Full title:	Managing Unusual Sensory Experiences (MUSE): A feasibility trial of a targeted, psycho-education toolkit for distressing hallucinations, in people with a first episode of psychosis: MUSE FEP trial.
Short title:	MUSE-FEP
Protocol version:	**Version 1**
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Summary

Title:	Managing Unusual Sensory Experiences (MUSE): A feasibility trial of a targeted, psycho-education toolkit for distressing hallucinations, in people with a first episode of psychosis: MUSE FEP trial.
Objectives:	To investigate the feasibility and acceptability of the MUSE therapy delivered by community psychiatric nurses to people with first-episode psychosis, and to inform a future definitive trial.
Design:	The study is a two-arm feasibility randomised controlled trial comparing MUSE therapy and treatment-as-usual (N=40) to treatment-as-usual alone (N=40). Blind assessments will be carried out before and after the treatment, and at 3-month follow-up. Qualitative feedback from both participants and therapists will consider the acceptability and value of the training, supervision, trial procedures, and the intervention.
Treatment schedule:	Forty participants will receive MUSE therapy delivered by community psychiatric nurses over 4-6 sessions (4 core sessions with an option of 2 extra).
Proposed start point:	1st April 2021
Proposed end point:	31st August 2022
Study duration:	17 months
Trial registration:	ISRCTN tbc
Funding	This trial is funded by an NHS National Institute for Health Research for Patient Benefit scheme NIHR 201078
Keywords:	Hallucinations; voices; visions; psychosis; schizophrenia-spectrum disorder; cognitive behaviour therapy

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Plain English summary

Aims

We want to increase access to psychological treatment for people with hallucinations (e.g. hearing voices) by having community nurses deliver a new therapy "toolkit". This study will look at how feasible this is and will help us plan a larger study assessing if the new treatment toolkit reduces the distress of having hallucinations.

Background

Psychosis is a term for conditions like schizophrenia. One common symptom is hearing things that are not there (hallucinations) which can cause distress, disability and social isolation. Whilst we have effective treatments like Cognitive Behavioural Therapy (CBT), less than 10% of people with psychosis have access to therapy owing to i) a shortage of therapists and ii) how long therapy takes. Our study addresses this issue by providing community nurses with training and tools to help them deliver a targeted and brief treatment in their day-to-day practice.

In this research, community psychiatric nurses (CPNs) will use a novel toolkit, MUSE (Managing Unusual Sensory Experiences) with people with psychosis and hallucinations.

The toolkit:

- explains why people have hallucinations and helps people develop strategies to cope and reduce their distress
- focuses only on hallucinations so treatment is short (4-6, one-hour weekly sessions);
- is loaded onto a smart tablet (e.g., iPad) so the same treatment is offered to everyone;
- has user-friendly and engaging content - using video clips to explain how the brain can experience hallucinations.

Design and methods

We will ask 80 people with psychosis and hallucinations to be in our study. Forty will have MUSE toolkit sessions with a CPN. Forty people will have treatment as usual. Participants will be assessed on a range of measures before and after treatment (at 6-8 weeks) and about a month later (at 3 months from the start of the treatment). This study will tell us how feasible it is to train staff to deliver this toolkit and if patients can be recruited to and retained in the study.

Using interviews and focus groups we will explore staff and patient views of the acceptability of MUSE. Our findings will inform a larger study to determine if the treatment works to reduce distress caused by hallucinations.

Patient and Public Involvement

Patient feedback has helped us to refine and revise the MUSE toolkit. A co-applicant on our study is a service-user trained to be a researcher, and we also have an expert-by-experience advisory group to help us recruit participants, run the study, interpret findings and share our results.

Dissemination

We will share our findings with participants, staff, and other researchers. For wider dissemination we will work with Durham University's *Hearing the Voice* project, which has expertise in working with stakeholder groups (e.g. Hearing Voices Network) and using innovative methods of sharing research (exhibitions, video games, radio and media).

Scientific Abstract

Background
Hallucinations (hearing or seeing things that others do not) are a common feature of psychosis, causing significant distress and disability. The National Institute for Health & Care Excellence (NICE) recommends that all individuals with psychosis be offered Cognitive Behaviour Therapy for psychosis (CBTp). However, in practice access is often limited owing to a lack of CBTp-trained staff. One solution is to develop shorter, targeted treatments that use CBTp-informed techniques to focus on specific symptoms. This has produced promising results for other symptoms of psychosis, such as delusions (i.e. unusual beliefs), but there has been less research on hallucinations.

Our toolkit, called MUSE, (Managing Unusual Sensory Experiences) explains why people have hallucinations and helps the person to develop and use coping strategies to reduce distress. The MUSE intervention focuses only on hallucinations, so treatment is short (4-6, one hour weekly sessions). It can be used on tablets, laptops or desktop computers (ensuring its accessibility to NHS staff) and provides information about hallucinations in a user-friendly and engaging way, including use of audio, video, and animated content. Crucially, it is designed for use not just by trained CBT therapists, but also non-specialist staff like Community Psychiatric Nurses (CPNs).

Aims

The long-term aim of this research is to increase the number of psychosis patients who have access to an intervention to reduce the distress of hallucinations. Prior to that effectiveness and cost-effectiveness need to be established. As a step towards that the proposed study aims to establish if it is feasible to conduct a future clinical- and cost-effectiveness study. It addresses the following questions.

Research questions

i) Is it feasible for CPNs to be trained in MUSE and to deliver it to psychosis patients within NHS Mental Health Services?

ii) Is MUSE – delivered by CPNs – acceptable to service-users and staff?

iii) Is it feasible to evaluate the clinical and cost effectiveness of the MUSE– thus informing the design of a definitive trial?

Plan of Investigation
The proposed study is a two-arm feasibility RCT comparing MUSE and treatment as usual (TAU) (n=40) to TAU alone (n=40), recruiting across two sites, using 1:1 allocation and blind assessments before and after treatment, and at 3-months follow up. Quantitative information on recruitment rates, adherence, and completion of outcome assessments will be collected. Qualitative interviews will capture service-users' experience of therapy and clinicians' experiences of the training and supervision in MUSE. Clinicians will also be asked about factors affecting uptake, adherence, and facilitators/barriers to implementation. These data will determine if it is feasible to deliver MUSE and evaluate it in the target population. If an evaluation is possible, the results from the current study will inform the parameters and stop/go/refine criteria for a future definitive trial (which would include an internal pilot and fully powered randomised controlled trial).

Potential benefits to patients and the NHS
If MUSE is found to be clinically and cost-effective when delivered by CPNs in a definitive multisite study, this intervention could considerably increase access to tailored treatment for psychosis patients distressed by hallucinations.

Introduction

Psychosis refers to a number of conditions – such as schizophrenia. Schizophrenia is among the top ten disorders in burden, disability, and societal and health costs worldwide (Hjorthøj et al., 2017; Kennedy et al., 2014). Almost all patients with psychosis at some stage have hallucinations (hearing or seeing things that others do not). These hallucinations can lead to withdrawal, with many people spending much of their time alone (Kennedy et al., 2014). Physical activity levels are reduced by about two thirds (Kennedy et al., 2014) and over 90% of patients with schizophrenia are unemployed. People with psychosis have an increased risk of early mortality and

high suicide rates (Hjorthøj et al., 2017). In 2012 the total annual cost to the public sector in England was estimated at over £7 billion (Andrew et al., 2012).

Treatments like Cognitive Behavioural Therapy for Psychosis (CBTp) are recommended by NICE (2014), but not many patients actually receive this therapy (Haddock et al., 2012). While estimates vary from 6% to 20% of service-users, typically less than 10% receive Cognitive Behavioural Therapy for psychosis (CBTp; Haddock et al., 2012). Few therapists are trained to provide CBTp and it is usually a lengthy treatment (typically 16–24 weekly sessions for over 9 months). This limits access to crucial psychological help for dealing with symptoms like distressing voices.

There has been significant investment in Early Intervention in Psychosis (EIP) services in recent years that has led to increased access to CBTp but still most people do not receive CBTp. To help increase access to therapy, attempts have been made to train non-psychological therapy staff such as community psychiatric nurses (CPNs) in the delivery of talking therapies (e.g. England, 2007; England 2008). However, they have not delivered the anticipated benefits, owing to the challenge of the providing brief training for a complex intervention and a lack of standardisation of delivery.

Our research directly addresses this unmet need by putting high quality treatment tools in the hands of Community Psychiatric Nurses (CPNs), meaning that there is increased access to high quality care. Rather than focusing on psychosis as a whole, we use a novel approach called the **MUSE (Managing Unusual Sensory Experiences)** toolkit that focuses only on hallucinations. MUSE blends input from people with lived experience and the latest theoretical and empirically supported research to tailor the treatment approach specifically to hallucinations, over 4–6 focused sessions. The toolkit is manualised and loaded onto a laptop meaning that treatment is standardised, reducing the training required and the risk that staff will not feel confident in delivery. MUSE presents the content in a user-friendly, engaging way. This approach could: substantially increase access to a high quality treatment; reduce delays to treatment; avoid the significant training and time costs of CBTp; improve outcomes; increase use of recovery focussed services and potentially provide cost-savings. Services may benefit as a key driver of costs is inpatient admission (approximately £380 per night). Many patients are admitted owing to a worsening in their psychotic experiences, such as hallucinations. MUSE directly targets hallucinations and is easily built into the existing work that staff undertake, using existing equipment. If MUSE helps people better manage hallucinations then it may reduce NHS costs overall by reducing the occurrence, frequency and length of inpatient admissions.

MUSE was developed through a collaboration between clinicians in the Cumbria, Northumberland, Tyne and Wear (CNTW) and Tees, Esk and Wear Valley (TEWV) NHS Foundation Trusts in North-East England, and Hearing the Voice (HtV), an

interdisciplinary study of hearing voices (or auditory verbal hallucinations; AVH), based at Durham University and funded by the Wellcome Trust since 2012. CNTW clinicians have led a research programme aimed at improving understanding of the psychological causes of voices and visions (Collerton & Dudley, 2004; Smailes et al., 2015). We have combined this knowledge and research expertise to develop the MUSE toolkit.

Research on auditory hallucinations has shown that AVH take different forms that may respond to specific therapeutic approaches (Waller et al., 2018). A review by the International Consortium on Hallucinations Research (McCarthy et al., 2014) outlined three different potential subtypes relevant to people with psychosis which may be suited to different kinds of tailored intervention: *inner speech* voices (postulated to result from the misattribution of ordinary inner speech to an external agent); *hypervigilance* voices (resulting from a biased attention to environmental stimuli); *memory* voices (the result of intrusions from traumatic memory).

MUSE was developed within Early Intervention in Psychosis (EIP) services and was based on current theoretical models of voice-hearing and specifically the voice subtypes described above. The collaboration has been led by senior clinicians in EIP, with strong engagement from 10 EIP teams in developing the tool. The manual represents refinements of existing psychoeducation and coping strategies used in CBTp and related mental health problems. Also, the manual is delivered via a smart tablet or on NHS computers for joint use of therapist and client in the therapy session. This allows clinicians to use prepared videos and other types of media to demonstrate complex psychological ideas and phenomena, and to help service-users to practice coping strategies and carry out behavioural experiments to test the reality of their experiences.

MUSE uses psychoeducation about the currently known causal mechanisms of hallucination as means of exploring, with service-users, why their specific experiences may be happening. This knowledge is then matched to specific, tailored interventions and coping strategies that enable the person to manage their experiences differently and reduce their distress. This process relies on psychoeducation as its basis, but it is more fundamentally about helping the person to change their understanding, manage their experiences better, and thus cope more effectively. It is an active treatment, not a passive educational tool.

MUSE is a departure from traditional CBTp as it focuses only on hallucinations and reduces the typical number of sessions to 4–6. This helps prevent the “drift” that can occur in treatment when there is not a specific target symptom or clear conceptual model underpinning treatment. As an approach CBTp also usually focuses on the consequences of psychotic experiences (Collerton & Dudley, 2004) rather than their causes. This misses important opportunities to help people understand why their experiences happen, and overlooks possible ways to reduce them. Crucially, it misses the opportunity to personalise and tailor the treatment to the specific needs of

the person. Different causes of hallucinations demand different kinds of coping strategies. Without matching the treatment to the correct understanding of the way the hallucination is caused there is a very real risk of using a mismatched treatment approach.

The MUSE toolkit and application have been developed iteratively in response to research and on-going feedback from clinical staff and service-users. An earlier version of MUSE was delivered to people with distressing voices by psychological therapists (not CPNs, who will deliver the toolkit in this project) in a recently completed uncontrolled single group feasibility study (MUSE PSYCHOSIS, Dodgson et al., 2020). Twelve participants who completed follow-up after 10 MUSE sessions reported very high treatment satisfaction and acceptability (87% & 90% mean overall ratings). Although the study was not powered to detect an effect (as its aim was to establish feasibility) the within-subject effect size for reducing auditory hallucination severity was considerable (d = 0.70). Even greater benefits were evident on a recently completed study in which MUSE was used by psychological therapists with a group of people in an "At Risk Mental State" for psychosis (i.e. a precursor stage with milder symptoms; Dodgson et al., in press). Effect sizes of d=0.8 for reduction the intensity of auditory hallucinations were found, alongside satisfaction ratings of 90%.

Feedback from post-treatment interviews and service evaluation has indicated that this approach is valued by service-users and staff. However, it also led to the toolkit being revised in a number of important ways. First, MUSE now incorporates more information about a range of hallucinations and not just voices. Working with service users we have developed a treatment using co-produced treatment materials specifically for distressing visual hallucinations in psychosis (Dodgson et al., 2020). MUSE integrates these approaches to provide a comprehensive package for both voices and visions. Second, we have strengthened the lived-experience perspective by recruiting a service-user to our team, who has helped us improve the relevance and accessibility of the MUSE materials. Third, we have adapted MUSE to make it easy to use for frontline staff: we have been asked repeatedly by CPNs to make MUSE materials available for use in day-to-day practice – highlighting the need for a treatment to support people with these distressing hallucinations. Hence, we have developed specialist training and supervision for these staff to enable them to use the MUSE toolkit.

The proposed study will further investigate the feasibility and acceptability of MUSE treatment delivered by CPNs in participants experiencing first-episode psychosis. An initial feasibility trial will help establish if we can undertake a larger trial to establish clinical-effectiveness and cost-effectiveness.

Study objectives

The main objective of the proposed study is to establish if it is possible to undertake a larger, definitive trial in the future. The proposed study will aim to i) assess the

feasibility of CPN staff training and delivery of the MUSE toolkit ; ii) asses the acceptability of the MUSE toolkit to patients and staff; and to iii) collect data to inform the effectiveness of future definitive trial. The long-term aim of this research is to increase access to effective treatment of distressing hallucinations.

