Greater Manchester Mental Health NHS Foundation Trust

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

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Contents

1. Project Details

The Talking With Voices (TwV) trial is a feasibility study to inform a definitive randomised controlled trial (RCT) of the TwV intervention compared to treatment as usual (TAU) for individuals with a diagnosis of schizophrenia spectrum disorder who hear distressing auditory hallucinations. The trial is funded by a National Institute for Health Research (NIHR) Post Doctoral Fellowship Award.

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2. Background and Rationale

2.1 Summary

There is growing recognition for the need to develop interventions that can address the impact of psychological trauma amongst patients with a diagnosis of psychosis/schizophrenia. Hearing voices is one symptom that is strongly associated with previous adversity exposure, and this programme of research will test a specific form of psychotherapy, Talking With Voices (TwV), for ameliorating the distress and disruption associated with the experience. The project will assess the acceptability and

feasibility of the intervention using a randomised control design, with the findings used to inform future large-scale randomised trials to determine the intervention's clinical efficacy and cost-effectiveness. It is anticipated that in reducing fear of the voices and increasing insight into their links with negative emotions and life events, the intervention could lead to improvements in patient outcomes.

2.2 Background

Hearing voices (the perception of human speech with no objective source) is considered a key diagnostic feature of psychosis/schizophrenia and can cause considerable distress and debilitation. There is substantial scope for improvement within NHS service provision in this area. Firstly, while medication is generally considered a first-line treatment response [1], many patients do not respond well to antipsychotics [2-5], particularly those with high levels of previous trauma exposure [6]. Likewise the prevailing psychological approach for psychosis in the NHS, cognitive behavioural therapy for psychosis (CBTp), is not associated with consistent improvements in voice-related distress [7-9] – a finding that may be partly attributable to the variable focus paid to voices during therapy [10], CBTp's greater emphasis on appraisals and beliefs about voices rather than their emotional representations and/or the interpersonal relationship between hearer and voice [11], and a negative perception of CBTp amongst some service-users that may lead to therapy refusal [12]. Furthermore, it is increasingly acknowledged that interventions for voice hearing should be able to address the long-term sequelae of adverse life events (particularly, but not exclusively, childhood maltreatment), which is known to be strongly associated with both psychosis generally and voice hearing specifically [13-16]. Despite this, limited access to psychological therapies amongst patients with a diagnosis of psychosis/schizophrenia is a known and recurring problem in the NHS [17]. The considerable expense of inpatient care, often required during periods of crisis, further highlights the need for improved outcomes in this area. Indeed, although only 1% of the population is diagnosed with schizophrenia [18] it is estimated that the total societal cost of the condition is £11.8 billion a year in the UK, in addition to a considerable proportion of the national health and social care budget [17,19]. Given the extent of the problem, there is a recognised need to "energetically pursue" [20: p.25] new treatment options for voice hearers, particularly evidence-based strategies that can address the role that trauma is known to play in voice onset and maintenance [10,13,21-22].

The recognised associations between adversity and voice hearing correspond with the rapid growth of research that argues voices may be better considered as a dissociative rather than psychotic phenomenon. Dissociation is understood as a psychological response to trauma wherein different emotional and cognitive systems become disconnected from one another; and numerous theoretical and experimental work in the past decade has supported the contention that dissociation is a central feature of voice hearing in both non-patient and transdiagnostic patient groups [13, 23-24]. The substantial clinical and conceptual overlaps between voice hearing in the context of dissociative disorders, psychosis, and posttraumatic stress disorder has therefore driven the claim that rigid distinctions in treatment strategies according to diagnosis are theoretically and therapeutically unjustified [13,22,25-27]. However, despite this, there are currently no interventions available for psychosis patients that specifically emphasise the role of dissociation in voice hearing.

TwV was developed within the International Hearing Voices Movement (HVM), a survivor-led coalition of voice hearers, academics, and clinicians that was founded in 1987 and draws its

inspiration from the work of social psychiatrist Marius Romme and researcher Sandra Escher [28-29]. Organized into local and national Hearing Voices Networks, the HVM has worked over the past few decades to promote approaches to voice hearing which are de-stigmatising, empowering, and challenge reductive disease models by emphasizing that voices can embody unbearable, yet psychologically meaningful, material that it is important to acknowledge and process [30-33]. As such, a central emphasis within the HVM is that it is possible to make sense of voices' content (either literally, or in terms of their emotional/psychological themes) by considering them within the context of adverse life events; for example, an individual who endured abuse during which they felt threatened may later experience aggressive, intimidating voices (which may also speak in similar ways to the original perpetrator in either tone or content). As discussed previously, this premise has been supported by substantial scientific literature associating voice hearing with previous experiences of trauma, loss and stress.

TwV is a specific strategy that approaches voice hearing in psychosis in a manner considered customary within treatment for dissociative disorders. That is, a therapist directly engages with the voices in a manner intended to instigate integration and reconciliation, enhance awareness of voice characteristics, examine relevant factors in voice emergence and maintenance, and redress unequal power dynamics between hearer and voice. In the first stage, a therapist works with the voice hearer to derive a psychological formulation of the voices. This explores features like voice identity, content, characteristics and triggers, as well as significant biographical events, to create a shared understanding of how the voices may relate to particular emotional and social conflicts (as well as other clinical complaints, such as non-auditory hallucinations or paranoid beliefs). In the second phase, the therapist poses direct questions to the voice, with the voice hearer repeating its responses verbatim. On one hand, the method strives for a transformation of the voice(s) to 1) a supportive and meaningful experience that is taken seriously by the voice hearer (without submission) and 2) to support the voice hearer to distance themselves from the voices' emotional content by relating to it in a more compassionate, curious way and from the perspective that the voice(s) reflect previous emotional conflicts that they have faced.

As discussed, TwV is consistent with existing interventions within the field of dissociative disorders and reflects numerous evidence-based positions for working with voices in psychosis. This includes the proposition that voice content and characteristics may often embody aspects of emotionally overwhelming life events [34-36], that improving relationships and communication styles between hearer and voice is a promising therapeutic approach [37-39] and that interpreting and deconstructing the psychosocial conflicts embodied in experiences like voice hearing can provide valuable information for guiding care-planning [40-42]. As such, the proposed mechanisms of change underlying the intervention are established. In turn, it has the potential to address areas of unmet need within the NHS in terms of offering support to individuals who, for the reasons discussed previously, have either not been offered CBTp within mental health services and/or have not engaged with it, or not derived benefit from it. Likewise, while Avatar therapy [38] has demonstrated the utility of using dialogical techniques with voices, it is not readily implementable in NHS settings due to technological and office space requirements. In turn, it is also largely based on role-play scenarios whereas TwV uses dissociation theory to directly engage with voices in order to instigate a process of reconciliation and integration.

Taken together, demonstrating TwV as safe and effective could offer significant advances in treating a vulnerable and clinically disadvantaged group. However, despite the conceptual/clinical rationale described above, as well the approach already being widely utilised within the HVM, the only published accounts are limited to descriptive case reports [23, 43-44] and the true extent of its feasibility, acceptability and utility is unknown. Key uncertainties include whether recruitment, retention and engagement with the intervention is possible and the most appropriate choice of outcome measures. This application proposes to address these issues using a single-site feasibility randomised control trial to compare TAU with TwV in order to guide the design of a future definitive, pragmatic, and clinical trial.

3. Trial aims and objectives

The overall aim is to identify psychosis patients who hear distressing voices and to investigate whether a novel intervention, TwV, is an acceptable, feasible and potentially effective treatment option to offer them within NHS settings.

We aim to conduct a feasibility study to inform a definitive RCT of 50 participants randomised 1:1 to receive either TwV plus TAU or TAU only. A nested qualitative study of participants' experiences of therapy and trial participation and the opinions and perceptions of trial therapists, their clinical supervisors, and NHS staff will also be conducted in order to identify the acceptability of this approach and to inform parameters of the definitive trial including therapy protocol, measures, recruitment and retention.

The objectives are to:

1. assess recruitment/retention rates (including willingness to be randomised), quality of data collection, proportion of participants receiving the allocated intervention, and follow-up under randomised conditions;
2. provide data from which a sample size can be calculated for a definitive trial;
3. provide a final check of the protocol in order to test its integrity to ensure all procedures are set-up prior to a definitive trial and to clarify inclusion and exclusion criteria;
4. test the randomisation procedure;
5. examine the appropriateness, feasibility and acceptability of the treatment intervention and measures under randomised conditions;
6. clarify training and supervision needs for implementing interventions and assessments prior to the commencement of a definitive trial.

Key outputs:

1. evidence of the acceptability/feasibility of delivering the intervention under randomised conditions in order to support an application for funding towards a definitive RCT;
2. data on which to base a power calculation for a definitive RCT;
3. data on which to refine and develop a finalised protocol to be used for a definitive RCT;

4. a finalised treatment manual to guide and standardise the intervention and associated fidelity scale, including parameters for acceptable deviation, and determining optimum length and number of sessions;
5. preliminary data on the associated effects with this form of treatment compared with TAU.

4. Project design

Study 1 will be a single (rater) blind randomised feasibility study with two conditions: Talking With Voices plus TAU vs. TAU alone amongst individuals with a schizophrenia spectrum diagnosis who hear distressing voices. The trial will randomly allocate participants who meet criteria to a six month package of either condition. An assessor blind and independent to treatment group will conduct all assessments at baseline and at post treatment (six months).

Study 2 will be a nested qualitative study that will identify key themes associated with the acceptability of the interventions as well as experiences of being involved in the trial. Additionally, all trial therapists, their clinical supervisors, and a sample of healthcare staff from recruitment sites will be invited to a series of focus groups and one-to-one interviews to explore their experience and/or perspectives of offering this intervention within the NHS.

5. Selection and withdrawal of participants

Inclusion criteria will be:

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 [45]);
3. who have had no changes to medication within the past month;
4. who have a lifetime diagnosis of ICD schizophrenia spectrum disorder;
5. who are able to provide written, informed consent;
6. who are not currently receiving, or waiting to receive, Cognitive Behavioural Therapy for psychosis;
7. who are willing and able to communicate with their voices and relay what the voices say to a therapist, and;
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).

Exclusion criteria will be factors that could adversely affect service-user safety, or could affect the ability to engage with therapy:

1. individuals 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 PANSS; and
7. homeless and/or of no fixed abode.

5.1 Sample size

A sample size of 50 is sufficient for a feasibility trial to obtain precise and reliable parameter estimates for sample size in a future definitive trial, as well as demonstrating the feasibility of such a trial [46]. Assuming a recruitment rate of approximately three cases per month, this will achieve a rate sufficient to recruit to this target over 15 months.

6. Randomisation

Once identified and consent for contact obtained, potential participants will be approached to arrange a baseline assessment. Following written consent and assessment of eligibility, participants will be randomised within 5 working days.

Blinded randomisation and allocation concealment will be undertaken using the online service SealedEnvelope.com, which is fully encrypted and secure with no personal data being transferred. Randomisation at the individual level will be independent and concealed, using randomised-permuted blocks of 6-8. Allocation is communicated to the Chief Investigator (to monitor adherence to the randomisation algorithm), the trial therapists, and made known to the participant and their care team by letter from the administrator. Blinding of allocation will be maintained for the research assistant until all outcome measures for all participants have been collected. Blindness will be maintained using a range of measures (e.g. separate offices for therapist and researchers, protocols for answering phones, message taking and secretarial support, separate diaries and pigeon holes; and datafile security, such as using passwords and encryption of randomisation information). We will develop a combined Trial Steering Committee and Data Monitoring and Ethics Committee (TSDMEC) to oversee the study.

7. Assessments

7.1 Primary outcome measures

The aims and objectives of the feasibility study will be measured using:

1. referral rates and recording the proportion of individuals eligible for the trial;
2. rates of recruitment and retention (including willingness to be randomised and compliance with allocation);
3. estimating selection bias by gauging how representative participants are of general psychosis populations using demographic and clinical data;
4. number and duration of attended sessions;
5. satisfactory delivery of competent and adherent therapy;
6. adherence to treatment (including between session work);
7. follow-up and questionnaire response rate;

8. any necessity for substantive changes to protocol;
9. assessing signals of safety and efficacy and no clear signals of harm using secondary outcomes measures and incidence of adverse events; and
10. qualitative data on acceptability from both service-users and staff.

