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Talking With Voices II

Submission date
22/06/2023

Recruitment status
No longer recruiting

Registration date
13/07/2023

Overall study status
Completed

Last Edited
09/06/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Hearing voices (also known as 'auditory hallucinations') can be very upsetting and disrupt people' s lives. It increases the risk of depression, self-harm, hospital admission and difficulties with family, friends, work and education. Most people diagnosed with schizophrenia hear voices (around 70%), and schizophrenia is one of the top 25 causes of disability worldwide. However, voices also affect people with other serious mental health problems in many similar ways. Increasingly, voices can occur at times of high stress or if people have had earlier trauma, such as abuse or neglect. Often the voice content echoes the themes of these challenging experiences, and this can make them particularly hard to cope with. Medication and talking therapy known as cognitive behavioural therapy (CBT) are the main treatment for voices. However, not everyone finds these approaches helpful, and they are often unavailable for people without a diagnosis of schizophrenia. Further, CBT does not always focus on voices, and/or the important links between stressful life events and the content of what voices say. Therefore, there is a need to make more treatments available that take account of peoples' unique stories and supports them to cope with the impact of their experiences. To meet this need, the study team have developed a treatment that specifically focuses on voices, regardless of diagnosis, and helps to understand and deal with the past. A study (https://www.isrctn.com/ISRCTN45308981) has already been conducted to assess whether this new form of therapy, Talking with Voices (TwV), is feasible and acceptable to offer in the NHS. It involves a therapist directly speaking with the voice while the client repeats their responses aloud. Over time, the therapist learns more about the voice(s) and supports the client and voice(s) to develop a more peaceful relationship. This includes helping the client manage difficult emotions and build a more positive sense of themselves, trying to understand how the voices may relate to difficulties in their life, and promoting recovery and reducing voice-related distress. The first study showed that it is possible to recruit people, treat them, and follow them up after the study ends. It also showed that the treatment worked in the way that was expected: important processes, or mechanisms, that may lead people to hear voices or find them really distressing began to change. Some participants changed their understanding of, and ways of relating to, their voices and therapy seemed to help how well people managed to live in everyday life. The study team now want to find out if 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, as well as 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 over 16 years old with severe mental health problems (SMHP) who are seeking help for distressing voices which they have heard for at least a year, who are not receiving another type of talking therapy, have been in contact with mental health services for at least 6 months, and who are willing and able for a therapist to directly speak with their voices.

What does the study involve?
Participants from mental health services who are distressed by their voices will be invited to take part in the study. Half the participants will have their usual care, and half will receive their usual care plus up to 26 1-hour sessions of TwV over 8 months. Which type of treatment participants get will be decided by chance using a computer.

What are the possible benefits and risks of participating?
The initial assessment could help to highlight any problems participants are experiencing, and some may find it helpful to discuss these. Currently, it is not yet known whether TwV provides any greater benefit compared to treatment as usual; however, this study is designed to help answer that question and the information gained may assist in providing better treatments in the future. Risks for participants are that discussing one's experiences during the assessments and/or therapy may be distressing and could potentially make existing difficulties feel worse.

Where is the study run from?
Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2023 to June 2025.

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

Who is the main contact?
Dr Emmeline Joyce / Dr Verity Bell (nee Smith) (Greater Manchester Mental Health NHS Foundation Trust), talkingwithvoices@gmmh.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Eleanor Longden

ORCID ID
https://orcid.org/0000-0003-3046-9697

Contact details
Psychosis Research Unit
Greater Manchester Mental Health NHS Foundation Trust
Harrop House

Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL
+44 (0)782 455 3926
eleanor.longden@gmmh.nhs.uk

Type(s)
Public

Contact name
Dr Verity Bell (nee Smith)

Contact details
Psychosis Research Unit
Greater Manchester Mental Health NHS Foundation Trust
Harrop House
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL
+44 (0)7950263390
talkingwithvoices@gmmh.nhs.uk

Additional identifiers

Integrated Research Application System (IRAS)
322330

Central Portfolio Management System (CPMS)
56170

Study information

Scientific Title
A novel dialogical therapy (Talking With Voices) in comparison to treatment as usual in adults with distressing and persistent auditory hallucinations: a randomised controlled trial to investigate the efficacy of a treatment strategy targeted at trauma-related mechanisms

Study objectives
Current study hypothesis as of 06/02/2025:
Primary clinical efficacy hypothesis
1. TwV + TAU will result in improved measures of personal recovery at post-treatment compared to TAU alone.

Secondary clinical efficacy hypotheses
1. TwV+TAU will lead to improvement in distressing voices at post-treatment compared to TAU alone.

