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Social Mind: improving social functioning in first episode psychosis

Submission date
30/01/2024

Recruitment status
Recruiting

Registration date
02/02/2024

Overall study status
Ongoing

Last Edited
03/09/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Mental health and social life are intrinsically connected. People with a first episode of psychosis (FEP) experience high levels of social stress, but none of the existing psychological interventions for psychosis focus on social stress. This study will involve testing the feasibility of implementing Social Mind, a new psychological intervention aimed at helping patients understand and manage social stress, minimising the risk of social withdrawal and promoting social functioning. This is achieved by combining the cognitive appraisal of social stress and an active behavioural component involving real-life situations. Social Mind was co-developed by a diverse team including lived experience experts, mental health professionals and academics.

Who can participate?
Participants aged 18 years and over who have received a diagnosis of first-episode psychosis will be recruited via early intervention services for psychosis in two NHS Foundation Trusts: South London and Maudsley (SLaM) and Central and North West London (CNWL).

What does the study involve?
Participants are randomly allocated to receive Social Mind + Treatment as Usual (TAU) or TAU. Outcomes will assess the feasibility and acceptability of recruitment methods; the acceptability of assessment measures, intervention mode and intervention delivery; treatment fidelity; follow-up rates; and estimates of sample size parameters. The researchers will use this information to inform a full-scale randomised controlled trial.

What are the possible benefits and risks of participating?
Participants will receive a new psychosocial intervention which could help minimise social stress and improve social functioning. Following full validation, this study could lead to a new evidence-based intervention for improving social functioning in people with FEP. This would reduce the burden of the illness on service users, their families and clinical services.

Where is the study run from?
Institute of Psychiatry, Psychology & Neuroscience, King's College London (UK)

When is the study starting and how long is it expected to run for?
October 2023 to April 2027

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof. Andrea Mechelli, a.mechelli@kcl.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
329378

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 329378, CPMS 56467

Study information

Scientific Title
A feasibility randomised control trial of Social Mind: a brief targeted intervention for reducing social stress and improving social functioning in first episode psychosis

Acronym
Social Mind

Study objectives
Participants engaging in the Social Mind Intervention will demonstrate statistically significant reductions in social stress, psychosis symptoms, anxiety, and depression as well as improvements in social functioning compared to the treatment as usual (TAU) group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/06/2024, London - Hampstead REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8345; hampstead.rec@hra.nhs.uk), ref: 24/LO/0363

Study design
Feasibility randomized control trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
First episode psychosis

Interventions
People with first-episode psychosis will be randomised into one of two intervention arms: the Social Mind CBT intervention or Treatment as Usual (TAU)

Treatment arm 1: Social Mind Intervention + Treatment As Usual
Treatment arm 2: Treatment As Usual

Social Mind Intervention:
Social Mind is a psychosocial intervention based on Cognitive Behaviour Therapy (CBT) principles aimed at reducing social stress and improving social functioning in people with a first episode of psychosis. It comprises six one-to-one face-to-face sessions with a therapist. Each session is 60 minutes in duration and occurs once a week for 6 weeks.

Session 1: Engagement & Assessment. Expected outcomes: engagement with therapist, goal identification, psychosocial stressors, appraisals, and coping

Session 2 & 3: Appraisal of Stress & formulation development. Expected outcomes: formulation development, and starting to reappraise psychosocial stressors.

Session 4 & 5: Behavioural Experiments: Expected outcomes: Introduce behavioural experiments to address psychosocial stressors, and introduce more adaptive ways of coping.

Session 6: Review and Summarize. Expected outcomes: Consolidate learning, summarize the work, and devise a relapse prevention plan.

Treatment As Usual:
Participating NHS Trusts are implementing treatment as usual based on NICE guidelines, which involves the combination of antipsychotic medication and Cognitive Behavioural Therapy for Psychosis (CBTp) with or without Family Intervention. While this provides some degree of consistency, there will still be variation in TAU, for example when a patient declines one or more treatments offered to them. To assess such variation the researchers will monitor participants in both allocation groups for the following: antipsychotic medication and dosage; antidepressant medication and dosage; recipient of CBT and number of sessions; recipient of Family Intervention and number of sessions.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rates measured in terms of the number of eligible participants who consent to participate in the study over a 14-month period
2. Follow-up rates measured in terms of the number of enrolled participants who take part in the 6-month follow-up
3. Acceptability will be assessed at the end of the last treatment sessions using the Treatment Acceptability Rating Form-Revised (TARF-R), consisting of 21 items on a seven-point Likert-type scale. In addition, qualitative data will be used to gain insight into why the trial was or was not acceptable to participants and how this aspect of the intervention could be enhanced in a full trial.
4. Safety will be assessed in terms of the frequency of adverse events. These will be monitored in terms of occurrence and severity throughout the trial using an unstructured log. This information will be collected from the clinical teams and retrospectively from the patient at each follow-up.
5. Treatment fidelity will be measured using the Revised-Cognitive Therapy for Psychosis Adherence Scale after each therapy session (a total of six times)
6. Estimates of sample size parameters for a subsequent full trial to be computed using standard power calculations at 6-month follow-up

The researchers will use this information to refine the intervention and inform a subsequent full-scale randomised controlled trial (RCT)

Key secondary outcome(s))
All measured at baseline, 3 months and 6 months:
1. Social functioning will be measured using the World Health Organization Disability Assessment Schedule (WHODAS 2.0). A further measure of social functioning will be collected using the Social Functioning Questionnaire
2. Measures of psychopathology will be collected using the SCID-Psychotic Symptoms, PANSS; Patient Health Questionnaire; Generalised Anxiety Disorder scale
3. Measures of cognition will be collected using the Perceived Criticism and Warmth Scale; Brief COPE; Brief Core Schema Scale; Young Schema Questionnaire
4. Measures of social behaviour will be collected using the UCLA Loneliness Scale; Social Connectedness Scale; Multidimensional Support scale; Interpersonal Sensitivity Scale; Quality of Life Health Questionnaire; Revised Psychosis Attachment Measure, and Perceived Stress Scales

Completion date
01/04/2027

Eligibility

Key inclusion criteria
1. Participants who have received a diagnosis of first-episode psychosis using the Structured Clinical Interview for DSM-V Diagnosis
2. Having suffered from a first episode of psychosis (i.e. diagnosis received by an experienced clinician at the treating clinical team)
3. A minimum age of 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. More than one previous episode of psychosis
2. A first episode that began more than 24 months prior to recruitment

3. Insufficient comprehension of the English language
4. Learning disability based on clinical records

Date of first enrolment
01/06/2024

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Central & North West London NHS Trust
Brent Early Intervention Service
27-29 Fairlight Avenue
Harlesden
London
United Kingdom
NW10 8AL

Study participating centre
South London & Maudsley NHS Trust
Southwark Early Intervention Service (STEP Team)
Early Intervention
St Giles House
St Giles Road
London
United Kingdom
SE5 7UD

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust

ROR
https://ror.org/015803449

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and/or analysed during the current study will be stored within the King's College London computer drives - a non-publicly available repository.
The type of data stored: raw and processed data.
The process for requesting access (if non-publicly available): data can be requested via email to Prof. Andrea Mechelli (a.mechelli@kcl.ac.uk).
Dates of availability: the data will be made available once the results of the feasibility study are published (exact date to be confirmed).
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: following the completion of the study, the data will be stored and made available to the wider research community in a fully anonymised format.
Any ethical or legal restrictions: none.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request