7.2 Secondary clinical outcome measures

The secondary clinical outcome measures have been chosen to inform the design of a future trial by highlighting potential methods of action for TwV and identifying relevant clinical variables to ensure future protocols target key mechanisms:

Targeted measures of voice hearing will be:

1. The PANSS; hallucinations subscale [45];
2. The Revised Beliefs about Voices Questionnaire [47]; and
3. The Voice and You scale [48]; and
4. The Subtypes of Voice Hearing Questionnaire [49].

General clinical presentation will be assessed with:

1. The Revised Dissociative Experiences Scale [50];
2. The PANSS [45]; and
3. The Questionnaire about the Process of Recovery [51].

Adversity exposure will be assessed with The Life Stressor Checklist – Revised [52].

Data on health status will be collected using the EQ-5D [53] and the use of health and social care services will also be recorded. Additional demographic data will be collected using a standardised form.

Assessments will be conducted at baseline and at six months post randomisation (approximating post-treatment for the control group). Payment for individual participants will be £10 per assessment. These will be conducted by a research assistant blind and independent to treatment group.

8. Intervention

A manual and adherence scale for The Talking With Voices intervention [43,44] will be developed as part of the study in consultation with the psychiatrist Dr Dirk Corstens, the originator of the technique, and the psychologist Professor Tony Morrison, a co-applicant with extensive experience of manualising psychological therapies for psychosis in the context of clinical trials. Additional sources will include existing clinical theory and research concerning: 1) associations between dissociation and adversity in psychosis patients who hear voices; 2) dialogical engagement with voices, 3) clinical and survivor-led literature assessing the role of psychosocial education and formulation in psychosis, and 4) an unpublished treatment manual by Dr Corstens around dialoguing with voices. Group consultation with service-users and therapists will also take place at this time in

addition to individual discussions with Dr Jacqui Dillon, the Chair of the English Hearing Voices Network.

The intervention will include up to 26 sessions with a clinical psychologist of up to an hour over a six month period. Sessions will focus on psychosocial education, psychological formulation, and dialogical engagement with voices. Participants will be seen by the same therapist for the duration of the study to maintain engagement and consistency of approach.

9. Statistical analysis

Analysis and presentation of results will follow Consolidated Standards of Reporting Trials (CONSORT) Statement for randomised pilot and feasibility trials [54] and be based on an intention-to-treat approach using all randomised participants. Hypothesis testing is considered inappropriate for feasibility trials, so quantitative analysis will focus on descriptive statistics, point estimates and associated 95% confidence intervals rather than tests of statistical significance (although some *p* values will be reported). An emphasis will be placed on tabulated and associated graphical summaries of the primary outcomes of the feasibility trial, as well as summary statistics of secondary clinical outcome measures. Further analysis will assess correlations between each measure across all time points, and variation within proposed outcome measures (mean and standard deviation) to inform a definitive sample size calculation for a future trial. All analyses will begin after full recruitment and follow-up and a statistical analysis plan will be produced prior to the examination of any of the outcome data.

10. Qualitative sub study

A nested qualitative approach will be employed to identify key aspects of acceptability that could not be detected by quantitative measures alone, including experiences of trial involvement, wanted and unwanted intervention effects, and disincentives to participate. Semi-structured interviews will explore participants' experience of being recruited to the study, completing assessments, randomisation to TAU, and for participants in the intervention arm, receiving TwV. Each participant will be paid £10 for their time completing the interview. Interviews will also aim to identify barriers (and potential solutions) to engagement in treatment. This will inform the design of a definitive trial and help further refine the intervention, recruitment and retention procedures. Semi-structured interviews will be conducted with participants approximately six months after randomisation; this will allow us to explore participant's experiences of receiving the intervention and also their experiences of being involved in the trial's control condition and we will additionally attempt to interview a number of individuals who declined to be randomised. It is anticipated that the final sample will be representative and include variance on key variables (e.g., intervention engagement, age/gender, clinical presentation). Our projected sample size for participant interviews is 20-25, which is sufficiently large to yield the necessary depth of coverage/thematic saturation, but remains realistic within the available timescale. We will additionally recruit all four trial therapists, their three clinical supervisors, and a sample of 24 NHS workers from the recruitment sites for a series of focus groups and one-to-one interviews in order to understand more about their experiences and

perceptions of the intervention, and explore possible barriers and solutions for implementation. These will be conducted at the beginning of the trial, mid-way, and at post-treatment for the therapists and their supervisors, and at the end of the trial for NHS staff. Anonymised notes and a checklist of recurring themes from clinical supervision will additionally be retained and used to inform interviews and focus groups.

