Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effectiveness of the supportive-educational program based on the COPE care model on the resilience and care burden of family caregivers of elderly people with Alzheimer's disease

Protocol summary

Study aim
To evaluate the effect of a COPE-based supportive educational program on resilience and caregiver burden among family caregivers of elderly with Alzheimer's disease

Design
A controlled, parallel-group, single-blind, randomized clinical trial on 68 caregivers. The Research Randomizer website was used for randomization.

Settings and conduct
The study is a randomized clinical trial with a control group, which will be conducted as a pretest-posttest design and a three-month follow-up on family caregivers of elderly people with Alzheimer's disease in Yazd city. . The samples will be selected by convenience method and then randomly assigned to two intervention and control groups. The intervention group will receive a support-educational program based on the COOP care model during 5 in-person and virtual sessions, and the control group will receive usual care. Data will be collected using caregiving burden and resilience questionnaires at three times before the intervention, immediately after it, and three months later. Data analysis will be performed with appropriate statistical tests in SPSS software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: family caregivers aged18-65, Ability to read, write Persian, informed consent. Exclusion criteria: severe chronic illness, participation in similar studies

Intervention groups
The control group will receive only the routine services provided, which are also received by the intervention group. The test group caregivers will participate in a total of five group training sessions (groups of 8-10 people) for 60 to 90 minutes, designed based on the COOP model. These sessions, which will be completed in a total of 5 weeks of intervention.

Main outcome variables
Resilience score and Care burden score of family caregivers of elderly people with Alzheimer's disease

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260606069667N1**
Registration date: **2026-06-23, 1405/04/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-23, 1405/04/02**
Update count: **0**

Registration date
2026-06-23, 1405/04/02

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-06-22, 1405/04/01
Expected recruitment end date
2026-09-06, 1405/06/15
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness of the supportive-educational program based on the COPE care model on the resilience and care burden of family caregivers of elderly people with Alzheimer's disease

Public title
The effect of the COPE care model on the resilience of Alzheimer's family caregivers
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Written informed consent and willingness Caregiver age over 18 years and under 65 years Ability to read, write, understand, and receive instruction in Persian Designation as primary caregiver based on self-declaration At least three months of continuous caregiving experience for the elderly (on a daily or almost daily basis)
Exclusion criteria:
Employment in health professions Concurrent care of another chronic patient Participating in a concurrent study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be selected by sampling method and after obtaining an informed consent, they will be randomly assigned to two intervention and control groups. Simple random assignment will be used to assign the samples to the two groups. For this purpose, the researcher will first perform randomization using web-based randomization (using the Research Randomizer site) and enter study information, including the number of groups and the number of samples in each group, so that companies will be assigned to the intervention or control group, respectively. Allocation concealment will be done using opaque, sealed, and randomly sequenced envelopes. The goal of this method is that the participant and the researcher do not know the assigned group (test or control) before opening the envelope. In this regard, the supervisor, as a third party and without the researcher's involvement in the allocation process, will place the codes and assigned group in a total of 68 envelopes according to the randomization list prepared in the previous step, and the envelopes will be closed and sealed after entering the information. At the time of allocation, each caregiver receives an envelope and, after opening it, announces the name of their group to the researcher; then, the researcher will register them in the test or control group list according to the allocation result.
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 shahid sadoughi university of Medical sciences
Street address
NO26، Resalat 4 Ave، Resalat Blvd ، Boroujen City
City
Yazd
Province
Yazd
Postal code
8871643783
Approval date
2026-02-16, 1404/11/27
Ethics committee reference number
IR.SSU.REC.1404.208

Health conditions studied

1

Description of health condition studied
Alzheimer's disease
ICD-10 code
G30.9
ICD-10 code description
Alzheimer's disease, unspecified

Primary outcomes

1

Description
Primary outcome: Care burden score of family caregivers of elderly people with Alzheimer's disease, measured using the Zarit Care Burden Questionnaire. Measurement times: before the intervention, immediately after the intervention, and three months after the intervention.
Timepoint

At the beginning of the study, immediately after the intervention, and three months after the intervention.

Method of measurement

Zarit Caregiver Burden Questionnaire

Secondary outcomes

1

Description

Resilience score of family caregivers of elderly people with Alzheimer's disease measured using the Connor and Davidson Resilience Questionnaire.

Timepoint

At the beginning of the study, immediately after the intervention, and three months after the intervention.

Method of measurement

Connor-Davidson Resilience Scale (CD-RISC)

Intervention groups

1

Description

The control group will receive only the routine services provided, which are also provided by the intervention group. These routine services include the center's standard education about the nature of Alzheimer's disease, how to properly take medications, timing and monitoring the patient's symptoms, general advice about patient safety, basic strategies for managing problematic behaviors, and brief, routine consultations from a nurse or physician about daily care.

Category

Other

2

Description

Intervention group: Type of intervention: Supportive-educational intervention based on the COPE caregiving mode. Caregivers of the test group will participate in a total of five group training sessions (groups of 8-10 people) for 60 to 90 minutes, designed based on the COOP model. These sessions will include three in-person sessions at the Yazd Alzheimer's Association and two virtual sessions on Google Meet. One session will be held each week, which will be completed in a total of 5 weeks of intervention. The timing of these sessions will be determined by agreement between the researcher and the caregivers to ensure that all participants can participate fully in this educational process. The presentation of the material will be through a combination of lecture methods using slides, group discussion, and scenarios. Also, weekly telephone follow-ups (every Thursday between 8:00 AM and 12:00 AM) will be conducted by the researcher for three months. It should be noted that at the end of the first in-person session, the researcher's phone number will be provided to the participants for calling and questioning. Also, at the end of the second in-person session, the participants will receive the necessary training to use the Google Meet platform in virtual meetings. the first session, which focuses on the emotional component and expert information (E), the goal is to provide emotional support and increase awareness about Alzheimer's. The second session focuses on cognitive skills (C) and aims to strengthen problem-solving abilities and provide creative solutions. In the third session, which is dedicated to the optimism and mental resilience component (O), caregivers practice cognitive review, positive self-talk, and recording three good things daily. The fourth session focuses on the planning and practical component (P) and aims to increase caregivers' control over daily activities and reduce caregiving burden. The fifth session is dedicated to integrating all components. In this session, a review of all sessions, questions and answers, and completion of the Personal Care Plan booklet are conducted to consolidate learning and enable caregivers to practically apply all COPE components in daily life. This process ensures that the training is not just theoretical and that caregivers actively and practically improve their skills.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Shadow of Forgetfulness Institute

Full name of responsible person

Ziba Parizy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Mehran Karimi

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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Hanie Hosseini
Position
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Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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

Title and more details about the data/document

Primary and secondary data, data coding, and study protocol

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

Researchers working in academic and scientific institutions People who are also involved in industry

Under which criteria data/document could be used

Participant data will be used solely for secondary analyses, meta-analyses, and related scientific research. Access to data is possible after submitting a written request and a valid scientific proposal, approval by the research team, and a commitment to maintaining confidentiality of information.

From where data/document is obtainable

By email haniehosseini7810@gmail.com or phone 098 9135564233

What processes are involved for a request to access data/document

The applicant must submit a written request to the principal investigator, including the research objectives, analysis plan, and research team specifications. Requests will be reviewed scientifically and ethically by the research team. If approved, and after signing a confidentiality and data use agreement, access to anonymized data will be provided.

Comments