

# The effects of metacognition-oriented social skills training (MOSST) on psychosocial outcomes in schizophrenia-spectrum disorders

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<b>Registration date</b> 30/11/2016	<b>Overall study status</b> Completed	
<b>Last Edited</b> 19/10/2017	<b>Condition category</b> Mental and Behavioural Disorders	

## Plain English summary of protocol

### Background and study aims

Schizophrenia spectrum disorders (SSD) are a serious mental health problems that affects how a person thinks, feels and behaves. It causes a range of psychological symptoms, including hallucinations (hearing and/or seeing things) and delusions (believing something that is not true). Impaired social functioning is one of the most characteristic symptoms of SSD and it has been widely described in the literature. Social skills-training (SST) is a well-validated treatment option, and it is recommended in several treatment guidelines for schizophrenia. However, many studies have found that the effects and generalizability of standard SST programs are poorer than desired regarding the benefits on social functioning of patients. For that reason, the main purpose of this study is to analyze the feasibility, effectiveness and potential benefits of a new Metacognition-Oriented Social Skills Training versus conventional SST in outpatients with schizophrenia-spectrum disorders.

### Who can participate?

Adults aged 18-65 years with Schizophrenia Spectrum Disorders from two partial hospitals of Navarre, a region located in the north of Spain.

### What does the study involve?

Over a period of 30 months eligible participants are invited to participate in this study. Participants finally included are randomly assigned to receive 16 group-sessions with MOSST plus treatment as usual (experimental group), or 16 group-sessions with conventional SST plus treatment as usual (control group). Participants allocated to the experimental group receive 16 weekly sessions of 90 minutes each with MOSST plus treatment as usual (TAU). This involves a group training in conversation skills, assertiveness skills, and conflict management skills. Throughout the MOSST sessions, participants carry out different role-playing exercises aimed at stimulating and developing the capacities to reflect on the thoughts, emotions, and intentions of others. Participants allocated to the control group receive 16 weekly sessions of 90 minutes each with standard SST plus treatment as usual (TAU). This involves a group training of the same social skills of MOSST but not stimulating and developing the metacognitive abilities of participants. At the start of the study and then again after 16 weeks (end of the programs) and

six months later, participants in both groups complete a range of questionnaires to assess their mental and social functioning.

What are the possible benefits and risks of participating?

There are no direct benefits or risks of participating.

Where is the study run from?

This study has been set up by the Complejo Hospitalario of Navarre in collaboration with the University of La Rioja.

When is study starting and how long is it expected to run for?

March 2014 to December 2016

Who is funding the study?

1. Complejo Hospitalario of Navarra (Spain)
2. University of La Rioja (Spain)

Who is the main contact?

1. Dr Felix Inchausti  
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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

NAVARRA\_MOSST\_2017

# Study information

## Scientific Title

The effects of Metacognition-Oriented Social Skills Training (MOSST) on psychosocial outcomes in schizophrenia-spectrum disorders: a single-blind randomized controlled trial

## Study objectives

The aim of this study is to analyze the feasibility, effectiveness and potential benefits of the Metacognition-Oriented Social Skills Training versus conventional Social Skills Training in outpatients with schizophrenia-spectrum disorders.

## Hypotheses:

1. The MOSST intervention provokes larger improvements on social and personal functioning than the conventional SST intervention
2. Only the intervention with MOSST enhances the metacognitive skills of participants

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Assistential and Research Ethics Committee of Benito Menni Hospital (HSC of Navarre), 01/06 /2014, ref: 0106/14

## Study design

Single-blind randomised controlled pilot trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

No participant information sheet available

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

Schizophrenia spectrum disorders

## Interventions

Participants will be randomly assigned (1:1) with permuted block sizes of three or five, to receive MOSST plus TAU (experimental group), or conventional SST plus TAU (control group). Social,

occupational and personal functioning, metacognitive abilities and clinical symptoms of participants will be assessed at baseline, post-treatment, and 6-month follow-up.

**Experimental group:** Participants will receive 16 sessions of MOSST plus treatment as usual (TAU) for 16 weeks. This involves 16-week sessions in which several social skills are targeted. The 16 target social skills have been divided into: (1) conversation skills such as listening to others, greeting others, starting and ending conversations, and maintaining conversations; (2) assertiveness skills such as making and refusing requests, making and receiving compliments, asking for information, suggesting activities to other people, and expressing unpleasant and positive feelings; (3) conflict management skills such as compromise and negotiation, making productive complaints, responding to negative complaints, and making apologies. MOSST employs role-playing exercises that seek to stimulate participants to develop greater capacities to reflect on the thoughts, emotions, and intentions of others. Compared to standard SST, MOSST offers several innovations: (1) MOSST seeks to promote a rich and articulated understanding of mental states necessary to act more effectively in social situations; (2) MOSST focuses on intersubjectivity, and thus, may promote change through thinking about the relationships in which patients and therapists are emotionally involved and contribute in their own way; (3) MOSST encourages therapists to use metacommunication in a technical way that is to speak openly about the mental states that they themselves experience during role-playing exercises with the patient

**Control group:** Participants will receive 16 sessions of standard SST plus TAU for 16 weeks. This involves 16-week sessions in which the same social skills and role-playing exercises of MOSST are trained but not developing and stimulating the metacognitive abilities of participants.

For both groups, all sessions will last approximately 90 minutes and will adhere to original protocol manuals. Sessions will be conducted by two Clinical Psychologists (doctoral level) with large experience in group therapy and who are versed in standard SST (control group) and metacognitive therapy (experimental group) for schizophrenia.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Metacognitive activity is measured using the Metacognitive Assessment Scale–Abbreviated (MAS-A) at baseline, 16 weeks, and 6 months
2. Social and occupational functioning controlling the influence of the clinical symptoms is measured using the Social and Occupational Functioning Assessment Scale (SOFAS) at baseline, 16 weeks, and 6 months
2. Functioning of patients in four areas independently of symptomatology (socially useful activities, personal and social relationships, self-care, and disturbing and aggressive behaviors) are measured using the Personal and Social Performance Scale (PSP) at baseline, 16 weeks, and 6 months

## **Secondary outcome measures**

1. Positive and negative symptoms of schizophrenia are measured using the Positive and Negative Syndrome Scale (PANSS) at baseline, 16 weeks, and 6 months
2. Depressive symptoms are measured using the Beck Depression Inventory–II (BDI-II) at baseline, 16 weeks, and 6 months
3. Anxiety is measured using the Beck Anxiety Inventory (BAI) at baseline, 16 weeks, and 6 months

**Overall study start date**

01/03/2014

**Completion date**

31/12/2016

## Eligibility

**Key inclusion criteria**

1. Aged between 18–65 years
2. Receiving psychosocial rehabilitation
3. Meet International Classification of Diseases–tenth revision (ICD–10) criteria for schizophrenia, schizoaffective disorder, or delusional disorder, as determined by trained Psychiatrists or Clinical Psychologists through clinical interview
4. Clinically stable
5. Treated with a stable dose of the same antipsychotic in the last 6 months
6. Score at least 4 on PANSS delusions or hallucinations, or at least 5 on suspiciousness or persecution, conceptual disorganization, or grandiosity

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

75

**Key exclusion criteria**

1. Concomitant substance abuse
2. Moderate to severe learning disabilities or developmental disorders
3. Non-Spanish-speaking participants
4. Major neurological illness
5. Impaired intellectual functioning (Wechsler Adult Intelligence Scale–IV Full Scale IQ score < 70)
6. Not having the capacity to consent to research participation

**Date of first enrolment**

01/06/2014

**Date of final enrolment**

31/12/2015

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

**CRPS Elizondo Benito Menni Hospital**

CL Mendinueta S/N, Planta Baja

Elizondo-Baztán

Navarra

Spain

31700

## **Sponsor information**

**Organisation**

Complejo Hospitalario of Navarra

**Sponsor details**

Centro de Salud Mental de Ermitagaña

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Pamplona

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31008

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/011787436>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Complejo Hospitalario of Navarra

**Funder Name**

University of La Rioja

# Results and Publications

## Publication and dissemination plan

Planned publication of study results in a peer reviewed journal.

## Intention to publish date

30/06/2017

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	12/06/2017		Yes	No