

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

preliminary evaluation of social skills training on symptom control and quality of life in patients with schizophrenia or schizo-affective disorder

Protocol summary

Summary

The aim of this study is to evaluate the efficacy of social skills training on symptoms and quality of life in patients with schizophrenia and schizoaffective disorder. Patients (males and females aged 18-65) with schizophrenia and schizoaffective disorder based on the DSM-IV-TR diagnostic criteria in the interview, whom will have the need to receive rehabilitation services, will be selected. These patients, will be in remission phase and will be treated, by conventional medications. Inclusion criterion: 1) men or women with schizophrenia or schizoaffective disorder (according to DSM IV-TR classification and interview) 2) 18-65 years old 3) At least fifth grade education 4) Being in remission (according to clinical judgment by psychiatrist, resident or faculty member and PANSS score) 5) being on medication 6) informed consent to participate in the study Exclusion criterion: 1) Age fewer than 18 or over 65 2) Presence of other psychiatric disorders (mood disorders, substance related disorder exception nicotine dependence in last year, anxiety disorders and obsessive compulsive disorder) 3) presence of any brain damage or neurological disorders or serious medical conditions 4) intellectual disability The sample size is 18. The benefits of attending educational sessions will be explained to patients and families and the written informed consent will be obtained. After that, preliminary assessment and history taking will be done by a trained psychologist and assessment by HDRS (Hamilton Depression Rating scale), PANSS (Positive and Negative Symptom Scale), GAF (global assessment of function) and WHO-QOL (World Health Organization-quality of life) will be done too. After the initial assessment, patients will participate in social skills training sessions twice a week for about an hour to an hour and a half. This training is based on Wallace method. The content of sessions are: listening, make a request, the skills for expression of pleasant and unpleasant emotions, criticizing, initiation of a conversation , maintaining the conversation , ending of

conversation, making conversation with unfamiliar person, the principles of conversations, find common ground and problem solving. These training will be taught, by a trained occupational therapist and a trained psychiatrist assistant, who were participated in social skills training workshops. Repetition, positive reinforcement and role playing, are the most common techniques which be used in this method. At the end of the 12 training sessions (after 6 weeks) and 3 months after the last session, re-evaluation with PANSS, GAF, HDRS, WHO-QOL and CSQ will be done again, by a trained psychologist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016043027691N1**

Registration date: **2016-10-30, 1395/08/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Zahra Mirsepassi

Name of organization / entity

Roobebeh Hospital- Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

preliminary evaluation of social skills training on symptom control and quality of life in patients with schizophrenia or schizo-affective disorder

Public title

Effect of social skills training in patients with schizophrenia or schizo-affective disorder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criterion: 1) men or women with schizophrenia or schizoaffective disorder (according to DSM IV-TR classification and interview) 2) 18-65 years old 3) At least fifth grade education 4) Being in remission (according to clinical judgment by psychiatrist, resident or academic member) 5) Being on medication Exclusion criterias: 1) Age fewer than 18 or over 65 2) Presence of other psychiatric disorders (mood disorders, substance related disorder exception nicotine dependence in last year, anxiety disorders and obsessive compulsive disorder) 3) Presence of any brain damage or neurological disorders or serious medical conditions 4) intellectual disability

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Medical School, Poorsina Street, 16 Azar Avenue, Tehran

City

Tehran

Postal code

1417613151

Approval date

2016-08-06, 1395/05/16

Ethics committee reference number

IR.TUMS.VCR.REC.1395-395

Health conditions studied**1****Description of health condition studied**

schizophrenia or schizoaffective disorder

ICD-10 code

F20, F25

ICD-10 code description

Schizophrenia, Schizoaffective disorders

Primary outcomes**1****Description**

positive symptoms

Timepoint

at the first and after termination of social skills training sessions(after 6 weeks) and 12 weeks after the last session

Method of measurement

positive and negative symptom scale

2**Description**

negative symptoms

Timepoint

at the first and after termination of social skills training sessions(after 6 weeks) and 12 weeks after the last session

Method of measurement

positive and negative symptom scale

3**Description**

quality of life

Timepoint

at the first and after termination of social skills training sessions(after 6 weeks) and 12 weeks after the last

session
Method of measurement
World Health Organisation-Quality Of Life

Secondary outcomes

1

Description

client satisfaction

Timepoint

after 6 weeks

Method of measurement

Client Satisfaction Questionnaire

2

Description

global patients performance

Timepoint

at the first and after termination of social skills training sessions(after 6 weeks) and 12 weeks after the last session

Method of measurement

Global Assessment of Function

3

Description

depression

Timepoint

at the first and after termination of social skills training sessions (after 6 weeks) and 12 weeks after the last session

Method of measurement

Hamilton Depression Rating Scale

Intervention groups

1

Description

patients will participate in social skills training sessions based on Wallace method. The frequency of sessions are twice a week and each session lasts for about an hour to an hour and a half. The content of sessions are: listening, make a request, the skills for expression of pleasant and unpleasant emotions, criticizing, initiation of a conversation , maintaining the conversation , ending of conversation, making conversation with unfamiliar person, the principles of conversations, find common ground and problem solving. These training will be taught, by a trained occupational therapist and a trained psychiatrist assistant, who were participated in social skills training workshops. Repetition, positive reinforcement and role playing, are the most common techniques.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Day center, Roozbeh Hospital

Full name of responsible person

Zahra Mirsepassi

Street address

South Kargar Ave, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Mirsepassi

Street address

Enghelab Avenue, Ghods street, Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Roozbeh Hospital, Tehran University of Medical Sciences

Full name of responsible person

Zahra Mirsepassi

Position

Psychiatrist, assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty