Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating The Effect of the Mindfulness-Based Living training on Healing Motivation in Cancer Patients Undergoing Chemotherapy and Illness Uncertainty in patients and Their Care givers: A Dyadic Patient-Caregiver Approach

Protocol summary

Study aim

Determining the effect of mindfulness-based life skills training on treatment motivation in cancer patients undergoing chemotherapy and on illness uncertainty in patients and their primary caregivers, using a patient–caregiver dyadic approach.

Design

This study is a randomized, parallel-group, open-label clinical trial with a control group, involving 76 patient–caregiver dyads, using permuted block randomization implemented in R software.

Settings and conduct

This study is conducted in the chemotherapy ward of Velayat Hospital in Qazvin Province on cancer patients and their primary caregivers. Eligible participants are randomly assigned to the intervention or control group. Questionnaires are completed by both groups at baseline, immediately after the intervention, and three months thereafter, and the data are analyzed. The intervention group receives mindfulness-based life program training, while the control group does not receive this training

Participants/Inclusion and exclusion criteria

Participants over 18 years of age with informed consent, having a primary caregiver identified by the patient, a score higher than 3 on the cancer performance status scale, no psychiatric disorders or psychiatric medications, not receiving other psychological interventions, literate, and with access to the internet and a smartphone are eligible. Individuals who do not provide consent or who score ≤3 are not included in the study

Intervention groups

The intervention group participates in an 8-session mindfulness-based life skills training program, with weekly sessions lasting 30 to 90 minutes delivered in a blended in-person and virtual format. The control group does not receive additional training and continues only with the routine care and education provided by the ward

Main outcome variables

Treatment motivation in cancer patients, illness uncertainty in the patient and their primary caregiver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260108068591N1**
Registration date: **2026-01-25, 1404/11/05**
Registration timing: **prospective**

Last update: **2026-01-25, 1404/11/05**
Update count: **0**

Registration date

2026-01-25, 1404/11/05

Registrant information

Name

Zahra Rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-02-14, 1404/11/25
Expected recruitment end date
2026-07-21, 1405/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating The Effect of the Mindfulness-Based Living training on Healing Motivation in Cancer Patients Undergoing Chemotherapy and Illness Uncertainty in patients and Their Care givers: A Dyadic Patient-Caregiver Approach

Public title
Investigating The Effect of the Mindfulness on Healing Motivation in Cancer Patients and Illness Uncertainty in patients and Their Care givers With Dyadic Approach
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having satisfaction with participation in the study Scoring above 3 on the Functional Status Scale in cancer patients Being over 18 years of age The patient must have a primary caregiver Not having any mental illnesses Not using any psychiatric medications Not receiving any other forms of psychological interventions Having a smartphone Having access to the internet Having literacy the ability to read and write The caregiver is recognized as the primary caregiver by the patient The caregiver does not receive any payment for providing care to the patient
Exclusion criteria:
The patient is unwilling to participate in the study The patient scores 3 or lower on the Performance Status Scale for cancer patients
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, permuted block randomization with block sizes of 2, 4, and 6 will be used. To implement this randomization method, a list of all possible permutations with the specified block sizes is first generated, and then a number of these permutations are randomly selected (with replacement). Based on the order of the selected permutations, participants are assigned to either the intervention or control group. The entire process of selecting permutations and generating the random allocation sequence will be performed using R software and the Blockrand package.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The study was designed in a dyadic manner, meaning that the cancer patient and their primary caregiver enter the study as a single unit, both receiving the mindfulness intervention, and the effect of this intervention is then assessed on the outcome variables

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Qazvin University of Medical Sciences
Street address
No. 7, Sadra 8th Alley, 22 Bahman Northern Street, Takestan, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3481744914
Approval date
2025-12-27, 1404/10/06
Ethics committee reference number
IR.QUMS.REC.1404.381

Health conditions studied

1

Description of health condition studied
Cancer
ICD-10 code
C80
ICD-10 code description
Malignant neoplasm without specification of site

Primary outcomes

1

Description
Treatment Motivation: The score that cancer patients receive from the cancer patient motivation scale. The score ranges from 25 to 125, and higher scores indicate

higher motivation for recovery.

Timepoint

Measurement is conducted at three time points: before the intervention begins, immediately after the intervention ends, and three months after the intervention ends.

Method of measurement

Cancer Patients' Treatment Motivation Questionnaire

2

Description

Uncertainty in illness: Refers to a score that patients and caregivers receive from the Mishel Uncertainty in Illness Scale. The score on this scale ranges from 33 to 165, and higher scores indicate greater uncertainty about the illness.

Timepoint

Measurement is conducted at three time points: before the intervention begins, immediately after the intervention ends, and three months after the intervention ends.

Method of measurement

Mishel Uncertainty in Illness Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: An educational intervention based on mindfulness-based life, following the standardized mindfulness-based stress reduction protocol by Jon Kabat-Zinn, as well as the book "Mindfulness-Based Life Skills Program," is designed as an 8-week weekly training program, combining in-person and virtual sessions. Each session lasts between 30 to 90 minutes, with home practice exercises of 10 to 20 minutes per day. These exercises include both formal and informal practices. Formal practices are structured with specific time durations, while informal practices are simpler activities to integrate mindfulness into daily life. In-person sessions will be provided during chemotherapy for patients and their primary caregivers, while virtual sessions will be offline, with pre-recorded videos and guided audio files sent through a messaging app to participants. Session 1: Introduction to mindfulness, its importance in managing illness-related stress, clear explanation of the study objectives (increasing treatment motivation and reducing uncertainty), and the rationale for couple participation. Session 2: Teaching mindful sitting with emphasis on breathing as an "anchor for attention." Explaining how to use breathing during moments of treatment-related anxiety. Session 3: Introducing the concept of separating "pain" from "suffering." Introducing body scan as a method to observe the body without catastrophizing. Session 4: Introducing movement as a form of meditation. Teaching gentle chair yoga and mindful walking with emphasis on being and sensing rather than doing. Session 5: Introducing the "guest house" model for dealing with difficult thoughts and emotions. Teaching self-compassion exercises as an alternative to self-criticism. Session 6: The role of supportive relationships in the treatment process. Teaching loving-kindness memory exercises and the expansion of kindness (toward oneself, loved ones, and all beings).Session 7: Introducing the "three-step breathing space" as an immediate technique. Teaching the "three circles" exercise (threat, motivation, calm) to raise awareness of life balance. Session 8: Review of the seven-week journey, emphasis on small progress. Summarizing how to continue the practices in life. Delivering a final message of hope and acceptance. Expressing appreciation for participation.

Category

Lifestyle

2

Description

Control group: The control group will not receive any training from the researcher and will only receive the usual care and standard education provided by the ward, just like others.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Educational and Treatment Hospital of Qazvin

Full name of responsible person

Ali Akbar Karami

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Cooperation Square, 22 Bahman Boulevard, Elahie Quarter, Minuder Settlement

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mehdi Mirhashemi

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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
Qazvin 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
Qazvin University of Medical Sciences

Full name of responsible person
Zahra Rahmani

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information available

Study Protocol
No - There is not 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

No - There is not 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