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Managing unusual sensory experiences for people with an at-risk mental state for psychosis

Submission date
02/03/2023

Recruitment status
No longer recruiting

Registration date
09/05/2023

Overall study status
Completed

Last Edited
24/10/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People who have hallucinations may receive a diagnosis of psychosis, which is a medical term for people who experience reality very differently from most other people. The early stage of psychosis is called 'At Risk Mental State' (ARMS). In ARMS, people may have milder versions of hallucinations, or problems with managing in their daily lives. Researchers want to see if they can help prevent hallucinations in ARMS becoming upsetting. This might prevent people from becoming more unwell.
Managing Unusual Sensory Experiences (MUSE) helps people understand why hallucinations happen. It helps people to develop ways of reducing their distress. It is short (4–6 one-hour weekly sessions) and runs on laptops. Psychological therapists present and discuss information about why people have hallucinations, using images and video-clips. MUSE helps people to understand the reasons for their experiences, and why they take different forms.

Who can participate?
People aged 14–35 years who have been accepted for treatment by an At Risk Mental State service who describe having frequent and distressing unusual sensory experiences which they want psychological treatment for

What does the study involve?
People who volunteer to participate will be randomly allocated to either the treatment group, where they will receive 6-8 sessions of a psychological treatment which aims to explain the origins of their experiences and helps them manage them more effectively. If they are allocated to the control group, they will be offered treatment from a psychological therapist, which is likely to focus on providing emotional support, problem solving and normalising their experiences. Participants in both groups will receive treatment as usual from the multi-disciplinary At Risk Mental State service.

What are the possible benefits and risks of participating?
All participants will be offered a psychological therapy which could include discussing distressing issues and provide new information that participants could find distressing. There is also a burden on participants as the three assessments will include completing different measures and cognitive tasks. The potential benefits are that the psychological therapies may help reduce

their distress. Participants may also feel satisfaction from contributing to research aimed to improve patient care.

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

When is the study starting and how long is it expected to run for?
January 2023 to September 2024

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

Who is the main contact?
Dr Guy Dodgson, guy.dodgson@cntw.nhs.uk

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323903

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RES-22-038, IRAS 323903, CPMS 55323

Study information

Scientific Title
Managing Unusual Sensory Experiences (MUSE): a feasibility trial of a targeted, psychoeducation toolkit for distressing hallucinations for people with an At-Risk Mental State (ARMS) for psychosis

Acronym
MUSE ARMS

Study objectives
1. To conduct a randomised feasibility trial to address key uncertainties of delivering Managing Unusual Sensory Experiences (MUSE) in an At-Risk Mental State (ARMS) population and identify any signal of efficacy
2. To test the feasibility of investigating which psychological mechanisms are influenced by MUSE and contribute to its clinical effect
3. To collect routine data to enable later studies to examine which features of MUSE are most relevant to the prevention of the development of psychosis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/02/2023, North East - Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048139, +44 (0)2071048255; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 23/NE/0032

Study design
Mixed-method feasibility trial employing a prospective randomized open-label observer-blinded endpoint design

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reducing distress from unusual sensory experiences in people with an At Risk Mental State for psychosis

Interventions
The intervention is the Managing Unusual Sensory Experiences (MUSE) treatment. This is a psychological intervention that focuses on the causes of voices and visions. The control arm involves time-matched needs-based interventions which focus on emotional support, normalising experiences etc. Both arms will receive Treatment as Usual (TAU) from the At Risk Mental State service which they have been accepted into. Randomisation is conducted by Sealedenvelope.

The treatment arm (MUSE+TAU) is 6 sessions, plus an additional 2 sessions if required. The researchers assume these 6-8 sessions will be completed within 12 weeks. The follow-up period is for an extra 8 weeks.

The control arm (TAU) includes a time-matched control where a psychological therapist will offer needs-based emotional support, problem-solving etc. The researchers assume these 6-8 sessions will be completed within 12 weeks. The follow-up period is for an extra 8 weeks.

Intervention Type
Behavioural

Primary outcome(s)
As this is a feasibility trial, feasibility outcomes for the delivery of a large-scale randomised controlled trial are of key importance. The primary outcome of this feasibility trial is the ability of the trial to recruit 88 participants, who reflect the diversity within the region, meet study inclusion criteria over the 9-month recruitment period, and complete assessment measures collected at baseline, post-intervention (12 weeks post-randomisation) and follow-up (20 weeks post-randomisation), until all participants complete the follow-up assessment or withdraw.

The researchers will use a traffic light system to inform progressions criteria (above 80%: green; 60–79%: amber; below 60%: red) and will use a consort diagram to plot progression through the trial and will review at end of the trial data collection (final assessment of final participant).

1. Referral rate. The researchers will check the percentage of potentially eligible clients who are referred. The date used to inform recruitment rate suggested quite different rates of eligibility across the two sites (65% in TEWV and 95% in CNTW).
2. Recruitment rate. The researchers calculated that they should be able to recruit 9.8 pcm. They will monitor across the study and green would be achieving 80%, therefore 7.85 pcm.
3. Reasons for declining participation. The non-consent group will be sensitively asked to share reasons for non-participation via the NIHR Participant Research Experience ‘Okay to say No’ (anonymous) questionnaire (https://myresearchexperience.com/), which asks an open question about the reasons for deciding not to take part, along with basic demographic information (age and ethnicity). This will happen at the point the potential participant declines to participate.
4. Allocation compliance rate and attrition rate. We will monitor this through our CONSORT