Three work streams map onto the objectives and will establish:

1: Feasibility of staff training and delivery of the MUSE toolkit

We will explore whether the planned training equips the CPNs with the skills and confidence to deliver MUSE. This will be assessed through quantitative and qualitative evaluation at the end of training, six months into the study, and at end of the study. We will also explore whether the supervision package is sufficient and useful to support CPNs in the delivery of this toolkit (using the same methods and time-points).

2: Acceptability of the MUSE toolkit to patients and staff

We will also explore the acceptability of the intervention to the participants engaging in the treatment and to CPNs delivering it. At the follow up meeting, participants will be asked to share their views. Staff will be asked in the latter stages of the study their views on the toolkit. We will also investigate whether the intervention needs further refinement, by asking staff and service users at these time points their views on the toolkit.

3: We will inform the development of future definitive trial by collecting the following data:

- Proportion of eligible individuals that clinicians are willing to refer (referral rate)
- Proportion of eligible individuals willing to participate (recruitment rate) and the proportion of participants who comply with their allocation (allocation compliance rate)
- Proportion of participants who drop-out of the study (attrition rate)
- Characteristics of trial participants to further clarify selection criteria
- Appropriateness and integrity of treatment protocols
- Randomisation procedures
- Completion rate of measures
- Acceptability, relevance and validity of the measures to assess clinical effectiveness and safety in a subsequent definitive trial

- Appropriateness of quality of life measures, and service use data needed to undertake a future full health economic evaluation
- Access to CBTp and MUSE like interventions in other EIP services in England

We will also explore the acceptability of the trial methods and procedures to the participants engaging in the study and to CPNs involved in supporting it.

Overview of methodology

The proposed study will aim to recruit 80 participants. It will investigate the feasibility and acceptability of the MUSE toolkit delivered by CPNs in first-episode psychosis patients. It will use a single (rater) blind randomised controlled design with MUSE and TAU (N=40) being compared to TAU alone (N=40). MUSE therapy will involve a patient meeting with a CPN over several weekly sessions – usually in their own home – to understand the causes and consequences of hallucinations (4 core sessions with an option of 2 extra).

The study will use a mixed methods approach. Quantitative information on recruitment rates, adherence, and completion of outcome assessments will be collected. Participants will receive assessments pre- and post-treatment (six weeks), and at three months follow-up. The assessments will measure distress and disability caused by hallucinations, depression, quality of life, perceived recovery, therapeutic relationship and intervention quality (the latter two will be measured at end of treatment and follow-up). These measures will not be used to determine effectiveness but to help identify important parameters for a future trial (i.e. completion rates and selection of best outcome measures). Additionally, at each MUSE session, a short self-assessment form monitoring variations in hallucination frequency and distress will be completed. We will also measure service use in a short interview and by reviewing a case records.

Qualitative interviews will capture service-users' and staffs' experience of the trial procedures and the therapy and CPNs' experiences of the training and supervision in MUSE. In-depth interviews will be conducted with patients and staff to inform future studies and the development of the intervention.

Study setting

There will be two recruiting sites in the North East of England (Cumbria, Northumberland, Tyne and Wear; Tees, Esk and Wear Valley), both of which are Foundation NHS mental health Trusts and serve large populations (CNTW population 1.7 million and TEWV 1.7 million). We will recruit from EIP services that accept approximately 690 (340 and 350 respectively) people each year. EIP services are community based services, usually operating office hours during the week. They work with people for up to three years, meaning there are about 1500-2000 people in receipt of EIP. At entry to service, prevalence of auditory hallucinations is estimated

as up to 75% of people with psychosis. For many, symptoms improve and they may leave the service before three years, but around a third continue to report persistent hallucinations (meaning perhaps 300-400 eligible participants will be in EIP at any one point in time).

The two NHS Trusts provide a comprehensive range of mental health care across a range of services in a variety of settings, for instance adult community mental health teams (CMHTs) and primary community mental health teams (PCMHTs), Community Treatment teams, Psychiatric Liaison teams, Assessment and Liaison (A&L) and Assessment and Treatment (AT) services, recovery teams, outreach teams, home treatment teams, residential units, inpatient wards, outpatient clinics, specialist services, allied third sector services.

Inclusion criteria
Participants will:

- Be in contact with Early Intervention in Psychosis (EIP) services
- Have an identified CPN acting as their care coordinator
- Meet ICD-11 criteria for schizophrenia, schizoaffective disorder or entry criteria for an EIP service
- Have a history of auditory hallucinations for at least four weeks
- Be aged 16 and above
- Consider their hallucinations as a main difficulty, and would like to receive an intervention specifically for hallucinations.
- Have the capacity to provide informed consent.
- Be judged by their clinician to be clinically stable for the preceding 4 weeks.
- Both individuals on antipsychotic treatment, and those who decline to take medication, will be included, as long as no medication changes have occurred in previous 1m (i.e., having started or stopped antipsychotic medication, or a switch to or from Clozapine).

Exclusion criteria
Participants with the following will not be eligible:

- Hallucinations/psychosis with a known biological basis
- Insufficient command of English to complete the study procedures;
- Intellectual disability, or severe cognitive dysfunction affecting the ability to provide fully informed consent to participate;
- A primary diagnosis of substance misuse/dependency;
- Currently engaged in CBTp or received CBTp in the past 6 months

Consenting procedures

Written informed consent will be obtained from each participant prior to any participation or study-specific procedures. Owing to the sensitive nature of the questions for determining eligibility, we will ensure that fully informed consent is obtained prior to eligibility assessments. Our specific procedures will be dictated by local NHS Trust consent procedures but will adhere fully to the principles outlined below.

Participants will be given the opportunity to discuss the study with the Research Worker (RW) prior to giving written informed consent, and they will be offered at least 24 hours to consider their participation in the trial. The RWs will assess risk and capacity to provide consent throughout the identification and assessment procedures, with input from the Trial Coordinator and/or Site Leads, who are all trained clinicians. The limits of confidentiality will be made clear to participants from the outset (see confidentiality section).

Unless people have previously provided written consent to be contacted, or contact the research team independently (see additional recruitment sources in Recruitment section), potentially eligible participants will first be approached by clinical teams responsible for their care to ascertain interest in being contacted about the study, and will be provided with a study leaflet with a summary of the research. If interested they will be invited by the clinical team to either contact the research team directly, or to give their permission to be contacted to learn more about the study. The potential participant will be provided with the Participant Information Sheets at this stage.

Potential participants will then be invited by the RW for a face to face meeting to be provided with further information about the study, to clarify any questions and to provide written informed consent to complete eligibility assessments and to participate in the study. The research team will not invite a potential participant without the responsible clinician or healthcare professional having indicated that it is appropriate to do so; i.e. that they meet study criteria and there are no clinical contra−indications.

Individuals who do not provide consent to participate (or who are assessed as unable to consent), and those who are determined not to be eligible at the assessment stage, will remain with the EIP team and will continue to have care provided as usual.

Eligible participants will then be invited to complete the baseline assessment. It will be made clear to participants that they have the right to withdraw from the study at any time for any reason, without the need to justify their decision, and that it will not affect their routine care. The investigator also has the right to withdraw participants from the study in the event of clinical contra-indications. Should a participant withdraw from MUSE treatment only but not from the study, efforts will be made to continue to obtain follow-up data, with the permission of the participant. Should a

participant withdraw from the study, we will still use any previous data collected from that participant up to the point of withdrawal, but will make no further attempt to contact or collect data, as specified by the UKCRC CTU network guidance.

Written informed consent will be documented on the consent form, with both a participant and RW signature. The original copy of the consent form will be retained in the investigator site file. Copies of the consent form will be scanned into the participant's clinical records and a hard copy given to the participant for their own personal records. The RWs who will be responsible for taking written informed consent will have received mandatory training in Good Clinical Practice (GCP) alongside internal additional training by the study team. Throughout the recruitment and research process all efforts will be made to tailor to participants' needs and preferences.

Participant Information Sheets for the trial randomisation and qualitative interviews were developed in line with requirements set out in the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH E6 (R2) guideline for GCP and the sponsors' Standard Operating Procedure for Informed Consent. Patient and Public Involvement (PPI) input was obtained to ensure appropriate wording and accessible formatting.

Additional consent provisions for collection and use of participant data

A qualitative approach will be employed with participants (N=10) and therapists (N=10) to identify key aspects of acceptability and tolerability in receiving and implementing the therapy that could not be detected by quantitative measures alone.

All trial participants will be asked whether they would be willing to be contacted at a later stage for the qualitative interview regarding the acceptability of the intervention, should they be randomised to the intervention group. It will be made clear that this is optional and that declining participation in this additional procedure will not prevent them from taking part in the trial. It will also be made clear that not everyone will be contacted, since we will only be recruiting a sub-sample. If they indicate willingness, an expert-by-experience researcher will contact them directly once they have completed the intervention (including people who choose to end therapy prematurely). Consent procedures will be as above. CPN therapists will also provide written informed consent to participate in the interview, according to the same principles outlined above.

For the evaluation of the training and supervision staff will be invited to take up the opportunity to attend a three-day MUSE training course. They will be asked to read the Staff Information Sheet (SIS), and sign a consent form and will be contacted to complete measures of skill and confidence in the use of the MUSE package and to be included in the interviews about the MUSE training and supervision.

Study intervention
The intervention we will use is a novel treatment manual for hallucinations. The treatment is divided into the following Modules:

1. *What are Voices?* This module provides normalising information about the frequency of voices and the factors that tend to increase voice-hearing (for example substance misuse and sleep deprivation), along with testimonies from other voice-hearers.

2. *How the Mind Works*. This module outlines current understanding of key psychological processes such as threat detection, the importance of prediction (top-down processing) and how intrusive thoughts work.

3. *Assessment.* This module identifies the subtype of hallucination a service-user is experiencing. After the assessment the therapist should be able to identify whether the voice-hearing is an Inner Speech-Auditory verbal hallucination (AVH), a Memory Based AVH or a Hypervigilance AVH

4. Inner Speech. This module provides psycho-education about the evidence that voice-hearing involves people not recognising their own inner speech. An individual understanding or formulation of voice-hearing experiences is co-produced and then targeted coping strategies and behavioural experiments are employed, such as means of interrupting and manipulating inner speech via singing or humming.

5. Memory-Based. This module provides psycho-education about how memories from trauma are more likely to be experienced as intrusive memories without contextual cues, and can therefore be experienced as belonging to the here and now. An individual formulation of how the memory may be experienced as a voice is followed by coping strategies and behavioural experiments that help people manage and reframe difficult memories.

6. Hypervigilance. This module provides psycho-education about how our brain uses prediction to interpret the world and manage the amount of sensory data received. If people are expecting threatening stimuli they may struggle to scrutinise poor quality sensory data and rely more heavily on predictions, whilst adopting a 'better safe than sorry' decision bias. These factors all make an individual more likely to hearing expected speech when it is absent. An individual formulation of how the hypervigilance hallucination occurred is developed and then targeted coping strategies and behavioural experiments are employed (such as reducing arousal and stress when under threat).

7. Seeing Visions. This module draws on these other modules, and explains how our visual perceptual system can lead to mistaken perceptions, for example how easily we see faces in clouds. An individual formulation and treatment plan is then

developed that normalises the experience and addresses the key cause of distress and then targeted coping strategies and behavioural experiments are employed (such as training oneself to switch attention to and from visions).

8. Sleep. This module provides psycho-education and treatment strategies about sleep, which is often a key factor in all types of unusual sensory experiences.

The psychoeducation materials, behavioural experiments, and coping strategies included in the manual are refinements of existing psychoeducation, behavioural experiments, and coping strategies used in CBT for psychosis and related mental health problems (e.g., post-traumatic stress disorder, reducing arousal). CPNs will not, therefore, be required to learn an extensive set of new techniques.

Schedule of intervention

CPNs will use the manual in 4-6 therapy sessions. The number of sessions is based on previous work with other groups, but the clinician can choose to use the manual for more sessions, if they deem necessary. This design will ensure that participants receive adequate exposure to the manual in therapy sessions for us to determine its acceptability.

Criteria for discontinuing or modifying allocated interventions

It is an important subsidiary goal of the trial to establish the safety of the intervention, and we will take all appropriate steps during the conduct of the trial for ensuring participant safety, in both arms of the trial. Concerns over safety of MUSE intervention, identified through Adverse Events (AEs) and Serious Adverse Events (SAEs), sessional ratings or qualitative interviews, would, in the first instance, lead to protocol amendments, but could lead to study termination at any time. We will operationalise with our experts-by-experience advisory groups what constitutes ‘unacceptable’ or ‘unnecessary’ distress for the sessional ratings, as temporary, sessional increase in distress during some of the therapy sessions is to be expected. Our experience with this population and type of therapy suggests that the therapy proving unacceptable or too distressing to participants is a low risk. However, we would see this unlikely eventuality as an important outcome of the study, as it would provide empirical evidence to inform future studies on what should be avoided in working with people with hallucinations and psychosis.

It will be made clear to each participant that, should they find any aspect of the research distressing, and/or no longer wish to continue with either the research or the therapy, they will be able to withdraw from either or both without having to give a reason or this impacting on their usual clinical care in any way. Nevertheless we will invite a sub-section of people who choose to end therapy prematurely to participate in the qualitative interviews so that they are given an opportunity to feedback on their reasons for doing so if they wish to, and to help us identify barriers and potential

solutions to engagement in therapy. The feedback from qualitative interviews will inform any future MUSE revisions.

Should the therapy prove aversive or too distressing to a significant minority of participants, we would consider an elective stop to the study. However, this was not a concern in the other previous completed MUSE PSYCHOSIS and MUSE ARMS studies and we think this unlikely. We also have the oversight of the Trial Steering Committee (TSC) who will be reviewing trial progress and the occurrence of SAEs.

The trial may be prematurely discontinued by the NIHR based on new safety information or for other reasons given by the Trial Steering Committee who can recommend discontinuing the study. If the study is prematurely discontinued, active participants will be informed and no further participant data will be collected.

Participant timeline

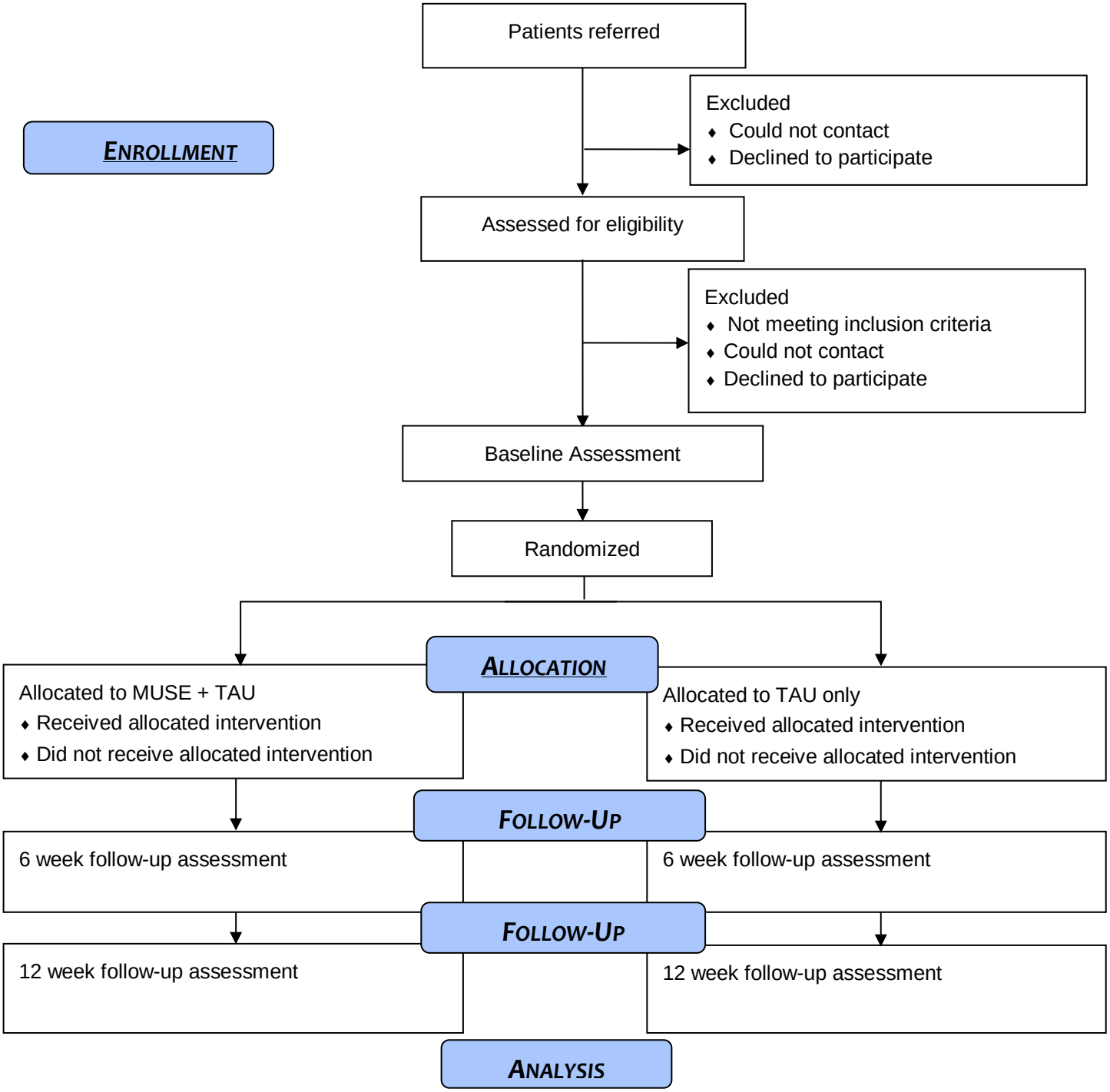
Independent assessors (RWs) blind to treatment group will conduct all eligibility and research assessments. Following providing written informed consent to participate and completing the baseline assessment, eligible participants will be randomised within two working days. They will be contacted with the outcome of the randomisation within a week by the trial coordinator. Therapy will last up to 2 months in the intervention group. Participants will remain enrolled in the study for three months in total.

Following written informed consent, research assessments will take place at three time points (baseline, 2m (end of therapy), 3m (1m post-therapy but with an allowance of another month if needed). Assessments will be conducted at locations convenient for the participant (at either NHS, or residential locations). It is anticipated that assessments will last 1.5-2 hours, including breaks. Participants will receive a reimbursement (for their time) of £10 for completing each research assessment, plus travel expenses. Participants will be offered choices regarding length of assessments, including the option of breaks and multiple testing sessions. Assessment measures will be clearly prioritised so that the most important will be collected first to avoid missing data.

A sub-sample of participants in the MUSE group (N=10), who give their consent, will be recruited across both sites in the study to take part in a qualitative interview. This will occur once they have concluded or chosen to end therapy. This interview will ask them for feedback on the therapy, to explore acceptability and satisfaction with the therapy they received. Close attention will be paid to any emotional distress resulting from trial or treatment procedures, in particular potential impact on psychotic symptoms, and whether this was considered unacceptable or unnecessary. Interviews will be conducted by a service user researcher with support from the research team in each site. It is anticipated that interviews will last approximately one

hour, and participants will receive a reimbursement (for their time) of £10, plus travel expenses.

Figure 1. Trial flow diagram



Recruitment

The research team will liaise with the staff in key NHS services through presentations, regular attendance at clinical team meetings and email/phone to identify potential participants. Recruitment will occur in 10 EIP services in the two NHS Trusts, to ensure as wide a range of ages and clinical presentations as possible.

Additional sources of recruitment will include:
1) Recruitment databases or consent for contact initiatives e.g. CNTW Consent for Contact provides access to existing research recruitment databases, using Clinical Record Interactive Search (CRIS), an IT system that anonymises and provides authorised researchers with access to CNTW's electronic health records.

2) Through direct approach: we intend to place recruitment posters and leaflets (one for participants, and one for staff) in the main clinical areas of EIP teams. Posters and leaflets will provide basic details of the study and will invite potential participants to approach the research staff either via their clinical team or directly. Additional self-referrals are also possible as a result of interest generated through media/public engagement events and NHS Trusts' R&D websites or newsletters. Further information will be available on the Trust website, which may also generate self-referrals. If a potential participant makes a direct contact to the research team, they will be asked for consent for us to approach their clinical team and access their basic personal information to make an initial suitability check, following the same procedures detailed in the consent section above.

A rate of recruitment of 4 cases per month per site is sufficient to recruit to target in 10 months. Previous trials conducted in the North East (Morrison et al., 2018; Thomson et al., 2017) both exceeded this recruitment target. Both sites have successful records of running psychological therapy trials with psychosis individuals, and of recruiting and retaining skilled CPNs. All have access to Clinical Research Network (CRN) facilities to assist with recruitment and blind breaks.

Recruiting below target is the most significant risk to the study and is an important outcome in our determination of feasibility of a definitive trial. We have a short recruitment time period of ten months, which leaves little time to change our procedures, however, we will monitor recruitment monthly and if recruitment falls below 80% at 5m, we will: (1) enlist further help from local CRNs; (2) if recruitment across teams or sites is uneven we will readjust targets so that they are increased at the teams/sites showing good recruitment, and lowered at struggling teams/sites.

Assignment of interventions: allocation

Sequence generation
Randomisation to the two groups will be undertaken using the web-based sealed envelope randomisation service. Randomisation will be in the ratio 1:1 to the two groups and will be stratified by site. Randomisation (at the individual level) will be independent and concealed, using permuted blocks of random size.

Concealment mechanism
The randomization system is web-based and allocation is made known to the CI and site PIs, the Trial Coordinator (in order to monitor adherence to the randomisation algorithm) and the trial therapists only at the point of randomization, by email. The allocation is dynamically generated and uses randomly varying blocks of sizes not known to the study team so allocation concealment is assured.

Implementation
Authorised individuals will be assigned usernames and passwords to log into the system and randomise participants. These individuals may be blind or unblind to treatment allocation. Randomisation is confirmed via two sets of emails generated by the system. The first set contains the unblinded treatment allocation and is sent to relevant unblinded individuals in the team. The second set contains no allocation details but is sent to relevant blinded individuals to confirm the participant is enrolled.

The RWs will enroll participants, and sealed envelope will assign participants to the two groups. The trial coordinator will inform the participants and the trial therapists to which group they have been allocated to.

Assignment of interventions: Blinding

Who will be blinded
The independent sealed envelope randomisation system will ensure blinding of the relevant members of the team. Outcome assessors will be blind. Clinicians, therapists and participants will be unblind. Trial statistician will be partially blind.

Maintaining blindness of the RWs is crucial, and care will be taken within the research team to avoid accidentally unblinding outcome assessors. Any cases of inadvertent unblinding will be discussed in a Trial Management Group (TMG) meeting, and TSC will monitor unblindings by each site regularly and implement corrective action if necessary.

Extensive procedures will be adopted to ensure blinding of assessors is maintained: strict separation of therapists from RWs; protocols for answering phones, message taking and secretarial support; separate diaries and security for electronic randomisation information; and separate accommodation and storage procedures for all data. Participants and clinical teams will be reminded prior to each assessment

timepoint by the research team that they must not inform the RWs of their group allocation. The Trial Coordinator will oversee the maintenance of blinding and will monitor any blinding breaches closely. Where this occurs during the assessment, measures that have been completed unblinded will be repeated by the other RW at the site or CRN support will be sought. If the break in blind occurs subsequent to the assessment, no further assessments or data entry will be carried out by that assessor. Breaks in blinding will be monitored and recorded.

Procedure for unblinding if needed
This circumstance is not applicable since participants and therapists are already unblinded.

Data collection and management

Plans for assessment and collection of outcomes

Procedure for assessments:
Independent assessors (RWs) blind to therapy group will conduct all assessments at the three time points. The RWs will be trained in the assessment battery over a training session at the start of the trial, which will include the use of videos and role-plays. Experts by experience will contribute to the training. Training will be repeated each year to accommodate any new RWs and provide top-up training, to maintain reliability and avoid assessor drift. RWs will be supervised by experienced research clinical psychologists (site leads and Trial Coordinator).

Data quality:
RWs will be trained to competence on the main interview outcome measures prior to starting any assessments i.e., they will need to have reached >80% agreement with ratings made by the Trial Coordinator on training videos and role-plays during the initial training stage. Once started, assessments will be audio-taped, with participants' consent, to conduct further inter-rater reliability on the interview measures. A selection of RW's assessments will be double-rated by the Trial Coordinator and site lead, again ensuring that >80% agreement has been reached. These procedures will be repeated every six months to minimise rater drift.

We will collect further information on participants and their hallucination experiences to characterise the sample, namely: demographic variables (age; gender; ethnicity).

Risks and benefits of assessments:
There is a risk of participants experiencing distress from the assessments, since they will be asked about past and current difficult experiences such as hearing voices. These risks will be minimised through the appointment of RWs who have a psychology/clinical background and have experience of working with populations with severe mental health problems. They will receive training in interviewing skills and how to respond sensitively and empathically to any distress that arises. There will be close supervision of RWs throughout the trial (by experienced Consultant and

research Clinical Psychologists) and regular review both within the main trial team (at monthly meetings) and at the TSC and TMG. Whilst there is evidence to suggest that the assessments are tolerable for people with psychosis, it is possible that some participants may find them to be cognitively demanding, or too lengthy. In order to manage this, RWs will make clear to participants from the start that they can withdraw from the study at any point, which will not affect their statutory care. If an individual becomes distressed whilst completing the assessments, they will be reminded that they take a break at any time, that their involvement is voluntary and that they can decline to answer questions or stop the interview altogether. The RWs will be sensitive to monitoring and assessing how participants are finding the assessments and adapt the pace and content accordingly. Participants will be offered choices regarding length of assessments, including the option of breaks and multiple testing sessions, to minimize fatigue or distress.

All measures have been selected or designed with the participant population in mind with input from people with lived experience and are considered suitable for people with psychosis to complete. We have made sure the short versions of questionnaires have been selected, when available, to minimize burden.

We will have a standard protocol for managing any distress potentially elicited by the completion of measures, which has been developed in collaboration with experts-by-experience. We have used this successfully in several trials. This includes offering telephone contact within 48 hours of assessments to check on participant well-being, and a summary of support and crisis numbers.

The research assessments are not designed to have any direct beneficial effect. However, they may have a nonspecific beneficial effect through providing participants with an opportunity to have empathic, warm and normalising conversations about their difficulties and experiences, which may not be discussed in routine clinical care.

Regarding the qualitative component of the trial, a potential risk is that some participants may find topics discussed in the interviews distressing, especially if they chose to end therapy prematurely, for instance due to an adverse event related to therapy procedures. However, previous trials of MUSE for people with psychosis have indicated that MUSE is safe and acceptable to participants (Dodgson et al., 2020; Dodgson et al., in press). Therefore, we anticipate adverse reactions or events related to therapy would only be experienced by a small minority of participants, if any. Further, it is anticipated that the qualitative interviews will provide participants with a supportive space in which to discuss any distress associated with trial participation, assisted by a lived experience expert. All interviewers will be trained in managing interviewer distress, and experienced clinicians will also be available if needed to provide support during interview or follow-up contacts. During qualitative interviews, participants will be reminded at the start and throughout the interview that

they are able to take breaks or stop at any point and that they do not have to answer any questions if they wish not to.

Study assessments

Measures
These measures are not to determine effectiveness but to help identify important parameters for a future trial (i.e. completion rates and selection of best outcome measures). Each measure has established psychometric properties for use with this population.

Hallucinations
Psychotic Symptom Rating Scales (PSYRATS, Haddock et al., 1999) is a clinician administered semi-structured interview of hallucinations (such as amount/intensity of distress). It consists of 11 items, with 5 items being used to identify voice related distress. PSYRATS and will be used to assess the multidimensional aspects of hallucinations (such as distress, preoccupation, and conviction; 11 items for hallucinations, and six items for delusions). PSYRATS is well suited to assess outcome in psychological therapies and has been used in major RCTs.

Additional items to cover hallucinations in non-auditory modalities (i.e., visual, somatic, olfactory and sense of presence), and whether these are experienced at the same or different times (multi-modality), will be included. Each item is rated by the interviewer on a 5 point nominal scale (0-4).

The self-report voice-impact subscale on the Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ) (17) will also be used. Scores on the HPSVQ correlate highly (all r>0.8) with scores on the clinician administered PSYRATS auditory hallucination (AH) scale.

Anxiety and depression
The short Depression, Anxiety and Stress Scales (DASS; Lovibond & Lovibond, 1995) is a 21 item self -report questionnaire designed to assess symptoms of anxiety, depression and stress.

Quality of intervention
The CHoice of Outcome In Cbt for psychosEs (CHOICE; Greenwood et al., 2010), is a 12 item service-user developed questionnaire to evaluate outcomes for people with psychosis and assess therapy-related goals.

