Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effectiveness of semantic therapy based on Rumi's thoughts and mindfulness-based stress reduction on caregiving pressure in family caregivers of the elderly

Protocol summary

Study aim

Comparing the effectiveness of semantic therapy based on Rumi's thoughts and mindfulness-based stress reduction on caregiving pressure in family caregivers of the elderly

Design

The research method will be semi-experimental, with a pre-test-post-test design with a control group and a two-month follow-up. 45 people will be selected from the G*Power program through purposive sampling and will be divided into two experimental groups and a control group (15 people each). The two groups will receive the experiment in 8 sessions, and the control group will not receive any intervention during this period.

Settings and conduct

The statistical population of the study will include all family caregivers of the elderly referring to the Mehr Nursing Home in Sari

Participants/Inclusion and exclusion criteria

The criteria for entering the research include the following: Informed consent to participate in the research. At least diploma education. Age range from 20 to 60 years. Non-use of psychiatric drugs and psychological treatments during the research based on clinical interview. Also, the exit properties included the following: Unwillingness to continue cooperation in the research. Existence of distorted questionnaires. Absence of more than two sessions

Intervention groups

The first experimental group will receive meaning therapy in 8 75-minute sessions, and the second experimental group will receive mindfulness-based stress reduction in 8 60-minute sessions. During this period, the control group will not receive any intervention.

Main outcome variables

The caregiving stress score is expected to decrease with each treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260504069259N2**
Registration date: **2026-07-04, 1405/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-04, 1405/04/13**
Update count: **0**

Registration date

2026-07-04, 1405/04/13

Registrant information

Name

Fateme Gholian nozari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3454 3597

Email address

fateme.qolian70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-07-06, 1405/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effectiveness of semantic therapy based on Rumi's thoughts and mindfulness-based stress reduction on caregiving pressure in family caregivers of the elderly

Public title
Comparing the effectiveness of semantic therapy based on Rumi's thoughts and mindfulness-based stress reduction on caregiving pressure in family caregivers of the elderly

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
No use of psychiatric medications No use psychological treatmentsduring the study based on clinical interviewInformed consent to participate in research Minimum education: Diploma

Exclusion criteria:

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
En The sample size in the G*Power program, version 1.3 (Faul et al., 2019), with a confidence level of 0.95, a power of 0.80, and a dropout rate of 10%, was calculated for each group of 15 people. Therefore, 45 people were selected based on the inclusion criteria and by exclusion using the purposive sampling method and will be divided into two experimental groups and a control group (each group 15 people). The first experimental group will receive meaning therapy based on Rumi's thoughts in 8 75-minute sessions, and the second experimental group will receive mindfulness-based stress reduction in 8 60-minute sessions (2 sessions per week). During this period, the control group will not receive any intervention.

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 in Biomedical Research

Street address
Imam Reza Blvd., Imam Reza 6, Saray Mehr

City
sari

Province
Mazandaran

Postal code
4841683648

Approval date
2025-07-19, 1404/04/28

Ethics committee reference number
IR.IAU.SARI.REC.1404.194

Health conditions studied

1

Description of health condition studied
Caregiving pressure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The score obtained from the care pressure questionnaire of Zarit et al. (1980).

Timepoint
Before the intervention, after the intervention, and two months after the intervention

Method of measurement
The score obtained from the care pressure questionnaire of Zarit et al. (1980).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The semantic therapy intervention based on Rumi's thoughts will be implemented in groups in 8 75-minute sessions (two sessions per week, for four weeks) for family caregivers of the elderly. The sessions will be held by an assistant professor of psychology and a scientifically qualified therapist in the Mehr Nursing Home in Sari. The content of the intervention is based on the principles of semantic therapy using the mystical and anthropological concepts of Rumi Jalaluddin Mohammad Balkhi's thoughts and includes training, group discussion,

interpretation and analysis of stories and parables from the Masnavi, reflection on personal experiences, reflective exercises, and homework assignments. The main themes of the sessions include understanding the meaning of life and the human position, self-knowledge, self-control, acceptance of aging, making meaning in suffering, remembrance and meditation, facing death anxiety, love, patience, resilience, and gratitude. At the end of each session, homework is given in accordance with the content taught, and at the beginning of the next session, feedback is reviewed and provided. During each session, about 15 to 20 minutes are allotted for participants to rest and receive refreshments. No drugs, consumables, or medical devices are used in this intervention, and the intervention is based solely on group education and psychological techniques.

Category

Behavior

2

Description

Intervention group:The mindfulness-based stress reduction intervention will be implemented as a group and based on the standard Mindfulness-Based Stress Reduction program adapted from Segal et al.'s (2016) program, in 8 60-minute sessions (two sessions per week, for four weeks) for family caregivers of the elderly. The sessions will be held by an assistant professor of psychology and a qualified therapist in the environment of Mehr nursing home in Sari city. The content of the intervention includes teaching the concepts of mindfulness, performing formal and informal mindfulness exercises, body inspection, conscious breathing, sitting meditation, walking meditation, conscious eating, simple stretching movements and gentle yoga, compassion meditation, and exercises to increase awareness of thoughts, emotions, bodily sensations, and environmental stimuli. Also, in each session, review of home exercises, group discussion, providing feedback and teaching practical strategies to manage stress and increase presence of mind are done. At the end of each session, homework is presented according to the content of the session for daily practice and reviewed in the next session. No drugs, chemicals, medical equipment or invasive methods are used in this intervention, and the intervention is based solely on psychological and behavioral training and exercises.

Category

Behavior

3

Description

Control group: Does not receive any intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarai Mehr Sari

Full name of responsible person

Dr Asghar Norouzi

Street address

Imam Reza Blvd., Imam Reza 6

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asgarnoruzi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fateme Gholian nozari

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Farahabad Road

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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

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Private

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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr seyed Hamze Hoseini

Position
Professor, Faculty Psychiatrist

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Razi Street, Imam Sari Hospital, Psychiatric Department

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr Asghar Norouzi

Position
Assistant Professor, Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Fateme Gholian nozari

Position
Student

Latest degree
Master

Other areas of specialty/work
Psychology

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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
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
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Can be shared with individuals unidentifiable

When the data will become available and for how long
Since the winter of 2026

To whom data/document is available
Researchers, industries and nursing homes

Under which criteria data/document could be used
Researchers - industries and nursing homes have the ability to use the data. In fact, they have the ability to use the results of the data to help family caregivers. Researchers have the ability to use it for review and referencing articles.

From where data/document is obtainable
fateme.qolian70@gmail.com Email Fatemeh Qolian Nozari and respond as soon as possible.

What processes are involved for a request to access data/document
Please send your request to the provided email address; a response will be given as soon as possible, within one week.

Comments