

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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

Name

Soheyla Ahangarzade Rezaei

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

rezaei.s@umsu.ac.ir

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

Contact

Name of organization / entity

Urmia Faculty of Nursing & Midwifery school

Full name of responsible person

Soheyla Ahangarzade Rezaei

Position

PHD

Other areas of specialty/work

Street address

Urmia Faculty of Nursing & Midwifery school, Pardis
Nazlou, 11 km of Nazlou Road, Urmia

City

Urmia

Postal code

Phone

+98 44 3275 4963

Fax

Email

nursing-college@umsu.ac.ir

Web page address

<http://www.nm.umsu.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia Faculty of Nursing & Midwifery school

Full name of responsible person

Mehrnaz Esmkhani

Position

Master of sciences in psychiatric nursing
student, head nurse

Other areas of specialty/work

Street address

Pardis Nazlou, 11 km of Nazlou Road, Urmia

City

Urmia

Postal code

Iran

Phone

+98 44 3275 4961

Fax

Email

mehrnazesmkhani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hojjat Kvhkmry hospital of Tabriz University of
Medical Sciences

Full name of responsible person

Mehrnaz Esmkhani

Position

Master of sciences in psychiatric nursing
student, head nurse

Other areas of specialty/work

Street address

Hojjat Kvhkmry hospital

City

Marand

Postal code

Iran

Phone

+98 414224444240

Fax

Email

mehrnazesmkhani@yahoo.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