ISRCTN16318074 https://doi.org/10.1186/ISRCTN16318074

Mindfulness for paranoia

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2025	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/02/2025	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/02/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people with schizophrenia experience distressing persecutory delusions (thinking other people are deliberately trying to harm them) and have high levels of depression. Talking therapies that include mindfulness, a type of meditation practice, are being used to help people with mental health difficulties. In our previous study, we found encouraging signs that mindfulness might be helpful for people with persecutory delusions. We found that 96% of people who agreed to take part stayed in the study until the end and everyone who received mindfulness therapy finished it. 64% showed a reduction in depression after finishing the therapy. These findings suggest that mindfulness therapy could be helpful, but we now need to conduct a bigger study (called a clinical trial) to find out if the therapy will help people with schizophrenia and persecutory delusions.

Who can participate?
144 individuals with schizophrenia and persecutory delusions will participate in the study. 72 people will receive group mindfulness therapy and their usual clinical care, and 72 will receive their usual care only. A secure online system will decide randomly who will receive the therapy and who will receive their usual care only.

What does the study involve?
All participants will fill out questionnaires at the start of the study, after therapy and at follow up. Participants will either receive a group mindfulness-based therapy alongside their usual clinical care, or their usual clinical care only. Comparing the groups will tell us whether the therapy group reduces depression and distress, improves psychological health and mindfulness, and results in greater progress towards recovery. We will also discover how the therapy works, who might benefit from it the most and whether the therapy is good value for money for the NHS.

What are the possible benefits and risks of participating?
As this is the first full trial of mindfulness therapy with this clinical group, we do not yet know whether the mindfulness-based group therapy will be more helpful than usual clinical care. There are few anticipated adverse outcomes of taking part in the study, though we will monitor this carefully throughout the study. The information sheet makes it clear that talking about

thoughts and feelings within therapy can sometimes be difficult for people, but that this is a normal part of the process and the therapists are skilled and experienced in keeping this to a manageable level for people.

Where is the study run from?
The study is hosted by Hampshire and Isle of Wight NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
March 2024 to March 2027

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (UK).

Who is the main contact?
Professor Lyn Ellett, L.A.Ellett@soton.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Lyn Ellett

ORCID ID
http://orcid.org/0000-0002-6051-3604

Contact details
School of Psychology, University of Southampton
Southampton
United Kingdom
SO17 1BJ
+44 2380 599599
l.a.ellett@soton.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327504

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55888, NIHR206786

Study information

Scientific Title
Mindfulness therapy for persecutory delusions: A randomised controlled trial

Study objectives
Compared with treatment as usual (TAU), group mindfulness therapy + TAU will result in a significant reduction in depression immediately after the intervention (4 months post randomisation).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/03/2024, London – Bromley Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8124; bromley.rec@hra.nhs.uk), ref: 24/LO/0141

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Other therapist office

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Paranoia

Interventions
Design
Randomised Controlled trial, randomising 144 participants to either a 10-week group mindfulness therapy alongside their usual treatment (n=72) or treatment as usual alone (n=72).

Measures
Participants will complete the following measures at baseline, after the therapy (4 months post-randomisation), and at follow-up (8 months post-randomisation):
- Patient Health Questionnaire 9
- GAD-7
- Recovery Assessment Scale
- Psychotic Symptoms Rating Scales - Delusions & Hallucinations Subscales

- Southampton Mindfulness Questionnaire
- Trait Forgivingness Scale
- EQ-5D-5L
- ReQol-10
- UCLA Loneliness Scale
- CSRI

A participant feedback survey will also be designed with our PPIEP group.

