ISRCTN10484951 https://doi.org/10.1186/ISRCTN10484951

Managing Unusual Sensory Experiences (sometimes called hallucinations), using a new treatment manual, in people who are showing early symptoms that could develop into psychosis

Submission date	Recruitment status	[_] Prospectively registered
08/01/2019	No longer recruiting	[X] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
17/01/2019	Completed	[X] Results
Last Edited	Condition category	[X] Individual participant data
30/08/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The Hearing the Voice research project has been developing a novel treatment approach for Unusual Sensory Experiences, often described as hallucinations. This approach uses current psychological understandings to explain voices, is based on a model of different subtypes of voices, and uses a Tablet to standardise the approach and to demonstrate key concepts. This research has been mainly conduced on people experiencing a first episode of psychosis (FEP), but clinical staff have found that the approach is particularly helpful for people who have an At Risk Mental State for psychosis (ARMs), which are people who have weakened psychotic experiences which place them at much higher risk of developing a full psychotic episode. The aim of this study is to investigate whether this approach is acceptable to people with ARMS, to refine the treatment and understand more about who can deliver the treatment and over how many sessions.

Who can participate?
Patients aged 16 and above with a history of hallucinations for at least six weeks or a recent history of brief but intense hallucinations

What does the study involve?
Participants complete an assessment before starting treatment. They are then offered a treatment of 2-4 sessions and complete a further assessment after finishing the treatment. Both the clinicians and participants also complete a structured interview about whether they found the treatment acceptable and how it could be improved.

What are the possible benefits and risks of participating?
The main benefit for 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. The only

potential risk is that they may find it distressing to answer the researchers' questions . It is absolutely fine to take a break or stop the session if this occurs.

Where is the study run from?
1. Tees, Esk and Wear NHS Trust (UK)
2. Cumbria Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2018 to October 2019 (updated 18/10/2019, previously: December 2019)

Who is funding the study?
Wellcome Trust (UK)

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

Contact information

Type(s)
Scientific

Contact name
Dr Guy Dodgson

Contact details
Greenacre Ctr
Green Lane
Ashington
United Kingdom
NE63 8BL
+44 (0)1670844670
guy.dodgson@ntw.nhs.uk

Additional identifiers

Protocol serial number
40375

Study information

Scientific Title
Managing Unusual Sensory Experiences in people with an At Risk Mental States for psychosis (MUSE-ARMS)

Acronym
MUSE-ARMS

Study objectives

The study aims to investigate whether the new treatment manual is acceptable to service users who receive the treatment and also feasible for clinical staff to deliver the treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & Humber- Leeds East REC, NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne, NE2 4NQ, Tel: 02071048088, Email: nrescommittee.yorkandhumber-leedseast@nhs.net, 10/12/2018, ref: 18/YH/0433

Study design
Non-randomised; Interventional; Design type: Treatment, Prevention, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hallucinations

Interventions
This study will take a mixed-methods research approach to establish feasibility and acceptability of the MUSE toolkit in a group of service-users with an At-Risk Mental State for Psychosis, using a single-group design. Mixed-methods research combines qualitative and quantitative methods and offers a pragmatic way of collecting data that is rich, rounded, and nuanced, while also being directly comparable to findings in other research (Johnson & Onwuegbuzie, 2004; Creswell & Clark, 2011). 20 service-user participants with ARMS will receive assessments on their entrance into the study and after completion of therapist sessions using the toolkit, (which we think will be 2-4 sessions). The baseline assessment will include quantitative measures of current symptoms, mood, quality of life, and aims for therapy. The follow-up assessment will include all of the above again, plus quantitative measures of recovery and satisfaction with therapy, plus a short, structured interview designed to gather qualitative data on treatment acceptability.

In parallel, staff participants (the psychological therapists administering the treatment) will be asked to complete quantitative measures of treatment adherence after each service-user has completed a session. They will also be invited to take part in a similar structured interview, at the end of the study gauging their views on the treatment acceptability and feasibility.

Quantitative and qualitative data from each of these study strands will be combined as part of the data interpretation stage (a triangulation design) following a convergence model (Cresswell & Clark, 2011), i.e. the data will initially separately before being combined and compared to elicit points of agreement, contrast, and new questions to examine.

SUMMARY OF PROCEDURES
The trialists are working with EIP services across the region to identify people who have an At Risk Mental State for psychosis and who would benefit from seeing a psychological therapist to

