

# Making sense of voices

<b>Submission date</b> 26/06/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/06/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Plain English summary under review

## Contact information

### Type(s)

Scientific

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

**Scientific Title**

Making sense of voices: a case series

**Study objectives**

The main hypothesis to be tested is whether the Making Sense of Voices intervention will reduce the level of distress associated with the experience of hearing voices.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES South Central Berkshire B, ref: 15/SC/0013

**Study design**

The study design is a multiple baseline case series design with a randomised duration of waitlist.

**Primary study design**

Interventional

**Secondary study design**

**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**

Hearing voices

## **Interventions**

### **1. Phase 1: Assessment and construct:**

The Maastricht Hearing Voices Interview: This is a clinical interview. For most voice hearers, the interview is part of an intervention as the conversation challenges cognitive avoidance of the topic.

The construct: The construct relates voices to the personal history of the voice hearing individual. Voice hearers acquire insight in the assumed original mechanisms of their voices. The individuals who represent the voices and the problems that the voices represent are identified. Making a construct is comparable with constructing a functional analysis as is done in behavioral therapy.

### **2. Phase 2: Intervention:**

The intervention is aimed at reducing distress, and improving the quality of the relationship between voice hearer and her/his voices. Often voice hearers experience an unequal relationship with their voices, where the voices dominate in a negative way and are responsible for disturbing daily functioning.

To improve the relationship with the voices 3 types of methods are used:

2.1. Homework assignments: to communicate with the voices at a set time during each day.

2.2. Role play: to exercise how to communicate with the voices in the session

2.3. Talking with the voices: the therapist communicates indirectly or directly with the voices.

The communication with the voices is guided by the assumption that voice hearing is traumatic in origin and that the voices are signals to protect certain vulnerabilities. Many voice hearers experience their voices as attacking self esteem and self-efficacy; by this intervention the communication is bent towards voices as 'allies', from a destructive towards a constructive relationship.

## **Intervention Type**

Other

## **Primary outcome measure**

Hallucination Change Scale (HCS). Each participant generates a narrative description of their auditory hallucinations (AH) scored for the 24-hour time period just prior to initiation of the trial, which was scored as a 10. The Hallucination Change Scale (HCS) is scored in subsequent assessments by requesting the patient to generate a new narrative description of AHs. Follow-up severity scores ranged from 0, corresponding to no hallucinations, to a maximum score of 20, corresponding to hallucinations twice as severe as baseline.

## **Secondary outcome measures**

### **1. Voice hearing:**

1.1. Psychotic Symptoms Rating Scale (PSYRATS (AH)): 11 items completed on the basis of a clinical interview, and enables analysis in relation to voice distress specifically as well as a wider range of voice characteristics

1.2. Positive and Negative Symptom Scale (PANNS): A widely used clinical interview assessing a wide range of symptoms associated with a diagnosis of a psychotic disorder

1.3. Beliefs about Voices Scale (BAVQ-R). A 35-item self-report measure of the appraisals made in relation to a voice hearing experience

1.4. The Voice and You Rating Scale (VAY). A 28-item self-report measure assessing the relationship an individual has with their voices

1.5. The DAIMON Scale. A 28-item self-report measure assessing how an individual relates to a voice hearing experience

## 2. Anxiety and Depression:

2.1. Generalised Anxiety Disorder (GAD7). A 7-item self-report anxiety measure

2.2. Physical Health Questionnaire (GAD9). A 9-item self-report measure of depression

## 3. Dissociation:

3.1. Dissociative Experience Scale (DES). 28-item self-report measure

## 4. Wellbeing

4.1. Warwick Edinburgh Mental Wellbeing Scale (WEMWB) - 14 item self-report measure

4.2. Self Compassion Scale (SCS) – a 12 item self-report measure

## Overall study start date

01/05/2015

## Completion date

31/12/2016

# Eligibility

## Key inclusion criteria

Participants will be eligible if they:

1. Report currently distressing voices as determined by a rating of 2 or above on the 'Intensity of Distress' item on the PSYRATS scale

2. Has had recorded contact and treatment from mental health services at the point of recruitment

3. Aged 18-65

4. No significant history of organic, or drug/alcohol factors implicated in the aetiology of psychotic symptoms

5. English speaking

6. Provides informed patient consent

7. Not receiving care from a learning disability service

8. Has a fixed abode. Having a fixed abode is operationalised as having a current address (including B&B or open access hostel) and evidence (e.g. from key worker) indicating that the person is more likely than not to have a reliable address throughout the 2 years. Although the exclusion of those with no fixed abode may limit the sample, this is a necessary restriction to avoid inevitable sample attrition from this group

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

65 Years

## Sex

Both

**Target number of participants**

15

**Total final enrolment**

15

**Key exclusion criteria**

1. Unable to provide informed consent
2. Unable to communicate sufficiently in English
3. Of no fixed abode

**Date of first enrolment**

01/05/2015

**Date of final enrolment**

31/12/2015

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Berkshire Healthcare Foundation Trust**

Fitzwilliam House

Skimped Hill Lane

Bracknell

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RG12 1BQ

## **Sponsor information**

**Organisation**

Berkshire Healthcare Foundation Trust

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/03t542436>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

University of Reading

**Alternative Name(s)**

UoR

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	02/01/2019	26/06/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No