2. TwV + TAU will lead to a reduction in negative appraisals of voices and increased positive appraisals of voices and helpful/functional responses towards voices at post-treatment compared to TAU alone.
3. TWV + TAU will result in improved measures of personal recovery and voice-related measures at 14-month follow-up compared to TAU alone.

Mechanistic aim
1. To examine the extent to which TwV + TAU impacts on measures of personal recovery via reductions in trauma-related psychological processes (dissociation and negative self-beliefs), and improvements in positive beliefs about voices and assertive relating skills with voices, at post-treatment and 14-month follow-up.

Mechanistic hypotheses
1. TwV + TAU will lead to reductions in dissociative symptoms and negative self-beliefs and improvements in positive beliefs about voices and assertive relating skills with voices at post-treatment and at 14-month follow-up.
2. The mechanisms by which TwV + TAU leads to improvements in personal recovery are due to a reduction in dissociative symptoms and negative self-beliefs, and improvements in positive beliefs about voices and assertive relating skills with voices at post-treatment and at 14-month follow-up.

Previous study hypothesis:
Clinical efficacy hypotheses
1. Talking With Voices (TwV) + treatment as usual (TAU) will result in improved measures of personal recovery at the end of treatment (8-month follow-up) and 14-month follow-up compared to TAU alone.
2. TwV + TAU will lead to improvement in distressing voices at the end of treatment compared to TAU alone.
3. TwV + TAU will lead to a reduction in negative appraisals of voices and increased positive appraisals of voices and helpful/functional responses towards voices at the end of treatment compared to TAU alone.

Mechanistic hypotheses
1. TwV + TAU will lead to reductions in dissociative symptoms and negative self-beliefs and improvements in positive beliefs about voices and assertive relating skills with voices.
2. The mechanisms by which TwV + TAU leads to improvements in personal recovery are due to a reduction in dissociative symptoms and negative self-beliefs, and improvements in positive beliefs about voices and assertive relating skills with voices.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/06/2023, Greater Manchester West Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8379; gmwest.rec@hra.nhs.uk), ref: 23/NW/0132

Primary study design
Interventional

Study design

Randomized interventional study

Study type(s)
Treatment

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

Interventions
The study will employ the treatment manual devised and refined during the Talking With Voices feasibility and acceptability trial (https://www.isrctn.com/ISRCTN45308981), which utilises individualised formulations to identify key psychosocial conflicts associated with voice hearing and determine targeted treatment strategies and shared goals for relational change. An 8-month treatment window permits ≤26 sessions, with an option for up to 4 booster sessions to consolidate therapeutic gains.

A range of interventions with associated milestones is delivered within the treatment timeframe (e.g., psychosocial education, coping enhancement, psychological formulation, and dialogical engagement with voices). The manual adheres to general best-practice principles for psychological therapy with psychosis patients, including building collaborative relationships, developing shared goals, using inclusive language, validating individual experiences, and providing hope that recovery is possible. In turn, these principles underpin many of the specific values of Talking With Voices, which can be summarized as the following:

1. A normalising approach: voice-hearing is recognized as a common human experience that may cause distress but from which many people recover. Consistent with the ethos of the user-led Hearing Voices Movement, the concept of recovery is not solely defined by the cessation of clinical symptoms as opposed to reducing distress and promoting positive goals, with full recognition that individuals can live fulfilling lives as voice-hearers.
2. A user-led intervention: clients have a central role in determining the pace and goals of therapy and identifying the most useful strategies to cope with their experiences.
3. A subjective interpretative framework: therapists respect their clients' explanatory framework for understanding voices (e.g., trauma-based, spiritual, cultural) without insisting their clinical perspective is the correct one.
4. Conceptualizing voices as representing parts of the self: voices are considered a dissociative phenomenon which may often originate from traumatic events and/or reflect overwhelming emotion along with negative beliefs about oneself, other people, and the world. Correspondingly, voice content is seen as meaningful in the sense of drawing attention to unresolved distress.
5. Facilitating a more peaceful hearer-voice relationship: in signposting emotional vulnerabilities, voices can be seen as performing a 'protective' role in the sense that features like persecution or aggression are often masks for unresolved pain. Because attempts to suppress the voice will also suppress the emotions/beliefs which they embody, a complementary goal is therefore to help the voice communicate its purpose and needs in ways that are more constructive and respectful of the hearer.

Intervention Type
Behavioural

Primary outcome(s)

Current primary outcome measure as of 06/02/2025:
Personal mental health recovery measured using the 15-item Questionnaire About the Process of Recovery (QPR) at 8 months (post-treatment). QPR data will also be collected at baseline and 8 months, and at 14 months (for approximately the first 207 participants).

