

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of participating in support groups on grief experience, quality of sleep and fatigue of family caregivers of persons with Alzheimer.

Protocol summary

Summary

This is a randomized controlled clinical trial study to examine the effect of participation in support groups on the grief experience, quality of sleep and the fatigue of the family caregivers of people with Alzheimer's disease. The study population includes the family caregivers referring to the Alzheimer's Association. Eighty caregivers out of the population are selected based on the inclusion criteria, including having at least one year experience in patient care, having the least literacy and the absence of specified mental illnesses. If the caregiver wishes not to continue cooperation, the patient dies or participates less than three sessions in the support group, he or she will be excluded. During a meeting before the intervention starts, grief experience questionnaire, quality of sleep and fatigue will be filled in. Then eight sessions of one and a half to two hours a support group of two nurses, a psychologist, a doctor and a social worker will be formed. At the end of the eighth session and a month after that the relevant questionnaire will be filled in. Finally, the data are collected analyzed by SPSS 16 software and the results will be extracted and interpreted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410267212N2**

Registration date: **2015-06-22, 1394/04/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-22, 1394/04/01

Registrant information

Name

Elham Navab

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, School of Nursing and Midwifery, Student

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of participating in support groups on grief experience, quality of sleep and fatigue of family caregivers of persons with Alzheimer.

Public title

The effect of participating in support groups on grief experience, quality of sleep and fatigue .

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All family caregivers of people with Alzheimer's, without considering the age requirement; having at least one year experience of caring for

Alzheimer's patients; least literate; a willingness to participate in a support group; not having a marked mental illness. Exclusion criteria: Not wanting to continue working; death of the person with Alzheimer's; changing the primary caregiver of someone with Alzheimer's; participating in supportive groups; attending in less than three days of support groups meetings.

Age
No age limit

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
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences

Street address
Qods St., Islamic Enghelab St., Tehran

City
Tehran

Postal code
1417614411

Approval date
2014-08-23, 1393/06/01

Ethics committee reference number
93/130/1223/3

Health conditions studied

1

Description of health condition studied
Alzheimer

ICD-10 code
G30

ICD-10 code description
Alzheimer Disease

Primary outcomes

1

Description
Grief Experience

Timepoint
Before the intervention, The final session of intervention, One month after the intervention.

Method of measurement
MM Caregiver Grief Inventory - Short Form

2

Description
Quality of sleep

Timepoint
Before the intervention, The final session of intervention, One month after the intervention.

Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

3

Description
fatigue

Timepoint
Before the intervention, The final session of intervention, One month after the intervention.

Method of measurement
Piper Fatigue Scale (PFS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Attending in support group, 8 sessions, one and a half to two hours once a week.

Category
Other

2

Description
Without intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Alzheimer's Association

Full name of responsible person
Samira Kianipour

Street address

Ekbatan, the mobilization, beginning nursing outlet
north, next to the Municipal District 6 Zip code
1396853111

City

Tehran

Email

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

Tehran University of Medical Science

Full name of responsible person

vice- chancellor for Research of Tehran University of
Medical Science

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Sixth Floor, Central Organization Of Univercity,At the
corner of Qods Street , Keshavarz Boulevard,

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 Science

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, School of N
ursing and Midwifery

Full name of responsible person

samira kianipour

Position

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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