and clinically disadvantaged groups.

Who can participate?
Adults aged 18 and older who have been diagnosed with schizophrenia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive

treatment as usual. Those in the second group receive the TwV programme. This includes up to 26 sessions with a clinical psychologist of up to an hour over six months. Participants are assessed before and after the treatment at six months.

What are the possible benefits and risks of participating?
Participants randomised to the treatment arm have the potential benefit of receiving a novel, specialised psychological therapy for voice hearing delivered by practitioners with extensive experience in supporting individuals with psychosis. The investigators consider the likelihood of risk from treatment to be minimal and will arrange therapeutic management within NHS safeguarding frameworks. GPs and healthcare staff from the participants' care teams will be made aware of a particular client's involvement to ensure participants have the opportunity to discuss any issues that may have arisen as a result of taking part in the study. Protocols will additionally be put in place in advance in the event of a serious adverse event and/or participants wishing to withdraw from the trial. Participation in the trial does not change existing treatment receipt, so there is no disadvantage in taking part. There is a risk of burden during the assessments, and to minimise possible fatigue or stress participants will be offered breaks, given flexibility in the timing/venue for appointments, and be reminded that they can stop at any time. If indicated, the assessment can be spread over several days. A small financial incentive (£10) will also be provided per assessment. Assessments will be administered by trained staff and will identify any risks to self/others that require immediate action. All participants will additionally receive a crisis card providing contact details for appropriate sources of help in psychiatric emergencies.

Where is the study run from?
This study is being run by the Greater Manchester Mental Health NHS Foundation Trust (UK) and takes place in GP surgeries in the Greater Manchester area.

When is the study starting and how long is it expected to run for?
October 2016 to December 2020

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

Who is the main contact?
Dr Eleanor Longden
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
36518

Study information

Scientific Title
A feasibility and acceptability study of the Talking With Voices intervention amongst adults with psychosis

Study objectives
The aim of the present research is to evaluate the feasibility and acceptability of the Talking With Voices intervention in NHS settings amongst individuals with a diagnosis of schizophrenia spectrum disorder who hear distressing voices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Preston Research Ethics Committee, 07/11/2017, ref: 17/NW/0633

Study design
Randomized; Both; Design type: Treatment, Psychological & Behavioural, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Schizophrenia spectrum disorder

Interventions
Randomisation is done in the ratio 1:1 to the two groups and is independent and concealed using randomised-permuted blocks of 6-8 administered via an encrypted web-based system. Participants are then allocated to one of two treatment arms:
1. Treatment as usual (TAU) only. Although this varies according to different clinical sites, TAU for schizophrenia/psychosis in community mental health team settings is based on the care programme approach to case management and typically includes antipsychotic medication prescribed by a psychiatrist, access to rehabilitative services, outpatient follow-up care, and the assignment of community psychiatric nurses and social workers.
2. Psychological intervention (‘Talking With Voices’) plus TAU. The intervention includes up to 26

sessions with a clinical psychologist of up to an hour over a six month period. Sessions focus on (1) psychosocial education, with an emphasis on normalising and de-shaming the voice hearing experience and providing coping and recovery literature, (2) psychological formulation, which involves the therapist and client co-constructing a shared understanding of what social /emotional conflicts the voices may represent, and (3) dialogical engagement with voices, wherein the therapist communicates directly with the voices by asking them questions and requesting the participant to repeat their responses. Participants are seen by the same therapist for the duration of the study to maintain engagement and consistency of approach.

All participants are invited to a research assessment with a blind (independent) assessor. These take place at baseline and then again at six months post-randomisation.

Intervention Type
Other

Primary outcome(s)
As this is a feasibility trial, a single primary outcome is not meaningful. Key outcomes to inform the design of a future definitive trial are:
1. Referral rates and recruitment rates, which will be assessed at the end of the recruitment period in April 2019.
2. Attendance at, and engagement with, therapy sessions; and follow-up and questionnaire response rates, which will be assessed at the end of the follow-up period in October 2019.
3. Acceptability of treatment, which will be assessed using drop-out rates at the end of the follow-up period by October 2019.

