Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mindfulness-based cognitive therapy on self-efficacy and rumination and resilience on family caregiver of patient with cancer

Protocol summary

Study aim
The effect of mindfulness-based cognitive therapy training on self-efficacy, rumination and resilience of family caregivers of cancer patients

Design
A randomized, non-blinded clinical trial with intervention and control groups on 90 family caregivers (45 in the intervention group and 45 in the control group) using Random Allocation software using a block random allocation method will be used for randomization. Given that the intervention is training in mindfulness techniques, the clinical trial phase is not applicable.

Settings and conduct
First, family caregivers of cancer patients in the oncology department of Imam Sajjad Hospital and the specialized clinic of the oncologist are selected using the convenience sampling method, considering the inclusion criteria. Then, they are divided into two intervention and control groups using the random assignment method. Interventions based on mindfulness-based cognitive therapy techniques are carried out in educational groups of fifteen people in the doctor's room of Imam Sajjad Hospital and the specialized clinic of the oncologist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 years and older Literacy Fluency in Persian Having a relative or causal relationship with the patient Caring for only one patient Not receiving a salary Not being a member of the treatment staff Caring for a patient with cancer for at least the past two months Not participating in similar training courses at the time of study entry Exclusion criteria: History of mental health problems such as anxiety disorders and depression, as reported by caregivers Unwillingness to participate in the study

Intervention groups
Participants will receive mindfulness techniques in groups of fifteen people, but in the control group participants will not receive any intervention.

Main outcome variables
self-efficacy Rumination Resilience

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260212068841N1**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**

Registration date
2026-06-20, 1405/03/30

Registrant information

Name
Reza Delfani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-02, 1405/03/12

Expected recruitment end date
2026-09-03, 1405/06/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of mindfulness-based cognitive therapy on self-efficacy and rumination and resilience on family caregiver of patient with cancer

Public title
Effect of Mindfulness on self-efficacy and rumination and resilience

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years and over Being literate Fluency in Persian Having a relative or causal relationship with the patient Caring for just one patient Not receiving wages Not being a member of the medical staff Caring for a patient with cancer for at least the past two months Failure to participate in similar training courses upon entering the study

Exclusion criteria:
History of mental health problems such as anxiety disorders and depression, as reported by caregivers Unwillingness to participate 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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to two treatment and control groups using a block-wise random allocation method of equal size. The random sequence will be generated using a block-wise allocation method with a block size of four by Random Allocation software. Allocation concealment will be performed using sealed, numbered opaque envelopes. Each random sequence will be written on separate cards and the cards will be placed in sealed, opaque envelopes. These envelopes will be numbered sequentially and placed in a special box. When each participant enters, one of the envelopes will be opened in order and the desired group will be determined. This process will be carried out to ensure that the random allocation remains hidden until the participant enters the study, which is in accordance with CONSORT recommendations, a method to prevent bias in the randomization process.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

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, Ganj Afrooz Ave

City
Babol

Province
Mazandaran

Postal code
47176-47745

Approval date
2026-04-22, 1405/02/02

Ethics committee reference number
IR.MUBABOL.HRI.REC.1405.071

Health conditions studied

1

Description of health condition studied
self-efficacy, rumination and resilience

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Self-efficacy

Timepoint
Before the start of the mindfulness training sessions, immediately, and two months after completing the eight mindfulness training sessions

Method of measurement
scherrer General Self-Efficacy Questionnaire

2

Description
Rumination

Timepoint
Before the start of the mindfulness training sessions, immediately, and two months after completing the eight mindfulness training sessions

Method of measurement
Hoeksma and Maru Rumination Questionnaire

3

Description
Resilience
Timepoint
Before the start of the mindfulness training sessions, immediately, and two months after completing the eight mindfulness training sessions
Method of measurement
Connor and Davidson Resilience Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Mindfulness techniques including conscious breathing, body scan, sitting meditation, conscious seeing and listening, and conscious walking will be taught in eight ninety-minute training sessions for eight consecutive weeks (one session per week) in groups of fifteen people. All educational materials provided will be presented in the sessions after the supervision and review of a psychiatrist. For the intervention group, the training program will be held in a group in the doctor's room of Imam Sajjad Hospital and the specialized clinic of an oncologist. The intervention will be carried out in the form of training and counseling. After each session, audio and video files, educational booklets, and weekly assignments will be provided to the participants.
Category
Behavior

2

Description
Control group: They will receive no educational intervention during the intervention period.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Sajjad Hospital
Full name of responsible person
Reza Delfani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
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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