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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/11/2016		☐ Protocol		
Registration date 30/11/2016	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 19/10/2017	Condition category Mental and Behavioural Disorders	Individual participant data		

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 a 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?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

- 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

Key secondary outcome(s))

- 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 symtoms 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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?
Results article	results	12/06/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes