

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of psycho-education on schizophrenia and their feedback on patients and their primary caregivers

Protocol summary

Study aim

Investigating the effectiveness of psychological training on schizophrenia patients and its feedback on patients and their primary caregivers.

Design

Quasi-experimental intervention with pre-test and post-test with control group. With a sample size of 176 people. The permuted random blocking method is used to do randomization

Settings and conduct

By referring to Ibn Sina hospital clinic in Mashhad, a number of schizophrenic patients and primary caregivers are selected from among the eligible patients. Then they are randomly divided into 2 intervention groups and control group. Blinding is not done in this study. Then only the intervention group will receive the psychological training booklet, they will be supported by phone every two weeks for 12 weeks.

Participants/Inclusion and exclusion criteria

People diagnosed with schizophrenia and aged 18 or older; Primary caregivers who take care of their relative with schizophrenia; All participants must be able to read and write; All participants must consent to participate in this research; Not suffering from learning disabilities; Not suffering from another mental disorder or drug abuse; Living without a caregiver or contact with close people; Primary caregivers who are involved in the care of more than one person suffering from psychological problems

Intervention groups

Only the intervention group will receive the psychological training booklet, they will be supported by phone every two weeks for 12 weeks. Follow-up phone calls are made to their primary caregivers to ensure that they have read and understood the psychological education manual and to allow them to ask questions about the content of the psychological education manual; But the control group will not receive any training.

Main outcome variables

Knowledge about schizophrenia, relapse rate, reduction

of schizophrenia symptoms, care burden of primary caregivers of schizophrenia, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210515051300N2**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-01-21, 1401/11/01**

Update count: **0**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Samane Soltanabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3734 4825

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soltanabadis981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-11, 1401/10/21

Expected recruitment end date

2023-02-10, 1401/11/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of psycho-education on schizophrenia and their feedback on patients and their primary caregivers

Public title

The effectiveness of psycho-education on schizophrenia and their feedback on patients and their primary caregivers

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

People diagnosed with schizophrenia and aged 18 years or older. Primary caregivers caring for a relative with schizophrenia. All participants must be able to read and write. All participants must consent to participate in this research. Primary caregivers who are involved in caring for more than one person with mental health problems.

Exclusion criteria:

Having a learning disability Suffering from another mental disorder or substance abuse Life without a caregiver or contact with close people

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **176**

Randomization (investigator's opinion)

Randomized

Randomization description

Permutation random block method is used for random allocation. In this method, 44 blocks of 4 will be randomly selected from the combination of letters A and B. These blocks are AABB, ABBA, BBAA, BAAB, ABAB, BABA. Allocation of letters A and B to the intervention and control groups will also be done randomly before randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Khaghani 19, No. 192

City

Mashhad

Province

Razavi Khorasan

Postal code

9146784698

Approval date

2022-11-15, 1401/08/24

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.554

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes**1****Description**

Awareness of schizophrenia disorder

Timepoint

Beginning and end of the study

Method of measurement

Knowledge Questionnaire about Schizophrenia (KASQ)

2**Description**

The rate of disease recurrence

Timepoint

Beginning and end of the study

Method of measurement

Sign test

3**Description**

Reduction of disease symptoms

Timepoint

Beginning and end of the study

Method of measurement

Positive and Negative Symptom Scale Questionnaire in Schizophrenias (PANSS)

4**Description**

Caring burden of primary caregivers of schizophrenia
Timepoint
Beginning and end of the study
Method of measurement
Family Interview Scale (FBIS)

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Description
Quality of life of primary caregivers of schizophrenia
Timepoint
Beginning and end of the study
Method of measurement
Quality of life scale (S-CQOL)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Only the intervention group will receive the psychological training booklet, they will be supported by phone every two weeks for 12 weeks. Follow-up phone calls are made to their primary caregivers to ensure that they have read and understood the psychological education manual and to allow them to ask questions about the content of the psychological education manual. The content of each psychological training manual includes information on diagnosis, symptoms, coping with symptoms, treatment options, and how to solve problems and identify stressors for people with schizophrenia.

Category
Rehabilitation

2

Description
Control group: They do not receive any intervention.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
EbneSina Hospital and Psychiatric Training Center
Full name of responsible person
Samane Soltanabadi
Street address
Bo Ali Square, Horemeli Blvd
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Postal code

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Taqfadi
Street address
Khorasan Razavi, Mashhad
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Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
tafaghodim@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Samane Soltanabadi
Position
phd student
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcomes can be shared.

When the data will become available and for how long

The information will be published after analyzing the data and printing the results.

To whom data/document is available

researchers

Under which criteria data/document could be used

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From where data/document is obtainable

Samane Soltanabadi samane.soltanabadi@gmail.com

What processes are involved for a request to access data/document

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Comments

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