

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of nurses' therapeutic relationship in schizophrenic patients on medication regimens compliance

Protocol summary

Summary

(1) Objectives: The main objective of this study is examining the effect of therapeutic relationship in schizophrenic patients on medication regimens compliance in Razi psychiatric hospital of Tabriz. (2) Design: This research is an experimental study with "pre-test and post-test with control group" design. (3) Setting and conduct: First pilot study will be done to determine sample size. The estimated sample size will be allocated randomly to interventional and control groups. Instruments for data gathering and measuring are Health Belief Model Scale and Observational Checklist for Medication Compliance. (4) Participants including major eligibility criteria: Schizophrenic patients who have ability and willingness to answer interview questions; are not residual schizophrenic type; have at least one history of recurrence; have at least 18 years old; have not co-disorders; and are not in acute phase of disorder. Exclusion criteria: Discharging the patient before the completion of relationship therapy sessions and not participating in the post- test. (5) Interventions: Firstly, the pre-test will be done in both groups. The experimental group will attend 7-12 sessions of relationship therapy. The control group will not receive any intervention in this duration. Finally, the post-test will be done in both groups and the results of two groups will be compared with together. (6) The main outcome variable: Increasing of medication regimen compliance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206206834N5**

Registration date: **2012-11-14, 1391/08/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-14, 1391/08/24

Registrant information

Name

Hossein Ebrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1475 1709

Email address

ebrahimih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2013-02-03, 1391/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nurses' therapeutic relationship in schizophrenic patients on medication regimens compliance

Public title

The effect of nurses' therapeutic relationship in schizophrenic patients on medication regimens compliance

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Schizophrenic patients who have ability and willingness to answer interview questions; are not residual schizophrenic type; have at least one history of recurrence; have at least 18 years old; have not co-disorders; and are not in acute phase of disorder.

Exclusion criteria: Discharging the patient before the completion of relationship therapy sessions and not participating in the post- test.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size:

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

Ethics Committee of Tabriz University of Medical Sciences, Vice chancellor for research

Street address

Third floor, Central Building- No 2, Golgasht Street

City

Tabriz

Postal code

Approval date

2012-10-20, 1391/07/29

Ethics committee reference number

91116

Health conditions studied

1

Description of health condition studied

Noncompliance with medical treatment and regimen,

Schizophrenia

ICD-10 code

Z91.1, F20

ICD-10 code description

Personal history of noncompliance with medical treatment and regimen; Paranoid schizophrenia, Hebephrenic schizophrenia, Catatonic schizophrenia, Undifferentiated schizophrenia, Post-schizophrenic depression, Simple schizophrenia, Other schizophrenia and

Primary outcomes

1

Description

Compliance with medication regimen

Timepoint

Before intervention and one week after finishing intervention

Method of measurement

Observational Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Firstly, the pre-test will be done. Intervention group will be receiving 7-12 sessions about relationship therapy. Then, the post-test will be done. Finally, the differences of compliance in pre-test and post-test will be compared with each other.

Category

Behavior

2

Description

Control group: This group will be not receiving any intervention. The differences of compliance in pre-test and post-test will be measured and will be compared with each other.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Hospital

Full name of responsible person

Dr Arash Mohagheghi

Street address

Tabriz Razi Psychiatric Hospital, Elgoli Boulevard

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Kazem Shakouri

Street address

Third floor, No 2 Building of Tabriz University of Medical Sciences, Golgasht Ave

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tabriz 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

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Hossein Ebrahimi

Position

PhD in nursing

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

Psychiatric Nursing Group, Tabriz Nursing and Midwifery Faculty, South Shariati Street

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Ebrahimih@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Fariba Mosaffa

Position

MSc in Psychiatric Nursing, Student

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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