Added 27/06/2019:
Progression criteria relate to recruitment, retention, adherence and data completeness and will have stop/refine/go (red/amber/green) criteria. The suggested criteria and cut-offs are:
1. Recruitment: Green >= 80% of target; Amber 60-79%; Red <= 59%
2. Retention (at the six month assessment point with the PANSS): Green >= 80%; Amber 60-79%; Red <= 59%
3. Intervention adherence: Green >= 80% attending at least 8 sessions; Amber 60-79%; Red <= 59%. Eight sessions has been agreed to constitute a therapeutic ‘dose’

Key secondary outcome(s))
All secondary outcomes are being collected to determine their suitability for use in a subsequent trial, rather than to draw conclusions about the safety or efficacy of the intervention:
1. Relationship with voices is measured using The Voice and You scale (VAY) at baseline and at six months post randomisation
2. Beliefs about voices are measured using The Revised Beliefs about Voices Questionnaire (BAVQ-R) at baseline and at six months post randomisation
3. Voice hearing phenomenology is measured using The Subtypes of Voice Hearing Questionnaire (SOV-Q) at baseline and at six months post randomisation
4. Dissociation is measured using The Revised Dissociative Experiences Scale (DES-II) at baseline and at six months post randomisation
5. Psychotic symptomology is measured using The Positive and Negative Syndrome Scale (PANSS) at baseline and at six months post randomisation
6. Social and occupational functioning is measured using The Questionnaire about the Process of Recovery (QPR) at baseline and at six months post randomisation
7. General health status is measured using the EQ-5D at baseline and at six months post randomisation

Completion date
30/12/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/05/2019:
1. Adults aged ≥18 years
2. Who have heard voices for at least one year and score ≥4 on the auditory hallucination subscale of the Positive and Negative Syndrome Scale (PANSS)
3. Who have had no changes to medication within the past month
4. Who meet criteria for ICD schizophrenia spectrum disorder
5. Who are able to provide written, informed consent
6. Who are not currently receiving structured psychological therapy for psychosis
7. Who are in contact with secondary care mental health services and have a care coordinator
8. Who are willing and able to communicate with their voices and relay what the voices say to a therapist
9. Whose voices are sufficiently personified to engage in dialogical work (i.e., voices which can engage in conversation and dynamically interact with the hearer)

Previous inclusion criteria from 07/06/2018 to 15/05/2019:
1. Aged ≥18 years
2. Has heard voices for at least 1 year and score ≥4 on the auditory hallucination subscale of the Positive and Negative Syndrome Scale (PANSS)
3. Has had no changes to medication within the past month
4. Meets criteria for ICD schizophrenia spectrum disorder
5. Able to provide written, informed consent
6. Not currently receiving structured psychological therapy for psychosis
7. In contact with secondary care mental health services and has a care coordinator
8. Willing and able to communicate with the voices and relay what the voices say to a therapist
9. Voices are sufficiently personified to engage in dialogical work (i.e. voices that can engage in conversation and dynamically interact with the hearer)

Original inclusion criteria:
1. Aged ≥18
2. Have heard voices for at least one year and score ≥4 on the auditory hallucination subscale of the Positive and Negative Syndrome Scale for Schizophrenia (PANSS)
3. Have had no changes to medication within the past month
4. Have a lifetime diagnosis of ICD schizophrenia spectrum disorder
5. Able to provide written, informed consent
6. Not currently receiving, or waiting to receive, cognitive behavioural therapy for psychosis
7. Willing and able to communicate with their voices and relay what the voices say to a therapist
8. Whose voices are sufficiently personified to engage in dialogical work (i.e. voices which can engage in conversation and dynamically interact with the hearer)
9. No restrictions have been placed on recruitment according to gender

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. At immediate risk of harm to self or others
2. Non-English speaking
3. Primary diagnosis of alcohol/substance dependence or autism spectrum disorder
4. Moderate/severe learning disability
5. Organic brain injury or illness implicated in the aetiology of psychotic symptoms
6. A score of > 5 on the conceptual disorganisation subscale of the Positive and Negative Syndrome Scale for Schizophrenia
7. Homeless and/or of no fixed abode

Date of first enrolment
15/01/2018

Date of final enrolment
30/12/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Harrop House
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

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 datasets generated during and/or analysed during the current study will be available upon reasonable request from Chief Investigator Eleanor Longden (Eleanor.Longden@gmmh.nhs.uk), which must include a protocol and statistical analysis plan, not be in conflict with the prespecified publication plan, and be consistent with the data sharing policy (available on request from EL). Anonymised data will be available indefinitely after the publication of the trial findings and requests for data sharing will be considered by EL and the independent combined Trial Steering and Data Monitoring Committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	primary outcomes	21/11/2022	25/11/2022	Yes	No
Protocol article		25/02/2021	29/10/2021	Yes	No

HRA research summary			26/07/2023	No	No
Other publications	clinical perspectives and experiences publication	11/11/2021	24/03/2022	Yes	No
Other publications	Qualitative results on service user perspectives	08/08/2023	14/08/2023	Yes	No
Protocol file	version V2	23/11/2017	15/12/2017	No	No
Protocol file	version V5	26/04/2018	07/06/2018	No	No
Protocol file	version V7	28/11/2019	12/02/2020	No	No
Statistical Analysis Plan	version V3	19/06/2018	19/02/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes