Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Impact of tele-mindfullness education on resiliance and life satisfaction of family caregivers of individuals with Alzheimer

Protocol summary

Study aim
Determining the Effect of Tele-Mindfulness Training on Resilience and Life Satisfaction of Family Caregivers of Individuals with Alzheimer's Disease

Design
This study is a randomized, single-blind clinical trial with a control group and parallel groups, conducted on 84 caregivers. After assessing the inclusion criteria, eligible caregivers will be randomly assigned to two groups of 42 participants each.

Settings and conduct
Eligible participants will be randomly assigned to the intervention or control group. The intervention group will receive eight online mindfulness sessions, held twice weekly for 30 minutes, covering topics such as mindful breathing, body scanning, walking, and compassion. The control group will not receive any training. Data analysts will be blinded to group assignments.

Participants/Inclusion and exclusion criteria
Eligible participants must be 18 or older, be a family caregiver for an Alzheimer's patient, and communicate effectively in Persian. They must provide at least four hours of daily care and not regularly engage in mindfulness practices. Participants should have no recent psychiatric diagnoses or history of substance abuse. A smartphone, internet access, and basic digital skills are required. Informed consent is mandatory.

Intervention groups
Family caregivers of individuals with Alzheimer's disease who visit the Iranian Dementia and Alzheimer's Association are screened based on the inclusion criteria.

Main outcome variables
Resilience and Life Satisfaction Questionnaire Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250129064562N1**
Registration date: **2025-04-23, 1404/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-23, 1404/02/03**
Update count: **0**

Registration date
2025-04-23, 1404/02/03

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-03, 1404/01/14

Expected recruitment end date
2025-09-05, 1404/06/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Impact of tele-mindfullness education on resiliance and life satisfaction of family caregivers of individuals with Alzheimer

Public title

Tele-mindfullness for family caregivers of individuals with Alzheimer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 years old or above Caregiver of a person with Alzheimer's Family member of the patient Must possess effective communication skills in Persian Must provide direct daily care for a minimum of four hours

Exclusion criteria:

Not having informed consent for participation in the research study Not Having enough proficiency in using a smartphone or tablet for messaging, attending classes, and downloading files Not owning a smartphone and have reliable internet access for participation in online sessions Having a history of substance or medication abuse Having a recently diagnosed psychiatric disorder such as severe depression, anxiety disorder, or psychosis Engaging in a regular mindfulness meditation, mindful yoga, or enrolled in a similar mindfulness-based program

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

To maintain consistent research environment conditions between the control and experimental groups, the random allocation of samples into the control and intervention groups will be performed in an alternating manner. For the assignment of the first sample, a coin toss will be employed to determine placement in either the control or intervention group. Subsequent samples will be alternately allocated to the corresponding groups. Sampling will continue until the required sample size, as determined by the specified formula, is achieved.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, data analysts are blinded to the placement of caregivers in the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Working Group of the Vice-Chancellor for Research and Technology at Iran Univers

Street address

Deputy for Research and Technology, Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2024-08-13, 1403/05/23

Ethics committee reference number

IR.IUMS.REC.1403.407

Health conditions studied

1

Description of health condition studied

Caregiving for individual with Alzheimer's disease

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

The score of resilience

Timepoint

Before and after the intervention

Method of measurement

Resilience Questionnaire for In-home Caregivers of the Elderly

2

Description

Life Satisfaction Score

Timepoint

Before and after the intervention

Method of measurement

Satisfaction with life scale (SWLS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The educational content for the intervention group is designed to provide mindfulness training for family caregivers of individuals with Alzheimer's disease. The training will be delivered over eight 30-minute sessions, conducted twice weekly over four weeks. Session topics include an introduction to mindfulness and mindful raisin eating (Session 1), mindful breathing (Session 2), mindful body scanning (Session 3), mindful seeing and listening (Session 4), mindful walking (Session 5), mindful sitting (Session 6), mindful compassion (Session 7), and a concluding session (Session 8). Additionally, participant experiences will be discussed throughout the sessions.

Category

Behavior

2

Description

Control group: After completing the study and analyzing the data, to maintain ethical principles, electronic pamphlets on mindfulness training (which were sent to the intervention group at the end of each session) will be provided to the control group (sent electronically to their respective groups). The researcher will also answer their questions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Dementia and Alzheimer's Association

Full name of responsible person

Masoumeh Salehi

Street address

Opposite District 6 Municipality, at the beginning of the exit toward North Sattari, Basij Square, Ekbatan Town, Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Majid Safa

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Raziye Sadat Hosseini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Geriatrics

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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