Previous primary outcome measure:
Personal mental health recovery measured using the Questionnaire About the Process of Recovery (QPR) at 8 months (post-treatment). QPR data will also be collected at baseline, 8 months, and 14 months.

Key secondary outcome(s)

Current secondary outcome measures as of 06/02/2025:
Secondary outcome measures are assessed at baseline and 8 months, and at 14 months (for approximately the first 207 participants) unless otherwise stated:
1. Voice hearing phenomenology and impact measured using the Psychotic Symptoms Rating Scale – Auditory Hallucinations Subscale
2. Attitudes and actions in relation to voices measured using the Voices Acceptance and Action Scale
3. The presence and impact of non-auditory hallucinations measured using the Psychotic Symptoms Rating Scale: Multimodal Hallucinations
4. Trauma-related symptoms measured using the PTSD Checklist for DSM-5
5. Daily frequency of dissociation across the domains of absorption, depersonalisation /derealisation, and dissociative amnesia, using The Revised Dissociative Experiences Scale
6. Connections between adverse life events and voices measured using the Trauma Voice Associations Questionnaire

Mechanistic outcome measures assessed at baseline, 8 months, and 14 months:
1. Negative self-beliefs measured using the Brief Core Schema Scale
2. Dissociative symptoms measured using the depersonalisation/derealisation subscale of the Revised Dissociative Experiences Scale
3. Beliefs and emotional and behavioural reactions to voices measured using the Beliefs About Voices Questionnaire - Revised
4. Assertiveness in response to voices measured using the Approve–Voices Questionnaire

Assessment of baseline characteristics:
The incidence of clinically significant traumas measured using the Trauma and Life Events Checklist at baseline

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Secondary outcome measures are assessed at baseline, 8 months, and 14 months unless otherwise stated:
1. Voice hearing phenomenology and impact measured using the Psychotic Symptoms Rating Scale – Auditory Hallucinations Subscale
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3. The presence and impact of non-auditory hallucinations measured using the Psychotic Symptoms Rating Scale: Multimodal Hallucinations
4. Trauma-related symptoms measured using the PTSD Checklist for DSM-5
5. Connections between adverse life events and voices measured using the Trauma Voice Associations Questionnaire

Mechanistic outcome measures assessed at baseline, 8 months, and 14 months:
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2. Dissociative symptoms measured using the depersonalisation/derealisation subscale of the Revised Dissociative Experiences Scale
3. Beliefs and emotional and behavioural reactions to voices measured using the Revised Beliefs About Voices Questionnaire
4. Assertiveness in response to voices measured using the Approve–Voices Questionnaire

Assessment of baseline characteristics:
The incidence of clinically significant traumas measured using the Trauma and Life Events Checklist at baseline

Completion date
30/06/2025

Eligibility

Key inclusion criteria
The study population are adult users of mental health services with severe mental health problems (SMHP) who hear persistent, distressing voices.

1. Aged > = 16 years
2. Heard voices for at least a year
3. Scoring > = 1 on item 8 of the Psychotic Symptom Rating Scales–Auditory Hallucinations Subscale (PSYRATS-AH)
4. Able to provide written informed consent
5. Actively help-seeking in relation to distressing voices
6. In contact with mental health services for > = 6 months
7. Willing and able to communicate with their voices and relay what the voices say to a therapist
8. Hear voices that are sufficiently personified to engage in dialogical work

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
110 Years

Sex
All

Total final enrolment

309

Key exclusion criteria
1. At the immediate risk of harm to self or others
2. Currently receiving structured, individual psychological therapy
3. Non-English speaking
4. Primary diagnosis of alcohol/substance dependence or autism spectrum disorder
5. Moderate/severe learning disability
6. Organic cause for VH
7. Homeless/of no fixed abode

Date of first enrolment
01/09/2023

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

Study participating centre
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
NE3 3XT

Study participating centre
Warneford Hospital
Warneford Lane
Headington
Oxford

England
OX3 7JX

Study participating centre
Maudsley Hospital
Denmark Hill
London
England
SE5 8AZ

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 the co-Chief Investigators, Prof Tony Morrison and Dr Eleanor Longden (tony.morrison@gmmh.nhs.uk; eleanor.longden@gmmh.nhs.uk) after the outcome paper is published. Requests to please include a pre-specified statistical analysis plan and will be reviewed by the trial management team.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/10/2025	31/03/2026	Yes	No
Statistical Analysis Plan	version 1.0	08/05/2025	04/11/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes