

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Study of the Effect of Nurse-Led Cognitive-Behavioral Therapy (CBT) on Elder Abuse and Guilt feeling among Family Caregivers of Persons with Alzheimer's Disease

Protocol summary

Study aim

Determination of the Effect of Nurse-Led Cognitive-Behavioral Therapy (CBT) on Elder Abuse and Guilt feeling among Family Caregivers of Persons with Alzheimer's Disease

Design

Randomized Clinical trials with control group, with parallel groups, without blindness,

Settings and conduct

The choice of 70 family caregivers of Alzheimer's patients referred to the Alzheimer's Association and divided into two groups: control and intervention with random allocation and in the intervention group, cognitive-behavioral intervention in the form of group meetings with a maximum of 15 caregivers with face-to-face method in 12-10 sessions will be held at the Alzheimer's Association with 2 sessions per week.

Participants/Inclusion and exclusion criteria

Inclusion Criteria The willingness to participate in research Caregivers that care the people with Alzheimer's who are over than 65 years old Alzheimer's family caregivers Having reading and writing skills No diagnosed psychological disorders Age over than 18 years old Give score 2 and above for MCTS **Exclusion Criteria** Unwillingness to continue presence in the research Death of a person with Alzheimer disease Change caregivers or give person with Alzheimer disease to care centers Not attending meetings (2 consecutive or 3 alternate session)

Intervention groups

Intervention group: Cognitive-behavioral intervention in the form of a group of 15 participants with face-to-face method in 12-10 sessions Control group: receive Alzheimer's Association routine

Main outcome variables

abuse: guilt feeling

General information

Reason for update

Acronym

CBT

IRCT registration information

IRCT registration number: **IRCT20190413043262N1**

Registration date: **2019-05-09, 1398/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-09, 1398/02/19**

Update count: **0**

Registration date

2019-05-09, 1398/02/19

Registrant information

Name

Elham Navab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4412

Email address

e-navab@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the Effect of Nurse-Led Cognitive-Behavioral Therapy (CBT) on Elder Abuse and Guilt feeling among Family Caregivers of Persons with Alzheimer's Disease

Public title
The Effect of Nurse-Led Cognitive-Behavioral Therapy (CBT) on Elder Abuse and Guilt feeling among Family Caregivers of Persons with Alzheimer's Disease

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Age over than 18 years old Having reading and writing skills The willingness to participate in research Alzheimer's family caregivers No diagnosed psychological disorders Give score 2 and above for MCTS Caregivers that care the people with Alzheimer's who are over than 65 years old
Exclusion criteria:
Diagnosis of psychiatric and cognitive conditions Unwillingness to continue presence in the research Death of a person with Alzheimer disease Change caregivers or give person with Alzheimer disease to care centers Not attending meetings (2 consecutive or 3 alternate session)

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
The samples were selected by continuous sampling and the patients will be placed in two groups of control and case by Block Balanced Randomization (BBR). Using the free web site <http://www.randomization.com/>, the assignment sequence will take place. In such a way that the number of subjects in each block is set to 5 and for the control group letter A and for the case group, the letter B will be considered and finally by confirming the creation of the sequence of allocation (Randomization Sequence) in the system for 14 blocks , The assignment sequence will be created for 70 examples by combining the letters A and B. Finally, the cards containing the blocks will be placed inside the standard envelope, and as a result, allocation concealment will be considered and observed. Based on qualified samples, an Envelope Shuffling Envelope will be removed by the researcher accidentally. Finally, the random allocation method is determined by the research samples.

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Tehran, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-11-06, 1397/08/15

Ethics committee reference number

IR.TUMS.FNM.REC.1397.148

Health conditions studied

1

Description of health condition studied

Abuse

ICD-10 code

T74.1

ICD-10 code description

Physical abuse, confirmed

2

Description of health condition studied

abuse

ICD-10 code

T74.31

ICD-10 code description

Adult psychological abuse, confirmed

3

Description of health condition studied

guilt feeling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Abuse

Timepoint

Before the intervention and after the end of session 6 and after the end of the intervention and 3 months after the end of the intervention

Method of measurement

Modified Conflict Tactics Scale

2

Description

Guilt feeling

Timepoint

Before the intervention and after the end of session 6 and after the end of the intervention and 3 months after the end of the intervention

Method of measurement

Caregiver Guilt Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Nurse-Led Cognitive-Behavioral Therapy will be held nurse-researcher in the form of face-to-face group meetings in 12-10 The meeting will be held at the Alzheimer's Association with 2 sessions per week.

Category

Behavior

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzheimer Association

Full name of responsible person

Masoumeh Salehi

Street address

Tehran, Ekbatan, between phase 1 and 2, Basij Square, the beginning of the exit to the northern side, next to the municipality of District 6

City

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Province

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Email

alzheimer.iran@yahoo.com

Web page address

http://iranalz.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammadali Sahraian

Street address

Keshavarz Blvd., Ghods St., Central Organization of the University, 6th floor of Research and Technology Department

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Email

vcr@sina.tums.ac.ir

Web page address

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Afsaneh Pourmillamirza

Position

Master student of geriatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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a.pourmollamirza@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Elham NAVAB

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Full name of responsible person

Afsaneh Pourmollamirza

Position

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available