# Mindfulness-based therapy groups for people distressed by hearing Voices

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
16/01/2012	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/01/2012	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
19/12/2017	Mental and Behavioural Disorders			

## 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 Leanne.Bogen-Johnston@sussexpartnership.nhs.uk

# **Contact information**

## Type(s)

Scientific

#### Contact name

Dr Clara Strauss

#### Contact details

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# Additional identifiers

Protocol serial number 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

# Study type(s)

Treatment

#### 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(s)

- 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

## Key secondary outcome(s))

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

# 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** 

## Healthy volunteers allowed

No

### Age group

Adult

# Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

England

# Study participating centre University of Surrey Guildford

Guildford United Kingdom GU2 7XH

# Sponsor information

# Organisation

# 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**

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes