Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of a Care Program Based on Pender's Health Promotion Model on the Caregiver Burden of Family Caregivers of patients with Alzheimer's Disease

Protocol summary

Study aim

Assessment of the effect of a Care Program Based on Pender's Health Promotion Model on the Caregiver Burden of Family Caregivers of patients with Alzheimer's Disease Attending Clinics Affiliated with Tabriz University of Medical Sciences

Design

This is a randomized, parallel-group, double-blind clinical trial. A total of 122 family caregivers will be enrolled and randomly assigned to either the intervention or control group using blocked randomization (block size of 6, allocation ratio 1:1). The allocation sequence will be generated by a researcher not involved in the intervention delivery (using computer software) and concealed in sequentially numbered, opaque, sealed envelopes.

Settings and conduct

Educational classroom, Imam Reza Hospital; Participants will be randomly assigned, with the intervention delivered to the intervention group; Outcome assessor and data analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Primary caregivers of Alzheimer’s patients, aged 18–65 years, with at least basic literacy, minimum 6 months caregiving experience, and a first-degree familial relationship with the patient. Exclusion Criteria: The patient under care has another illness besides Alzheimer's disease, such as cancer and cardiovascular diseases.

Intervention groups

Intervention Sessions: Six in-person sessions covering program introduction, caregiver burden and mental health education, introduction to Pender’s Health Promotion Model, stress and caregiver fatigue management skills, effective communication with the patient, time management and care planning, and finally, review of topics, supplementary resources, and Question & Answer. Control participants will receive educational materials after study completion if effective.

Main outcome variables

Caregiver burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250902067101N1**
Registration date: **2025-12-06, 1404/09/15**
Registration timing: **prospective**

Last update: **2025-12-06, 1404/09/15**
Update count: **0**

Registration date

2025-12-06, 1404/09/15

Registrant information

Name

Reza Nematollahi Maleki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 561 8507

Email address

r.nematollahi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-04-21, 1405/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a Care Program Based on Pender's Health Promotion Model on the Caregiver Burden of Family Caregivers of patients with Alzheimer's Disease

Public title

The effect of a Care Program Based on Pender's Health Promotion Model on the Caregiver Burden of Family Caregivers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 18-65 Being literate Being the primary caregiver of the patient Having taken care of the patient for at least 6 months Being the first degree relative

Exclusion criteria:

The patient under care has another illness besides Alzheimer's disease, such as cancer and cardiovascular diseases.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 120 participants meeting the inclusion criteria will be recruited for the study. A blocked randomization sequence (block size = 6, allocation ratio 1:1) will be generated using SPSS version 27 by one of the authors who is blinded to the study hypothesis and the intervention assignment. The allocation sequence will be placed in sequentially numbered, opaque, sealed envelopes and concealed until the initiation of the intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor and the data analyst will be blinded to participants' group allocation to minimize detection and analysis bias. Due to the nature of the intervention (educational program), blinding of participants and the primary investigator will not be feasible.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Tabriz University of Medical Sciences

Street address

Azadi boulevard

City

Tabriz

Province

East Azarbaijan

Postal code

5163958156

Approval date

2025-06-02, 1404/03/12

Ethics committee reference number

IR.TBZMED.REC.1404.252

Health conditions studied

1

Description of health condition studied

caregiver burden of patients with Alzheimer's Disease

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

Caregiver burden

Timepoint

The caregiver burden of family caregivers will be assessed at two time points: once before the intervention (baseline) and once two months after the final educational session (follow-up).

Method of measurement

Measurement will be conducted using the Caregiver Burden Inventory (CBI), administered by a trained assessor either in person or via telephone.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After completing the demographic questionnaire and the Caregiver Burden Inventory (CBI), participants in the intervention group will be divided into six subgroups of ten individuals each for group-based sessions. The caregiving program, based on Pender's Health Promotion Model, will be delivered by one of the researchers in six 45–60-minute sessions.In the first session, following an initial assessment, the researcher, with the assistance of the patient's caregiver, will review the goals that the caregiver needs to achieve and determine the desired outcomes for each participant. The content of the sessions will be as follows:Session 1: Introduction to the program, education on the concept of caregiver burden, and mental health.Session 2: Introduction to Pender's Health Promotion Model and its application in caregiving.Session 3: Stress management and coping strategies for caregiver fatigue.Session 4: Training in effective communication techniques with the patient.Session 5: Time management and planning for caregiving tasks.Session 6: Review and summary of the topics, provision of supplementary resources, and addressing participants' questions.

Category

Behavior

2

Description

Control group: Caregivers of patients with Alzheimer's disease who meet the inclusion criteria will not receive the caregiving program based on Pender's Health Promotion Model. If the intervention proves to be effective, the educational materials will be made available to this group in the form of a booklet.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurology Clinics of Imam Reza Hospital
Full name of responsible person
Hamed Gholizad Gougjehyaran
Street address
Azadi boulevard, Azadi dormitory
City
Tabriz
Province
East Azarbaijan
Postal code
5163958156
Phone
+98 936 898 3732
Email
h.gholizad1991@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Khosro Adibkia
Street address
Azadi boulevard
City
Tabriz
Province
East Azarbaijan
Postal code
5163958156
Phone
+98 41 3335 7310
Email
adibkia@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Reza Nematollahi Maleki
Position
PhD Nursing Student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Azadi boulevard, Azadi dormitory
City
Tabriz
Province
East Azarbaijan
Postal code
5163958156
Phone

+98 914 561 8507

Email

r.nematollahi@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Reza Nematollahi Maleki

Position

PhD Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Azadi boulevard

City

Tabriz

Province

East Azarbaijan

Postal code

5163958156

Phone

+98 914 561 8507

Email

r.nematollahi@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Reza Nematollahi Maleki

Position

PhD Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Azadi boulevard

City

Tabriz

Province

East Azarbaijan

Postal code

5163958156

Phone

+98 914 561 8507

Email

r.nematollahi@tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to ethical considerations and confidentiality concerns regarding patient caregivers, there is no plan to share deidentified IPD from this study.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study Protocol – This document includes details of the study objectives, design, methodology, participant selection criteria, intervention content, and data collection tools. Only the protocol document will be shared; no individual participant data will be included.

When the data will become available and for how long

The protocol will be available upon reasonable request after publication of the main study results and will remain accessible for 3 years following publication.

To whom data/document is available

The protocol will be available to researchers and academic staff affiliated with recognized research institutions and universities.

Under which criteria data/document could be used

The protocol may be used for academic and scientific purposes only, such as designing similar studies, systematic reviews, or meta-analyses. Any use requires proper citation of the original study. Requests will be reviewed by the principal investigator.

From where data/document is obtainable

Requests should be directed to the principal investigator via email: r.nematollahi@tbzmed.ac.ir.

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

Interested researchers should send an email request including their name, institutional affiliation, and purpose of use. Requests will be reviewed within 2–4 weeks, and approved applicants will receive the protocol in PDF format.

Comments