ISRCTN54370851 https://doi.org/10.1186/ISRCTN54370851

Making sense of voices

Submission date
26/06/2015

Recruitment status
No longer recruiting

Registration date
08/07/2015

Overall study status
Completed

Last Edited
26/06/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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Sponsor information

Organisation
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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?
Results article	results	02/01/2019	26/06/2020	Yes	No
HRA research summary			28/06/2023	No	No