work on unusual sensory experiences, often called hallucinations. If the care team identify a person is appropriate to participate, they will briefly outline the research and ask if they are interested in taking part in the research. Their contact details will be passed to the local Clinical Research Network and a Research Assistant (RA) will contact them provide more information and ask if they would be prepared to meet and discuss participation. If the potential participant remains interested, then the RA will arrange an appointment and send out the Patient Information Sheet. At the appointment the RA will answer any queries about the research and if the potential participant still wishes to participate, the RA will go through the consenting procedure and they will then conduct a pre-treatment assessment of questionnaires. They will then see the therapist they were going to be referred to for 2-4 sessions of treatment that would focus on their unusual sensory experiences. The treatment would be delivered on a Tablet. The therapist would have received two days of training on the theories behind the treatment and how to use the Tablet to enhance treatment. Therapists will be offered fortnightly supervision on delivering the treatment from the research team. Once the treatment had been delivered then the participant would be asked to complete the same set of questions to see if their difficulties had changed. The RA would also conduct a structured interview about their experience of the treatment and what they found helpful or unhelpful about it. The assessments would take place at either a clinic room or their home, depending on their preference and any risk factors. Most psychological therapy sessions are conducted in clinic rooms, but sometimes they may happen at someone's home if that is agreed to be most helpful. The trialists would also ask the therapists what they thought about the treatment they had offered in a structured interview. We would also ask the therapists to list after each session the things from the treatment they had used, to ensure that they had delivered the treatment and that we have a way of checking this.

The intervention is a novel treatment manual for hallucinations, which has been developed by the CI, in collaboration with the co-applicants and other clinicians. The treatment is divided into the following Modules:-
1. 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.
2. What are Voices? This module provides normalising information about the frequency of voices, the factors that tend to increase voice hearing (for example substance misuse and sleep deprivation) and gives testimonies from other voice hearers.
3. Assessment. This module encourages therapists to identify the subtype of hallucination a service-user is experiencing. For voice-hearing specifically, this is achieved by asking the voice-hearer about the content of the voice's utterances, the sensory characteristics of the voice, and the cognitive, emotional, and environmental triggers of the voice. After the assessment the therapist should be able to identify whether the voice hearing is an Inner Speech-Auditory verbal hallucination (IS-AVH), a Memory Based AVH (MB-AVH) or a Hypervigilance AVH (HV-AVH).
4. Inner Speech. This module provides psychoeducation about the evidence that suggests that voice hearing may be people not recognising their own inner speech. It outlines the conditions that make this more likely and the properties of inner speech that make voice hearing possible. An individual formulation of voice hearing experiences is co-produced and then targeted coping strategies and behavioural experiments are employed. The PowerPoint version of this module has been attached as additional information to provide a detailed example about the treatment.
5. Memory Based. This module provides psychoeducation 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 developed and then targeted coping strategies and behavioural experiments are employed.
6. Hypervigilance. This module provides psychoeducation 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 tend to scrutinise poor quality sensory data and therefore rely more heavily on predictions, whilst adopting a 'better safe than sorry' decision bias. These factors all make an individual more likely to have a false positive, of hearing the 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.
7. Seeing Visions. This module covers psychoeducation about how our perceptual system can easily be fooled, for example the strong use of predictions and has certain biases, for example searching for faces. An individual formulation is developed which identifies what it is about the experiences that is most distressing (content, persistence or meaning of having the vision). A treatment plan is then develops that normalises the experience and tried to address the key cause of distress.
8. Sleep. This module tries to provide psychoeducation and treatment strategies about sleep, which is often a key factor in the development and maintenance of 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). Therapists will not, therefore, be required to learn an extensive set of new techniques. Rather, the manual tries to guide therapists to tailor existing therapeutic approaches to the needs of the voice-hearer, based on a more powerful explanation of their experiences (formulation) and matching approaches to specific subtypes. The modules are designed so that the therapist can choose to work through a full module, or select topics within modules to enable them to provide a more bespoke treatment for the service user.

MEASURES

The following primary and secondary outcome assessments and treatment acceptability measures will be included in the study.

Service-user participant measures:

Potential primary outcome assessments:

The Psychotic Symptom Rating Scales (PSYRATS; Haddock, McCarron, Tarrier, & Faragher, 1999)
This is a clinician administered semi-structured interview of hallucinations (including questions about frequency and intensity of distress). This measure will be used in both assessment sessions.

The Comprehensive Assessment of At-Risk Mental States (CAARMS; Yung et al., 2005)
This is a semi-structured interview that will be used to assess psychotic symptoms in both sessions. To shorten the assessment interview, only the perceptual abnormalities subscale will be used in the first interview.

Potential secondary outcome assessments:

The short Depression, Anxiety and Stress Scales (DASS-21; Lovibond & Lovibond, 1995)
The questionnaire assesses emotional distress, including symptoms of anxiety and depression. This measure will be administered during both sessions.

Investigating Choice Experiments Capability Measure for Adults (ICECAP-A; Flynn et al., 2015).
This measure will be used to assess the emotional and mental aspects of quality of life at both sessions.

The Questionnaire about the Process of Recovery (QPR; Neil et al., 2009).
Subjective recovery in intrapersonal functioning and interpersonal functioning will be assessed at the follow-up from the study.

Treatment acceptability
The CHoice of Outcome In CBT for psychosEs (CHOICE; Greenwood et al., 2010)
This service user-led measure will be used to evaluate outcomes of CBT for psychosis and assess therapy-related goals during both sessions.

Satisfaction with Therapy and Therapist Scale (STTS; Oei & Shuttlewood, 1999)
This short scale will be used to assess the overall acceptability of the therapeutic intervention at the study follow-up only.

