

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effect of coping strategies training on caregiver's burden of care and anxiety in Family caregivers of patients with mental disorder

#### Protocol summary

##### Study aim

Determining the Effect of coping strategies training on caregiver' care burden and anxiety in Family caregivers of patients with mental disorder

##### Design

A clinical trial with a control group, with parallel group design, without blindness, randomized through a random numbers table

##### Settings and conduct

This study was conducted in the psychiatric ward of Atieh Hospital in Tehran. Using available sampling method, individuals were selected and randomly assigned into intervention and control groups. The samples of both groups completed Zarit's Burden questionnaire and Spielberg's Clear Anxiety Questionnaire. For the intervention group, training sessions were conducted in eight sessions. The post-test was taken one month after the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in research and having cooperation; having a family relationship with the patient with mental disease; Minimum age of 20 and maximum age of 60 years old; Having at least 6 months of patient care history. Non Inclusion criteria: participation in previous same educational program in Last three months; take care of a patient with other chronic conditions

##### Intervention groups

Intervention group: For the intervention group, an educational program is implemented including 1. Identify and define the problem 2. Need help during problems 3. Identify measures to help solving problems 4. Identify possible barriers to the care plan 5. Set up an app for caregivers. In intervention group, there are 8 60-minute training sessions (two sessions a week) will be performed. Control group: The control group receive routine care.

##### Main outcome variables

Care burden; Anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181209041907N1**

Registration date: **2019-01-08, 1397/10/18**

Registration timing: **retrospective**

Last update: **2019-01-08, 1397/10/18**

Update count: **0**

##### Registration date

2019-01-08, 1397/10/18

##### Registrant information

##### Name

Razieh Mehranian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 0036

##### Email address

ra.mehranian@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2018-12-11, 1397/09/20

##### Actual recruitment start date

2018-12-10, 1397/09/19

##### Actual recruitment end date

2018-12-11, 1397/09/20

##### Trial completion date

2018-12-11, 1397/09/20

##### Scientific title

Effect of coping strategies training on caregiver's burden of care and anxiety in Family caregivers of patients with mental disorder

**Public title**

Effect of coping strategies training on caregiver burden and anxiety

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Consent to participate in research and having cooperation Ability to communicate effectively with researcher ability to handle meetings and prepared to respond to questions physically and mentally Having a family relationship with a mental patient Minimum 20 and maximum 60 years old having the ability to read and write Have at least 6 months of patient care history

**Exclusion criteria:**

participation in previous same educational program in Last three months take care of a patient with other chronic conditions

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Table of random numbers was used for randomization

**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 University of Social welfare and Rehabilitation Sciences

**Street address**

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Approval date**

2018-04-28, 1397/02/08

**Ethics committee reference number**

IR.USWR.REC.1396.172

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

Schizophrenia

**ICD-10 code**

F20.9

**ICD-10 code description**

Schizophrenia, unspecified

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

Care burden

**Timepoint**

Before and one month after Intervention

**Method of measurement**

Zarit's Burden questionnaire

**2****Description**

Anxiety

**Timepoint**

Before and one month after intervention

**Method of measurement**

Spielberg's Anxiety Questionnaire

**Secondary outcomes**

empty

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

Intervention group: For the intervention group, an educational program is implemented including 1. Identify and define the problem 2. Need help during problems 3. Identify measures to help to solve problems 4. Identify possible barriers to the care plan 5. Set up an app for caregivers. In the intervention group, there are 8 60-minute training sessions (two sessions a week) will be performed.

**Category**

Behavior

## 2

### Description

Control group: Only routine care and training were provided for the control group.

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Atieh Hospital

##### Full name of responsible person

Razieh Mehranian

##### Street address

Farahzadi Blvd, Qods Town, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1467773661

##### Phone

+98 21 8858 0048

##### Email

Atiehhospital@yahoo.com

##### Web page address

<https://www.atiehhospital.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Hamidreza Khankeh

##### Street address

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713834

##### Phone

+98 21 2218 0036

##### Email

mehranianrazeye@gmail.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Razieh Mehranian

##### Position

Nurse

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713834

##### Phone

+98 21 2218 0036

##### Email

mehranianrazeye@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Abolfazl Rahgoi

##### Position

Associated Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

##### Street address

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713834

##### Phone

+98 21 2218 0036

##### Email

rahgouin@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Razieh Mehranian

**Position**

Nurse

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

**City**

tehran

**Province**

Tehran

**Postal code**

1985713834

**Phone**

+98 212218003

**Email**

mehranianrazeye@gmail.com

## 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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available