Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effectiveness of Mindfulness-Based Cognitive Therapy and Usual Care in Reducing Anxiety and Improving Quality of Life in Patients with Kidney Cancer

Protocol summary

Study aim

The aim of this study is to examine the effectiveness of Mindfulness-Based Cognitive Therapy (MBCT) in reducing anxiety and improving quality of life in patients with kidney cancer.

Design

This study is a randomized, parallel, single-blind clinical trial. Kidney cancer patients will be randomly assigned via Randomization.com to either the intervention group (MBCT in eight weekly 120-minute sessions) or the control group (usual care without structured psychotherapy). The sample includes 32 participants (16 per group) and the trial is Phase II.

Settings and conduct

Study Location: Psychological Sciences House Clinic, Mashhad, Iran. Study Population: Eligible patients diagnosed with kidney cancer. Blinding Type: Single-blind. Blinding Method: Participants, outcome assessor, and data analyst are unaware of group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmed kidney cancer, high anxiety (STAI), ≥6 months since diagnosis with ongoing disease, age 40–60 years and written informed consent. Exclusion criteria: Complete cancer recovery, psychiatric medication use within 3 months, psychotherapy within 6 months, personality disorder or psychotic symptoms and uncontrolled pain at baseline.

Intervention groups

Intervention Group: Participants attend 8 weekly MBCT sessions (120 minutes each), including mindfulness practices, home exercises, and brief CBT-based skills. Control Group: Participants receive no intervention during the study and continue their usual care. For ethical reasons, MBCT will be offered to them after the study post-test.

Main outcome variables

State and trait anxiety score based on the Spielberger State–Trait Anxiety Inventory (STAI); Health-related quality of life score based on the World Health Organization Quality of Life questionnaire (WHOQOL)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251026067770N2**
Registration date: **2025-11-27, 1404/09/06**
Registration timing: **prospective**

Last update: **2025-11-27, 1404/09/06**
Update count: **0**

Registration date

2025-11-27, 1404/09/06

Registrant information

Name

fatemeh bardideh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3855 4625

Email address

fbardideh98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-01, 1404/09/10

Expected recruitment end date

2025-12-31, 1404/10/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Mindfulness-Based Cognitive Therapy and Usual Care in Reducing Anxiety and Improving Quality of Life in Patients with Kidney Cancer

Public title
Evaluating the Impact of a Mindfulness Training Program on Anxiety and Quality of Life in Patients with Kidney Cancer
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Receiving a confirmed diagnosis of kidney cancer from a specialist physician Obtaining a high score on the Spielberger State-Trait Anxiety Inventory (STAI) Providing informed consent to participate in the study Being between 40 and 60 years of age At least 6 months having passed since the initial cancer diagnosis, with the cancer still ongoing (i.e., not in complete remission).
Exclusion criteria:
Recovery from / remission of kidney cancer Lack of willingness to continue participation in the study Use of any psychiatric medication in the past three months, or participation in psychotherapy sessions within the past six months Presence of any personality disorder or transient psychotic features, as assessed by the Minnesota Multiphasic Personality Inventory (MMPI) Uncontrolled pain at the time of entering the intervention.
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using the website https://www.randomization.com. The random allocation list will be generated by a statistician who is not involved in the implementation or assessment of the study. Variable block randomization with block sizes of 4 and 6 will be used to maintain balance in the number of participants between the Mindfulness-Based Cognitive Therapy (MBCT) group and the no-intervention control group. Allocation codes will be placed in opaque, sealed, sequentially numbered envelopes to ensure concealment of the random sequence until the moment of assignment. Upon each participant's entry into the study, the envelope corresponding to their order of enrollment will be opened by the registration officer, and the participant will be assigned to the appropriate group.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study was designed as a single-blind trial with participant and outcome-assessor blinding. Participants were not informed of their allocation to either the Mindfulness-Based Cognitive Therapy (MBCT) group or the control group, and they were not told which intervention condition they would receive. Psychological outcomes (including anxiety and quality of life) were assessed by evaluators who were blinded to the randomization sequence and group assignments. In addition, statistical analyses were conducted by a data analyst who received group labels in coded and anonymized form and was therefore unaware of the intervention status of each participant. Only the therapist was aware of group allocations in order to deliver the intervention. Participants, outcome assessors, and the data analyst had no direct knowledge of the randomization process or its results.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical Research Ethics Committee, Faculty of Medicine, Islamic Azad University, North Tehran Branch
Street address
5th Floor, Shahid Fakhrizadeh Research and Laboratory Building, Islamic Azad University, North Tehran Branch, Vafadar Boulevard, Shahid Sadooghi Street, Hakimiyeh Exit, Shahid Babayi Expressway (West to East)
City
Tehran
Province
Tehran
Postal code
1651153511
Approval date
2025-01-27, 1403/11/08
Ethics committee reference number
IR.IAU.TNB.REC.1403.249

