

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of cognitive-behavioral group training of self-care Skills on positive, negative symptoms, general psychopathology and self-care in patients with schizophrenia

Protocol summary

Study aim

Determining the effect of cognitive-behavioral group training of self-care skills on positive, negative, general psychopathology symptoms and self-care in patients with schizophrenia

Design

In this randomized controlled clinical trial, 52 eligible patients with schizophrenia will be selected by convenience method. then, they will be assigned to two groups of intervention and control by permuted block randomization One-way blind method.

Settings and conduct

This study was performed in Ebn'e Sina Psychiatric Hospital in Mashhad. Patients with schizophrenia were invited to enter the study after obtaining written consent from their guardian. Then, by permuted block randomization one-way blind method, they were assigned to the intervention and control groups by a researcher who was blind to the study conditions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: A minimum of six months and a maximum of three years have elapsed since the diagnosis of schizophrenia History of at least one previous hospitalization Achieve a score above 50 on the Positive and Negative Clinical Syndrome Scale (PANSS) Having verbal ability, education of 8 grades or more No change in standard antipsychotic dose in the last 3 months Exclusion criteria: History of substance and alcohol abuse Physical involvement with group members and therapists before initiating therapeutic interventions Conflict with legal issues

Intervention groups

Intervention group will receive cognitive behavioral group training with self-care skills content by challenging cognitive errors related to self-care skills during 10 one-and-a-half hour sessions. Control group will receive the routine care.

Main outcome variables

Positive, negative symptoms and general psychopathology, self-care

General information

Reason for update

Correction of sample size and completion date of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20180817040818N2**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-16, 1400/05/25**

Update count: **1**

Registration date

2020-08-23, 1399/06/02

Registrant information

Name

Masoud Kashani Lotfabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2701

Email address

kashanim1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-19, 1399/04/29

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

2020-07-22, 1399/05/01

Actual recruitment end date

2020-10-31, 1399/08/10

Trial completion date

2021-05-20, 1400/02/30

Scientific title

The effect of cognitive-behavioral group training of self-care Skills on positive, negative symptoms, general psychopathology and self-care in patients with schizophrenia

Public title

The Effect of Cognitive-Behavioral Group Training of Self-Care Skills on Positive, Negative Symptoms, General psychopathology and Self-Care

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

A minimum of six months and a maximum of three years have elapsed since the diagnosis of schizophrenia
History of at least one previous hospitalization
Achieve a score above 50 on the Positive and Negative Clinical Syndrome Scale (PANSS)
Having verbal ability, education of 8 grades or more
No change in standard antipsychotic dose in the last 3 months

Exclusion criteria:

History of substance and alcohol abuse
Physical involvement with group members and therapists before initiating therapeutic interventions
Conflict with legal issues

AgeFrom **25 years** old to **55 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **52**Actual sample size reached: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Sampling will be performed by permuted block randomization. Eligible patients will be selected by the convenience method and will be divided into two groups A and B by a researcher. For this purpose, 13 blocks of four (AABB, ABAB, BABA, BBAA, ABBA, BABA, etc.) were determined and each of them was assigned a number between 1 and 13. Based on the table of random numbers, it was determined that the order of entry of blocks into the study and assignment of individuals to intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher who performs the study statistics will be

blind to the study conditions.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Islamic Azad university Torbat-e Jam branch

Street address

Campus of Islamic Azad University of Torbat-e Jam, 5 km of Freeman road, Torbat-e-Jam

City

Torbat-e Jam

Province

Razavi Khorasan

Postal code

9576174814

Approval date

2020-07-18, 1399/04/28

Ethics committee reference number

IR.IAU.TJ.REC.1399.007

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

Schizophrenia

ICD-10 code

F20-F29

ICD-10 code description

Schizophrenia, schizotypal and delusional disorders

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

Positive, negative symptoms and general psychopathology

Timepoint

Before intervention, after intervention and six months after intervention

Method of measurement

Positive and Negative Clinical Syndrome Scale (PANSS)

2**Description**

Self-care

Timepoint

Before intervention, after intervention and six months after intervention

Method of measurement
Self-Care Needs Scale (SCRS-H)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will receive cognitive behavioral group training with self-care skills content by challenging cognitive errors related to self-care skills during 10 one-and-a-half hour sessions.

Category

Rehabilitation

2

Description

Control group: They will receive the routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn'e Sina psychiatric hospital

Full name of responsible person

Mohammad Hossein Bayazi

Street address

Next Astan Ghods Naghlie, end Hor Ameli of the street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

919583134

Phone

+98 51 3732 6767

Email

Bayazi123@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Islamic Azad university Torbat-e Jam branch

Full name of responsible person

Sayyed Mehdi Sadat

Street address

Campus of Islamic Azad university Torbat-e Jam branch, 5 km of Freeman road, Torbat-e Jam

City

Torbat-e Jam

Province

Razavi Khorasan

Postal code

9576174814

Phone

+98 51 5251 0220

Fax

Email

mh.bayazi@iautj.ac.ir

Web page address

<http://iautj.ac.ir/index.php/en/>

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 of Islamic Azad university Torbat-e Jam branch

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad university Torbat-e Jam branch

Full name of responsible person

Masoud Kashani Lotfabadi

Position

PhD student in psychology

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Campus of Islamic Azad university Torbat-e Jam branch, 5 km of Freeman road, Torbat-e Jam

City

Torbat-e Jam

Province

Razavi Khorasan

Postal code

9576174814

Phone

0098515282210222

Fax

Email

Kashanim1@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University Torbat-e Jam branch

Full name of responsible person

Masoud Kashani Lotfabadi

Position

PhD student in psychology

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Campus of Islamic Azad University Torbat-e Jam branch, 5 km of Freeman road, Torbat-e Jam

City

Torbat-e Jam

Province

Razavi Khorasan

Postal code

9576174814

Phone

+985282210222

Email

Kashanim1@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University Torbat-e Jam branch

Full name of responsible person

Masoud Kashani Lotfabadi

Position

PhD student in psychology

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Campus of Islamic Azad University Torbat-e Jam branch, 5 km of Freeman road, Torbat-e Jam

City

Torbat-e Jam

Province

Razavi Khorasan

Postal code

9576174814

Phone

+985282210222

Email

Kashanim1@mums.ac.ir

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

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Clinical outcomes of the study will be published in the form of a paper

When the data will become available and for how long

The results of the study will be published after data collection over the next 6 months

To whom data/document is available

Data documents will be shared in thesis and article form.

Under which criteria data/document could be used

Islamic Azad university Torbat-e Jam branch license will only be available to researchers working in academic institutions

From where data/document is obtainable

Islamic Azad university Torbat-e Jam branch license will only be available to researchers working in academic institutions

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

It should be done through the research vice chancellor of Islamic Azad university Torbat-e Jam branch.

Comments