Recovery
The process of recovery questionnaire is a user-defined measure (Neil et al., 2009), assessing subjective recovery in intrapersonal and interpersonal functioning.

Quality of life
Two measures which capture emotional and mental aspects of quality of life: the Short Form-36 (Ware & Sharebourne, 1992), and the EQ-5D (EuroQol Research

Foundation, 2019). Generic health-related quality of life will be measured using the EQ-5D-5L, introduced by the EuroQol Group in 2009 as an alternative to the standard EQ-5D-3L, to provide greater sensitivity and to reduce ceiling effects. The EQ-5D descriptive system comprises five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) each with five levels (no problems, slight problems, moderate problems, severe problems and extreme problems). The score for each dimension can be combined into a 5-digit number that describes the person's health state.

Capability measures:
Investigating Choice Experiments Capability Measure for Adults (ICECAP-A; Flynn et al., 2015) is used.

Therapeutic alliance & therapy acceptability:
We will use a revised version of the Satisfaction with Therapy and Therapist Scale (Oei & Green, 2008), a short scale assessing overall acceptability of the therapeutic interaction. Therapeutic alliance will be assessed with the Working Alliance inventory (Horvath & Greenberg, 1986).

Treatment session measures:
In addition, at each session, a short self-assessment form comprising items adapted from the main measure of hallucinations will monitor variations in voice frequency and distress.

Service use measure:
Service use will be measured by interview and case record review using a tool developed during the review process of the therapeutic interaction.

Treatment session measures
In addition, at each session, a short self-assessment form comprising items adapted from the main measure of hallucinations will monitor variations in voice frequency and distress.

Service use measure
Service use will be measured by interview and case record review using a tool developed during the review process.

Comparator
The control condition is treatment-as-usual which is support from EIP services, a high quality service proven to help people manage their symptoms and stay well. NHS England describe EIP services in the following way:

"An EIP service is a multidisciplinary community mental health service that provides treatment and support to people experiencing or at high risk of developing psychosis. This support typically continues for three years. The defining characteristic of an EIP service is its strong ethos of hope and whole-team commitment to enabling recovery

through the provision of individually tailored, evidence-based interventions and support to service users and their families / carers."

Each participant will have a CPN, who will see the person weekly in their home usually for around 30 to 60 minutes. The person will be offered: help to manage their symptoms, groups and resources that may be helpful. Where appropriate patients are offered low dose antipsychotic medication (and are regularly reviewed by a psychiatrist), psychological therapies (CBTp and Family Interventions), social support, and recovery-based activities. We will not be asking referrers to withhold any treatment. A case report form based on the TIDIER checklist will be used to track TAU content throughout the trial. The MUSE intervention group will also receive TAU. All routine or additional treatments (including medication changes) in both conditions will be monitored as part of the service-use data collection.

It would be unethical to restrict the therapeutic options of the clinical teams participating, and we will not be asking referrers to withhold any treatment or interfere with decisions to discharge to primary care or other care pathways, in either group.

Interviews

Using individual interviews, we will explore participants' views of:

- the recruitment and consent processes: subject to ethical approval, we will sensitively approach those who do not consent to participate and ask if they would be willing to share reasons for non-participation and suggest how to make participation in future studies more appealing – utilising a barriers and facilitators approach.
- assessment process: At the end of the study we will ask participants in the MUSE and TAU arms their experience of completing the assessment process on three occasions.
- the intervention: for those in the MUSE arm we will ask their views on the content relevance, the length and duration of sessions, the usefulness of the MUSE format, and the value and acceptability of the treatment.

<u>Acceptability:</u>

The participants will be offered interviews once they have finished therapy to explore acceptability and satisfaction with the therapy they received. Close attention will be paid to any emotional distress resulting from treatment procedures, in particular potential impact on psychotic symptoms, and whether this was considered unacceptable or unnecessary. The view of those who chose to end therapy early will be gathered at point of ending, using additional questions about their reasons for doing so and to identify barriers and potential solutions to engagement in therapy. Therapists will be interviewed once they have completed therapy with two or three

participants to obtain feedback about acceptability, and any potential difficulties in delivery.

Experts by experience researchers with lived experience of psychosis will inform the content of the participant interviews, which will be undertaken by the research team with appropriate supervision and support from a qualitative researcher (BA), and therapists will be interviewed by the trial coordinator or RWs. It is anticipated that the final patient sample will be representative and include variance on key variables (e.g., therapy engagement, age, gender, ethnicity, clinical presentation). All interview data will be audio-recorded, with participants' permission, and transcribed verbatim for analysis.

Staff participant measures

Adherence Checklist
After each session, therapists will record which modules they used from the treatment. This will allow us to assess to what extent clinicians have followed the manual in therapy, as well as how often they used the manual. In addition, we will ask therapists to note the type of voice experience reported and determine if the relevant treatment module was used with this identified hallucination type. We will make a copy of the formulation the clinician and service-user developed during therapy after the participants have completed the treatment. These steps will be taken so that we can investigate whether the understanding or formulations clinicians and service-users develop directs them to the relevant intervention.

Structured Interview
Using focus groups (of 3 or 4 members, with up to 10 participants in total) we will explore MUSE trained CPNs views of:

- MUSE training: one month after the training we will ask about issues of usefulness of the training, the adequacy of the training in increasing skills and confidence in use of hallucination treatments, confidence in using the MUSE package.
- MUSE supervision: at the end of the study we will ask about issues of usefulness, frequency, barriers to attendance, implementation of skills.
- At the end of the study we will ask about confidence in and use of the MUSE intervention as well as barriers to implementation and methods to overcome these.

Using focus groups of EIP CPNs (not just MUSE trained ones, so 10) we will explore views of the trial processes:

- We will ask EIP CPNs reasons for non-participation of service users or for not referring service users. We will seek their suggestions for ways to improve

trial processes. We will discuss identification of suitable participants and discuss methods to aid recruitment, which will inform the protocol of future studies.

Staff training and supervision

We will train CPNs to deliver MUSE on a three-day training course. The training will provide the knowledge to enable the CPNs to use the MUSE package with confidence. It will cover the modules in the MUSE toolkit, and role plays will provide demonstration of how skills/coping can be developed with patients. Within the three days we will also ask all staff to complete the GCP training as they will be involved in a role as a research therapist, and in addition, specific training on consent procedures, and issues such as blinding will be addressed. The impact of the MUSE training in terms of knowledge, and confidence will be assessed before and after the training days, and then the impact of training will be assessed again, midway through the recruitment phase of the study (approximately six months after the training was delivered) and at the conclusion to the study.

Fortnightly group supervision groups for up to 90 minutes will be offered whilst the MUSE therapists are delivering the intervention. Attendance at supervision will be recorded. The attendees will be asked to rate the usefulness of the supervision and confidence in use of MUSE following each supervision session. The experience of supervision and training will also be discussed in the qualitative interviews conducted with staff at the end of the study. The training and supervision will be provided by a suitably trained and experienced band 7 Psychological Therapist.

The RAs will require training in using the PSYRATS. We will provide supervision to the trial coordinator and research assistant on qualitative methodology to ensure that the structured interviews are not biased.

The copies of measured are available in the Appendix.

Plans to promote participant retention and complete follow-up

A number of strategies are planned to maximise participant retention into the trial and ensure completeness of outcomes, in addition to those mentioned in the risk and benefits section above.

A 1m window will be allowed for completion of assessments at each time point. Assessment measures will be clearly prioritised so that the most important will be collected first to avoid missing data. The hallucination measures will always be administered first.

Participants who choose to end the therapy early or deviate from the allocation protocol (e.g., someone receiving MUSE in the TAU group) will still be invited to complete all follow-up assessments. Participants will be remunerated for their time

and travel, which secures good concordance with trial procedures, even in those who end therapy early. Home visits will be arranged for participants who are unable to travel, or taxi fares paid if preferred. As a last resort, assessments can be done by telephone or via online methods. Anyone who moves within the UK will be followed up.

A short therapy period is purposefully designed in order to minimise attrition from the trial, and the trial duration is only as 3m which is not a long period and there will be regular contact with the research team during this time.

Participant withdrawal
Participants will withdraw from the study if they withdraw their consent to continue. There are no specific criteria for premature withdrawal. If participants wish to withdraw from the study, they may do so at any time. We will ask for their consent to retain the data that they have already provided during their involvement in the study.

End of study definition
The study will finish after the final assessment with the final participant is completed.

Data management
Data will be stored in accordance with trust and research guidance. Electronic database access will be strictly restricted through user-specific passwords to the authorised research team members. Only those authorised to access the system are allowed to do so.

Data quality will be ensured by close monitoring and routine auditing for accuracy throughout the data collection period. In order to ensure the accuracy of the data entered into the database, the main outcome measure entry will be checked for every participant by comparing the paper record with that on the database.

The PI team will undertake appropriate reviews of the entered data, in consultation with the statistician, for the purpose of data cleaning and will request amendments as required.

At the end of the trial, the site PI will review all the data for each participant to verify that all the data are complete and correct. At this point, all data can be formally locked for analysis.

Pseudonymised recordings of the qualitative interviews will be transcribed by the RWs or an approved transcription service. All recordings will be transferred and stored securely, and the transcription service will follow GDPR regulations (2018).

Confidentiality

Clinical confidentiality

Issues relating to confidentiality will be addressed at all stages of research participants involvement and potential participants will be advised of the limits of confidentiality (i.e. that the researcher will have a duty to inform health professionals if the participant discloses information which highlights any safeguarding or risk issues). It is also possible that disclosure of criminal or other acts potentially requiring action will occur during assessment and therapy sessions. The research team will be trained in both local and national policies for dealing with such disclosures and will follow our Standard Operational Procedures for managing risk disclosures. All RWs and trial therapists will have access to supervisory input to ensure appropriate action is taken with no delay. The limits of confidentiality and possibility of action arising from certain disclosures will be clearly noted in the information sheets. The potential participant will be offered at least 24 hours to consider all the information provided before written consent is obtained. Therapists will address confidentiality issues again with participants allocated to the MUSE group at the start of therapy, and at any appropriate subsequent points during the therapy.

Data confidentiality

Research data will be confidential unless a participant discloses information that indicates that they are at risk of harm or another person is at risk of harm. If harm is disclosed the RW or trial therapist would be required to share this information with the participant's care team (in line with NHS Trusts Safeguarding Vulnerable Adults policy) and documented in the NHS trust's electronic patient record system. The RW or trial therapist would endeavour to discuss this with the participant before confidentiality is broken. All participants will be informed of this during the written informed consent process and reminded of this at the start of the intervention, outcome assessments and qualitative interviews.

The only other exception where research data or Personally Identifiable Data (PID) may be accessed by another person outside of the research team is if individuals from the sponsor organisation and other regulatory organisations conduct a monitoring or audit visit. In this instance only the person/s conducting the audit may look at the participants' clinical and research records to check the accuracy of the research trial. All participants are made aware of this during the written informed consent process.

All data will be pseudonymised. Each participant will be assigned a unique trial identification number at the start of the assessment process. This number will be written on all clinical assessment forms/datasheets and databases used to record data on participants. A hard copy of a record sheet linking PID (participant identity, contact details, trial identification number) for all participants will be kept separate from all the research data at each site. It will be placed securely in locked filling cabinets separate from datasheets.

Referral forms will contain PID. The PID obtained for the referral will be processed in line with Caldicott principles. The referral forms will be completed electronically in a Microsoft word document and saved password protected on a secure NHS Drive only accessible to the research team. The password will only be shared with the research team. Log of contact of the participant with research team, and of the research team with the clinical team, will be stored as above. All data will be kept secure at all times and maintained in accordance with General Data Protection Regulation (GDPR, 2018) requirements and archived according to clinical trial GCP regulations. Participant consent forms will be retained, kept confidential and stored securely. All identifiable data will be destroyed following a period of 5 years (as determined by relevant information governance policies) after the completion of the trial.

No participant identifiable information is recorded on the research assessment records and the computerised database is held on NHS encrypted password protected computers. Data from the assessments are entered into this central record by RWs using a secure network connection.

Therapy files will be kept in a secure office and are not accessible to the staff collecting the research outcome data.

Audio-recordings

Encrypted audio recording equipment (such as encrypted Dictaphone or equivalent devices) will be used to record assessments (with participant consent) to check fidelity to assessment protocols and allow for multiple ratings of assessments to ensure interrater reliability. The therapy sessions will also be audio recorded (with participant consent) for monitoring the fidelity of the intervention delivery. These audio files named with a unique participant identifier will be transferred to secure central storage as soon as possible and stored as computer files on secure NHS servers. Audio recordings of the therapy will be accessible to the participant's therapist, the supervisor, and a random selection to the independent fidelity rater. The study will adhere to the guidance on secure audio recording issued by the NHS Trusts. When not in use, encrypted devices will be stored in a locked cabinet within a locked office. Each device will be password protected. In the event of the device being lost or stolen this will be reported as a data incident to the Information Governance Team at the relevant NHS Trust.

Anonymised recordings of the qualitative interviews will be transcribed by RWs or an approved transcription service. All recordings will be transferred and stored securely, and the transcription service will follow GDPR regulations (2018).

Data analysis

Statistical considerations

A formal sample size calculation has not been performed for this feasibility study. Our goal is not to assess treatment effectiveness but to establish whether we can undertake future pilot and definitive studies to address effectiveness. We have a target of recruiting 80 individuals over the 10-month recruitment period. Based on past research of psychological therapy conducted in the North East (Morrison et al., 2018; Thomson et al., 2017) and similar brief interventions (Foster et al., 2010) we have estimated attrition of 12.5% meaning approximately 70 people will complete the study.

Guidance on external pilot studies indicates that samples of 35 per arm or more give a reliable estimate of the standard deviation of the outcome measure (Moore et al., 2011); however, the aim of the present study is not primarily to generate parameter estimates for a full trial, but to establish MUSE's acceptability and feasibility. We believe the planned sample size is adequate for achieving those aims, while also enabling us to understand the attrition rate for future studies. We will be interviewing staff and patients to better understand factors affecting uptake and retention in the study, and we will ask if there is more we can do to help minimise attrition in future studies.

We will report data in line with the CONSORT - Social and Psychological Interventions (CONSORT-SPI) statement showing attrition rates and loss to follow-up. In line with the recent CONSORT-SPI guidance, which recommends minimising the distinction between primary and secondary outcomes, all outcomes will be reported at the end of the trial.

Descriptive statistics within each randomised group will be presented for baseline values. These will include frequency and percentages for binary and categorical variables, and means and standard deviations, or medians with interquartile range (QR), for continuous variables, along with minimum and maximum values, and frequency and percentages of missing values. There will be no tests of statistical significance or confidence intervals for differences between randomised groups on any baseline variable.

As this is a feasibility, randomised controlled trial, a single primary effectiveness outcome is not meaningful and the key outcome is to inform the decision to go to a larger study. Hence, all statistical analysis will be primarily descriptive. However, given we are collecting data from outcome measures that would likely be used in the definitive trial it will allow examination for any signals of efficacy. We will calculate change scores for any of the quantitative measures used across assessments using difference-in-difference approach to estimate effect size between MUSE+TAU and TAU alone. We will estimate intra-site correlation using mixed effect models. Path analysis and structural equation modelling (SEM) will be used to explore

interrelationships between the different outcomes, where appropriate. The analyses will be done for the different outcomes at 2 months and 3 months.

These will be used to inform the overall interpretation of participants' experience of therapy (combining qualitative and quantitative data). We are also interested in understanding which areas of the participant's life the intervention may impact upon, for example, distress linked to voice hearing, interpersonal functioning etc.

Qualitative interview analysis

Qualitative data, gathered from the structured interviews with patients and staff, will be analysed using an inductive thematic analysis (Braun and Clarke, 2006). This form of analysis allows for both basic and more complex themes to be classified from interview data (based on categorising sections of transcripts), based on the data themselves rather than a prior theory (Patton, 1990).

Researchers will familiarize themselves with the transcript through reading it through several times and consulting notes taken at the time. For coding the researcher reads through line-by-line and applies a 'code' that applies to the phrase. Codes are applied both deductively (informed by an existing framework/theory) and/or inductively (informed by the transcript itself). Coding aims to classify all of the data. An analytical framework is developed through grouping together codes into categories and setting clear definitions of these. The framework is iteratively developed, it is not final until the last transcript is coded. The final analytical framework is applied to all transcripts. The data are extracted into a framework matrix – so that the data by category from each transcript is summarized. Quotes to illustrate each category will be selected.

Initial findings from the qualitative analyses will be presented to the LEAP group to gather their views on the thematic framework and ensure that the patient perspective is at the heart of the analysis.

Economic evaluation

As this is a feasibility study we are not undertaking a formal economic evaluation, mainly owing to the small sample size which means a cost and benefit estimate will be too imprecise and potentially too unreliable to be useable. However, for a definitive trial an economic evaluation will be important to include. Therefore, in this feasibility study we are focussing on collecting information that will help to inform the design of a future health economic evaluation in a definitive trial. To achieve this, first of all we are using two measures of quality of life that could be used in an economic evaluation (the SF-36 which can be used to estimate the SF-60 utility that can allow QALY to be estimated) and the EQ-5D. A similar approach is possible with the ICECAP-A which is used to measure capability. As part of the feasibility study we will review existing tools for the collection of data on health service use (www.dirum.org). Few QoL measures are tailored to people with psychosis, so the

systematic literature review will be conducted to establish candidate measures. This will be shared with the LEAP group for their views on relevance, acceptability, burden and utility of the scales in relation to the MUSE intervention. We will also use the feasibility study to see if we can access service use information from the existing clinical records across two different NHS trusts that use different clinical records systems. Information about care received will be investigated using information on the delivery of MUSE and TAU as assessed using the TIDIER checklist. This will help us establish if we can in a future study access the resource requirements and costs of each arm.

Essentially our focus is on clarifying what should be collected and which tool(s) should be used to measure the impact of intervention on quality of life (QoL) years.

Survey information

Using online methods we will survey EIP services in England to determine access to CBT for Psychosis and if they offer either brief CPN delivered interventions or use digital technology equivalent to MUSE, in order to inform the feasibility of implementation across other sites in a subsequent trial. The information we request will be anonymised, and group data with no personally identifiable information and will ask about rate of access to CBTp or whether brief manualised treatments for voices and hallucinations are routinely used in the services. We will be able to use national audits undertaken by NHS-E as part of the routine data collection on EIP services to assess access to CBTp, and will use the national EIP clinical leads forums for recruitment of services for the survey. We will also pilot the use of the CRIS system in CNTW to review case notes of service users in EIP and Community treatment teams to determine access to CBTp and if there is reference to the MUSE package. This automated system can scan clinical records searching for keywords like CBT, or MUSE and will enable us to determine the use and availability of CBT and MUSE in CNTW services.

Criteria for proceeding to a full trial

We will use criteria for assessing study success and identifying feasibility factors required for delivering the definitive study (Malterud, Siersma & Guassora, 2016) and follow a systematic process for decision making after pilot and feasibility trials (ADePT; Bugge et al., 2013) which helps identify criteria used to go to a full trial. These criteria will be developed with the LEAP to help determine if a full trial is warranted. We will likely use criteria on participant recruitment, adherence with the intervention, and retention at follow-up to assess the trial (as set out in ADePT), plus data on uptake, retention of participants, intervention fidelity and acceptability. This will use both quantitative and qualitative data derived from the study. The progression criteria will be divided into three categories (green, red and amber; Malterud, Siersma & Guassora, 2016). Areas that are amenable to change before a

pilot trial will be investigated and solutions discussed with the patient LEAP for acceptability. This will help consider if a full trial is timely, necessary, and deliverable.

PPI involvement

1. A Lived Experience Advisory Panel (LEAP) is being set up in line with recommendations of advisory groups that encourage service-user involvement in NHS research (http://www.invo.org.uk/). It consists of a panel of local service-users with experience of psychosis. They have agreed to support the MUSE project and in this context the meetings will be involve our PPI lead (co-applicant and service-user researcher) CG. A group provides opportunity for support, and reduces burden on any individual. The LEAP will provide input at all phases of the research. Training will be provided to help understand the research methods/issues involved in this study. We will ensure that LEAP members wellbeing is considered when dealing with sensitive issues and support is in place.

2. The PPI lead will contribute to the MUSE three-day training.

3. At least two LEAP members will be invited to all TSC meetings with a particular remit to provide advice from a service-user perspective. They will receive information on the meetings in advance and will meet with facilitator/service user co-applicant beforehand to discuss what they would like to contribute. They will also have a debrief meeting afterwards to check that they had the opportunity to contribute and any additional points will be shared with the wider TSC. Where attendance in person is not possible, there will be opportunities to phone or Skype into meetings.

4. The LEAP will provide advice on the development of the topic guides for the qualitative interviews, patient information leaflets and consent forms. Their views on qualitative themes will also be gathered. The group will also provide input on the appropriateness of economic evaluation measures.

5. Members of the LEAP will provide advice the interpretation of results and in determining whether a full trial would be undertaken.

6. LEAP members and the Hearing the Voice team will advise on and support the dissemination of accessible information from this study in engaging, innovative ways. Previous dissemination work by Hearing the Voice has included presenting at the World Hearing Voices Congress, and the creation and hosting of the world's first dedicated exhibition on voice-hearing, *Hearing Voices: Suffering, Inspiration, and the Everyday* (in 2016-2017*)*. Sections of the exhibition and a series of satellite events were co-produced with people with lived experience.

Ethical considerations

The proposed study will be conducted in accordance with the principles of the Declaration of Helsinki (WHO, 2000) and with the principles of Good Clinical Practice. In general, we anticipate few ethical concerns for patients entering this study. Participation in the trial does not affect existing treatment. Half of the patients will receive an additional intervention: the MUSE treatment. MUSE has been used with patients with psychosis with no reported adverse effects.

However, we are aware that the proposed study raises a number of specific ethical issues. One concern is that the relationship between service-users and their clinician, who will be the first person to discuss the study, will have undue influence over the service-users' decisions about whether or not to participate. However, we feel we have taken reasonable steps to avoid this. While clinicians will inform clients about the study, and will ask whether they are interested in hearing more about the research, clinicians will not be involved in the consent process beyond that point. The study RAs, who are not involved in the clinical care of any potential participants, will perform consenting procedures, which will reduce any influence of service-users' clinicians.

For participants, a small set of burdens and of risks will be associated with taking part in the proposed study. There is the risk that participants will be exposed to an ineffective or dangerous therapy. However, this risk can be considered to be small for two reasons. First, the novel treatment manual does not involve any novel therapeutic techniques. It simply tries to tailor existing therapeutic techniques, which clinicians are typically familiar with, to the type of voice-hearing or hallucinations that service-users report. At worst, therefore, participants will receive therapy that spends longer examining the factors (e.g., emotions, situations) that trigger their hallucinations and the nature of their hallucinations (e.g., addressing questions about their content, such as whether or not it is repetitive). While this may prove distressing for some service-users (e.g., some voice-hearers find discussion of the content of their voices very upsetting), this distress will be manageable within a clinical setting. Second, previous feasibility studies using MUSE have not registered any distress or complaints from participants (Dodgson et al., 2020; Dodgson et al., in press).

Another risk for participants who take part in the proposed study is that discussing their experiences during symptom and functioning assessments may be distressing. These assessments are unavoidable, and so this risk has to be accepted. However, we have taken care not to minimise assessment sessions, for example selecting the short forms of some measures. In addition, participants will be reminded at each assessment, that they can halt their participation (or simply rearrange an assessment session) if they are feeling distressed.

Another ethical issue relates to the confidentiality of data. A number of steps will be taken to ensure confidentiality. All data collected in the proposed study will be

pseudo-anonymised. Consent forms, which could provide information that would compromise pseudo-anonymity, will be stored in a locked filing cabinet in a locked office in a secure building at NHS premises. Paper versions of data will be stored in a locked filing cabinet in a separate locked office in the same secure building on NHS premises. Anonymised electronic data will be stored in password protected files, on password-protected NHS computers.

One burden for participants who take part in the proposed study will be the time taken to obtain informed consent, to complete psychological and functioning assessments, and to complete debriefing. In sum, these non-clinical interventions will take around five hours. To try to minimise this burden, we have been careful not to plan very lengthy assessments, and have tried to keep to a (reasonable) minimum the number of symptom and functioning assessments participants are asked to complete. We have also made it clear in the Participant Information Sheet (and will make it clear when obtaining informed consent) the time burden involved in participating in the proposed study.

Finally, at the end of the proposed study, the intervention will remain available to clinicians who have delivered it as part of the.

Safety considerations

It is possible that participating in the proposed study will elicit psychological distress in some participants (e.g., participants may become distressed when discussing their voice-hearing with the researchers, or when discussing triggers of their voice-hearing during therapy sessions). A number of measures are in place to protect the safety of participants. The study RAs who will be conducting assessments have experience of conducting potentially distressing research with vulnerable groups, and throughout the study, all participants will remain in the care of their normal clinical teams.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee

The trial is sponsored by CNTW NHS Foundation Trust and will be responsible for sub-contracting to all other participating Trusts and HEIs.

The trial has been carefully designed to ensure compliance with GCP and scientific integrity. The research programme development, design and implementation will be managed by the PI and the co-applicants, in consultation with service-user consultants and other expert collaborators from within and outside of the PI's institution. The trial will comply fully with CNTW and TEWV Standard Operating Procedures. A dedicated Trial Coordinator post will assist in the day-to day management of the project reporting to the PI. A trial management group (TMG) will meet monthly, its membership will include the investigators and the Trial Coordinator and site leads. It will be chaired by the PI and will manage the day–to-day running of the study and ensure good communication between trial sites, receiving monthly

reports from each site on recruitment, therapy completion, adverse events, reviewing progress against milestones and finding solutions to problems as they arise. It will oversee the preparation of reports to the TSC. The PI and the co-applicants are highly experienced in working clinically with people with psychosis, and in carrying out research studies in this population.

The TSC will oversee the study on behalf of the of the trial Sponsor and Funder and ensure that the study is conducted within appropriate NHS and professional ethical guidelines. It will provide advice on all appropriate aspects of the project; will oversee progress of the trial, adherence to the protocol, participant safety and the consideration of new information of relevance to the research question; will ensure the rights, safety and well-being of the participants are given the most important considerations and should prevail over the interests of science and society; will ensure appropriate ethical and other approvals are obtained in line with the project plan; will agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments. It will comprise three independent members: a chairperson, a clinician, health economist.

A Data Monitoring Committee will not be established owing to the small scale of the study and the tasks will be managed by the TSC.

Composition of the Trial Steering committee, its role and reporting structure
The DMEC will monitor: (1) recruitment of study participants; (2) ethical issues of consent; (3) quality of data (including missing data and unblindings); (4) the incidence of Serious Adverse Events; (5) any other factors that might compromise the progress and satisfactory completion of the trial. It will make recommendations to the TSC on whether there are any ethical or safety reasons why the trial should not continue, with the safety, rights and well-being of participants being paramount. It will consider the need for any interim analyses, including potential requests from the Funder, and will advise the TSC regarding the release of data and/or information. The DMEC will consist of three independent members: a chairperson, a clinical academic and a statistician.

Adverse event reporting and harms
Best practice, professional guideline and local NHS policies for monitoring mental state and risk will be followed throughout the participants' involvement in the trial and will be facilitated by close liaison with clinical teams. The safety of the intervention will be monitored closely during therapy sessions and through regular contact with the participant's clinical team or GP.

