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Mindfulness for paranoia

Submission date
19/12/2016

Recruitment status
No longer recruiting

Registration date
03/01/2017

Overall study status
Completed

Last Edited
24/05/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] 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 mediation 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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Ms Eryna Tarant

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

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
England

United Kingdom

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

Sponsor details
18 Mole Business Park
Randalls Road
Leatherhead
England
United Kingdom
KT22 7AD

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
1. The study findings will be disseminated to both local (e.g. Forum of Carers & People who use services, FoCUS, in SABP) and national (e.g. National Paranoia Network) service user and carer organisations to ensure the research outcomes are accessible to people with lived experience of paranoia. This will involve both written material and oral presentations. Results from the pilot study will be published in a high-impact peer reviewed academic journal, such as British Journal of Clinical Psychology, or Psychiatry Research. Results from the full trial will be submitted to the British Journal of Psychiatry. A paper from the pilot study will be submitted for presentation at the British Association of Behavioural and Cognitive Psychotherapy conference in 2018.
2. A written report will be produced in collaboration with Peter Jones for the National Paranoia Network, a service-user led organisation that aims to raise awareness of how disabling paranoia can be, for posting on their website. This will be cautious in tone given that definitive conclusions cannot be drawn from this pilot study.
3. Several seminars will be held in Surrey & Borders Partnership in order to present the findings of the pilot study and plans for the full trial. This will include presentations at the R&D department's annual research day, to the FoCUS service user forums, and at the Mental Health Clinical Academic Group.
4. A summary of study findings will be written for distribution to all study participants. This will be written jointly between Paul Chadwick and Peter Jones

Intention to publish date

31/12/2018

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