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Managing Unusual Sensory Experiences using a new treatment manual, in people who are experiencing psychosis for the first time

Submission date
22/11/2021

Recruitment status
No longer recruiting

Registration date
24/11/2021

Overall study status
Completed

Last Edited
29/04/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hallucinations are a common feature of psychosis, causing significant distress and disability. Although there are 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 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. MUSE is a novel toolkit based on current theoretical models of voice-hearing. It uses psychoeducation about the currently known mechanisms of hallucination as means of exploring, with service-users, why their specific experiences may be happening. MUSE explains why people have hallucinations and helps develop strategies to cope and reduce distress. It is loaded on a smart tablet so that everyone is offered the same treatment. The toolkit focuses only on hallucinations, which makes the treatment short (4-6, one-hour weekly sessions). It has user-friendly and engaging content with many video clips to explain how the brain can experience hallucinations.
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, the effectiveness of this treatment needs to be established. As a step towards that, this study aims to establish if it is feasible to conduct a future clinical- and cost-effectiveness study. The research will aim to answer the following questions:
1. Is it feasible for CPNs to be trained in MUSE and to deliver it to psychosis patients within NHS Mental Health Services?
2. Is MUSE – delivered by CPNs – acceptable to service-users and staff?
3. Is it feasible to evaluate the clinical and cost-effectiveness of the MUSE– thus informing the design of a definitive trial?

Who can participate?
Participants aged 16 or above with a history of auditory hallucinations in the last four weeks, meeting entry criteria for Early Intervention in Psychosis (EIP) service.

What does the study involve?
Participants will be randomly allocated to either the MUSE therapy with treatment-as-usual, or treatment-as-usual alone. MUSE therapy will involve 4-6 sessions with the CPN (each session approximately 30-60 minutes long). Treatment-as-usual will involve the standard treatment provided by the EIP services. This will involve resources to manage symptoms. 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.
Assessments will include qualitative and quantitative measures and will take place at baseline, 6-8-weeks, and 3-months after the participants have been randomised. Patient and staff participants will also be invited to take part in interviews to investigate 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.

What are the possible benefits and risks of participating?
The main benefit to research participants is the knowledge that they are taking part in research that is likely to help improve the care that is provided to people with mental health problems. For those in receipt of the MUSE intervention, there is the potential that they will better understand their experienced and learn new methods and approaches to reduce the impact of hallucinations, in a brief time scale.
The staff participants will have the chance to learn about psychological interventions and receive three days of training and close supervision of their practice. This is a greater amount of training and supervision than would routinely be available and may enhance their confidence and skill in working with hallucinations.
The anticipated risks for patients taking part in this study are estimated to be very low. Nevertheless, to monitor for any adverse events, we will maintain close links with participants' clinical teams throughout the duration of their participation. Any risk issues will be discussed before consenting by the care team and research team. Participants' existing treatment will not be affected by participation in the trial – half of the participants taking part will receive MUSE alongside the existing treatment.
We also acknowledge the potential burden of taking part in the research assessment sessions, which will take approximately 90 minutes per session. In a situation where participant becomes tired/distressed, they will be given the opportunity to take a break from testing, stop the session completely, or rearrange for another time.

Where is the study run from?
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (UK) and Teesk, Esk and Wear Valleys NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
From January 2021 to October 2022

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

Who is the main contact?
Dr Robert Dudley
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
292150

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 292150, NIHR201078, CPMS 49015

Study information

Scientific 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 (FEP).

Acronym
MUSE FEP

Study objectives
To establish whether it will be possible to undertake a larger, definitive trial of the MUSE treatment in the future. We will attempt to answer the following questions in order to inform the development of a definitive trial:
1. Is it feasible for community psychiatric nurses (CPNs) to be trained in MUSE and to deliver it to psychosis patients within NHS Mental Health Services? Does the planned 3-day training equip CPNs with the skills and confidence to deliver MUSE?
2. Is MUSE – delivered by CPNs – acceptable to service-users and staff?
3. Is it feasible to evaluate the clinical and cost effectiveness of the MUSE– thus informing the design of a definitive trial? We will aim to identify parameters important for a future definitive trial. Measures of distress and disability caused by hallucinations, depression, quality of life, perceived recovery, therapeutic relationship and intervention quality will be recorded to support the decision for selection of best outcome measures for future trials.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/05/21, Yorkshire and the Humber Sheffield Research Ethics Committee (NHS Blood and Transplant Donor Centre, Holland Drive, Newcastle Upon Tyne, NE2 4NQ; +44 (0)207 1048224; Sheffield.rec@hra.nhs.uk), ref: 21/YH/0090

Study design
Multi-centre interventional single-blind feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Treatment of hallucinations in people with Psychosis

Interventions

Managing Unusual Sensory Experiences psychoeducation (MUSE) treatment focuses on hallucinations, explains why people have them, and helps the person to develop and use coping strategies to reduce distress. The treatment is short and will be delivered by community psychiatric nurses over several sessions (4 core with an option of 2 extra sessions, each session will last approximately 30-60 mins). Sessions will be conducted face-to-face at participants' homes or NHS clinics, in case if COVID-19 restrictions are still in place, the sessions will be conducted remotely.

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.

Control
Treatment-as-usual interventions provided by the EIP services. Participants will be offered resources to manage their symptoms. 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.

Randomisation
Following consent, eligible participants from two NHS sites will be randomised within two working days through an independent randomisation service (sealedenvelope.com). Randomisation will be in the ratio 1:1 to the two groups (MUSE or treatment-as-usual) and will be stratified by site. Randomisation (at the individual level) will be independent and concealed, using randomised-permuted blocks of random size (block sizes of 4 or 6). The allocation will be made known to the participant by phone call and letter from the trial manager. Blinding of the allocation code will be maintained for research assistants until all outcome measures for all participants have been collected.

Intervention Type
Behavioural

Primary outcome measure
Establishing whether a larger, definitive trial future study can be undertaken using the following:
1. Whether the planned 3-day training equips CPNs with the skills and confidence to deliver MUSE, and whether the supervision package is sufficient and useful to support CPNs in the delivery of this toolkit, assessed through a quantitative and qualitative evaluation at the end of the training, 6 months into the study, and at end of the study
2. The acceptability of the intervention to the participants engaging in the treatment and to CPNs delivering it assessed using the following:
2.1. Participants being asked to share their views on the treatment and the toolkit at the 3-month follow-up meeting
2.2. Staff being asked to share their views on the toolkit at the end of the study
3. To inform a future trial we will collect data on the following throughout the trial:
3.1. Proportion of eligible individuals clinicians are willing to refer (referral rate)
3.2. Proportion of eligible individuals willing to participate (recruitment rate) and the proportion of participants who comply with their allocation (allocation compliance rate)
3.3. Proportion of participants who drop-out of the study (attrition rate)
3.4. Characteristics of trial participants to further clarify selection criteria
3.5. Appropriateness and integrity of treatment protocols
3.6. Randomisation procedures
3.7. Completion rate of measures
3.8. Acceptability, relevance and validity of the measures to assess clinical effectiveness and safety in a subsequent definitive trial
3.9. Appropriateness of quality of life measures, and service use data needed to undertake a future full health economic evaluation
3.10. Access to CBTp and MUSE like interventions in other EIP services in England

Secondary outcome measures
The following will be measured at baseline, after 8 weeks, and at 3 months post-randomisation (unless stated otherwise):
1. Hallucinations measured using the following:
1.1. The Psychotic Symptom Rating Scales (PSYRATS; Haddock et al., 1999), 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. 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).
1.2. The Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ; van Lieshout & Goldberg, 2007) - the self-report voice-impact subscale from the questionnaire 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.
2. Anxiety and Depression measured using the Depression, Anxiety and Stress Scales (DASS; Lovibond & Lovibond, 1995), a 21-item self -report questionnaire designed to assess symptoms of anxiety, depression and stress.
3. Quality of Intervention measured using the CHoice of Outcome In Cbt for psychosEs (CHOICE; Greenwood et al., 2010), a 12 item service-user developed questionnaire to evaluate outcomes for people with psychosis and assess therapy-related goals.
4. Recovery measured using the process of recovery questionnaire (QPR; Neil et al., 2009), a user-defined measure, assessing subjective recovery in intrapersonal and interpersonal functioning.
5. Quality of Life measured using the Short Form-36 (SF36; Ware & Sherbourne, 1992) and the EQ-5D (Herdman et al., 2011)
6. Capability measures measured using the Investigating Choice Experiments Capability Measure for Adults (ICECAP-A; Al-Janabi, Flynn & Coast, 2012)
7. Therapeutic alliance and therapy acceptability measured using the Satisfaction with Therapy and Therapist scale (STTS; Oei & Shuttlewood, 1999) – revised version will be used to assess overall acceptability of the therapeutic interaction at 6 weeks and 3 months
8. Treatment session measures measured using a short self-assessment form comprising items adapted from the main measure of hallucinations will monitor variations in voice or vision frequency and distress at each MUSE session

Overall study start date
01/01/2021

Completion date
31/10/2022

Eligibility

Key inclusion criteria
Patients:
1. In contact with Early Intervention in Psychosis (EIP) services
2. Have an identified CPN acting as their care coordinator
3. Meet ICD-11 criteria for schizophrenia, schizoaffective disorder, or entry criteria for an EIP service
4. Have a history of auditory hallucinations for at least four weeks
5. Aged ≥16 years
6. Consider their hallucinations as a main difficulty, and would like to receive an intervention specifically for hallucinations
7. Have the capacity to provide informed consent
8. Judged by their clinician to be clinically stable for the preceding 4 weeks
9. Individuals on antipsychotic treatment, and those who decline to take medication, will be included, as long as no medication changes have occurred in the previous month (i.e., having started or stopped antipsychotic medication, or a switch to or from Clozapine).

Staff involved in the trial delivery will be asked to help evaluate the training, supervision, and therapy process. These are NHS staff, offering the MUSE treatment. However, the main aspect of feasibility is focussed on the trial and so these details are reported here.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
80

Total final enrolment
82

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

Date of first enrolment
02/06/2021

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
Jubilee Rd
Gosforth
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United Kingdom
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Study participating centre
Tees, Esk and Wear Valles NHS Foundation Trust
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
https://www.cntw.nhs.uk

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
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. The trial protocol and a paper describing the main feasibility issues in relation to the MUSE intervention will be submitted for publication to peer review journals. The protocol and main paper will be published in open access format.

Public and patient involvement dissemination: A current Lived Experience Advisory Panel (LEAP) has been set up in line with recommendations of advisory groups that encourage service-user involvement in NHS research. LEAP members will advise on and support the dissemination of accessible information from this study in engaging, innovative ways.

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the CI, Robert Dudley rob.dudley@cntw.nhs.uk or rob.dudley@ncl.ac.uk. Data from the questionnaires, and measures used will be available in excel format, with item and summary scores available. We expect to make it available according to the requirements of the journal that accepts the study, and our trust store data for five years from the end of a trial. So, we would expect the data as described to be available for up to five years from October 2022. We will share the data with any researcher or body with a legitimate interest (ie replication, meta analytic review etc), and will pass on anonymised, group data for these purposes. Interested researchers should email the CI as indicated above.
On our consent form we included the following consent:
"I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers".
So we understand we are free to share data provided it is used for legitimate purposes, and each request will be considered by the CI.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	18/03/2021	23/11/2021	No	No
Protocol article		16/05/2022	18/05/2022	Yes	No
Statistical Analysis Plan	version 3.0	29/09/2022	26/10/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		16/04/2024	29/04/2024	Yes	No