

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effectiveness of intervention based on family psycho-education in reducing expressed emotion, quality of life, mental health, Knowledge of disease on families of patients with schizophrenia and its impact on reducing positive and negative symptoms of the disease, Adherence to Drug Therapy and Insight

Protocol summary

Summary

Objectives: To increase families understanding of the disease, early symptoms and prevent re-admissions and reduce hospitalization Design: This research is a quasi-experimental design with a control group, pre-test and post-test. Setting and conduct: At baseline, After explaining the research project for participants, they will fill forms for participation in the study. The sample is then used as input into the process of evaluation and treatment. The samples were chosen based on convenience sampling. And with the confirmation of inclusion criteria, they were allocated in two groups of intervention and control. All participants to the program will complete the appropriate management tools. Also after the intervention, will complete the tests. Intervention time, is Shahrivar 1395. Participants including major eligibility criteria: The sample consisted of 40 patients and their families (20 cases and 20 controls) from Shiraz Psychiatric Hospital. Patients in the study entry criteria: Having schizophrenia spectrum disorders. Aged 18 to 50 years. Intervention: In Group psycho-education training program will start in 6 sessions with her family groups. The control group received their usual treatment. Main outcome measures: Adherence to Drug Therapy, quality of life, mental health, Expressed emotion, Positive and negative symptoms, Knowledge of disease, Insight

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081729402N1**
Registration date: **2017-01-08, 1395/10/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-08, 1395/10/19

Registrant information

Name

samad fereidooni

Name of organization / entity

shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 917 714 5203

Email address

daneshmoa1@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Private funding

Expected recruitment start date

2016-10-06, 1395/07/15

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of intervention based on family psycho-education in reducing expressed emotion, quality of life, mental health, Knowledge of disease on families of patients with schizophrenia and its impact on reducing positive and negative symptoms of the disease, Adherence to Drug Therapy and Insight	
Public title	The effectiveness of intervention based on family psycho-education in reducing positive and negative symptoms of patients with schizophrenia
Purpose	Treatment
Inclusion/Exclusion criteria	Patients in the study entry criteria: Having schizophrenia spectrum disorders diagnostic criteria; Aged 18 to 50 years; Minimum education, Guidance and maximum license; Lack of ECT treatment for at least two months before admission and during hospitalization; At the same time you do not receive psychological therapy or 3 months before entering the study and research both; for the patient and for the family; Patient and family consent to participate in research; Living with a family member for at least three months before admission. Exclusion criteria from the study: Acute phase or active substance abuse! Full criteria of borderline personality disorder !Having suicidal thoughts! History of severe medical illness! Mental retardation! mental damage! An absence of more than one session! Under the age of 18 years and above 50 years! Comorbidity of substance dependence disorder! The comorbidity of other disorders.
Age	From 18 years old to 50 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 40
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	Name of ethics committee Ethics Committee of Shiraz University of Medical Sciences Street address Shiraz University of Medical Sciences (Vice President of Research) City Shiraz Postal code Approval date 2016-09-25, 1395/07/04 Ethics committee reference number IR.SUMS.REC.1395.113
Health conditions studied	
<u>1</u>	
Description of health condition studied	Schizophrenia
ICD-10 code	F20
ICD-10 code description	Schizophrenia
Primary outcomes	
<u>1</u>	
Description	Adherence to Drug Therapy
Timepoint	Before the intervention, after intervention
Method of measurement	Medication Adherence Rating Scale (MARS)
<u>2</u>	
Description	quality of life
Timepoint	Before the intervention, after the intervention
Method of measurement	World Health Organization Quality of Life Scale-Short Form
<u>3</u>	
Description	mental health
Timepoint	Before the intervention, after the intervention
Method of measurement	General Health Questionnaire (GHQ-28)
<u>4</u>	
Description	Expressed emotion
Timepoint	Before the intervention, after the intervention
Method of measurement	

Expressed emotion questionnaire (FEQ)

5

Description

Positive and negative symptoms

Timepoint

Before the intervention, after the intervention

Method of measurement

Positive and Negative Syndrome Scale Kay, Fyzbyn and Appler (1986)

6

Description

Knowledge of disease

Timepoint

Before the intervention, after the intervention

Method of measurement

Knowledge of Schizophrenia Questionnaire (KASQ)

7

Description

Insight

Timepoint

Before the intervention, after the intervention

Method of measurement

Insight and Treatment Attitudes questionnaire (ITAQ)

Secondary outcomes

1

Description

Relapse

Timepoint

6 months after intervention

Method of measurement

Review patient records and reporting of family

Intervention groups

1

Description

In Group psychoeducation training, program by the researcher, in 6 sessions (twice a week) based on the third edition of the implementation of psycho-educational sessions (Mottqy Pur, 1387) with her family groups will start. Training sessions as follows: Session I: Introduction and family stories. Session two: Understanding the disease and symptoms. Session three: treatment and follow-up. Session Four: What families can do to help? Session Five: problem solving method. Session Six: specific issues and crisis prevention. Questions and discussion meetings with the early starts and then for one and a half hour session will continue on the same subject. At the end of each session, information about the meeting will be summarized in a brochure that patients be communicated to them. In each session, the assignments will be discussed.

Category

Treatment - Other

2

Description

Control group will receive thire Usual treatment (meeting with the psychiatrist). In order to observe professional ethics and justice, after the intervention and the implementation of the post-test than control group caregivers are invited to participate in the educational program family.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric hospital of Moharreri Professor

Full name of responsible person

Sanad Fereidooni

Street address

Shiraz- Niayesh City (Bajgah) Psychiatric Hospital of Professor Moharreri

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

no

Full name of responsible person

no

Street address

no

City

no

Grant name

Grant code / Reference number

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

Yes

Title of funding source

no

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

Samad fereidooni

Position

MA in Clinical Psychology

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

Psychiatric Hospital of Professor Moharreri, Niayesh
City (Bajgah), Shiraz, Iran

City

Shiraz

Postal code**Phone**

+7 136277503

Fax

+98 36277502

Email

samadpsy@gmail.com

Web page address

+98 36277502

Email

samadpsy@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Samad fereidooni

Position

MA in Clinical Psychology

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

Psychiatric Hospital of Professor Moharreri, Niayesh
City (Bajgah), Shiraz

City

Shiraz

Postal code**Phone**

+7 136277503

Fax

+98 36277502

Email

samadpsy@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences (SUMS)

Full name of responsible person

Samad fereidooni

Position

MA in Clinical Psychology

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

Psychiatric Hospital of Professor Moharreri, Niayesh
City (Bajgah), Shiraz

City

Shiraz

Postal code**Phone**

+7 136277503

Fax

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