

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The Effect of Stress management Training on the Caregiver Experience in Families Members of Patients

#### Protocol summary

##### Summary

This study aimed to investigate the effect of stress management training on patient care experience families of patients with schizophrenia, using clinical trial two groups with the control group method. The study population is families of schizophrenic patients hospitalized in Mashhad Ibn Sina Hospital. The most important entry criteria include having reading and writing literacy training and individual recipient of first-degree relatives of the patient and caregiver is most important as the main exit criteria also include the lack of desire to continue the company drgelsat and the absence of more than one training session was. The main carers of 60 patients to non-probability sampling methods in the selected baseline are individual demographic and profile form and a questionnaire to provide patient care experience for all participants. After random assignment of subjects (using the table of numbers) into two groups(intervention and control) the intervention group People are divided into 15 members groups, and stress management training is issued as a lecture, question and answer during 9 sessions (90 minutes) three times a week. For The control group no interference is conducted, but at the end of data collection they are being invited to participate in the one session of stress management training. The research units will be invited, to complete the data collection tool three months after the intervention. Finally, descriptive and analytic statistics will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016122731248N2**

Registration date: **2017-01-10, 1395/10/21**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-01-10, 1395/10/21

##### Registrant information

###### Name

Mahdi Rezaei

###### Name of organization / entity

Mashhad University of Medical Sciences, Mashhad, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 915 805 5323

###### Email address

rezaeim922@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-05-22, 1396/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Stress management Training on the Caregiver Experience in Families Members of Patients

##### Public title

Stress management Training on the Caregiver Experience in Families Members of Patients with Schizophrenia

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

Family entry criteria Family consent (caregivers) for the study; the person who is trained should be of the close relatives as main caregiver and live with the patient in the same home ; be literate (at least fifth-grade education); be Iranian and live in Mashhad and ; aged 18 at least and 60 at most years old; have no known mental disorder and not use of related drugs ; have no history of drug abuse and criminal record; physical defects, hearing and vision disorders that disrupt the educational process; not have experienced any other crisis such as divorce or death of a loved one during the past six months; not any other chronic mental or physical patient be existed in the family simultaneously . Inclusion criteria for patients (to determine the research unit): Schizophrenia should be confirmed by a psychiatrist; At least six months should have passed from the time of diagnosis; Patients should not have any other chronic disease simultaneously; not having cognitive disorders and addiction simultaneously; not having mental illness or disability caused by; should have history of at least one previous hospitalization in psychiatry hospital. Exclusion criteria: The family is not willing to continue participation in the meetings; have missed more than one meeting; the main caregivers of patients experience a "major stress" after completion of the training process until the test or take part in similar training courses during the research or is majored in one of medicine, nursing, psychology fields; Failure to participate in the post-test

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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**

Mashhad University of Medical Sciences

**Street address**

Mashhad University of Medical Sciences

**City**

Mashhad

**Postal code****Approval date**

2016-02-27, 1394/12/08

**Ethics committee reference number**

IR.MUMS.REC.1394.713

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

Schizophrenia

**ICD-10 code**

f20

**ICD-10 code description**

Schizophrenia

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

Caregiver Experience of Patients

**Timepoint**

Before and 3 months after intervention

**Method of measurement**

Standard Szmukler and partners validated and reliable questionnaire translated by doctor Mottaghipour et al.

**Secondary outcomes****1****Description**

N/A

**Timepoint**

N/A

**Method of measurement**

N/A

**Intervention groups****1****Description**

The intervention consists of six sessions of stress management training which is issued by lecture, question and answer during 9 sessions (90 minutes) three times a week, ) three times a week, in week days and an hour before the meeting.

**Category**

Lifestyle

## 2

### Description

At the end of the data collection The control group will be invited for Stress management group training to participate in 1 stress management group training session in 10 member groups which is hold by lecture and in person.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mashhad University of Medical Sciences Faculty  
Nursing & Midwifery

##### Full name of responsible person

Dr Latifnejad

##### Street address

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Robab Latinejad

##### Street address

Rzashhr- Rudaki 2 p 237/1

##### City

mashhad

#### 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

*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

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Rezaee Mahdi

#### Position

Nurse

#### Other areas of specialty/work

#### Street address

Alavi Hospital Mashhad

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Saeed Vaghee

#### Position

Faculty Member, School of Nursing and Midwifery

#### Other areas of specialty/work

#### Street address

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#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Mashhad University of Medical Sciences Faculty  
Nursing & Midwifery

#### Full name of responsible person

Mahdi Rezaee

#### Position

Master of Science in Psychiatric Nursing Education

#### Other areas of specialty/work

#### Street address

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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*