

Mindfulness-based therapy groups for people distressed by hearing Voices

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| Submission date 16/01/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 16/01/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 19/12/2017 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

This study aims to investigate the effectiveness of a psychological treatment that uses mindfulness meditation within group-based therapy to help people diagnosed with schizophrenia who hear voices. People diagnosed with schizophrenia often hear voices. Although for some hearing voices is comforting, for others it causes distress, low self-esteem and social isolation. Mindfulness meditation has been adapted by Professor Paul Chadwick's research team for people who hear voices and focuses on helping people to learn new ways of managing and living with their voices. The treatment incorporates elements of cognitive behavioural therapy (CBT) but emphasises the principles and practices of mindfulness meditation. In a previous study mindfulness-based therapy (MBT) groups were found to be beneficial as voice hearers reported less distress, improved personal control and improved psychological health.

Who can participate?

Service users aged 18 or over who have been diagnosed with schizophrenia or schizoaffective disorder and are distressed by hearing voices.

What does the study involve?

Participants are randomly allocated to one of two groups. One group receives mindfulness-based therapy (MBT) offered in a group format over a 12-session period (each group will contain a maximum of 12 service users). The other group receives the treatment they usually receive from their mental health teams. Participants' psychological health, distress and personal control are assessed at the start of the study, after treatment and at six months follow-up.

What are the possible benefits and risks of participating?

If mindfulness therapy is found to be effective then support will be offered to mental health teams to provide group therapy to people.

Where is the study run from?

University of Surrey (UK).

When is the study starting and how long is it expected to run for?
November 2011 to November 2012.

Who is funding the study?
National Institute of Health Research (NIHR) (UK).

Who is the main contact?
Leanne Bogen-Johnston
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11045

Study information

Scientific Title
Mindfulness-based therapy groups for people distressed by hearing Voices: a pragmatic randomised controlled trial

Acronym
M4V

Study objectives
The study aims to evaluate the therapy using a more robust, randomised controlled design. It aims to recruit 144 mental health service users who are distressed by hearing voices.

More details can be found at <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11045>

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South East Coast - Brighton and Sussex, First MREC approval date 08/09/2011, ref: 11/LO/1330

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network; Subtopic: Psychosis; Disease: Psychosis

Interventions

Participants will be allocated at random to either attending a 12 session mindfulness for voices group or to continuing with their usual mental health care.

Follow Up Length: 6 month(s); Study Entry : Single Randomisation only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Psychological wellbeing (CORE)
2. Mindfulness skills (Southampton Mindfulness Questionnaire)
3. Anxiety and depression [Hospital Anxiety and Depression Scale (HADS)]
4. Self-esteem (Rosenberg Self-esteem Scale)
5. Recovery from psychosis (CHOICE)

Timepoint(s): At 6 months

Secondary outcome measures

Fewer Voices, voice hearing experiences (Psychotic Symptom Rating Scales (PSYRATS);
Timepoint(s): At 6 months

Overall study start date

15/11/2011

Completion date

09/11/2012

Eligibility

Key inclusion criteria

1. Is aged 18 years or over
 2. Has been experiencing distressing voices for the preceding one year period
 3. Has a current International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD 10) diagnosis of schizophrenia or schizo-affective disorder
- Target Gender: Male & Female; Upper Age Limit 75 years ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 144; UK Sample Size: 144

Key exclusion criteria

1. Organic illness
2. Primary diagnosis of substance misuse

Date of first enrolment

15/11/2011

Date of final enrolment

09/11/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Surrey

Guildford

United Kingdom

GU2 7XH

Sponsor information

Organisation

Sussex NHS Research Consortium (UK)

Sponsor details

Research & Development Department

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Sponsor type

Government

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit Programme (RFPB)

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

Not provided at time of registration

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 | 01/08/2016 | | Yes | No |