Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The investigation of the effect of intervention on treatment adherence on quality of life of schizophrenia patients

Protocol summary

Summary

Objectives:The investigation of the effect of intervention on treatment adherence on quality of life of schizophrenia patients in Urmia Razi Psychiatric Center in 2016. Design: This research is a experimental study with “pre-test and post-test with control group” design. Setting and conduct: The sample size of this study has been estimated 70 persons with 35 persons in control group and 35 persons in experimental group allocated randomly. The data for this study will be gathered through demographic questionnaire, quality of life questionnaire schizophrenia (SQLS). Participants inclusion criteria:The diagnosis of schizophrenia, patient satisfaction and patient guardian to participate in the study. exclusion: Not having a psycho-education classes simultaneously or six months ago. Intervention: First, the pre-test will be done in both groups. The experimental group will attend 6 sessions of lectures and discussions, 60-minutes , but the control group will not receive any intervention. The treatment adherence of promoting interventions for experimental group will be done by compliance method and providing pamphlets and educational booklet. Finally, the post-test will be done in both of the groups and the results will be compared. The main outcome variable: Improving the quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050526347N3**
Registration date: **2016-05-29, 1395/03/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-29, 1395/03/09

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Urmia University of Medical Sciences

Expected recruitment start date

2016-02-27, 1394/12/08

Expected recruitment end date

2016-05-28, 1395/03/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation of the effect of intervention on treatment adherence on quality of life of schizophrenia patients

Public title

The investigation of the effect of intervention on treatment adherence on quality of life of schizophrenia patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The diagnosis of schizophrenia based on diagnostic criteria DSM 5 and patient records by

psychiatrist; being in the age range 18 to 65; having at least ability to read and write; the ability to understand content; patient satisfaction and patient guardian to participate in the study Exclusion criteria: A debilitating physical illness and dependence on drug abuse; Lack of educational meetings for two consecutive sessions; having a psycho-education classes simultaneously or six months ago

Age
From **18 years** old to **65 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)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Urmia University of Medical Sciences

Street address
UMSU Central Site: Orjhans Street, Resalat Blvd, Urmia , Iran

City
Urmia

Postal code

Approval date
2016-02-27, 1394/12/08

Ethics committee reference number
ir.umsu.rec.1394.427

Health conditions studied

1

Description of health condition studied
schizophrenia

ICD-10 code
F20

ICD-10 code description
schizophrenia

Primary outcomes

1

Description
Quality of life

Timepoint
Before intervention, after intervention

Method of measurement
SQLS Persian

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, the pre-test will be done. The experimental group will participate in 6 sessions of lectures and discussions managed by the researcher. The content of sessions is designed and implemented Based on the dose and do not with medical treatment and solving problems. Then, the post-test will be done and the results of the pre-test and the post-test will be compared.

Category
Treatment - Other

2

Description
Control group: This group will not receive any intervention. The difference of the quality of life, compliance of the pre-test and the post-test will be measured and compared with each other.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Urmia Razi Psychiatric Center

Full name of responsible person
Mehrnaz Esmkhani

Street address
The first Salmas, Urmia road

City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Ghafarzadeh
Street address
UMSU Central Site: Orjhans Street, Resalat Blvd, Urmia
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urmia 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

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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