Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

The effects of informational support on anxiety and quality of life in family caregivers of elders with dementia

Protocol summary

Summary

The empowerment and support of family caregivers is important; so the aim of this study is to investigate the effect of information support on anxiety and quality of life of family caregivers with dementia elderly. In this quasi-experimental and interventional two-grouped and three-stage study, 70 family caregivers with dementia elderly ask to participate through a call in neurologic and psychologic clinics affiliated to Shiraz University of Medical Sciences. Caregivers should be above 18 years old, experience in patient care for at least three consecutive months, and access to the mobile and social networks. They should also get average score of anxiety caregivers obtained from Spielberger questionnaire more than 31; and the score of quality of life obtained from Thomas quality of life questionnaire less than 80. Referring the elderly to long-term care centers, the occurrence of a crisis events or severe stress such as the death of loved ones and divorce for the caregiver during the study; and the caregiver's attendance in training sessions on the care of the elderly with dementia over the past 6 months leads to caregiver's exclusion from the study. The caregivers divide into two experimental (35 people) and control (35 people) groups by random block allocation. The experimental group receive information support in two distinct parts including training (elderly with dementia care and self-care in seven 90-minute training sessions) and information-counseling support (by phone, SMS, video call with virtual messenger programs or email for 4 weeks, 3 hours a day). Blinding is not done in this study. The control group receive no information support during the study. In this study, family caregiver's anxiety and quality of life measure, compare and evaluate in three stages: pre-study, immediately after the last counseling session and three months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080915426N4**
Registration date: **2017-10-03, 1396/07/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-03, 1396/07/11

Registrant information

Name
Maryam Hazrati
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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+98 71 3631 3949
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effects of informational support on anxiety and quality of life in family caregivers of elders with dementia

Public title
Effects of informational support on elder family caregivers

Purpose
Supportive

Inclusion/Exclusion criteria
• Inclusion criteria: The caregiver’s willingness to participate in the research and to complete the self-consent form; taking the main responsibilities towards the patient; having the caregiver’s reading and writing skills; being the caregiver’s age above than 18 years old; the caregiver’s access to phone, mobile, and social networks; experience in patient care for at least three consecutive months; having at least six months to five years dementia disease history; getting average score of anxiety caregivers obtained from Spielberger questionnaire more than 31; and the score of quality of life obtained from Thomas caregiver quality of life questionnaire less than 80. • Exclusion criteria: The caregiver physical and mental illnesses during the study; taking liquors or psychotropic drugs by the caregiver; referring the patient to long-term care centers during the study; the occurrence of a crisis events or severe stress such as the death of loved ones and divorce for the caregiver during the study; the caregiver’s attendance in training sessions on the care of the elderly with dementia over the past 6 months; the elderly’s suffering from other disabling diseases such as heart failure, asthma or uncontrolled diabetes before or during the study; the caregiver’s responsibility of taking care of someone else in the family.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

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
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand street

City
Shiraz

Postal code
71348-14336

Approval date
2017-07-19, 1396/04/28

Ethics committee reference number
IR.SUMS.REC.1396.76

Health conditions studied

1

Description of health condition studied
Dementia in Alzheimer disease

ICD-10 code
G30.1

ICD-10 code description
Alzheimer disease with late onset

2

Description of health condition studied
Vascular dementia

ICD-10 code
F01

ICD-10 code description
Vascular dementia

3

Description of health condition studied
Dementia in other diseases

ICD-10 code
F02

ICD-10 code description
Dementia in other diseases classified elsewhere

Primary outcomes

1

Description
Anxiety

Timepoint
Before, exactly and 3 months after intervention

Method of measurement
Spielberger questionnaire

2

Description

Quality Of life

Timepoint

Before, exactly and 3 months after intervention

Method of measurement

Thomas caregivers quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The case group receive informative support in two distinct parts, including: in-person training (caring elder with dementia and self-care; in seven 90-minute training sessions) and Informative-counseling support: (by phone, SMS, video call with virtual messenger programs or email for 4 weeks, 3 hours a day). Also a book that approved by university professors give to the caregivers.

Category

Other

2

Description

The control group received no informative support during the study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza clinic

Full name of responsible person

Ganj Karimi

Street address

Namazi square

City

Shiraz

2

Recruitment center

Name of recruitment center

Ebn Sina hospital

Full name of responsible person

Shojaee Ali

Street address

Hafez street

City

Shiraz

3

Recruitment center

Name of recruitment center

Professor Moharrery psychological hospital

Full name of responsible person

Homayoonfar Farzad

Street address

Next to Shiraz agriculture college

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Hashemi Seyed Basir

Street address

Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Maryam Hazrati

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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