

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Randomized controlled trial of Social and Independent Living Skills Training on function and quality of life for Schizophrenic Patients

Protocol summary

Summary

The purpose of the study is to assess the efficacy of Social and Independent Living Skills Training package on patients with schizophrenia. This is a single blind study with randomized parallel group. The studied population consists of the schizophrenic patients met the requirements of the study (scoring 40 to 70 on GAF scale, not diagnosed with two conditions at the same time) who have been admitted at three outpatient and inpatient centers in the cities of Tehran and Mashhad. Considering the experience of a similar study, the size of the sample was decided to be 160 patients. The intervention for the experimental group is the Social and Independent Living Skills Training Package, including the clinical symptom management, medication, leisure management and basic communication skills. Moreover, the family members of the experimental group are provided, in separate sessions, with certain information concerning the training skills and problem solving. The intervention for the control group is occupational therapy services including group therapy, leisure time activities, art activities and structured activities. The intervention for both groups is conducted in group sessions at least three times a week at outpatient centers and five times at inpatient centers for 90 to 120 minutes per session. These interventions will commence in late upcoming November and will last 1.5 month at inpatient centers and three months at outpatient centers per patient. The expected outcome of the study would be a decrease in psychopathology, an increase in the patient's quality of life, increased satisfaction of the patient, increased global psychosocial functioning and reduced family burden in the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091414499N3**

Registration date: **2013-12-07, 1392/09/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-07, 1392/09/16

Registrant information

Name

Ashraf Karbalaee Nouri

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0037

Email address

nouri@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and Technology Deputy Office of University of Social Welfare and Rehabilitation Sciences, Ministry of Health and Medical Education.

Expected recruitment start date

2013-11-16, 1392/08/25

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized controlled trial of Social and Independent

Living Skills Training on function and quality of life for Schizophrenic Patients

Public title

The effects of living skills training on treatment of the patients with Schizophrenia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria 1 Informed willingness and consent of the patient for participation in the study. 2 Being Diagnosed with schizophrenia according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) criteria; however, after the active phase of illness. 3 Scoring between 40 and 70 on Global Assessment of Functioning (GAF). 4 Having been hospitalized at least for one time. 5 Ranging between 18 to 55 years old. 6 Living in the vicinity of the therapy center. 7 Being literate. 8 Living with family. Exclusion Criteria 1 Any known current drug dependence or abuse and mental retardation. 2 Seizure disorder requiring medication. 3 Serious psychotic disorders other than schizophrenia. 4 Clinically significant physical or neurological disorder. 5 Risk of harming himself/herself and others.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Eligible patients will be randomly allocated into two intervention and control groups. There is equal allocation of participants between arms. Eligible participants will be assigned by stratified balanced block randomization method with allocation concealment. The allocation lists will be generated independently by the trial statistician. This is a single blind study because patients are not blind to their treatment group. The assessors will not be selected from among the trainers or therapists.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Social Welfare and Rehabilitation Sciences

Street address

Koodakyar Dead-end, Daneshjoo Blvd, Evin.

City

Tehran

Postal code

1985713834

Approval date

2012-01-08, 1390/10/18

Ethics committee reference number

۲/۱۸۴۶۳/۸۰۱/۹۰/۱

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

f20-f21-f2

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

Primary outcomes

1

Description

Severity of Psychopathology

Timepoint

Before intervention, upon completion of intervention, and 6 months after completion of intervention

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

2

Description

Quality of life

Timepoint

Before intervention, upon completion of intervention, and 6 months after completion of intervention

Method of measurement

WHO-Quality of Life Questionnaire

Secondary outcomes

1

Description

Global Function

Timepoint

before intervention, upon completion of intervention, and 6 months after completion of intervention

Method of measurement

Global Assessment of Functioning

2

Description

Patient Satisfaction

Timepoint

Before intervention, upon completion of intervention, and 6 months after completion of intervention

Method of measurement

Client Satisfaction Questionnaire

3

Description

Drug Compliance

Timepoint

Before Intervention, upon completion of intervention, and 6 months after completion of intervention

Method of measurement

Drug Compliance Questionnaire

4

Description

Family Burden

Timepoint

Before intervention, upon completion of intervention, and 6 months after completion of intervention

Method of measurement

Experience of Caregiving Inventory

5

Description

Family Quality of Life

Timepoint

before intervention, upon completion of intervention, and 6 months after completion of intervention

Method of measurement

WHO-Quality of Life

Intervention groups

1

Description

Intervention for control group (occupational therapy): The control group will receive psychosocial services including group therapy (group discussion), leisure activities, arts and structured activities. Like the intervention group, the patients in the control group will attend occupational therapy sessions three times per week at outpatient centers and five times per week at inpatient centers, for 90 to 120 minutes per session.

Category

Rehabilitation

2

Description

The treatment for the intervention group is the

independent and social living skills package. These skills include medication and symptom management, leisure management and basic conversational skills. Also family members of the intervention group will participate, as a generalization agent, in separate sessions (four sessions) where they will be provided with information concerning learned skills as well as problem solving and home assignment. Moreover, the family will be contacted by phone (once a month) during the follow-up period (transition of skills to the home). Interventions will be conducted three times per week at outpatient centers and five times per week at inpatient centers, for 90 to 120 minutes per session.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Psychiatric Hospital

Full name of responsible person

Mona Esmaeeli

Street address

7th Km of Karaj Special Road, Azadegan Ring Road

City

Tehran

2

Recruitment center

Name of recruitment center

Hasti Rehabilitation Center

Full name of responsible person

Najmeh Najjaran

Street address

No.85, 2nd South Hamed St., Sajjad Blvd.

City

Mashhad

3

Recruitment center

Name of recruitment center

12 Farvardin Social Welfare Services Complex

Full name of responsible person

Mohammad Bagher Ghaemi

Street address

17 Shahrivar Blvd, Next to Shahid Fahmideh Park.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Deputy Office of University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Hassan Shakery

Street address
University of Social Welfare and Rehabilitation
Sciences, Koodakyar Dead-end, Daneshjoo Blvd, Evin.

City
Tehran

Grant name
129200

Grant code / Reference number
30318

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

Title of funding source
Research and Technology Deputy Office of University of
Social Welfare and Rehabilitation 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
University of Social Welfare and Rehabilitation
Sciences

Full name of responsible person
Ashraf Karbalaee Nouri

Position
Ph.D. student/faculty member

Other areas of specialty/work

Street address
Koodakyar Dead-end, Daneshjoo Blvd, Evin.

City
Tehran

Postal code
1985713834

Phone
+98 21 2218 0037

Fax

Email
nouri@uswr.ac.irashraf1345@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Social Welfare and Rehabilitation

Sciences

Full name of responsible person
Seyyed Ali Hosseini

Position
Ph.D.

Other areas of specialty/work

Street address
Koodakyar Dead-end, Daneshjoo Blvd, Evin.

City
TEHRAN

Postal code
1985713834

Phone
+98 21 2218 0123

Fax

Email
alihosse@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
University of Social Welfare and Rehabilitation
Sciences

Full name of responsible person
Ashraf Karbalaee Nouri

Position
phD student

Other areas of specialty/work

Street address
Koodakyar Dead-end, Daneshjoo Blvd, Evin.

City
Tehran

Postal code
1985713834

Phone
+98 21 2218 0037

Fax

Email
nouri@uswr.ac.irashraf1345@yahoo.com

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