diagram and review at the end of the trial, using our traffic light system.
5. Appropriateness and integrity of treatment protocols. Therapists will be asked to complete adherence checklists for each session. Adherence checklists will be specific to the intervention (MUSE/Supportive Psychotherapy). With consent, each session will be audio-recorded to enable an independent review of a random 10% sample to ensure fidelity to protocol within and across sites. Treatment fidelity will be assessed by the site PI or Co-Investigator/Clinical lead /Supervisor who is not a trial therapist.
6. Completion rates of measures and psychological tasks. This will be provided by the statisticians at the end of the analyses and assessed using the traffic light system for progression.
7. Time needed to collect, clean and analyse data. The statisticians have been allocated 3 months to clean and analyse the data at the end of the study. They will inform us of the time required for this task.
8. Robust estimates of effect size (primary/secondary outcomes) to inform sample-size calculations for future trials. The effects will be estimated using generalised linear mixed-effect models with the appropriate distribution and link function. Normal distributions with identity link will be used for continuous outcomes, and negative-binomial distributions with log link for count data outcomes. All binary or categorical outcomes will be analysed using generalised estimating equations (GEE). The mixed-effects models and GEE account for the repeated measurements per participant over the follow-up time points. All models will be adjusted for treatment arms and stratification variables. The mixed model approach taken will allow identifying the individual effect of the two interventions w.r.t their baseline, as well as the difference in their effects through an interaction parameter of time and intervention. This can be considered as a model-based difference-in-difference analysis.
9. Analysis of components of TAU at each site. Details of all treatment received in both groups will be recorded using the Client Service Receipt Inventory CSRI (mental health) questions 4 to 5, amended for this trial to add specific questions to measure receipt of relevant interventions in both arms for the duration of the study.

Qualitative data will inform the researchers' understanding of participants' subjective experiences of the intervention and its impact on their understanding of their voice-hearing experiences (e.g. changes in beliefs about origin), along with the acceptability of the intervention (including experiences of the quality of intervention and participant responsiveness) and trial procedures for participants and therapists. Audio recordings will be transcribed and analysed (in NVivo software). Interview transcripts will be analysed using thematic analysis allowing a transparent, replicable and robust process and demonstration of reflexivity and quality. Transcripts will be coded by two researchers until coding reliability is established; coding will then be conducted by one researcher, with reliability checks by the qualitative lead. Data will be extracted into a framework matrix, summarising data by category from individual transcripts, with quotations selected as illustrative exemplars. Initial findings from the qualitative analyses will be presented to LEAP for feedback on interpretation.

Key secondary outcome(s))

The treatment delivered in this intervention aims to improve functioning and reduce the distress associated with hallucinations. Accordingly, candidate primary outcome measures that will be investigated for suitability for future trials are global functioning, as measured on the SOFAS, and hallucinations measured using the PSYRATS hallucination scale, with attention to subscales of interest: distress and attribution. The effect of the interventions on outcomes will be estimated from the change from baseline as well as changes in the mean scores in each trial arm. The feasibility of measuring caseness and caseness change, or clinically meaningful levels of response will be explored.

1. Functioning assessed using the Social and Occupational Functional Assessment Scale (SOFAS)
2. Mental State assessed using the Psychotic Symptom Rating Scale (PSYRATS) hallucinations total
3. Hallucinations assessed using the Psychotic Symptom Rating Scale (PSYRATS) distress
4. Attribution assessed using the Psychotic Symptom Rating Scale (PSYRATS) attribution

These measures are collected at three timepoints; baseline, post-treatment (12 weeks post-baseline), follow-up (20 weeks post-baseline).

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. In contact with an ARMS service or accepted on an ARMS pathway by Early Intervention in Psychosis (EIP) services
2. Aged 14–35 years
3. Hallucinations/unusual sensory experiences scoring at least 3 on the Perceptual Abnormalities Subscale of the CAARMS
4. Hallucinations considered by the patient to be a key target problem
5. Judged to have been clinically stable for the preceding 2 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 years

Upper age limit
35 years

Sex
All

Total final enrolment
93

Key exclusion criteria
1. Intellectual disability or severe cognitive dysfunction affecting ability to engage with research materials
2. Lacking capacity to give informed consent

Date of first enrolment

14/04/2023

Date of final enrolment
23/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Nicholas Hospital (newcastle upon Tyne)
Jubilee Road, Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3XT

Study participating centre
West Park Hospital
Edward Pease Way
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DL2 2TS

Sponsor information

Organisation
Cumbria Northumberland Tyne and Wear NHS Foundation Trust

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Government

Funder Name

Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

Added 19/03/2024:
The name of the repository: Durham University research data repository.
A persistent weblink to the dataset: This will be available from 03/09/2024
The type of data stored: Quantitative data for randomised participants, collected at baseline, week 12 and week 20 timepoints.
Dates of availability: From 02/09/2024
Whether consent from participants was required and obtained: Consent is obtained for the anonymised data set from the study to be published in open access and or for wider research.
Comments on data anonymization: Potentially deanonymizing data (e.g. ethnicity and gender) is de-linked from participant ID for public open access data sharing to protect anonymity.
Any ethical or legal restrictions: Person identifiable information will not be shared.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/05/2025	24/10/2025	Yes	No
Protocol article		30/06/2023	04/07/2023	Yes	No
Dataset		03/09/2024	02/09/2024	No	No
HRA research summary			26/07/2023	No	No
Protocol file	version 2.0		01/06/2023	No	No
Protocol file	version 5.0	15/12/2023	07/03/2024	No	No
Protocol file	version 6.0	26/05/2024	27/06/2024	No	No
Statistical Analysis Plan	version 1.0	29/11/2023	30/11/2023	No	No