

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of supportive educational intervention on medication management and perceived stress of elderly family caregivers

Protocol summary

Study aim

Determining the impact of a supportive educational intervention on medication management and the perceived stress level of family caregivers of the elderly

Design

A controlled trial with parallel groups, non-blinded, non-randomized, conducted on 52 family caregivers of the elderly

Settings and conduct

The research will be conducted in Gonabad and Ferdows counties. In the intervention group, the researcher will visit the elderly person's home for three in-person sessions to review the medication bag and provide medication management education. Then, 2 to 3 follow-up phone calls will be made to address any issues or concerns the caregivers have regarding medication management. No intervention will be done in the control group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The main caregiver must be a family member of an elderly person with chronic diseases. The family caregiver must be the primary person responsible for caring for an elderly person with multiple chronic diseases. Exclusion Criteria: Death of the elderly person. Caregiver's unwillingness to continue participating in the study.

Intervention groups

In the intervention group, the researcher will visit the elderly person's home for three in-person sessions to: Review the elderly person's medication bag, Provide general information about the purpose and side effects of each medication, Teach how to prepare medications, Educate on the correct dosage, timing, and method of medication administration. After completing the in-person sessions, the researcher will follow up by phone 2 to 3 times to address any issues or concerns the caregivers may have regarding the topics mentioned. No specific intervention will be conducted in the control group.

Main outcome variables

Medication management level of family caregivers; perceived stress level of family caregivers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241102063567N1**

Registration date: **2024-11-12, 1403/08/22**

Registration timing: **prospective**

Last update: **2024-11-12, 1403/08/22**

Update count: **0**

Registration date

2024-11-12, 1403/08/22

Registrant information

Name

Mahmood Baniasad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3273 1314

Email address

mahmood.baniasad@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-05, 1403/09/15

Expected recruitment end date

2025-02-03, 1403/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of supportive educational intervention on medication management and perceived stress of elderly family caregivers

Public title
The effect of supportive educational intervention on medication management

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Be the primary caregiver for an elderly family member with chronic illnesses Be at least 18 years old The family caregiver must be primarily responsible for caring for an elderly person with multiple chronic illnesses (providing the majority of daily care hours and recognized by the patient as the main caregiver) Have primary responsibility for managing the elderly person's medications Have provided care for more than six months The caregiver should not have any mental illness and should not be using psychiatric medications No major stressful events for the caregiver in the past 6 months Be willing to participate in the study
Exclusion criteria:
Occurrence of a stressful event for the caregiver during the study Death of the elderly person Caregiver's unwillingness to continue participating in the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be classified into two age groups of family caregivers: under 50 years and over 50 years. Then, randomization will be done within each class, so that the samples from each of the two age classes will be assigned equally and using simple random sampling to the intervention and control groups, based on a random numbers table.

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 Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, on the side of Asian Road

City

Gonabad

Province

Razavi Khorasan

Postal code

info@gmu.ac.ir

Approval date

2024-10-15, 1403/07/24

Ethics committee reference number

IR.GMU.REC.1403.060

Health conditions studied

1

Description of health condition studied

Medication management of family caregivers, perceived stress of family caregivers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Medication management

Timepoint

Before and after the intervention

Method of measurement

Medication Management Instrument for Deficiencies in the Elderly

2

Description

Perceived stress

Timepoint

Before and after the intervention

Method of measurement

The Cohen Perceived Stress Scale (1983)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Review of the elderly person's medication bag (prescription medications, over-the-counter medications, supplements, herbal medicines), identification of duplicate medications, providing general information on the use of each medication, educating on the side effects of the elderly person's medications and necessary interventions in case of side effects, ensuring adherence to prescribed dosages, teaching how to prepare medications, teaching the correct timing for medication administration, educating on the proper way to use medications (e.g., how each medication should be administered, such as sublingually, swallowed, chewed, sprayed, etc., and the correct technique for using each type, such as how to administer eye and nasal drops, how to spray, and other specific considerations for each method), providing information on medication storage and specific instructions for each medication (e.g., how much liquid to use with each medication, whether it should be taken with food or on an empty stomach, after using an antacid, etc.), and educating on sources for obtaining each medication.

Category

Other

2

Description

Control group: There will be no special intervention in this group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ferdows Health Center

Full name of responsible person

Mohammad Reza Hosseinizadeh

Street address

Health and Medical Department, Khorramshahr Street

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2

Recruitment center

Name of recruitment center

Gonabad Health Center

Full name of responsible person

Dr. Javad Sadeghi Nasab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Ali Firouzi Chahak

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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

Gonabad 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**

Birjand University of Medical Sciences

Full name of responsible person

Mahmood Baniasad

Position

clinical supervisor

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Leila Sadegh Moghadam Abbaspour

Position

Specialized doctorate in gerontology

Latest degree

Ph.D.

Other areas of specialty/work

Geriatrics

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data obtained regarding the target population of this study pertains to demographic information and the two main outcomes of the study, namely medication management and perceived stress. These data will be reported anonymously and presented as results from the analysis of the obtained findings.

When the data will become available and for how long

The access period will begin 6 months after the publication of the results.

To whom data/document is available

Researchers in the fields of nursing and aging, all healthcare providers, health policymakers, nursing professionals, and aging specialists.

Under which criteria data/document could be used

Citing the researchers of this study

From where data/document is obtainable

To receive the documents, send a request to the following email address: mahmood.baniasad@bums.ac.ir

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

To request documentation, please send an email to the address below. A response will be provided as soon as possible after the review is completed.

