

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The Effect of Cognitive-Behavioral Group Therapy on Improving Self-Care Skills in Women with Chronic Schizophrenia

Protocol summary

Study aim

Determining the effect of cognitive behavioral group therapy on improving self-care skills in women with chronic schizophrenia

Design

In this randomized clinical trial, 40 women with chronic schizophrenia were selected randomly and then randomly assigned to two groups of intervention and control

Settings and conduct

This study was conducted in Hejazi Psychiatric Hospital in Mashhad. Women with chronic schizophrenia were invited to receive a written consent from their donations if they were eligible for inclusion in the study and then randomly assigned to intervention and control groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: duration of the disease recorded in the medical record was 3 years or more; having verbal ability Minimum grade 8th grade, lack of standard dose change for anti-psychotics in the past 3 months Exclusion criteria: a history of opium and alcohol abuse; severe physical illness requires treatment; unwillingness to continue attending in therapeutic sessions; affected by epilepsy and mental retardation

Intervention groups

Cognitive-Behavioral Group Therapy with the content of self-care skills will be implemented for 35 days during 10 sessions of 60 minutes (two sessions a week).

Main outcome variables

Self-care skills in patients with chronic schizophrenia;
Positive and Negative Symptoms of Schizophrenia;
Anxiety, Depression, Self-esteem

General information

Reason for update

Correction of some clinical trial information

Acronym

IRCT registration information

IRCT registration number: **IRCT20180817040818N1**

Registration date: **2018-08-27, 1397/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-05, 1399/06/15**

Update count: **2**

Registration date

2018-08-27, 1397/06/05

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

2018-08-15, 1397/05/24

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2018-08-15, 1397/05/24

Actual recruitment end date

2018-11-22, 1397/09/01

Trial completion date

2019-05-26, 1398/03/05

Scientific title

The Effect of Cognitive-Behavioral Group Therapy on Improving Self-Care Skills in Women with Chronic Schizophrenia

Public title

The Effect of Cognitive-Behavioral Group Therapy on Improving Self-Care Skills

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Primary admission with the diagnosis of schizophrenia
the diagnosis of chronic schizophrenia in the last 3 months
Duration of the disease recorded in the medical record was 3 years or more
Having verbal ability
Minimum grade 8th grade
Lack of standard dose change for anti psychotics in the past 3 months

Exclusion criteria:

A history of opium and alcohol abuse
History of conflict with legal issues
Severe physical illness requires treatment
Physical involvement with group members and therapists during treatment interventions
Unwillingness to continue attending in therapeutic sessions
Affected by epilepsy and mental retardation

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The random numbers table were assigned to intervention and control groups. A list of eligible patients was prepared and assigned a number to each of them. Then, a randomly selected number was selected randomly from the random numbers table and two digits to the right of it were considered. If the two digits on the right match the number of people listed, they were selected as the first person in the intervention group. and Subsequently, the numbers were assigned to the control group (in the case of the number of persons listed). This will continue until the sample size is completed in each group.

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, next to the Hovezeh Cinema, University avenue, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2018-07-18, 1397/04/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.298

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

Self care skills in patients with chronic schizophrenia

Timepoint

Before intervention, after intervention, six months after intervention

Method of measurement

Researcher-made Self Care Skills Questionnaire in Patients with Chronic Schizophrenia

2

Description

Positive and Negative Symptoms in Patients with Schizophrenia

Timepoint

Before intervention, after intervention, six months after intervention

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

3

Description

Anxiety

Timepoint

Before intervention, after intervention, six months after intervention

Method of measurement

Hamilton Anxiety Rating Scale

4

Description

Depression

Timepoint

Before intervention, after intervention, six months after intervention

Method of measurement

Hamilton Depression Rating Scale

5

Description

Self-Esteem

Timepoint

Before intervention, after intervention, six months after intervention

Method of measurement

Eysenck Self-Esteem Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group was assigned to a cognitive-behavioral group

Category

Behavior

2

Description

Control group: they will receive routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hejazi Psychiatric Hospital

Full name of responsible person

dr Ali Talaei

Street address

Hejazi psychiatric hospital, after Majlesi crossroad, Mashhad, Ebadi Avenue, Mashhad

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Vice chancellor for research; Mashhad University of Medical Sciences; next to the Hovezeh Cinema; University avenue; Mashhad

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vcresearch@mums.ac.ir

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

Masoud Kashani Lotfabadi

Position

PhD Student in Clinical Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoud Kashani Lotfabadi

Position

PhD Student in Clinical Psychology

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Email

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is 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

The results of this study will be open to the public in prestigious domestic and foreign journals

Under which criteria data/document could be used

If the ethics committee of Mashhad University of Medical Sciences approves, the data file will be usable

From where data/document is obtainable

Vice chancellor for research of Mashhad University of Medical Sciences

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

To request documentation and data files, go to the Vice chancellor for research of Mashhad University of Medical Sciences

Comments