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A mindfulness-based therapy to improve social functioning of people with severe mental illness

Submission date
14/11/2024

Recruitment status
No longer recruiting

Registration date
16/11/2024

Overall study status
Ongoing

Last Edited
18/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Serious mental illness (SMI) typically refers to diagnoses such as psychotic disorders, bipolar disorder, and personality disorders (when they result in severe functional impairment). These disorders are chronic in nature and are marked by significant limitations, with social functioning being one of the most profoundly affected domains. The MINDPSY project focuses on how to improve social functioning in SMI by comparing two treatment arms in a community setting. The first treatment arm is the Spanish National Health System recommended treatment (IRT): pharmacotherapy and cognitive-behavioural therapy. The second treatment arm is the same treatment improved with a mindfulness and acceptance-based intervention for persistent psychotic experiences (IRT+MABI). This kind of intervention applied to psychotic experiences in a community setting is feasible, can be combined with the treatment as usual, is more effective than the latter improving psychological well-being and executive functioning, and does not increase positive symptoms while reducing negative symptoms.

Who can participate?
Adult patients diagnosed with SMI

What does the study involve?
Participants will be randomly allocated to IRT or IRT+MABI. Both treatment arms will last for 18 weeks. Participants will be assessed before and after treatment starts, and two follow-up assessments are scheduled at 6 and 12 months after treatment completion. Therefore, the study will last for 18 months.

What are the possible benefits and risks of participating?
The potential benefits of participating in the study include improved social functioning in the community and an improvement in feelings of depression associated with the condition being studied. Based on our experience and previous research, there are no risks associated with participating in the study.

Where is the study run from?
The University of the Balearic Islands (Spain)

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

Who is funding the study?
The MINDPSY project is funded by the Spanish Ministry of Science and Innovation (PID2021-122987OA-I00).

Who is the main contact?
Dr Emilio López-Navarro, emilio.lopez@uib.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
PID2021-122987OA-I00

Study information

Scientific Title
Mindfulness and Acceptance-Based therapy for social functioning improvement in people experiencing persistent psychotic experiences: a randomized controlled clinical trial.

Acronym
MINDPSY

Study objectives
1. Both interventions will improve social functioning but IRT+MABI to a greater degree than IRT alone.
2. IRT+MABI will improve to a greater degree than IRT the overall clinical status of the participants.

3. Dispositional mindfulness will mediate the changes on social functioning by IRT+MABI, but not IRT.
4. There will be differences in the use of health services and prescription of drugs in favor of the IRT+MABI group in the different assessment moments after the end of treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/06/2023, Comitè d'Ética de la Recerca (Carretera Valldemossa, km 7.5, Palma, 07122, Spain; 971173000; caty.pou@uib.es), ref: 321CER23

Primary study design
Interventional

Study design
Pragmatic controlled randomized clinical trial

Study type(s)
Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied
Improvement of social functioning of people diagnosed with severe mental illness

Interventions
The project will use a pragmatic, controlled, randomized clinical trial, with pre-treatment, post-treatment, and follow-up assessments at 6 and 12 months after the end of the intervention.

Procedure and randomization
A clinical psychologist from the rehabilitation center will contact potential participants to schedule an interview to explain the details of trial participation and assess eligibility. Eligible participants will be invited to participate. Once informed consent is obtained, a randomization ID will be assigned to each participant and recorded in the clinical record form. A master randomization list will be created, accessible only to the Principal Investigator (PI).

Participant assessments will be conducted by a clinical psychologist blinded to the participant's group allocation. Following the assessment, the PI will use software to randomly assign participants to either IRT or IRT+MABI. To ensure strong external validity, the assessment and intervention protocols will be integrated into the participants' routines.

Treatment arms
1. Active control condition
The active control condition (IRT+CBTp) will comprise two components: Integrated Rehabilitation Treatment (IRT) and Cognitive Behavioral Therapy for psychosis (CBTp). IRT will include: 1) Pharmacological management, involving a psychiatrist monitoring each participant's medication every 15 days; and 2) Group-based psychoeducation, consisting of 18 weekly one-hour sessions focusing on managing SMI, strategies for preventing relapse and managing conflict, as well as social skills training with an emphasis on assertiveness.

The CBTp program will also consist of 18 weekly one-hour sessions. These sessions will cover the following content:

- Introduction to the A-B-C framework to understand how beliefs influence emotional and behavioral responses.
- Exploration of the meaning of beliefs, their logical structures, and the development of alternative beliefs.
- Testing both pre-existing and alternative beliefs generated during therapy.
Identification of the function of psychotic experiences and beliefs in participants' lives, along with the creation of a list of precipitating and protective factors.

