

# Mindfulness for paranoia

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<b>Registration date</b> 07/02/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/02/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Prof Lyn Ellett

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## 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 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 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

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**Study participating centre**

**Pennine Care NHS Foundation Trust**

225 Old Street

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# Sponsor information

## Organisation

University of Southampton

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## Sponsor type

University/education

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## 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