Structured Interview
The trialists will conduct an acceptability, structured interview with participants at the end of the intervention. This interview will cover several topics (see Appendix A), including whether the service-user would have been prepared to be randomised into a TAU arm, if they found the tablet format helpful, whether they found that the tablet hindered the development of a therapeutic alliance with the therapist, how helpful being presented with an scientific explanation of unusual sensory experiences was and if there was anything unhelpful about the intervention.

Staff participant measures
Adherence Checklist
The trialists will take a copy of the formulation the clinician and service-user developed during therapy after the participants have completed the treatment. After each session, therapists will record which modules they used from the treatment. These steps will be taken so that we can investigate how the use of the study intervention influences the formulations clinicians and service-users develop, and so that we can assess to what extent clinicians have followed the manual in therapy, as well as how often they used the manual.

Structured Interview
The trialists will conduct an acceptability, structured interview with staff participants at the end of the intervention. This interview will cover similar topics to the service users structured interview. We will ask whether they found the tablet format helpful, whether they found the tablet hindered the development of a therapeutic alliance with the service user, how effective they found the tablet in presenting complex ideas that explained the onset of unusual sensory experiences, and if there was anything unhelpful about the intervention. The therapists will also be asked about any potential improvements or additions to the tablet, so we can continue to try to improve the intervention.

Intervention Type
Other

Primary outcome(s)
Psychotic symptoms measured by the Psychotic Symptom Rating Scale (PSYRATS) both before and after the treatment

Key secondary outcome(s))
1. Psychotic symptoms measured by the Comprehensive Assessment of At Risk Mental state (CAARMS), perceptual abnormalities and functioning scales only, both before and after the treatment
2. Emotional distress measured by the Depression, Anxiety and Stress Scales (DASS-21) both before and after the treatment
3. Quality of Life measured by the Investigating Choice Experiments Capability Measure for Adults (ICECAP-A) both before and after the treatment
4. Recovery in functioning measured by the Questionnaire about the Process of Recovery (QPR) after the treatment
5. Achieving the service users outcomes from therapy measured by The Choice of Outcome In CBT for psychosEs (CHOICE) both before and after the treatment
6. Acceptability of treatment measured by Satisfaction with Therapy and Therapist Scale (STTS) after the treatment
7. Acceptability of the treatment investigated through structured interviews with both the service user and the clinician after the treatment

Completion date
15/10/2019

Eligibility

Key inclusion criteria
Participants will:
1. Be in contact with Early Intervention in Psychosis services and accepted on the ARMs pathways following assessment by the Comprehensive Assessment of At Risk Mental state (CAARMs)
2. Have a history of hallucinations for at least six weeks or a recent history of brief but intense hallucinations.
3. Be aged 16 and above
4. Consider their unusual sensory experiences (voices or visions) as a main presenting difficulty, and indicate that they would like to receive a psychological intervention specifically designed to address hallucinations
5. Have the capacity to provide informed consent
6. Be judged by their clinician to be clinically stable for the preceding 4 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
24

Key exclusion criteria
Potential participants will not be eligible if:
1. The experience of hallucinations/psychosis has a strong biological basis (owing to traumatic brain injuries, organic psychoses, or dementia)
2. They have insufficient command of English to complete the research interviews and measures
3. They have an intellectual disability, or severe cognitive dysfunction that might preclude their ability to provide informed consent, understand the study procedure and/or fully appreciate the potential consequences of their participation
4. They have a primary diagnosis of substance misuse dependency
5. They are identified by the care team as being too acutely unwell to participate in the research

Date of first enrolment
12/12/2018

Date of final enrolment
26/09/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Tees, Esk and Wear NHS Trust
Flatts Lane Centre
Flatts Lane
Normanby
Middlesbororugh
United Kingdom
TS6 0SZ

Study participating centre
Cumbria Partnership NHS Foundation Trust
Voreda House
Portland Place
Penrith
United Kingdom
CA11 7BF

Sponsor information

Organisation
Northumberland, Tyne and Wear NHS Foundation Trust

ROR
https://ror.org/01ajv0n48

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust; Grant Codes: 108720/Z/15/Z

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 30/08/2022:
All quantitative data is stored at the Open Science Framework (https://osf.io/h9rsp/?view) for 5 years. Consent from participants was obtained, there is a participant ID for the data and no patient identifiable information is shared, as specified in the IRAS application and participant consent sheet.

Previous IPD sharing statement:
The data sharing plans for the current study are not yet defined. The trialists plan to make the anonymised quantitative data available on a publically available repository (possibly Open Science Framework). This is likely to be available within 3 months of the final participant being assessed. The REC-approved consent form enables them to share this information with other researchers. Qualitative data will not be shared as there is a risk that it would be identifiable, so this information will only be available as analysed for themes and presented in the subsequent publication.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2020	08/06/2021	Yes	No
Dataset		03/09/2020	30/08/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 3	11/11/2025	11/11/2025	No	Yes
Protocol file		26/11/2018	30/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes