Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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\۱۸۴۶۲\۸۰۱\۹۰\آ

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
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Person responsible for updating data

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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