

# 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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

919583134

**Phone**

+98 51 3732 6767

**Fax****Email**

TalaeiA@mums.ac.ir

**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

**Street address**

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

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9919191778

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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

**Street address**

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

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**Email**

Kashanim1@mums.ac.ir

## Person responsible for scientific 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**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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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**