All interview and focus group data will be audio-recorded, transcribed verbatim and analysed using Thematic Analysis [55], which results in a rich and accessible account of qualitative data. This process involves systematically and iteratively coding information from the interviews/focus groups under main headings and subcategories, and then using previous literature to support the validity of categories. Member checking strategies [56] will be employed for this stage of the analysis with participants, members of the multidisciplinary research team and service user consultants in order to maximise the transparency and trustworthiness of the data. Data management and analysis will be supported by NVivo software. Analysis will occur in parallel with data-generation and will continue until thematic saturation is achieved (the point at which no new categories emerge).

11. Trial supervision and management

Project management for the trial will be delivered by Chief Investigator Eleanor Longden with additional input from Tony Morrison and Melissa Pyle. This will include responsibility for monitoring recruitment, training staff, the design and production of trial promotional materials, conduct of the trial, report writing and data monitoring. Longden, Pyle and Morrison will jointly supervise research assistants during the trial around trial management issues (e.g., adherence to the protocol, recruitment and retention rates) and relevant clinical issues (e.g., managing risk and safeguarding, engagement).

A trial management group (TMG) including key applicants will meet regularly throughout the trial. An independent TSDMEC will monitor data entry and analysis, safety, confidentiality and adherence to Research Ethics Committee protocols and will meet on a bi-annual basis. The TSDMEC will consist of an independent statistician, an independent clinician with clinical trial expertise and a PPI consultant with lived experience of voice hearing. A protocol for monitoring adverse events will be employed (and monitored by the TSDMEC).

12. Data handling and management

Each participant will be given a unique trial Participant Identification Number (PIN). Data will be entered onto paper Case Record Forms (CRFs) or assessment packs prior to entry onto the database. Data will be entered onto the central SPSS database, stored on secure NHS servers. Training on paper CRF completion, use of the databases, and storage for site staff listed on the delegation of responsibilities log will be provided in addition to weekly supervision and refresher training; all of which will have a continual focus on accurate assessment completion, documentation and use of the database.

Data collection, data entry and any queries raised by a member of the trial team will be conducted in line with the trial specific working practice documents. Identification logs, screening logs and enrolment logs will be kept at the trial site in a locked cabinet within a secured room. Trial team members will receive trial protocol training. All data will be handled in accordance with the Data Protection Act 1998. Audio recordings of qualitative interviews, therapy sessions and assessments will be stored on an encrypted NHS network. Audio recordings will be stored for five years following completion of the study.

The sponsor will permit monitoring and audits by the relevant authorities, including the Research Ethics Committee. The investigator, in line with responsibilities set out in the Research Governance Framework, will allow monitoring and audits by these bodies and the sponsor and provide direct access to source data and documents to perform source data verification and data completeness checks. A general check of the continued suitability of the site will also be performed.

13. Ethical considerations and regulatory approvals

The protocol and all material to be given to prospective participants will be submitted to the relevant Research Ethics Committee for approval prior to initiation of the trial. Any subsequent amendments to these documents will be submitted for further approval.

Local research governance approvals will be sought from participating NHS Trusts via Health Research Authority approval processes.

The ethical issues in this trial will be related to the identification and recruitment of patients; the procedure for gaining fully informed consent; data protection arrangements; and issues pertaining to risk, burden and benefit. Written informed consent will be obtained from every participant. Patients' data collected during the course of the research will be processed in accordance with the Data Protection Act 1998. We will also seek the patient's permission to inform their general practitioner that they are taking part in this study.

14. Publication policy

The results of the trial will be disseminated regardless of the direction of effect. Ownership of the data arising from the study resides with the trial team. The TMG will decide on authorship, with any difficulties being resolved by the TSCDMEC.

15. Financial aspects

The study is funded by a National Institute for Health Research (NIHR) Post Doctoral Fellowship Award and details have been drawn up in a separate agreement/s.

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