The occurrence of adverse events (AEs) will be monitored actively and systematically and recorded by RWs and therapists, following guidance from the CONSORT-SPI (Grant et al., 2018) with the extension for non-pharmacologic

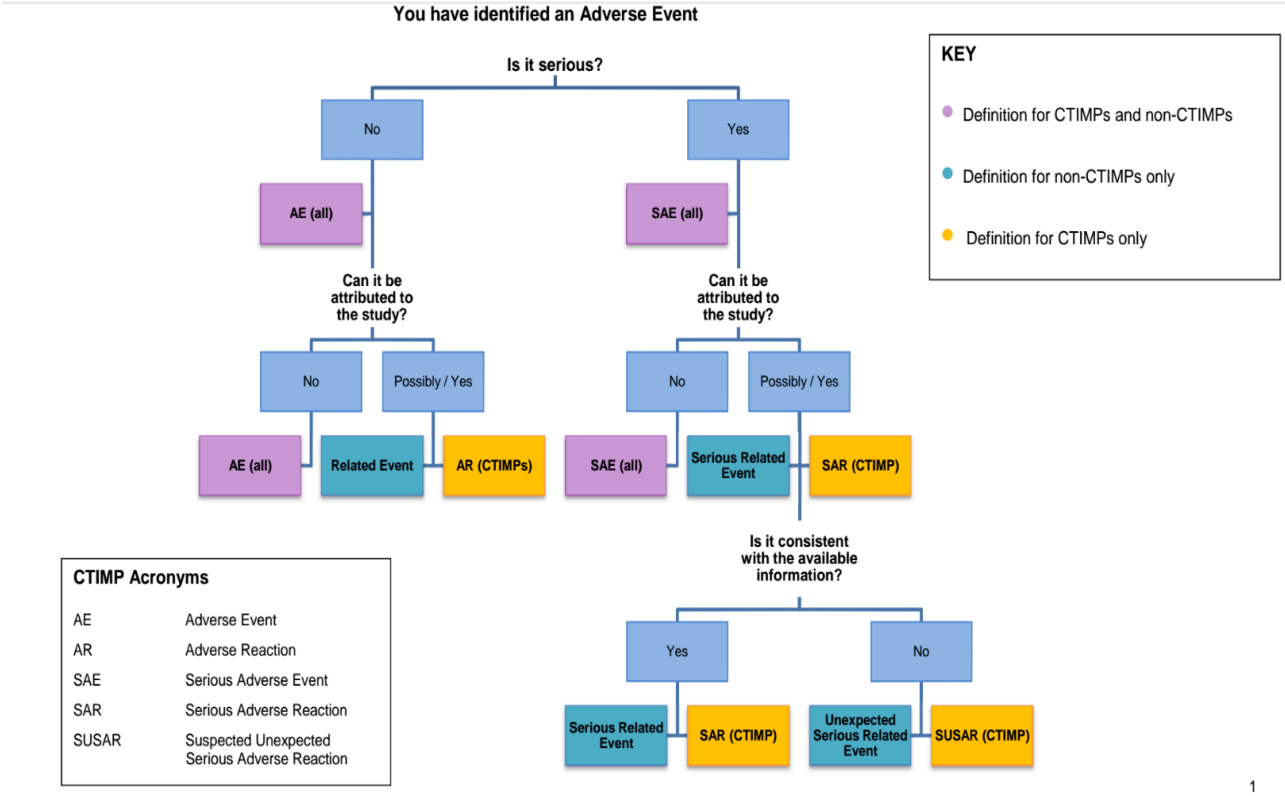
treatment, and the extension for reporting of harms. Medical Research Council (MRC) GCP in Clinical Trials will also be followed to ensure good governance of the trial for integrity and participants' safety and wellbeing.

In the event of any AEs and participant withdrawal, the Trial Coordinator/ Site Leads will review the clinical notes and contact clinicians for any important additional information. In order to ensure active surveillance of harms, at each assessment point, RWs will actively check for the occurrence of specific AEs using a structured checklist completed with the participant during the interview. At the completion of the trial, all clinical notes will additionally be checked, for the total duration of enrolment, for any previously undisclosed record of AEs. This is to ensure completeness of records and to address the possibility that the disclosure of AEs might be greater in the TF-CBTp condition, as a result of greater frequency of contact and the therapeutic relationship. For the final reports of the trial, the numbers, types and severity of AEs by trial condition, as well as discontinuations, will be reported, using descriptive statistics (since there are no pre-specified hypotheses concerning adverse events or harms, and, given the expected low frequency of AEs, the data will not be suitable for an ITT statistical analysis).

GCP guidance for non-CTIMPs studies (see Figure 2) will be followed to make decisions regarding seriousness (i.e., AEs vs SAEs), relatedness to the trial (i.e., Related Events (REs) and Serious Related Events (SREs), and Unexpected Serious Related Events (USREs).

AEs are defined by the Health Research Authority (HRA) as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs in participants, whether or not related to the treatment. In addition, issues specific to psychological therapies, and for specific concerns clinicians have about trauma-focused therapy in psychosis individuals, will also be monitored, namely: clinically significant increases in distress and/or psychosis; harm to self/others; suicidal ideation/attempts; excessive use of drugs/alcohol; emergency room visits or crises; complaints about therapy. Distress associated with completion of assessment measures would also constitute AEs. AEs will be initially assessed at three levels of intensity; mild, moderate and severe, which reflect the impact of the event on the person at the time. Please note there is a distinction between "severe" and "serious". Seriousness is the criteria for defining regulatory reporting obligations: SAEs are defined as death and life-threatening events (Category A), incidents which acutely jeopardise the health or psychological wellbeing of the individual, resulting in immediate hospital admission and/or persistent or significant disability or incapacity (category B), or resulting in injury requiring immediate medical attention (category C).

Figure 2: GCP Decision Tree for Adverse Events



All AEs and SAEs (from each site) will be pooled and reported monthly to the TMC and at each meeting of the DMEC, or at any time at the request of the DMEC Chair; there are no AEs or SAEs that do not require reporting in this trial, as it is an important subsidiary goal of the trial to establish the safety of the intervention. Urgent actions concerning participant and staff safety, communication with others, and clinical care will be immediately addressed by the Trial PI and Site Leads and reported to the TMC.

AEs will be categorized for severity and seriousness by the site leads/Trial Coordinator. SAEs will be reviewed for relatedness to trial procedures and unexpectedness by the PI initially, and additionally by the chair of the DMEC.

Relatedness and unexpectedness of an event to the intervention will be judged based on the following:

1. Related: the event resulted from administration of any of the research procedures, judged according to a temporal relationship (i.e., SREs);
2. Unexpected: the event is unexpected or unexplained given the participant's clinical course, previous conditions and history, and concomitant treatments (i.e., USREs)

Only SAEs that have been judged by the PI and the chair of the DMEC to be USREs will be reported to the main REC. The DMEC will be responsible for investigating further, if there are any concerns about unexpectedly high rates of SAEs, SREs or

USREs, which may include being unblinded as to trial condition or seeking further data on adverse events, and will advise the TSC on any ethical or safety reasons why the trial should be prematurely ended. The Funder will immediately be notified on receipt of any information that raises material concerns about safety or efficacy, and of any recommendations from the DMEC to end the trial.

Data handling and security
Electronic research data collected during the proposed research will be stored on password-protected files, on password-protected computers and will be accessible only to the co-applicants. Manual (i.e., paper) data will be stored in locked filing cabinets in locked offices on NHS premises. All data will be pseuonymised, with access to consent forms the only means of breaching pseudonymity. Consent forms will be stored in locked filing cabinets in locked offices on NHS premises. Consent forms and manual data will be stored in separate offices. Results reported in publications will deal only with aggregated data and will not include personally identifiable information. Data will be handled in accordance with the General Data Protection Regulation, the NHS Caldicott Principles, and the Research Governance Framework for Health and Social Care (2005). Data will be held for 5 years, in line with the Research Governance Framework, and will be stored in secure archiving at CNTW.

Finance and funding
This research is funded by the NIHR research for patient benefit scheme NIHR 201078. The Funder reviewed and approved the content of the protocol, but does not have a role in data collection, management, analysis, or interpretation; nor in the writing of the final report or decision to submit the report. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Funding is provided to cover salary costs for the applicants, and research staff, and treatment costs for the CPNs. A small payment of £10 per assessment is provided to the participants as an acknowledgement of their time, and travel expenses are covered too.

Indemnity
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust has agreed to act as the sponsor for this research. Indemnity is, therefore, provided through NHS schemes. Dr Robert Dudley, the CI, is an NHS employee, and the NHS indemnity scheme applies in his case. The study RAs are also employed by the NHS, and the NHS indemnity scheme applies in their cases. Three of the co-applicants (Charles Fernyhough, Ben Alderson-Day and Adetayo Kasim) are employed by Durham University. Bronia Arnott, is employed by Newcastle University. Both Newcastle and Durham University has in force a policy providing legal liability cover and the activities are included within that coverage for University's involvement in this study.

Dissemination of research findings

LEAP group members and experts-by-experience associated with the Hearing the Voice project will advise on and support the dissemination of the findings. Participants in the trial will be offered feedback and information on the outcome of the study at an event organized by Hearing the Voice. Staff, services and service managers will also be provided with written feedback and/or presentations describing the study.

Findings in relation to the training and supervision, as well as the trial itself will be presented at national conferences, as well as service-user/voluntary sector organisations and websites. In addition, research findings will be disseminated through blog posts, podcasts, and research seminars. We will submit to peer review journals the trial protocol and a paper describing the main feasibility issues in relation to the MUSE intervention. These two papers will be published in open access formats.

Availability of data and materials

The Investigator(s) will permit trial-related monitoring, audits and REC review by providing the Sponsor(s), the TSC and REC direct access to source data and other documents as required.

An anonymised version of the main outcome data will be available from the trial team on reasonable request after publication of the main results paper.

Competing interests

RD, GD, SC provide psychological therapies for individuals with psychosis in NHS settings, RD has written manuals for psychological therapies for psychosis for which he receives book royalties (Guildford). RD receives fees (or generate fees for his clinics or research units) for workshops and presentations on psychological therapies for psychosis and RD, CF, GD, SC, BAD hold or have held grants to carry out trials of psychological therapy for individuals with psychosis.

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Appendix A Contents

The Psychotic Rating Scale (PSYRATS)

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AUDITORY HALLUCINATIONS

1. Frequency

Probing questions

How often have you heard your voices over the last week?

Thinking about the last week, what has it been like?'' e.g. every day, all day long etc"

Scoring criteria:

0 Voices not present or present less than once a week (specify frequency if present) 1 Voices occur for at least once a week 2 Voices occur at least once a day 3 Voices occur at least once an hour 4 Voices occur continuously or almost continuously i.e., stop for only a few seconds or minutes

2. Duration

Probing questions

When you have heard your voices over the last week, how long have they lasted?

Have they lasted for a few seconds, minutes, hours, all day long for example....?"

Scoring criteria:

0 Voices not present 1 Voices last for a few seconds, fleeting voices 2 Voices last for several minutes 3 Voices last for at least one hour 4 Voices last for hours at a time

3. Location

Probing questions

When you have heard your voices over the last week, where did they sound like they were happening?

Did they sound like they were inside your head and/or outside your head? Whereabouts do your voices sound like they are coming from?

Scoring criteria:

0 No voices present 1 Voices sound like they are inside head only 2 Voices outside the head, but close to ears or head. Voices inside the head may also be present. 3

Voices sound like they are inside or close to ears and outside head away from ears 4 Voices sound like they are from outside the head only

4. Loudness

Probing questions

How loud are your voices? Are they louder than my voice, about the same loudness, quieter or just a whisper?

Scoring criteria:

0 Voices not present 1 Quieter than own voice, whispers. 2 About same loudness as own voice 3 Louder than own voice 4 Extremely loud, shouting

5. Beliefs regarding the origin of voices

Probing questions

What do you think has caused your voices?

Are the voices caused by factors related to you, or due to other people or factors?

Are your voice caused by your mental health problems or illness?

How much do you believe that your voices are caused by (add interviewee's contribution) on an scale from 0-100 with 100 being that you are totally convinced, have no doubts and 0 being that it is completely untrue?

Scoring criteria:

0 Voices not present 1 Believes voices to be solely internally generated and related to self 2 Holds a less than 50% conviction that voices originate from external causes 3 Holds 50% or more conviction (but less than 100%) that voices originate from external causes 4 Believes voices are solely due to external causes (100% conviction)

6. Amount of negative content of voices

Probing questions

Do you think that your voices have said unpleasant things or negative things over the last week?

How much of the time do the voices say these types of unpleasant or negative items?

Scoring criteria:

0 No unpleasant content 1 Occasional unpleasant content 2 Minority of voice content is unpleasant or negative (less than 50%) 3 Majority of voice content is unpleasant or negative (50% or more) 4 All of voice content is unpleasant or negative

7. Degree of negative content

Probing questions

Can you tell me a bit about what you have heard your voices saying over the last week?

Can you give me some examples of the things you have heard this week?

Scoring criteria:

0 Not unpleasant or negative 1 Some degree of negative content, but not personal comments relating to self or family e.g. swear words or comments not directed to self, e.g. “the milkman’s ugly” 2 Personal verbal abuse, comments on behaviour e.g. “shouldn’t do that or say that” 3 Personal verbal abuse relating to self-concept e.g. “you’re lazy, ugly, mad, perverted” 4 Personal threats to self e.g. threats to harm self or family, extreme instructions or commands to harm self or others and personal verbal abuse as in (3)

8. Amount of distress

Probing questions

Have you found your voices to be distressing over the last week?

How much of the time have they caused you distress over the last week?

Scoring criteria:

0 Voices not distressing at all 1 Voices occasionally distressing, majority not distressing (<10%) 2 Minority of voices distressing (<50%) 3 Majority of voices distressing, minority not distressing (≥ 50%) 4 Voices always distressing

9. Intensity of distress

Probing questions

Over the last week when your voices have been distressing, how distressing has that been?

Thinking about the worst distress you could feel, over the last week, how have your voices compared to that? For example, has it been slightly, moderately distressing etc?

Scoring criteria:

0 Voices not distressing at all 1 Voices slightly distressing 2 Voices are distressing to a moderate degree 3 Voices are very distressing, although interviewee could feel worse 4 Voices are extremely distressing, feel the worst he/she could possibly feel

10. Disruption to life caused by voices

Probing questions

How much disruption have the voices caused to your life over the last week?

Can you tell me how the voices stopped you from working or doing any other daytime activity that you wanted to do?

How much have they interfered with your relationships with friends and/or family?

How much have they prevented you from looking after yourself, e.g. bathing, changing clothes, etc.?

Scoring criteria: 0 No disruption to life, able to maintain social and family relationships (if present)

1 Voices cause minimal amount of disruption to life e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and be able to maintain independent living without support.

2 Voices cause moderate amount of disruption to life causing some disturbance to daytime activity and/or family or social activities. The interviewee is not in hospital although may live in supported accommodation or receive additional help with daily living skills.

3 Voices cause severe disruption to life so that hospitalisation is usually necessary. The interviewee is able to maintain some daily activities, selfcare and relationships whilst in hospital. The interviewee may also be in supported accommodation but experiencing severe disruption of life in terms of activities, daily living skills and/or relationships. 4 Voices cause complete disruption of daily life requiring hospitalisation. The interviewee is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted.

11. Controllability of voices

Probing questions

What control had you had over your voices over the last week?

How much control have you had over your voices when they happened over the last week?

Can you get rid of, dismiss or bring on your voices?”

Scoring criteria:

0 Interviewee believes they can have control over the voices and can always bring on or dismiss them at will

1 Interviewee believes they can have some control over the voices on the majority of occasions

2 Interviewee believes they can have some control over their voices approximately half of the time

3 Interviewee believes they can have some control over their voices but only occasionally. The majority of the time the interviewee experiences voices which are uncontrollable

4 Interviewee has no control over when the voices occur and cannot dismiss or bring them on at all.

Optional items

(i) Number of voices

How many voices do you experience?

(ii) Form of each voice

How does each voice refer to you? Does it say things that start with 'you', or 'he/she' or 'I'?(1st person, 2nd person, 3rd person etc.)

(iii) Sex of voices

Are the voices males or female? How many voices are male and how many are female?

DELUSIONAL BELIEFS

1. Amount of preoccupation with delusions

Probing questions

Over the last week, how much time have you spent thinking about your beliefs about ……[insert client's beliefs] ?

Scoring criteria:

0 No delusions, or delusions which the interviewee thinks about less than once a week. 1 Interviewee thinks about beliefs at least once a week. 2 Interviewee thinks about beliefs at least once a day. 3 Interviewee thinks about beliefs at least once an hour. 4 Interviewee thinks about delusions continuously or almost continuously.

2. Duration of preoccupation with delusions

Probing questions

When you have thought about any of your beliefs (i.e. [insert interviewee's beliefs]…) over the last week, how long do they tend to stay in your mind? - Few seconds/minutes/hours, etc.?

Scoring criteria:

0 No delusions 1 Thoughts about beliefs last for a few seconds, fleeting thoughts 2 Thoughts about delusions last for several minutes 3 Thoughts about delusions last for at least one hour 4 Thoughts about delusions usually last for hours at a time

3. Conviction

Probing questions

At the moment, do you have any doubts about any of your beliefs, for example do you sometimes wonder whether they are real or not? (Go through each belief in turn).

How much do you believe in,,,[insert belief/beliefs]? Can you estimate this on a scale from 0 – 100, where 100 means that you are totally convinced by your beliefs and 0 being that you are not convinced at all?

Scoring criteria:
0 No conviction at all 1 Very little conviction in reality of beliefs, less than 10% 2 Some doubts relating to conviction in beliefs, between 10-49% 3 Conviction in belief is very strong, between 50 – 99% 4 Conviction is 100%

4. Amount of Distress

Probing questions

Have your beliefs about [insert interviewee's beliefs] caused you distress over the last week? How much of the time have they caused you distress over the last week?

Scoring criteria:

0 Beliefs never cause distress 1 Beliefs cause distress on the minority of occasions. 2 Beliefs cause distress on less than 50 % of occasions 3 Beliefs cause distress on the majority of occasions when they occur between 51-99% of time

4 Beliefs always cause distress when they occur

5. Intensity of Distress

Probing questions

Over the last week, when you have felt distressed by your beliefs about [insert interviewee's beliefs] how severe does this feel?" Have you felt slightly, distressed, moderately distressed etc.

Scoring criteria:

0 No distress 1 Beliefs cause slight distress 2 Beliefs cause moderate distress 3 Beliefs cause marked distress 4 Beliefs cause extreme distress, couldn't be worse

6. Disruption to life caused by beliefs

Probing questions

In what way have your beliefs caused disruption for you over the last week?

In what way have they stopped you working or carrying out a day-time activity?

In what way have they interfered with your relationships with family or friends?

In what way have they interfered with your ability to look after yourself, e.g. washing, changing clothes, etc.?

Scoring criteria:

0 No disruption to life, able to maintain independent living with no problems in daily living skills. Able to maintain social and family relationships (if present) 1 Beliefs cause minimal amount of disruption to life, e.g. interferes with concentration although able to maintain daytime activity and social and family relationships and be able to maintain independent living without support. 2 Beliefs cause moderate amount of disruption to life causing some disturbance to daytime activity and/or family or social activities. The interviewee is not in hospital although may live in supported accommodation or receive additional help with daily living skills.

3 Beliefs cause severe disruption to life so that hospitalisation is usually necessary. The interviewee is able to maintain some daily activities, self-care and relationships whilst in hospital. The interviewee may also be in supported accommodation but experiencing severe disruption of life in terms of activities, daily living skills and/or relationships.

4 Beliefs cause complete disruption of daily life requiring hospitalisation. The interviewee is unable to maintain any daily activities and social relationships. Self-care is also severely disrupted.

Optional items

(i) Number of beliefs

Record the number of beliefs considered in the interview, use further probing questions if necessary

(ii) Content of each belief

Record the content of each belief considered in the interview, use further probing questions if necessary.

(iii) Conviction in each belief

It may be useful to record the conviction that the individual has in each of their beliefs that have been considered during the interview.

PSYRATS –Hallucinations
MULTIMODALITY

1. Which type of unusual experiences have you experienced in the last month (tick all that apply):

☐Auditory / Hearing
☐Visual / Seeing
☐Olfactory / Smelling
☐Somatic / Feeling in body (not including sexual nature)
☐Sexual somatic sensations/ Sexual feelings in genitals
☐Felt presence/felt sense

2. How do these occur:

2a: Simultaneously/ At the same time ☐Yes ☐No
2b: Serially/ At different times (one occurring after the other) ☐Yes ☐No

Are the unusual experiences or hallucinations related or not? For example, seeing a man and hearing his voice = related; seeing a dog but hearing the voice of a woman = unrelated

2c. Simultaneous experiences

Please tick: ☐Yes related ☐No not related

2d. Serial experiences

Please tick: ☐Yes related ☐No not related

2e. Can you briefly please describe the content of these experiences? For example, hearing the voice of a man whilst smelling his aftershave

** ***ADMIN PROMPT – if participant answered Yes to both 2a and 2b, clarify which modalities are simultaneous & which are serial***

At the time that this is happening, can you show/tell me a number on the thermometer, how distressing it is?

PROMPT: the bottom being only slightly distressing, top being extremely distressing/worst could feel; use the 0 if not at all distressing

☐ **3a. Simultaneous** ☐ **3b. Serial**

At the time that this is happening, can you show/tell me a number on the thermometer, how much do you believe it's real?
PROMPT: the bottom being only a little bit convinced, top being totally certain they are real; use the 0 if you don't believe it at all

4a. Simultaneous 4b. Serial

Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ)

Van Lieshout, R. J., & Goldberg, J. O. (2007). Quantifying self-reports of auditory verbal hallucinations in persons with psychosis. *Canadian Journal of Behavioural Science / Revue Canadienne Des Sciences Du Comportement*, 39(1), 73–77. https://doi.org/10.1037/cjbs2007006

1. How frequently did you hear a voice or voices? Least severe 0 1 2 3 4 Most severe
2. How bad are the things the voices say to you? Least severe 0 1 2 3 4 Most severe
3. How loud are the voice? Least severe 0 1 2 3 4 Most severe
4. How long do the voices usually last? Least severe 0 1 2 3 4 Most severe
5. How much do the voices interfere with your daily activities? Least severe 0 1 2 3 4 Most severe
6. How distressing are the voices that you hear? Least severe 0 1 2 3 4 Most severe
7. How *bad* (worthless/useless) do the voices make you feel about yourself? Least severe 0 1 2 3 4 Most severe
8. How clearly do you hear the voices? Least severe 0 1 2 3 4 Most severe
9. How often do you do what the voices say? Least severe 0 1 2 3 4 Most severe

Depression, Anxiety and Stress Scales (DASS21)

Lovibond, P. F., & Lovibond, S. H. (1995). The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behaviour Research and Therapy*, 33(3), 335–343. https://doi.org/10.1016/0005-7967(94)00075-u

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.
The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree or a good part of time
3 Applied to me very much or most of the time

1 (s) I found it hard to wind down 0 1 2 3
2 (a) I was aware of dryness of my mouth 0 1 2 3
3 (d) I couldn't seem to experience any positive feeling at all 0 1 2 3
4 (a) I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion) 0 1 2 3
5 (d) I found it difficult to work up the initiative to do things 0 1 2 3
6 (s) I tended to over-react to situations 0 1 2 3
7 (a) I experienced trembling (e.g. in the hands) 0 1 2 3
8 (s) I felt that I was using a lot of nervous energy 0 1 2 3
9 (a) I was worried about situations in which I might panic and make a fool of myself 0 1 2 3
10 (d) I felt that I had nothing to look forward to 0 1 2 3
11 (s) I found myself getting agitated 0 1 2 3
12 (s) I found it difficult to relax 0 1 2 3
13 (d) I felt down-hearted and blue 0 1 2 3
14 (s) I was intolerant of anything that kept me from getting on with what I was doing 0 1 2 3
15 (a) I felt I was close to panic 0 1 2 3
16 (d) I was unable to become enthusiastic about anything 0 1 2 3
17 (d) I felt I wasn't worth much as a person 0 1 2 3
18 (s) I felt that I was rather touchy 0 1 2 3
19 (a) I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat) 0 1 2 3
20 a) I felt scared without any good reason 0 1 2 3
21 d) I felt that life was meaningless 0 1 2 3

CHOICE – Short form

This questionnaire has been developed by asking the opinions of people who have used services for distressing difficulties. It looks at the sorts of things that you may want to be different in life. It is made up of 11 statements and 1 personal goal. You can fill it in on your own or with the research worker. For each statement, please begin by reading it carefully and then circle a number to show how you have felt about it **over the last month**.

1. The ability to approach problems in a variety of ways

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 *worst* *best*

2. Self-confidence

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

3. Positive ways of relating to people

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

4. The ability to question the way I look at things

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

5. Ways of dealing with everyday life stresses

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

6. Ways of dealing with a crisis

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

7. Facing my own upsetting thoughts and feelings

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

8. Peace of Mind

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

9. Understanding myself and my past

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

10. Understanding my experiences (e.g. beliefs, thoughts, voices, and related feelings)

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

11. Positive ways of thinking

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

12. This is space to write a personal goal that you would like to achieve in therapy.
Personal Goal……

How would you rate yourself for this?	0 1 2 3 4 5 6 7 8 9 10 worst best

The Questionnaire about the Process of Recovery (QPR)

Neil, S., Kilbride, M., Pitt, L., Nothard, S., Welford, M., Sellwood, W., & Morrison, A. (2009). The questionnaire about the process of recovery (QPR): A measurement tool developed in collaboration with service users. *Psychosis*, 1, 145–155. https://doi.org/10.1080/17522430902913450

We developed this questionnaire in order to understand more about the process of recovery, what's helpful and what's not so helpful. Everyone is different and there will be differences for everyone. The items on this questionnaire were developed through a process of interviewing service users about their recovery journeys. We hope that by filling in this questionnaire you will help us find out information that is important to you and your own recovery. Not all factors will be important to you since everyone is different. This questionnaire is not intended to be used to impose anything against your wishes.

If you would like to fill in the questionnaire, please consider and sum up how things stand for you at the present time, in particular over the last 7 days, with regards to your

mental health and recovery. Please respond to the following statements by putting a tick in a box that best describes your experience.

	Disagree Strongly	Disagree	Neither Agree or Disagree	Agree	Agree Strongly
I feel better about myself					
I feel able to take chances in life					
I am able to develop positive relationships with other people					
I feel part of society rather than isolated					
I am able to assert myself					
I feel that my life has a purpose					
My experiences have changed me for the better					
I have been able to come to terms with things that have happened to me in the past and move on with my life					
I am basically strongly motivated to get better					
I can recognise the positive things I have done					
I am able to understand myself better					
I can take charge of my life					
I can actively engage with life					
I can take control of aspects of my life					
I can find the time to do the things I enjoy					

The short form-36 (SF-36)
Ware, J. E., & Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care*, 30(6), 473–483.

Choose one option for each questionnaire item.

1. In general, would you say your health is:

1 - Excellent

2 - Very good

3 - Good

4 - Fair

5 - Poor

2. Compared to one year ago, how would you rate your health in general now?

1 - Much better now than one year ago

2 - Somewhat better now than one year ago

3 - About the same

4 - Somewhat worse now than one year ago

5 - Much worse now than one year ago

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

5. Lifting or carrying groceries

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

6. Climbing several flights of stairs

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

7. Climbing one flight of stairs

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

8. Bending, kneeling, or stooping

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

9. Walking more than a mile

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

10. Walking several blocks

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

11. Walking one block

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

12. Bathing or dressing yourself

1 Yes, limited a lot 2 Yes, limited a little 3 No, not limited at all

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

13. Cut down the amount of time you spent on work or other activities

1 Yes 2 No

14. Accomplished less than you would like

1 Yes 2 No

15. Were limited in the kind of work or other activities

1 Yes 2 No

16. Had difficulty performing the work or other activities (for example, it took extra effort)

1 Yes 2 No

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

17. Cut down the amount of time you spent on work or other activities

1 Yes 2 No

18. Accomplished less than you would like

1 Yes 2 No

19. Didn't do work or other activities as carefully as usual

1 Yes 2 No

20. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups?

1 - Not at all

2 - Slightly

3 - Moderately

4 - Quite a bit

5 - Extremely

21. How much bodily pain have you had during the past 4 weeks?

1 - None

2 - Very mild

3 - Mild

4 - Moderate

5 - Severe

6 - Very severe

22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

1 - Not at all

2 - A little bit

3 - Moderately

4 - Quite a bit

5 - Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

23. Did you feel full of pep?

24. Have you been a very nervous person?

1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

25. Have you felt so down in the dumps that nothing could cheer you up?

1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

26. Have you felt calm and peaceful?

1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

27. Did you have a lot of energy?

1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

28. Have you felt downhearted and blue?

1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

29. Did you feel worn out?

1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

30. Have you been a happy person?

1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

31. Did you feel tired?

1 All of the time 2 Most of the time 3 A good bit of the time 4 Some of the time 5 A little of the time 6 None of the time

32. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

1 - All of the time

2 - Most of the time

3 - Some of the time

4 - A little of the time

5 - None of the time

How TRUE or FALSE is each of the following statements for you.

33. I seem to get sick a little easier than other people

1 Definitely true 2 Mostly true 3 Don't know 4 Mostly false 5 Definitely false

34. I am as healthy as anybody I know

1 Definitely true 2 Mostly true 3 Don't know 4 Mostly false 5 Definitely false

35. I expect my health to get worse

1 Definitely true 2 Mostly true 3 Don't know 4 Mostly false 5 Definitely false

36. My health is excellent

1 Definitely true 2 Mostly true 3 Don't know 4 Mostly false 5 Definitely false

EQ-5D

EuroQol Research Foundation. EQ-5D-5L User Guide, 2019. Available from: https://euroqol.org/publications/user-guides.

