

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The effect of family education program on family caregivers' burden in elderly patients with dementia

Protocol summary

Summary

This research is a clinical trial which was done on 50 family caregivers of elderly patients with dementia who had referred to Shariati psychiatric clinic & Modarres hospital of Isfahan city. Caregivers were selected with convenient sampling then randomized to experimental & control groups. The main inclusion criteria were being main family caregiver, having age of above 21 years and education level of above elementary. Caregivers of experimental group participated in a family education program but caregivers of control group didn't participate in this program. This program was based on a booklet codified by researcher. The purpose of this study was determining & comparing caregiver burden before, immediately & one month after execution of family education program in intervention & control group & between groups. The data were collected by Zarit caregiver burden scale which completed by caregivers of both groups before, after & one month after executing family education program. Also Mini Mental Status Examination was used for old adults before execution of the program.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809302200N2**

Registration date: **2010-03-18, 1388/12/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-03-18, 1388/12/27

Registrant information

Name

Saeid Pahlavanzadeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Isfahan university of medical sciences

Expected recruitment start date

2009-04-09, 1388/01/20

Expected recruitment end date

2009-07-11, 1388/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family education program on family caregivers' burden in elderly patients with dementia

Public title

The effect of family education program on families' burden in elderly patients with dementia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: family caregiver knows yourself as main caregiver of patient, age of caregiver is above 21 years, he or she would have education level above elementary, she or he would be as main caregiver only for one patient with chronic condition (with dementia),

she or he didn't participate in family education meetings about care of elderly before, other caregivers (such as private nurses) didn't help for caring of patient. Exclusion criteria: caregiver would participate in less than 4 education meetings, patient would pass away during study, caregiver has acute or chronic physical & mental diseases which obstruct patient care, caregiver would use psychotropic drugs, caregiver abandon care of elderly to long term care centers during one month after intervention

Age

To **91 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Vice chancellor for research of Isfahan university of medical sciences

Street address

Hezarjarib street

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8174673461

Approval date

2010-01-13, 1388/10/23

Ethics committee reference number

387407

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

Dementia

ICD-10 code

F00, F01,

ICD-10 code description

Dementia

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

Reduction of caregiving burden

Timepoint

5 weeks after intervention

Method of measurement

caregiving burden index

Secondary outcomes

empty

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

Family education program about care of elderly

Category

Other

2**Description**

No intervention in control group

Category

N/A

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

Modarres hospital & Shariati psychiatric clinic

Full name of responsible person

Fatemeh Ghaedi Heidari

Street address**City**

Isfahan

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

Vice chancellor for research of Isfahan university of medical sciences

Full name of responsible person

Peyman Adibi

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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 Isfahan 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

Isfahan university of medical sciences

Full name of responsible person

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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