Procedure
The study will run in Hampshire and Isle of Wight NHS Foundation Trust, Greater Manchester Mental Health NHS Foundation Trust, and Pennine Care NHS Foundation Trust. The step-by-step procedure is outlined below:

1. Information about the study will be sent to clinical teams.
2. Eligible participants will be identified by clinical teams in all Trusts, e.g., Community Mental Health Teams and Early Intervention in Psychosis Teams.
3. Potential participants will be given the participant information sheet and will be able to discuss with the research team if they have any questions. Participants will be given at least 24 hours to decide if they would like to participate. Following confirmation of participation, all participants will sign the consent form.
4. Baseline assessments will then be undertaken within four weeks of the groups starting, using the measures outlined above. Participants will be given the option of completing paper and pencil versions of the questionnaires, or completing them online using Qualtrics.
5. After baseline assessments have been completed, participants will be randomly allocated to either mindfulness therapy or TAU. Randomisation will be overseen by Queen Mary University of London Clinical Trials Unit. Participants will be recruited in cohorts of 20 in each site, and within each cohort, half will be randomised to treatment as usual, and half to mindfulness therapy alongside treatment as usual.
6. The therapy groups will be jointly facilitated by two qualified clinicians, following our 10-session manualised protocol. Each session will last for one and a half hours. Clinicians have already attended a 2-day training workshop on the therapy protocol.
7. Post-group assessments will be conducted, again using paper/pencil at the end of the final group session, or online using Qualtrics, depending on individual preference.
8. Follow-up assessments will be conducted, again using paper/pencil or online using Qualtrics, approximately 8 months post-randomisation.

Therapy Protocol
Mindfulness group therapy will be conducted over 10 group sessions; each session will be 1.5 hours in duration. Consistent with the manualised protocol, each group will have two therapists who have already received training on delivery of the therapy. Weekly supervision will also be provided. Mindfulness meditation will be practiced at all 10 sessions, and home practice will be supported through audio guided meditations. 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.

Treatment as Usual (TAU)
Individuals randomised to TAU will receive the usual treatment offered within their clinical

teams. This typically involves psychiatric consultation and medication, and regular support and contact with a key worker. Electronic patient records will be accessed to record the number and type of contacts with psychiatrists and key workers for each participant in the study.

Intervention Type
Behavioural

Primary outcome measure
Depression – measured by the PHQ9 at baseline, after the therapy (4 months post-randomisation), and at follow-up (8 months post-randomisation)

Secondary outcome measures
At baseline, post therapy (approx. 4 months post randomisation) and follow up (approx. 8 months post randomisation):
1. Recovery – measured by the Recovery Assessment Scale
2. Anxiety – measured by the GAD-7
3. Psychotic symptoms – measured by the PSYRATS
4. Forgiveness – measured by the Trait Forgivingness Scale
5. Loneliness – measured using the UCLA Loneliness Scale (3-item version)
6. Mindfulness – measured by the Southampton Mindfulness Questionnaire
7. Health economic measures – including CRSI, EQ-5D-5L, and ReQOL-10

Overall study start date
04/03/2024

Completion date
01/03/2027

Eligibility

Key inclusion criteria
1. Have a diagnosis of a Schizophrenia Spectrum Disorder, or attending an Early intervention in Psychosis Service, and be experiencing current distressing persecutory delusions (confirmed by clinical team psychiatrist).
2. Be aged over 18 years of age.
3. Be 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: 144; UK Sample Size: 144

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
01/09/2024

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hampshire and Isle of Wight Healthcare NHS Foundation Trust
Tatchbury Mount Hospital
Calmore
Southampton
United Kingdom
SO40 2RZ

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Sponsor information

Organisation
University of Southampton

Sponsor details
University Road
Southampton
England
United Kingdom
SO17 1BJ
+44 2380 595058
rgoinfo@soton.ac.uk

Sponsor type
University/education

Website
http://www.southampton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trial protocol will be published.
The findings in relation to effectiveness, mediators and moderators and cost effectiveness will be reported in scientific journals and will be presented at a number of conferences.
A plain English summary of the findings will be co-produced in a written and video format with our PPIEP group and we plan to write a paper on PPIEP in the study so that other people can benefit from our experiences.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
Reasonable requests for access to the data will be considered by the chief investigator (Professor Lyn Ellett, L.A.Ellett@soton.ac.uk) subject to ethical constraints and following publication of the main findings. A summary of the proposed study for which the data are requested will be required and a data sharing agreement.

IPD sharing plan summary
Available on request