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about

I have slight problems in walking about

I have moderate problems in walking about

I have severe problems in walking about

I am unable to walk about

SELF-CARE

I have no problems washing or dressing myself

I have slight problems washing or dressing myself

I have moderate problems washing or dressing myself

I have severe problems washing or dressing myself

I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities

I have slight problems doing my usual activities

I have moderate problems doing my usual activities

I have severe problems doing my usual activities

I am unable to do my usual activities

PAIN / DISCOMFORT

I have no pain or discomfort

I have slight pain or discomfort

I have moderate pain or discomfort

I have severe pain or discomfort

I have extreme pain or discomfort

PAIN / DISCOMFORT

I have no pain or discomfort

I have slight pain or discomfort

I have moderate pain or discomfort

I have severe pain or discomfort

I have extreme pain or discomfort

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

The best health you can imagine 0 5 10 15 20 25 30 35 40 45 50 55 60 6570 75 80 85 90 95 100 The worst health you can imagine

Your Health today = □

Investigating Choice Experiments Capability Measure for Adults (ICECAP-A)
Al-Janabi, H., N Flynn, T., & Coast, J. (2012). Development of a self-report measure of capability wellbeing for adults: The ICECAP-A. *Quality of Life Research*, 21(1), 167–176. https://doi.org/10.1007/s11136-011-9927-2

Please indicate which statements best describe your overall quality of life at the moment by placing a tick in ONE box for each of the five groups below:

1. Feeling settled and secure

I am able to feel settled and secure in all areas of my life

I am able to feel settled and secure in many areas of my life

I am able to feel settled and secure in a few areas of my life

I am unable to feel settled and secure in any areas of my life

2. Love, friendship and support

I can have a lot of love, friendship and support

I can have quite a lot of love, friendship and support

I can have a little love, friendship and support

I cannot have any love, friendship and support

3. Being independent

I am able to be completely independent

I am able to be independent in many things

I am able to be independent in a few things

I am unable to be at all independent

4. Achievement and progress

I can achieve and progress in all aspects of my life

I can achieve and progress in many aspects of my life

I can achieve and progress in a few aspects of my life

I cannot achieve or progress in any aspects of my life

5. Enjoyment and pleasure

I can have a lot of enjoyment and pleasure

I can have quite a lot enjoyment and pleasure

I can have a little enjoyment and pleasure

I cannot have any enjoyment or pleasure

Revised Satisfaction with Therapy and Therapist Scale (RSTTS)

Oei, T. P., & Shuttlewood, G. J. (1999). Development of a Satisfaction with Therapy and Therapist Scale. *The Australian and New Zealand Journal of Psychiatry*, 33(5), 748–753. https://doi.org/10.1080/j.1440-1614.1999.00628.x
Oei, T. P. S., & Green, A. L. (2008). The Satisfaction With Therapy and Therapist Scale--Revised (STTS-R) for group psychotherapy: Psychometric properties and confirmatory factor analysis. *Professional Psychology: Research and Practice*, *39*(4), 435–442. https://doi.org/10.1037/0735-7028.39.4.435

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I am satisfied with the therapy	1	2	3	4	5
The therapist listened to what I had	1	2	3	4	5
The therapy helped me with the	1	2	3	4	5
The therapist provided a good	1	2	3	4	5
I would recommend the therapy to	1	2	3	4	5
The therapist was critical towards	1	2	3	4	5
The therapist seemed to know what	1	2	3	4	5
The therapist was friendly	1	2	3	4	5
I believe the therapy will help me	1	2	3	4	5
The therapy focused on problems	1	2	3	4	5
The therapist seemed to understand	1	2	3	4	5

Working Alliance Inventory – Short Form Revised (for participants)

Horvath, A. O., & Greenberg, L. S. (1986). *The development of the Working Alliance Inventory.* In L. S. Greenberg & W. M. Pinsof (Eds.), *Guilford clinical psychology and psychotherapy series. The psychotherapeutic process: A research handbook* (p. 529–556). Guilford Press.

Instructions: Below is a series of statements about experiences people might have with their therapy or therapist. Some items refer directly to your therapist

with an underlined space -- as you read the sentences, mentally insert the name of your therapist in place of _____in the text. For each statement, please take your time to consider your own experience and then fill in the appropriate bubble.

Important: The rating scale is not the same for all the statements. **PLEASE READ CAREFULLY!**

1. As a result of these sessions I am clearer as to how I might be able to change.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

2. What I am doing in therapy gives me new ways of looking at my problem.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

3. I believe _____ likes me.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

4. _____and I collaborate on setting goals for my therapy.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

5. _____and I respect each other.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

6. _____and I are working towards mutually agreed upon goals.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

7. I feel that _____ appreciates me.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

8. _____and I agree on what is important for me to work on.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

9. I feel cares about me even when I do things that he/she does not approve of.

   1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

10. I feel that the things I do in therapy will help me to accomplish the changes that I want.

    1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

11. _____ and I have established a good understanding of the kind of changes that would be good for me.

    1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

12. I believe the way we are working with my problem is correct.

    1 – Seldom, 2 – Sometimes, 3 – Fairly Often, 4 – Very Often 5 – Always

Working Alliance Inventory – Short Revised - Therapist

Instructions: Below is a list of statements about experiences people might have with their client. Some items refer directly to your client with an underlined space -- as you read the sentences, mentally insert the name of your client in place of ___ in the text.

1. ___ and I agree about the steps to be taken to improve his/her situation.

□	□	□	□	□
Seldom	Sometimes	Fairly Often	Very Often	Always

2. I am genuinely concerned for ___'s welfare.

□	□	□	□	□
Always	Very Often	Fairly Often	Sometimes	Seldom

3. We are working towards mutually agreed upon goals.

□	□	□	□	□
Seldom	Sometimes	Fairly Often	Very Often	Always

4. ___ and I both feel confident about the usefulness of our current activity in therapy.

□	□	□	□	□
Seldom	Sometimes	Fairly Often	Very Often	Always

5. I appreciate ___ as a person.

□	□	□	□	□
Always	Very Often	Fairly Often	Sometimes	Seldom

6. We have established a good understanding of the kind of changes that would be good for ___.

□	□	□	□	□
Always	Very Often	Fairly Often	Sometimes	Seldom

7. ___ and I respect each other.

□	□	□	□	□
Seldom	Sometimes	Fairly Often	Very Often	Always

8. ___ and I have a common perception of his/her goals.

□	□	□	□	□
Always	Very Often	Fairly Often	Sometimes	Seldom

9. I respect ___ even when he/she does things that I do not approve of.

□	□	□	□	□
Seldom	Sometimes	Fairly Often	Very Often	Always

10. We agree on what is important for ___ to work on.

□	□	□	□	□
Always	Very Often	Fairly Often	Sometimes	Seldom

PSYRATS – Multimodal hallucinations

1. Which type of unusual experiences have you experienced in the last month (tick all that apply):

☐Auditory / Hearing ☐Somatic / Feeling in body (not including sexual nature)

☐Visual / Seeing ☐Sexual somatic sensations/ Sexual feelings in genitals

☐Olfactory / Smelling ☐Felt presence/felt sense

2. How do these occur:

2a: Simultaneously/ At the same time ☐Yes ☐No

2b: Serially/ At different times (one occurring after the other) ☐Yes ☐No

Are the unusual experiences or hallucinations related or not? For example, seeing a man and hearing his voice = related; seeing a dog but hearing the voice of a woman = unrelated

2c. Simultaneous experiences

Please tick: ☐Yes related ☐No not related

2d. Serial experiences

Please tick: ☐Yes related ☐No not related

2e. Can you briefly please describe the content of these experiences? For example, hearing the voice of a man whilst smelling his aftershave
***** ADMIN PROMPT – if participant answered Yes to both 2a and 2b, clarify which modalities are simultaneous & which are serial***

At the time that this is happening, can you show/tell me a number on the thermometer, how distressing it is?
PROMPT: *the bottom being only slightly distressing, top being extremely distressing/worst could feel; use the 0 if not at all distressing*

3a. Simultaneous ☐ **3b. Serial** ☐

At the time that this is happening, can you show/tell me a number on the thermometer, how much do you believe it's real?
PROMPT: the bottom being only a little bit convinced, top being totally certain they are real; use the 0 if you don't believe it at all

4a. Simultaneous ☐ **4b. Serial** ☐

Structured Interview Topic – Service-User participants

Thank you for agreeing to answer some questions about your experience of the therapy. We want to understand how people found the approach and if there was anything that you would suggest we change. We want to record the interview so we can see if any themes emerge about the treatment and might also use some

anonymous quotes from people in the next stage of the research. You are welcome to say as much or as little as you like to each question, or not answer at all. Are you ready for us to begin? (**RA switches on the recorder**)

My first questions are about the sessions you did with the therapist involving the smart tablet….

1. What was the intervention like for you?

2. How was it using the computer/tablet?

3. Were there any particular things about the session that were helpful for you?

4. Were there any particular things about the session that were unhelpful for you?

5. Is there anything you would change about it?

6. Did it help you make sense of any of the unusual experiences you have?

7. Do you think the tablet made it influenced how easy it was to form a strong working relationship with your therapist?

8. Would you recommend the intervention to someone else with similar experiences?

My next questions are more about taking part in the research
.

1. When you started the study, we asked you to tell us about some of your experiences in an interview, and to fill out some questionnaires. What was that like for you? Is there anything you think should be done differently?

2. In our future research, we might need to run studies where people get "randomised" at the start – so some people would get to use the MUSE package, and some people wouldn't. How would you feel about this?

3. If you were in a trial where you might randomly get placed in a part of the research where you get treatment as usual, or the new treatment, would you have agreed to participate?

4. Are there any other comments you would like to make about the research?

Structured Interview Topic – Staff participants

Thank you for agreeing to answer some questions about your experience of the therapy. We want to understand how people found the approach and if there was anything that you would suggest we change. We want to record the interview so we can see if any themes emerge about the treatment and might also use some

anonymous quotes from people in the next stage of the research. You are welcome to say as much or as little as you like to each question, or not answer at all. Are you ready for us to begin? (**RA switches on the recorder**)

My first questions are about the sessions you did with the service user involving the smart tablet….].

1. What was the intervention like for you?

2. How was it using the computer/tablet?

3. Were the materials easy to use in the sessions?

4. Were there any particular things about the session that were helpful for you?

5. Were there any particular things about the session that were unhelpful for you?

6. Is there anything you would change about it?

7. Did it help you make it easier to build a formulation of the service users unusual experiences?

8. Do you think the tablet made it influenced how easy it was to form a strong working relationship with your therapist?

9. Would you recommend the intervention to another therapist?

My next questions are more about taking part in the research
.

1. Did the research procedure run smoothly? Would you suggest making any changes to it?

2. In our future research, we might need to run studies where people get "randomised" at the start – so some people would get to use the MUSE treatment, and some people wouldn't. How would you feel about this?

3. If you participated in the next stage of the research and were asked to be a treatment as usual therapist, do you think you would be able to stop yourself using the ideas from the treatment?

4. Are there any other comments you would like to make about the research?

Adherence Checklist For

(Please tick topic used in any session)

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
1. **What are voices?**							
What are voices?							
How many people hear voices?							
Why does it become a problem?							
Can things get better?							
Personal experiences							
2. **How the mind works?**							
Thoughts and senses							
How thoughts work							
Embarrassing thoughts							
The power of attention							

How we use expectation							

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
3. **Assessment**							
Types of unusual sensory experiences.							
What kind of voices do we hear?							
4. **Inner Speech**							
What is inner speech?							
Our inner speech can do amazing things							
Why do people not recognise voices?							
Thoughts are hard to control							
Blocking the loop							
Inner speech – what is the evidence?							
Tracking the self – Was that me?							

Writers and voice hearing							
Imaginary friends							
Formulation							
					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
Voices and Relationships							
Transforming the voice							
Testing out your explanations							
Living well with voices							
5. **Memory Based Voices**							
Memory, dissociation, trauma							
The importance of trauma							
Threat system and Soothing system							
Formulation							
Treating trauma							
6. **Hypervigilance**							

Nature versus Nurture							
Filling in the gaps							
What our perception system is designed to do							

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
Response to danger							
Formulation							
Threat system and soothing system							
Mistrust							
7. **Seeing Visions**							
Is seeing believing?							
What do your visions mean to you?							
Perception system design							
Filling in the gaps							

Tracking the self – was that me?							
Imaginary friends							
Testing distressing appraisals							
Changing images							

					Additional Sessions		
Module/Topic	**S1**	**S2**	**S3**	**S4**	**S5**	**S6**	**Comments**
Living well with visual experiences							
Voices, visions and relationships							
Challenging unacceptability							
Testing out your explanations							
Living well with voices and visions							
8. **Sleep**							
Why do we sleep?							

Demographic and background information form
Contact information. (store this page separately)

Participant number:	
Name:	
Address:	
Home telephone number:	
Mobile number:	
Email:	
GP name and address: Care coordinator name and contact details:	

Participant number:	
Demographic information	
Sex:	Male Female
Age	
Nationality:	
Ethnicity:	White – Caucasian Asian Black Middle-Eastern Mixed-race Other:
First Language:	English Other:
Are you married? IF NO: Were you ever?	1. married or living with someone as if married 2. widowed 3. divorced or annulled 4. separated 5. never married
How far did you get in school?	1. Before GCSEs 2. GCSE (without doing A-levels) 3. A-levels 4. part university 5. graduated from university 6. Post grad at University
How many years did you spend at school all together?	
Are you working or studying at the moment?	1. Unemployed 2. Working full or part time 3. Studying 4. Volunteering
Overview of present illness	
	1. Current inpatient 2. Current outpatient 3. No current patient

Have you been in any kind of treatment in the past month?	
IF IN-PATIENT: When did you come to hospital?	1. < 1 week 2. 1-4 weeks 3. > 4 weeks 4. n/a
Sometimes people hear voices, whispers or noises that other people can't hear or see things others do not Has this happened to you in the past four weeks? When last? Is this an issue you would want to work with someone to help better understand and or manage these experiences	1. YES 2. NO 1. YES 2. NO
Unusual experience history	
Do you remember when these experiences started? What was it that you first noticed, can you tell me about the experience when it first started? When did they first become a problem for you?	

Have you ever been a patient in psychiatric hospital? IF YES: What was that for? (How many times?)	
Do you take any medication? (Write down the name of the medication and the dose).	

Therapy session measure
Please answer the following questions about the voices you experienced <u>in the past week</u>

<u>How frequent were the voices?</u>

0%	10	20	30	40	50	60	70	80	90	100%
Voices not present					Once a day					Voices always present

<u>Were the voices distressing? How much of the time?</u>

0%	10	20	30	40	50	60	70	80	90	100%
Voices never distressing					Voices were distressing about half of the times					Voices always distressing

If relevant please answer the following questions about the visions you experienced <u>in the past week</u>

<u>How frequent were the visions?</u>

0% 10 20 30 40 50 60 70 80 90 100%
Visions not present — Once a day — Visions always present

Were the vision distressing? How much of the time?

0% 10 20 30 40 50 60 70 80 90 100%
Visions never distressing — Moderately distressing — extremely distressing

Overall, how distressing were the experiences listed above?

0% 10 20 30 40 50 60 70 80 90 100%
not at all distressing — Moderately distressing — extremely distressing