

Mindfulness for paranoia

Submission date 27/01/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/02/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/11/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

327504

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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 Forgiveness 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

0

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

United Kingdom

England

Study participating centre

Hampshire and Isle of Wight Healthcare NHS Foundation Trust

Tatchbury Mount Hospital

Calmore

Southampton

England

SO40 2RZ

Study participating centre

Greater Manchester Mental Health NHS Foundation Trust

Prestwich Hospital

Bury New Road

Prestwich

Manchester

England

M25 3BL

Study participating centre

Pennine Care NHS Foundation Trust

225 Old Street

Ashton-under-lyne

England

OL6 7SR

Sponsor information

Organisation

University of Southampton

ROR

Funder(s)

Funder type

Government

Funder Name

Research for Patient Benefit Programme

Alternative Name(s)

NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/11/2025	28/11/2025	Yes	No