Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effectiveness of Spiritual–Psychological Skills Training on Caregiving Burden, Mental Health, and Relationship Quality with the Elderly among Female Caregivers Sandwich Generation of Frail Older Adults (Randomized Controlled Trial)

Protocol summary

Study aim
Effectiveness of spiritual-psychological skills training on caregiver burden, mental health and relationship quality in sandwich-generation female caregivers of frail elderly

Design
Randomized clinical trial with control group, parallel groups, Non-blinded, Block randomization (block size 4), 116 participants (58 participants in each group), Single-center.

Settings and conduct
Sandwich generation female caregivers who were caregivers for frail older adults living at home and participated in the third phase of the Amirkola Cohort Study on the Elderly (AHAP) will be identified. if they are eligible for the inclusion criteria of this study, they will be randomly assigned to intervention and control groups using randomized blocks. Due to the educational-behavioral nature of this study, blinding is not possible.

Participants/Inclusion and exclusion criteria
Inclusion: Women 30-65 years; Caring at least 3 months for at least one frail older adult at home; Simultaneous care of at least one child under 18; Living in Babol or Amirkola; Smartphone access; Written consent Exclusion: History of similar training in past 6 months; Simultaneous care of more than one frail older adult; Pregnancy or childbirth in past 3 months; Plan to migrate from Babol within 4 months; history of diagnosed severe psychiatric disorder.

Intervention groups
Intervention will include eight 90-minute sessions (first 4 in-person, next 4 virtual) which are held over 4 weeks for the intervention group. The content of sessions is: meaning of care, self-awareness, spirituality and resilience, stress management, communication skill, conflict management, support seeking, self-care. Routine care will be done for the control group. They will also receive educational files after the study.

Main outcome variables
Primary: Caregiver Burden. Secondary: Mental Health, Spiritual Well-being, Relationship Quality, Elderly Daily Functioning.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260207068788N1**
Registration date: **2026-06-27, 1405/04/06**
Registration timing: **prospective**

Last update: **2026-06-27, 1405/04/06**
Update count: **0**

Registration date
2026-06-27, 1405/04/06

Registrant information
Name
Marjan Niktalemi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 3383 6393
Email address
mn.niktalemi74@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-08-06, 1405/05/15

Expected recruitment end date
2027-01-05, 1405/10/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effectiveness of Spiritual–Psychological Skills Training on Caregiving Burden, Mental Health, and Relationship Quality with the Elderly among Female Caregivers Sandwich Generation of Frail Older Adults (Randomized Controlled Trial)

Public title
The effect of spiritual–psychological skills training on mental health and caregiving experiences of female caregivers of older adults
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Women who provide in-home care for at least one frail older adult (with a minimum caregiving duration of three months). Concurrent membership in the sandwich generation (having at least one child under 18 years of age while also caring for an elderly parent). Age between 30 and 65 years. Living in Babol or Amirkola; Smartphone access Willingness and full informed consent to participate in the study.
Exclusion criteria:
History of participating in similar spiritual-psychological skills training programs in the past six months. Simultaneous care of more than one frail older adult at home. Pregnancy or childbirth in the past three months. Having a plan to migrate from Babol city within the next four months. History of diagnosed severe psychiatric disorder.
Age
From **30 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **116**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals will be randomly allocated to the intervention and control groups using block randomization (with a block size of 4). The randomization list will be generated by a statistical collaborator using random allocation software and will be provided to the principal investigator.
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 Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrouz Street, Babol, Mazandaran, Iran
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2026-02-02, 1404/11/13
Ethics committee reference number
IR.MUBABOL.REC.1404.238

Health conditions studied

1

Description of health condition studied
Caregiver burden in female sandwich-generation caregivers of frail elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Caregiver burden score as measured by the Zarit Burden Interview (ZBI)
Timepoint
Before intervention, immediately after intervention, and 3 months after intervention
Method of measurement
The Zarit Burden Interview (ZBI) questionnaire, consisting of 22 items on a 5-point Likert scale. Total score ranges from 0 to 88, which higher scores indicating greater caregiver burden.

Secondary outcomes

1

Description
General mental health score
Timepoint
Baseline (before intervention), immediately after intervention (post-test), and 3 months after intervention (follow-up)
Method of measurement
General Health Questionnaire (GHQ-12): A 12-item self-administered questionnaire for screening general psychological distress. Items are scored on a 4-point Likert scale (with total scores ranging from 0 to 12). Higher scores indicate poorer mental health status.

