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Mindfulness-based therapy groups for people distressed by hearing Voices

Submission date
16/01/2012

Recruitment status
No longer recruiting

Registration date
16/01/2012

Overall study status
Completed

Last Edited
19/12/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 mediation 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

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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