2. Experimental condition
The experimental condition (IRT+MABI) will include two components: the same Integrated Rehabilitation Treatment (IRT) as in the control condition, plus a Mindfulness and Acceptance-Based Intervention (MABI).

The MABI program will be conducted over 18 weekly group sessions, covering the following content:

Sessions 1 to 3: These sessions aim to teach participants how to be present in the group and identify avoidance strategies. Mindfulness exercises will be used, and participants will receive instructions for home practice.
Sessions 4 to 6: The goal of these sessions is to promote cognitive defusion, fostering a different relationship with thoughts, auditory hallucinations, and delusions. Mindfulness exercises will be central to understanding that these experiences are mental constructs, learning to distinguish them from other internal experiences, and recognizing that the mind is trained from birth to generate verbal material (mental content) and treat it as truth.
Sessions 7 to 9: These sessions focus on addressing experiential avoidance and fostering acceptance. Through mindfulness exercises, participants will be guided to confront unwanted thoughts and emotions, recognize the ineffectiveness of avoiding these experiences in their personal lives, and introduce acceptance as an alternative response.
Sessions 10 to 12: These sessions will explore the concept of self as a consistent context that remains unchanged despite varying experiences. Experiential and mindfulness exercises will be used to emphasize that while the self remains constant, the content of experiences within it evolves. This approach aims to enhance participants' flexibility in responding to unwanted experiences and increase their willingness to engage in meaningful activities.
Sessions 13 to 15: Mindfulness exercises will be continued to reinforce cognitive defusion, alongside identifying the most valuable and meaningful domains in each participant's life.
Sessions 16 to 18: The final sessions will focus on fostering committed actions aligned with the identified meaningful domains. Participants will work on identifying barriers to acting in accordance with their goals, planning actionable strategies to achieve these goals, and generalizing the skills needed to maintain orientation toward meaningful goals beyond the completion of the protocol.

Intervention Type
Behavioural

Primary outcome(s)
Social functioning measured using the Personal and Social Performance scale (PSP) at pre-treatment, post-treatment, and 6 and 12 months after the end of the intervention

Key secondary outcome(s)
The following secondary outcome measures are assessed at baseline, post-treatment, 6 months and 12 months follow-up

1. Frequency and intensity of psychotic symptoms measured using the Positive and Negative Syndrome Scale (PANSS) interview
2. Relationship with positive psychotic symptoms measured using the Psychotic Symptom Rating Scales (PSYRATS) interview
3. Blunted affect, alogia, asociality, anhedonia, and avolition measured through the Brief Negative Symptom Scale (BNSS)
4. Depression symptoms measured with the Calgary Depression Scale (CDS)
5. Dispositional mindfulness measured using the Mindful Attention Awareness Scale (MAAS)

Added 18/07/2025:
6. Psychological flexibility assessed using the comprehensive assessment of Acceptance and Commitment Therapy processes (compACT) at baseline, post-treatment, 6 months and 12 months follow-up

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Diagnosis, according to clinical history, based on the DSM-5 criteria for Schizophrenia Spectrum and Other Psychotic Disorders or Bipolar disorder with psychotic features
3. No hospitalization for acute psychotic symptoms in the past month
4. Proficiency in understanding Spanish
5. Provision of informed consent, either by the participant or their legal guardian

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Presence of psychotic symptoms due to an organic condition
2. Inability to attend intervention sessions
3. Presence of a degenerative, severe infectious disease, or other neurological condition
4. Refusal to sign the informed consent by the participant or their legal guardian

Date of first enrolment
01/12/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
Spain

Study participating centre
UCR Son Serralta
C/ de Femenies 33
Palma
Spain
07013

Study participating centre
Asocación Girasol
Passatge Marratxí, 11
Palma
Spain
07008

Sponsor information

Organisation
Ministerio de Ciencia e Innovación

ROR
https://ror.org/05r0vyz12

Funder(s)

Funder type
Government

Funder Name
Ministerio de Ciencia e Innovación

Alternative Name(s)
CienciaGob, Ministerio de Ciencia e Innovación de España, Ministry of Science and Innovation, Spanish Ministry of Science and Innovation, Ministry of Science and Innovation of Spain, Spain, Ministry for Science and Innovation, Ministeri de Ciència i Innovació, MCIN, MICINN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The 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