Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of group spiritual care on caregiving burden and quality of life in family caregivers of elders with Alzheimer's disease

Protocol summary

Summary
Objective: To determine the effect of group spiritual care on caregiving burden and quality of life in family caregivers of elders with Alzheimer's disease. Inclusion criteria include: moslem, minimum one year experience of care, personal statement on the role of primary caregiver for the elderly, without diagnose mental disorder. Study population include family caregivers of elders with Alzheimer's disease of Iran Alzheimer Association in 2014. Participants will 100 family caregivers who select from study population based on inclusion criteria and randomly allocate in three control and intervention groups. Interventions consist of five sessions of Spiritual training based on Richards and Bergin’s technique in five days. Each session continue for 45 to 60 minutes. Caregiving burden and quality of life measure before, after intervention. Rate of caregiving burden and quality of life compare before and after intervention in intervention and control groups.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2014111119898N1**
Registration date: **2014-12-26, 1393/10/05**
Registration timing: **retrospective**

Last update:
Update count: **0**
Registration date
2014-12-26, 1393/10/05

Registrant information
Name
Behrooz Mahdavi
Name of organization / entity
University of Social Welfare and Rehabilitation
Country
Iran (Islamic Republic of)
Phone
+98 21 2218 0036
Email address
behroozmahdavi84@gmail.com

Recruitment status
Recruitment complete
Funding source
University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date
2014-12-06, 1393/09/15
Expected recruitment end date
2014-12-21, 1393/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of group spiritual care on caregiving burden and quality of life in family caregivers of elders with Alzheimer's disease

Public title
The effect of spiritual care on caregiver burden and quality if life
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Acceptance to be as a research participants; literacy to read and write in Persian; ability to talking with Persian language; moslem; minimum one year experience of care; personal statement on the role of primary caregiver for the elderly; Exclusion criteria: Absence of more than two sessions; if you are under the care of elderly people die during the study; caregivers who has medical background of depression or

schizophrenia; caregivers who doesn't complete their questionnaires

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
University of Social Welfare and Rehabilitation Sciences

Street address
Koodakyar Ave, Daneshjoo Blv, Evin, Tehran

City
tehran

Postal code

Approval date
2014-06-10, 1393/03/20

Ethics committee reference number
USWR.REC.1393165

Health conditions studied

1

Description of health condition studied
Alzheimer

ICD-10 code
G30.9

ICD-10 code description
Alzheimer disease, unspecified

Primary outcomes

1

Description
Caregiver Burden

Timepoint
Before intervention and five sessions after interventions

Method of measurement
Robinson Caregiver Strain Index

2

Description
Quality Of Life

Timepoint
Before intervention and five sessions after interventions

Method of measurement
Caregiver's QOL Scale

Secondary outcomes

1

Description
Age, Gender, Education, Economic situation

Timepoint
Befor intervention

Method of measurement
Demographic Questionnaire

Intervention groups

1

Description
Intervention group: The intervention will include of five sessions of spiritual-religious group therapy with emphasis on the Richards and Bergin's spiritual therapy technique and based on Islamic Zikrs (holy Quran and Hadith with positive approach). Each session including 5-7 people and last from 45 min to one hour in average of five days.

Category
Behavior

2

Description
Control 1 group: This group without special intervention will participate in team meetings for 5 weeks, 45-60 minutes per session. Just to talk about everyday issues.

Category
N/A

3

Description
Control 2 group: Without intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzheimer's Association of Iran

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Dr.Roshanak Vameghi

Street address
Koodakyar Ave, Daneshjoo Blv, Evin, Tehran

City
tehran

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
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
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Behrooz Mahdavi

Position
MSc student

Other areas of specialty/work

Street address
Koodakyar Ave, Daneshjoo Blv, Evin, Tehran

City
tehran

Postal code

Phone
+98 21 2218 0036

Fax

Email
behroozmahdavi84@gmail.commahdavib67@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Masoud Fallahi khoshknab

Position
PhD

Other areas of specialty/work

Street address
Koodakyar Ave, Daneshjoo Blv, Evin, Tehran

City
tehran

Postal code

Phone
+98 21 2218 0036

Fax

Email
msflir@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Behrooz Mahdavi

Position
MSc student

Other areas of specialty/work

Street address
Koodakyar Ave, Daneshjoo Blv, Evin, Tehran

City
Tehran

Postal code
1985713834

Phone
00

Fax

Email
behroozmahdavi84@gmail.com

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