Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Email address

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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

1

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

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Adherence to Drug Therapy
Timepoint
Before the intervention, after intervention
Method of measurement
Medication Adherence Rating Scale (MARS)

2

Description
quality of life
Timepoint
Before the intervention, after the intervention
Method of measurement
World Health Organization Quality of Life Scale-Short Form

3

Description
mental health
Timepoint
Before the intervention, after the intervention
Method of measurement
General Health Questionnaire (GHQ-28)

4

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
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+7 136277503
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samadpsy@gmail.com
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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work
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Person responsible for updating data

Contact

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Other areas of specialty/work
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+98 36277502
Email
samadpsy@gmail.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