

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of family members' psycho-educational intervention for on caregiver burdens and psychiatric symptoms in patients with schizophrenia in Shiraz, Iran

Protocol summary

Summary

The objective of this study was the investigation of the effectiveness of family psychoeducation in reducing patients' symptoms and on burden of family caregivers, and the relationship between these two aspects. A total of seventy Iranian outpatients with a diagnosis of schizophrenia disorder and their caregivers were randomly allocated into the experimental (n=35) or control groups (n=35) from Hafez and Ebnesina hospital in 2009. The patients in the experimental group received antipsychotic drug treatment and a psychoeducational program was arranged for their caregivers. The patients in the control group only received routine treatment. At the baseline, immediately post-intervention and one month later, validated tools were used to assess patients' psychological status and caregiver's burden.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809122812N1**

Registration date: **2011-07-25, 1390/05/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-25, 1390/05/03

Registrant information

Name

Farkhondeh Sharif

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research- Shiraz University of Medical Sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2009-12-22, 1388/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family members' psycho-educational intervention for on caregiver burdens and psychiatric symptoms in patients with schizophrenia in Shiraz, Iran

Public title

schizophrenic family members' psycho-education and its effect on patients psychiatric symptoms

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for the patients: a diagnosis of schizophrenia disorder according to DSM-IV criteria within the preceding 5 years, lack of any comorbidity, no any other mental illnesses. All caregivers who were invited to participate identified themselves as the primary caregiver with the greatest responsibility for providing care within the family, and they themselves

had not any known mental illness Exclusion criteria: the family's participation in another psychoeducational programs within the preceding year, caring for more than one family member with mental illness, substance abuse problem in the patient

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shiraz University of Medical Sciences

Street address

Beside red crescent organization, Zand Street,

City

Shiraz

Postal code

713451359

Approval date

2010-03-18, 1388/12/27

Ethics committee reference number

88-5007

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

Schizophrenia

ICD-10 code

F20, F29

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

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

psychological symptom

Timepoint

Before and immediately and one month after intervention

Method of measurement

by psychological symptom questionnaire

2**Description**

Family burden

Timepoint

before and immediately and one month after intervention

Method of measurement

family burden questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: receiving antipsychotic drug treatment as well as psychoeducational program was held for their caregivers

Category

Rehabilitation

2**Description**

Control group: routine care

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hafez Hospital

Full name of responsible person

Project coordinator

Street address

Abiverdi Blvd,

City

Shiraz

2**Recruitment center****Name of recruitment center**

Ebn Sina Hospital
Full name of responsible person
project coordinator
Street address
Ebne-Sina Hospital, Quran Gate
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Dabbaghmanesh
Street address
Central building of Shiraz University of Medical Sciences, Zand St.,
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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

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Person responsible for updating data

Contact

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