2

Description
Depression score
Timepoint
Baseline (before intervention), immediately after intervention, and 3 months after intervention
Method of measurement
Geriatric Depression Scale (GDS-15): A 15-item yes/no self-report scale designed specifically to assess depressive symptoms in older adults. Total scores range from 0 to 15, with higher scores indicating greater severity of depressive symptoms.

3

Description
Spiritual well-being score
Timepoint
Baseline (before intervention), immediately after intervention, and 3 months after intervention
Method of measurement
Spiritual Well-Being Scale (SWBS): A 20-item self-report scale measuring religious well-being (relationship with God), and existential well-being (sense of purpose and satisfaction in life). Items are rated on a 6-point Likert scale. Total scores range from 20 to 120, with higher scores indicating greater spiritual well-being.

4

Description
Relationship quality score
Timepoint
Before intervention, immediately after intervention, and 3 months after intervention
Method of measurement
Quality of Relationship Inventory (QRI): A 25-item inventory assessing three dimensions of relationship quality: support, conflict, and depth. Items are rated on a 5-point Likert scale. Total scores range from 25 to 125.

5

Description
Elderly daily functioning score
Timepoint
Before intervention, immediately after intervention, and 3 months after intervention
Method of measurement
Katz Index of Independence in Activities of Daily Living (ADL): A 6-item observer-rated scale assessing independence in six basic activities: bathing, dressing, toileting, transferring, continence, and feeding. Scores range from 0 (completely dependent) to 6 (completely independent).

Intervention groups

1

Description
Intervention group: Participants receive a spiritual-psychological skills training program over four weeks (eight 90-minute sessions, two sessions per week). The first four sessions are held in person at the Amirkola elderly cohort center and the next four sessions are held virtually via the Bale messaging app. Each session includes three parts: educational presentation (30 minutes), practical workshop (30 minutes), and group discussion with Q&A (30 minutes). Session content in order: (1) meaning of caregiving and spiritual well-being, (2) self-awareness and role conflict, (3) spirituality and resilience with breathing-contemplative exercises, (4) stress management with muscle relaxation techniques, (5) communication skills and active listening, (6) conflict management and support seeking, (7) self-care and burnout prevention, (8) summary and personal action plan. Audio and PDF files of session content are provided to participants. Absence from more than two sessions is an exit criterion.
Category
Behavior

2

Description
Control group: Participants continue their usual caregiving for the older adult throughout the study (assistance with feeding, bathing, medication, treatment follow-up). This group receives no educational intervention. After study completion, all educational materials will be available for them free of charge.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola Health and Ageing Project Executive Site
Full name of responsible person
Seyed Reza Hosseini
Street address
Next to Amirkola Urban Comprehensive Health Center, Naghavi Street, Amirkola, Babol, Mazandaran, Iran
City

Amirkola

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۵۴

Phone
+98 11 3219 0560

Email
hosseinirezaseyed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Reza Ghadimi

Street address
Babol University of Medical Sciences, Ganjafrouz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴۵

Phone
+98 11 3219 9592

Email
info@mubabol.ac.ir

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
Marjan Niktalemi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Geriatrics

Street address
Babol University of Medical Sciences, Ganjafrouz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
4117647745

Phone
+98 13 3383 6393

Email
mn.niktalemi74@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Samaneh Pourhadi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Geriatrics

Street address
Babol University of Medical Sciences, Ganjafrouz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴۵

Phone
+98 11 3219 0181

Email
samaneh.pourhadi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Marjan Niktalemi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Geriatrics

Street address
Babol University of Medical Sciences, Ganjafrouz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran
Postal code
4717647745
Phone
+98 13 3383 6393
Email
mn.niktalemi74@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be published after being de-identified.
When the data will become available and for how long
6 months after results are published.
To whom data/document is available
For the purpose of therapeutic practices and in accordance with all ethical principles.
Under which criteria data/document could be used
For the purpose of therapeutic practices and in accordance with all ethical principles.
From where data/document is obtainable
Corresponding author, Dr. Samaneh Pourhadi, via email at samaneh.pourhadi@gmail.com
What processes are involved for a request to access data/document
It must be clear who the request is from and for what purpose. The request is then reviewed by the research team and the university's vice president for research. If approved, the data will be sent.
Comments