Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Roozbeh Hospital- Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 5541 1811
Email address
z-mirsepassi@sina.tums.ac.ir

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 professsor

Other areas of specialty/work

Street address

Roozbeh Hospital, South Kargar Avenue, Tehran, Iran

City

Tehran

Postal code
1333715914
Phone
+98 21 5541 4084
Fax
Email
zahesbanoo@yahoo.comz-mirsepassi@sina.tums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Day Center, Roozbeh Hospital, South Kargar Avenue, Tehran, Iran
City
Tehran
Postal code
1333715914
Phone
+98 21 5541 4084
Fax
Email
zahesbanoo@yahoo.comz-mirsepassi@sina.tums.ac.ir
Web page address

Person responsible for updating data

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
Street address
Roozbeh Hospital, South Kargar Avenue, Tehran, Iran
City
Tehran
Postal code
1333715914
Phone
+98 21 5541 4084
Fax
Email
zahesbanoo@yahoo.com, z-mirsepassi@sina.tums.ac.ir
Web page address

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