

Mindfulness for paranoia

Submission date 19/12/2016	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 03/01/2017	Overall study status Completed	☐ Protocol
Last Edited 24/05/2018	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Schizophrenia is a long-term mental health condition that affects how a person thinks, feels and behaves. Many people with a diagnosis of Schizophrenia experience persecutory delusions, thinking that other people are intentionally trying to harm or kill them. Persecutory delusions are often associated with high levels of depression and distress. Treatments that use mindfulness, a type of meditation which helps people to become more aware of themselves and their surroundings, are being used to help people with mental health problems. Until recently, these treatments have rarely been made available to people with a diagnosis of schizophrenia, despite the significant level of need within this group. This study is looking at a mindfulness-based group therapy programme which has been developed for people who hear distressing voices. This small scale study aims to find out whether it would be possible to conduct a full scale study by looking at the effectiveness of the mindfulness treatment as well as how many patients can be recruited and take part in the entire study.

Who can participate?

Adults with a diagnosis of schizophrenia, experiencing current distressing persecutory delusions

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in 12 sessions of group therapy which are run by two therapists. Each session lasts for an hour and a half and involves exploring what leads to paranoia and how to avoid it using established mindfulness techniques. Those in the second group continue to receive the usual treatment offered within their community mental health recovery services, and may involve medication and support and contact from a key worker. At the end of the study, the number of participants who took part and the number who stayed in the study all the way through are recorded. In addition, participants complete a number of questionnaires at the start of the study and after 12 weeks in order to assess their mental wellbeing.

What are the possible benefits and risks of participating?

The therapy group used in this study is a new type of therapy group and so it is not known whether or not it will be helpful. Talking therapies can sometimes involve talking about feelings, thoughts or experiences which may be upsetting at times. This is a completely normal part of therapy and the therapists are very experienced in keeping this to a level you can manage. For the research assessments, there are no right or wrong answers and participants do not have to

answer any questions they do not want to. Participants are free to ask the interviewer to move on to another subject or to stop the session altogether if they find any of the questions upsetting. By taking part in the study participants will be helping the researchers to learn if this therapy is helpful for people with distressing paranoia and this will help mental health services when they are planning what therapies they offer.

Where is the study run from?

1. Community Mental Health Recovery Service: Woking (UK)
2. Community Mental Health Recovery Service: Runnymede (UK)
3. Community Mental Health Recovery Service: Guildford (UK)

When is the study starting and how long is it expected to run for?
December 2016 to November 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Eryna Tarant
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
31912

Study information

Scientific Title
Group mindfulness-based therapy for distressing persecutory delusions: A pilot study for a randomised controlled trial

Study objectives

The aim of this study is to test the feasibility of conducting a full scale randomised controlled trial comparing the effectiveness of group mindfulness-based therapy (MBT) plus treatment as usual for individuals distressed by persecutory delusions with treatment as usual (TAU) alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East Coast – Surrey Research Ethics Committee, 18/10/2016, ref: 16/LO/1685

Study design

Randomised; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Qualitative

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Mental Health, Primary sub-specialty: Psychosis - schizophrenia; UKCRC code/ Disease: Mental Health/ Schizophrenia, schizotypal and delusional disorders

Interventions

After baseline assessments have been completed, participants will be randomly allocated to either one of two groups by the Clinical Trials Unit at King's College London using block randomisation.

Intervention group: Participants will receive the manualised mindfulness-based group intervention (MBT). This involves taking part in mindfulness-based group therapy, conducted over 12 1.5-hour-long group sessions. The sessions will explore, through participants' experience, how rumination, interpersonal beliefs and avoidance help to maintain paranoia, and key mindfulness principles of acceptance, self-compassion and turning towards the difficult will be used to target these maintenance processes and to support behaviour change in relation to paranoia.

Control group: Participants will receive the usual treatment offered within their community mental health recovery services (CMHRS). This involves psychiatric consultation and medication, and regular support and contact with a key worker.

Follow up takes place at the participants CMHRS base and involves participants completing the post-group assessments, which are identical to the assessments completed prior to the Mindfulness Intervention or TAU. Participants who have completed the intervention will be invited to complete a qualitative interview which will include questions on the implementation and acceptability of the intervention.

Intervention Type

Other

Primary outcome(s)

Current primary outcome measures as of 24/05/2018:

1. Depression is measured using Beck Depression Inventory II (Beck et al, 1996) at baseline and 12 weeks
2. Psychotic symptoms are measured using the Psychotic Symptoms Rating Scale (PSYRATS): Delusions subscale at baseline and 12 weeks

Previous primary outcome measures:

1. Depression is measured using Beck Depression Inventory II (Beck et al, 1996) at baseline and 12 weeks
2. Recruitment rate is recorded as the number of participants consented to the study per research assistant days, measured at trial end
3. Retention rate is recorded as the number of participants contributing to all data collection points (providing full baseline and post-group data) at 12 weeks. The number of participants classified as completers (attended at least 6 mindfulness sessions) will also be reported

Key secondary outcome(s)

Current secondary outcome measures as of 24/05/2018:

1. Recruitment rate is recorded as the number of participants consented to the study per research assistant days, measured at trial end.
2. Retention rate is recorded as the number of participants contributing to all data collection points (providing full baseline and post-group data) at 12 weeks. The number of participants classified as completers (attended at least 6 mindfulness sessions) will also be reported

Previous secondary outcome measures:

1. Quality of Life is measured using the World Health Organisation Quality of Life-Bref (WHOQOL-BREF) at baseline and 12 weeks
2. Psychotic symptoms are measured using the Psychotic Symptoms Rating Scale (PSYRATS): Delusions subscale at baseline and 12 weeks
3. Progress towards recovery is measured by The Choice of outcome in CBT for Psychosis (CHOICE) at baseline and 12 weeks

Completion date

30/11/2018

Eligibility

Key inclusion criteria

1. Diagnosis of schizophrenia, and be experiencing current distressing persecutory delusions (assessed using the PSYRATS)
2. Stable on psychiatric medication for at least three months prior to the consent meeting
3. No plans for changes to psychiatric medication during the course of the study
4. Not received psychological therapy in the past three months or to have any plans for psychological therapy during the course of the study
5. Aged over 18 years of age
6. Able to provide informed consent to take part

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Participants will not have an identified organic cause for their symptoms
2. Diagnosis of a learning disability.
3. Participants with a significant risk of violence to others.

Date of first enrolment

19/12/2016

Date of final enrolment

31/03/2018

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Community Mental Health Recovery Service: Woking**

Bridgewell House
Claremont Avenue
Woking
United Kingdom
GU22 7SF

Study participating centre**Community Mental Health Recovery Service: Runnymede**

Lake House
St Peter's Hospital Site
Guildford Road
Chertsey
United Kingdom
KT16 0QA

Study participating centre
Community Mental Health Recovery Service: Guildford
Redwood Centre
Farnham Road Hospital
Farnham Road
Guildford
United Kingdom
GU2 7LX

Sponsor information

Organisation
Surrey and Borders Partnership NHS Foundation Trust

ROR
<https://ror.org/00f83h470>

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No