

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

City

Mashhad

Postal code

Phone

+98 383234681

Fax

Email

www.rezaeim922@mums.ac.ir

Web page address

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

Rodaki 26, Rezashahr

City

Mashhad

Postal code

Phone

+98 5105138513258

Fax

Email

www.vaghees@mums.ac.ir

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

Hospital Alavi Mashhad

City

Mashhad

Postal code

Phone

+98 51 3823 4681

Fax

Email

Mahdirezaei922@mums.ac.ir

Web page address

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