Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of a remote empowerment training program on stress, caregiving burden, self-efficacy, and caregiving experience in family caregivers of Alzheimer's patients, based on the caregiving stress process model

Protocol summary

Study aim

Determining the effectiveness of a remote empowerment training program on reducing perceived stress, reducing caregiving burden, improving self-efficacy, and improving the caregiving experience in family caregivers of elderly people with Alzheimer's disease based on the caregiving stress process model

Design

This study is a randomized, double-blind, parallel-group, two-arm clinical trial. The sample size is estimated at 120 subjects (60 subjects per group). Block randomization is performed using Excel software, and allocation concealment is performed through sealed envelopes.

Settings and conduct

A list of names of dementia patients who have an active diagnosis file in the family physician system under the supervision of Babol University of Medical Sciences' health and treatment department, and their family caregivers are invited to cooperate.

Participants/Inclusion and exclusion criteria

Be a primary and informal (family) caregiver of a person with Alzheimer's disease (not a substitute or temporary caregiver) At least 6 months of caregiving experience with at least 20 hours per week Age 18 to 70 years Internet access and ability to use a smartphone or computer Literacy Informed consent to participate in the study

Intervention groups

In the intervention group, an empowerment training program was designed based on reliable resources from the World Health Organization (WHO) and care guidelines (iSupport) for caregivers of elderly people with Alzheimer's. This program was implemented in a non-face-to-face format in the form of 8 training sessions, each session lasting 30 to 40 minutes, in accordance with the steps of the Caregiver Stress Process Model (SPM).

Main outcome variables

Caregiving Burden; Stress, Self-Efficacy, and Caregiving Experience in Family Caregivers of Patients with Alzheimer's Disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251211068284N1**
Registration date: **2026-02-23, 1404/12/04**
Registration timing: **prospective**

Last update: **2026-02-23, 1404/12/04**
Update count: **0**

Registration date

2026-02-23, 1404/12/04

Registrant information

Name

Maryam Ghorbanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3724 4495

Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-24, 1404/12/05

Expected recruitment end date

2027-02-19, 1405/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of a remote empowerment training program on stress, caregiving burden, self-efficacy, and caregiving experience in family caregivers of Alzheimer's patients, based on the caregiving stress process model

Public title

Investigating the effect of a remote empowerment training program on stress, caregiving burden, self-efficacy, and caregiving experience in family caregivers of people with Alzheimer's disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Primary caregiver of a patient with Alzheimer's disease(not a substitute or temporary caregiver) Informal caregiver(family caregiver) At least 6 months of caregiving experience (at least 20 hours per week) Age 18 to 70 years Ability to use a smartphone or computer and access the Internet Literacy Willingness and informed consent to participate in the study

Exclusion criteria:

Having a physical disorder, severe psychiatric disorder, or chronic debilitating illness Discontinuation of caregiving relationship with the elderly person during the study (e.g., death of the elderly person or abandonment of care) Participation in a similar educational program in the last 6 months Withdrawal from further cooperation at any stage of the study Lack of active cooperation in digital empowerment programs Occurrence of critical incidents

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be used to balance the size of the groups. Stratified randomization based on important variables (e.g., caregiver age, duration of care, patient severity) will be used to reduce bias. Randomization will be performed using Excel software and allocation concealment will be provided via sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is designed as a double-blind study. The participants are unaware of the characteristics of the groups. The researcher is aware of the grouping and implements the intervention. A statistician who is separate from the study process and unaware of all the procedures performed will be used to analyze the data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Street

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2025-12-08, 1404/09/17

Ethics committee reference number

IR.MUBABOL.REC.1404.178

Health conditions studied

1

Description of health condition studied

Family caregivers with Alzheimer's disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Caregiving burden

Timepoint

At the beginning of the study (before the start of the intervention), at the end of the training sessions (end of the intervention), and 1 month after the last training session.

Method of measurement

Zarit Burden Interview

Secondary outcomes

1

Description
Perceived stress
Timepoint
At the beginning of the study (before the start of the intervention), at the end of the training sessions (end of the intervention), and 1 month after the last counseling session
Method of measurement
Perceived Stress Scale

2

Description
Self-efficacy
Timepoint
At the beginning of the study (before the start of the intervention), at the end of the training sessions (end of the intervention), and 1 month after the last counseling session
Method of measurement
Caregiver Self-Efficacy Scale

3

Description
Care experience
Timepoint
At the beginning of the study (before the start of the intervention), at the end of the training sessions (end of the intervention), and 1 month after the last counseling session
Method of measurement
Revised Care Experience Assessment Scale

Intervention groups

1

Description
Intervention group: Intervention group: Intervention group: Remote empowerment training program based on the Caregiver Stress Process Model (SPM) that is implemented for 4 weeks. The training content includes 8 sessions (two sessions per week) in the form of audio podcasts, educational videos, etc. 30 to 40 minutes long along with a visual summary file of key points (JPEG or PDF) are sent to participants via WhatsApp messenger. The session titles are: 1. Introduction to Alzheimer's and the role of caregivers, 2. Identification of primary stress factors, 3. Identification of secondary stress factors, 4. Perceived stress and caregiver emotions, 5. Psychological coping strategies, 6. Social support and available resources, 7. Promoting a sense of self-efficacy, 8. Review, summarization, and planning for the future. In addition to the training content, participants join a WhatsApp support group and receive a weekly follow-up phone call from the researcher to ensure receipt of the content, answer questions, and encourage participation. Reminder and motivational SMS messages are also sent twice a week. Weekly exercises are also sent and followed by participants via a Pressline link or a WhatsApp group link.
Category
Behavior

2

Description
Control group: Control group: Participants in this group do not receive any specific educational intervention from the researcher and only receive routine care, which includes common services in the comprehensive health centers under their coverage (such as doctor visits, regular counseling sessions, distribution of general brochures, and common support services). These individuals will be placed on a waiting list to receive the educational program, and after completing the study and following up, if desired, all the educational content of the empowerment program will be made available to them. Participants in the control group will complete research questionnaires at the same time points as the intervention group (pre-test, post-test immediately after 4 weeks, and one-month follow-up).
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
مراکز جامع سلامت تحت پوشش دانشگاه علوم پزشکی بابل
Full name of responsible person
افسانه بختیاری
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi

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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
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Bakhtiari Afshane
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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

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