

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Efficacy of psycho- social intervention for psychological burden in families of schizophrenic patients

Protocol summary

Summary

The aim the present study is to examine the efficacy of Psychosocial intervention for family burden in families with schizophrenic patients. The participants, who recruited via systematic random sampling, are consisting of 40 family members of schizophrenic patients referred to psychiatric clinics in Shiraz. Participants then divided to intervention and control groups randomly. Inclusion criteria are: 1- definite diagnosis of schizophrenia or schizo-affective disorder in patient; 2- a family member who lives with or be in-charge of the patient; 3- desire of family member for participating in study. Exclusion criteria are: 1- the diagnosis of learning disability in the family member; 2- diagnosis of personality disorders that could interfere intrusively with participation in intervention sessions. Psychosocial intervention consists of many interventions such as giving insight to family members about the nature and manifestations of schizophrenia, problem solving skills, life skills and communication inside the family. The participants in the intervention group will participate in 6 intervention sessions. In this study, independent variable is Psychosocial intervention which done by only one therapist and dependent variable is family burden in the two groups that will be measured before the intervention, immediately after, one month, six months and one year after finishing intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203129267N1**

Registration date: **2014-05-16, 1393/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-16, 1393/02/26

Registrant information

Name

Giti Setoodeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

setoodeh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2013-03-09, 1391/12/19

Expected recruitment end date

2014-03-10, 1392/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of psycho- social intervention for psychological burden in families of schizophrenic patients

Public title

Efficacy of psychosocial intervention for psychological burden in families of schizophrenic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- definite diagnosis of schizophrenia or schizo-affective disorders through a psychiatrist; 2- a family member who lives with patient and/or be responsible for caring the patient; 3- a family member who would like to attain and participate in psychosocial intervention and assign the consent form. Exclusion criteria: 1- learning disability diagnosed through a psychiatrist; 2- personality disorders diagnosed through a psychiatrist that could interfere with psychosocial intervention.

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The participants are recruited via systematic randomization sampling.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Shiraz University of Medical Sciences

Street address

Ethics Committee, Shiraz University of Medical Sciences, Zand Street, Beside Helal Ahmar, Shiraz, Iran

City

Shiraz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

91-01-08-4268

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20,F23,F2

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

Primary outcomes

1

Description

family burden

Timepoint

immediety, 1month, 6 months, 1 year after finishing the intervention.

Method of measurement

Family Burden Questionnaire

Secondary outcomes

1

Description

recurrence of the disorder

Timepoint

immediately, 1 month, 6 months, 1 year after finishing the intervention.

Method of measurement

examining the times of hospitalization

Intervention groups

1

Description

Intervention group will be assigned in 4 subgroups of 5 individuals, then will attend in 3 stages of psychosocial intervention. First stage contains 1 section in introducing the process. The second stage contains 3 psycho-educational sessions and the third stage contains 2 problem solving sessions. Psychosocial intervention consists of many interventions such as giving insight to family members about the nature and manifestations of schizophrenia, problem solving skills, life skills and communication inside the family.

Category

Rehabilitation

2

Description

Control group does not receive any intervention but they are monitored for comparing with the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebnesina Psychiatric Clinic

Full name of responsible person

Giti Setoodeh

Street address

Shiraz University of Medical Sciences

City

Shiraz

2

Recruitment center

Name of recruitment center

Hafez Psychiatric Clinic

Full name of responsible person

Fatemeh Fereiduni

Street address

Psychiatric Ward, Hafez Hospital, Abivardi Bluvare,
Shiraz, Iran.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of
Medical Sciences

Full name of responsible person

Gholamreza Hatam

Street address

Shiraz University of Medical Sciences, Nemazi Square,
Shiraz, Iran

City

Shiraz

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Giti Setoodeh

Position

MSc, Faculty member

Other areas of specialty/work**Street address**

Room 57, Third Floor, Fatemeh School of Nursing and
Midwifery, Nemazi Square, Shiraz, Iran.

City

Shiraz

Postal code**Phone**

+98 71 1647 4256

Fax**Email**

setoodeh@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Giti Setoodeh

Position

MSc, Faculty member

Other areas of specialty/work**Street address**

Room 57, Third Floor, Fatemeh School of Nursing and
Midwifery, Nemazi Square

City

Shiraz

Postal code**Phone**

+98 71 1647 4256

Fax

+98 71 1647 4252

Email

setoodeh@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Giti Setoodeh

Position

Faculty member, MSc

Other areas of specialty/work**Street address**

Room 57, Third Floor, Fatemeh School of Nursing and
Midwifery, Nemazi Square

City

Shiraz

Postal code

Phone

+98 71 1647 4258

Fax

Email

setoodeh@sums.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