

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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Abolfazl Rahgoi

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Associated Professor

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Other areas of specialty/work

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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

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Latest degree

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Other areas of specialty/work

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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

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