

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparative study of role of "current" and "need assessment based" family education of schizophrenic patients on recurrence of shizophrenia, patients performance and quality of life and family members, quality of life. A controlled study

Protocol summary

Summary

Family psycho-education is one of the most effective interventions for preventing relapse in patients with schizophrenia. We are going to evaluate the efficacy of a needs-assessment based educational program and compared it with a current program in the treatment of schizophrenia. Patients with schizophrenia and their families (n = 60) are going to allocated to needs-assessment based education (treatment) and current education (control) programs; both will include 10 sessions of education within about six months. Symptoms will be assessed by the Positive and Negative Syndrome Scale (PANSS) ,GAF, WHO-QOL-Brief, SQLS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303172266N3**

Registration date: **2013-05-15, 1392/02/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-15, 1392/02/25

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 1222 2135

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kheirabadi@bsrc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-05-01, 1390/02/11

Expected recruitment end date

2013-02-20, 1391/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of role of "current" and "need assessment based" family education of schizophrenic patients on recurrence of shizophrenia, patients performance and quality of life and family members, quality of life. A controlled study

Public title

Role of need assessment based family education of schizophrenic patients on recurrence of shizophrenia, patients performance and quality of life and family members, quality of life.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criterion: patients with schizophrenia, diagnosed based on DSM-IV-TR Criteria and their families. Exclusion criteria: patients with debilitating diseases such as uncontrolled epilepsy and mental retardation and those who were addicted to any

substance, drug, or alcohol were not included into the study. Also, those who had received psycho-education or family therapy during the past two years.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

The study was approved by the and all participants signed an informed consent

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

184145

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

The primary outcome of the study was improvement in symptoms severity

Timepoint

Every 3 months for 18 months

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

1

Description

Global function of the patients

Timepoint

Baseline and then every 6 months for 18 months.

Method of measurement

Global assessment of function index(GASO)

2

Description

Patients' quality of life

Timepoint

Baseline and then every 6 months for 18 months.

Method of measurement

Schizophrenia Quality of Life Scale

3

Description

Quality of life of families

Timepoint

Baseline and then every 6 months for 18 months.

Method of measurement

World Health Organization Quality of Life Questionnaire-Short Form

Intervention groups

1

Description

Those in the control group will receive psycho-education based on the current protocols. Number of the sessions (10 sessions with 15 days intervals) and the structure were similar for the two groups (Atkinson and Coia).The subjects for education include 1) What do you know of schizophrenia?, 2) What is schizophrenia?, 3) What causes schizophrenia?, 4) Different methods of treatment for schizophrenia, 5) Problems of patient's family, 6) Family and Schizophrenia (learning ways to deal with stress), 7) Creating an environment with minimal stress (coping skills), 8) How to manage and control the chaotic behavior of the patient, 9) Use of services and deal with crises, and 10) Where are we and where are we going?.Educators of the control group will be mental health nurses who are working for the clinic and will unaware that some of their participants are under observation by the study.

Category

Treatment - Drugs

2

Description

Those in the study group will receive psycho-education based on the current protocols. Number of the sessions (10 sessions with 15 days intervals) and the structure were similar for the two groups (Atkinson and Coia).The subjects for education include 1) What do you know of schizophrenia?, 2) What is schizophrenia?, 3) What causes schizophrenia?, 4) Different methods of treatment for schizophrenia, 5) Problems of patient's family, 6) Family and Schizophrenia (learning ways to deal with stress), 7) Creating an environment with minimal stress (coping skills), 8) How to manage and control the chaotic behavior of the patient, 9) Use of services and deal with crises, and 10) Where are we and where are we going?. Educators of the study group will be two residents of psychiatry educated with family education based on need assessment program.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Peiman Adibi

Street address

School of Medicine, Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Behavioral Sciences Research Center, Department of Psychiatry, school of medicine, Isfahan Universit

Full name of responsible person

Gholam Reza Kheirabadi

Position

Assistant Prof. of Psychiatry

Other areas of specialty/work

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Position

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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