

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of coping strategies training on the burden and quality of life among the family caregivers of People with chronic mental disorders

#### Protocol summary

##### Summary

This study aims to assess the effects of coping strategies on the burden of care and quality of life of family caregivers of people with chronic mental disorders. Type non-randomized clinical trial is a test group and control. Is available sampling and control tests will be two groups of people. A sample of 47 people. The questionnaire put two hands. The intervention of 8 sessions for 2 months and each session will be held for 90 minutes in the test group. After the intervention groups and 2 months after completion of the questionnaire will be completed in the control group will run the same routine. Inclusion criteria: (a) careful: age range 60-18 years, literacy, health, sight and hearing, did not receive previous training on coping strategies, mental illness and chronic physical well-known lack of care, non-disorder drug abuse or drug dependence, lack of crisis situations in the past six months in care, no responsibility for the emotional and physical care of a sick patient (b): at least 1 year of diagnosis. exclusion criteria: no the desire to continue to receive training and participate in the research, participate in the second session of the eighth meeting of the classes, participate in similar training sessions in parallel.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120925450N1**  
Registration date: **2016-11-26, 1395/09/06**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-11-26, 1395/09/06

#### Registrant information

##### Name

Fahimeh Ramezani

##### Name of organization / entity

Iran University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8888 2885

##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for research of Iran University of Medical Sciences

#### Expected recruitment start date

2016-01-21, 1394/11/01

#### Expected recruitment end date

2016-05-21, 1395/03/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of coping strategies training on the burden and quality of life among the family caregivers of People with chronic mental disorders

#### Public title

Coping strategy training to family caregivers of people with chronic mental disorders

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criteria: a - watch out: aged 60 -18 years, literacy, health, sight and hearing, did not receive

previous training on coping strategies, mental illness and chronic physical well-known lack of care, non-disorder drug abuse or drug dependence, lack of crisis situation in care in the last six months (severe stress, death of close family members), lack of responsibility for the emotional and physical care of a sick patient (b): passed at least 1 year of diagnosis; exclusion criteria from the study: lack of desire to continue to receive training and participate in the research, participate in the second session of the eighth meeting of the classes, participate in similar training sessions in parallel

**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: **94**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

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

Ethics Committee Of Iran University Of Medical Sciences

**Street address**

Ethics Committee, Iran University of Medical Sciences, Sheikh Shahid Chamran highway lighting, the grace of Allah, Hemmat, Tehran

**City**

Tehran

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

2015-10-13, 1394/07/21

**Ethics committee reference number**

IR.IUMS.REC.1394.9211196214

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

chronic mental disorders(schizophrenia,bipolar)

**ICD-10 code**

V

**ICD-10 code description**

F20,F31

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

Burden

**Timepoint**

Before and two months after intervention

**Method of measurement**

Zarit burden interview

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

Quality of life

**Timepoint**

Before and two months after intervention

**Method of measurement**

Quality of Life Questionnaire sf36

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

Intervention group: A non-randomized clinical trial is a test group and control. And for caregivers in the intervention group teaching coping strategies consists of 8 training sessions with given objectives will be for 2 months, during 8 consecutive weeks (week 1 time) and each session lasts 90 minutes in groups and each group consisted of 10 people the groups will be held. The first meeting of coping strategies training program content: Introduction, Introduction and referrals, training program outlines and goals, second session: Introduction to Mental Disorders (definition, etiology, signs and symptoms), the third session: conceptualization and description of stress, symptoms and its consequences on life, sources of stress, the fourth session: the importance of learning coping strategies, problem-focused coping strategies are familiar with the types of emotion-driven and ineffective, the fifth session: effective methods of coping include stress management, time management, decision skills making, management, lifestyle (sleep, rest and exercise), sixth session: Introduction to other ways to reduce caregiver's anxiety such as relaxation techniques, deep breathing seventh session: verbal and non-verbal communication, body language, how to communicate with the patient and conflict resolution related to the effective use of resources, support, eighth session: Analysis and review past sessions, will be

**Category**

Lifestyle

**2****Description**

Control group: control group will not be any intervention pamphlet prepared for the control group and in the end they will be delivered.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hospitals martyr Yahya Nejad and Ayatollah Rouhani

**Full name of responsible person**

Mehrnoosh Inanloo

**Street address**

School of Nursing and Midwifery, Shahid Yasemi street, Valiasr, Tehran

**City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Iran University of Medical Sciences

**Full name of responsible person**

Seyed ali gavad musavi

**Street address**

Headquarters, Iran University of Medical Sciences, Sheikh Shahid Chamran highway lighting, the grace of Allah, Hemmat, Tehran

**City**

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**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 Iran 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**

Iran University of Medical Sciences, School of Nursing and Midwifery

**Full name of responsible person**

Mehrnoosh Inanloo

**Position**

Master of Science in Nursing/ teacher

**Other areas of specialty/work****Street address**

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**Position**

teacher

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**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*