

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation the effect of participating in support groups on the depression, loneliness and quality of life of family caregivers of Alzheimer's persons.

Protocol summary

Summary

The aim of this study is evaluation the effect of participation in the support groups on the depression, loneliness and quality of life of family caregivers of Alzheimer's persons referring to Iran Alzheimer Association. Design: Randomization, with control group, Before and after Of intervention. Inclusion criteria: All family caregivers of Alzheimer's persons, without considering the age range. Having at least one year of experience caring of Alzheimer's person. Having at least literacy of Reading and writing. Having a desire to participate in a support group. Lack of identified mental illness. Exclusion criteria: Lack of desire for maintaining participation. Death of Alzheimer's person. Change of the primary caregiver of Alzheimer's person. Participation in support groups. Participating in less than three sessions of support groups. Sample size: 80. Intervention: support group. length of the intervention: 8 session within eight weeks and every session takes 1.5-2 hours. Primery outcome: Depression, loneliness, quality of life

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108037212N1**

Registration date: **2012-04-17, 1391/01/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-04-17, 1391/01/29

Registrant information

Name

Elham Navab

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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enavab@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, Vice chancellor for Research

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-05-05, 1394/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of participating in support groups on the depression, loneliness and quality of life of family caregivers of Alzheimer's persons.

Public title

The effect of participating in support groups on the depression, loneliness and quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All family caregivers of Alzheimer's persons, without considering the age range. Having at least one year of experience caring of Alzheimer's

person. Having at least literacy of Reading and writing. Having a desire to participate in a support group. Lack of identified mental illness. Exclusion criteria: Lack of desire for maintaining participation. Death of Alzheimer's person. Change of the primary caregiver of Alzheimer's person. Participation in support groups. Participating in less than three sessions of support groups

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Quods St., Keshavarz Av.

City

Tehran

Postal code

Approval date

2014-08-23, 1393/06/01

Ethics committee reference number

1222

Health conditions studied

1

Description of health condition studied

Quality of Life

ICD-10 code

G30

ICD-10 code description

Alzheimer disease

Primary outcomes

1

Description

Depression

Timepoint

before intervention and one month after intervention

Method of measurement

Depression, Anxiety and Stress Scale - 21 Items (DASS-21)

2

Description

Loneliness

Timepoint

before intervention and one month after intervention

Method of measurement

short form of the social and emotional loneliness scale for adults (SELSA-S),

3

Description

Quality of life

Timepoint

before intervention and one month after intervention

Method of measurement

SF- 36 standard questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Eight sessions of support group will be held for every participant. Every session would be 1/5-2 hours in length and the researcher will attend all sessions as a nurse.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Alzheimer Association,Iran

Full name of responsible person

Elham Navab

Street address

School of Nursing and Midwifery, Eastern Nosrat, Tohid Square, Tehran,Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, PO Box: 14155-6446, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences, Vice chancellor for research

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**

Tehran University Of Medical Sciences

Full name of responsible person

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Position

PhD of Nursing

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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