Health conditions studied

1

Description of health condition studied
Kidney cancer
ICD-10 code
C64
ICD-10 code description
Malignant neoplasm of kidney, except renal pelvis

Primary outcomes

1

Description
Anxiety score on the State–Trait Anxiety Inventory (STAI) developed by Spielberger
Timepoint
At the beginning of the study (before the intervention) and after the end of the intervention
Method of measurement
Spielberger State-Trait Anxiety Inventory

2

Description
Quality of life score on the World Health Organization Quality of Life (WHOQOL) questionnaire
Timepoint
At the beginning of the study (before the intervention) and after the end of the intervention
Method of measurement
World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The Mindfulness-Based Cognitive Therapy (MBCT) program will be delivered in 8 weekly group sessions, each lasting 120 minutes. The intervention follows the standard MBCT protocol developed by Segal, Williams, and Teasdale. Each session includes mindfulness practices (such as mindful breathing, body scan, and attention to thoughts and emotions), cognitive-behavioral exercises targeting maladaptive thinking patterns, homework assignments, and group discussions. Participants will be trained to increase awareness of their automatic thoughts, reduce rumination, and cultivate nonjudgmental attention to present-moment experiences. They will receive audio recordings and weekly home practice instructions (approximately 30 minutes per day). The sessions will be conducted by a licensed clinical psychologist experienced in delivering MBCT.
Category
Treatment - Other

2

Description
Control group: The control group will not receive any intervention during the study period. However, to ensure ethical considerations, participants in the control group will be offered the Mindfulness-Based Cognitive Therapy (MBCT) program after the completion of the study and the post-test assessments.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Home of Psychology Sciences
Full name of responsible person
Fatemeh Bardideh
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No. 56, After Boostan, 11 South Khayyam, Khayyam Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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sup619001@iau.ir
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
Islamic Azad University
Full name of responsible person
Fatemeh Bardideh
Position
Educational Assistant
Latest degree
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Psychology
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
A data dictionary describing the structure of the dataset (variable names, coding schemes such as intervention group=1 and control group=0, score ranges for psychological instruments, and time points such as pre-test and post-test) will be made available after completion of data collection and publication of the primary results. This file contains only variable

definitions and coding rules; it does not include any identifiable participant information.

When the data will become available and for how long

It will be available after completion of data collection and publication of the main study results in a scientific journal.

To whom data/document is available

Access will be granted only to qualified researchers who provide a written request and formally agree to a confidentiality commitment.

Under which criteria data/document could be used

These data/documents may be used only for scientific and research purposes, such as methodological review, replication of the statistical analyses, or comparison with similar studies. Use for commercial purposes, attempts to re-identify participants, or any use outside a research context is not permitted. Access and use are conditional on a written commitment to confidentiality and non-disclosure.

From where data/document is obtainable

Requests should be directed to the Principal Investigator of the study: Hossein Salimi Bajestani, Assistant professor. Email: H.salimi.b@gmail.com. Access will be considered after scientific review of the request and a signed confidentiality commitment.

What processes are involved for a request to access data/document

The requester must submit a written request to the Principal Investigator, including the research purpose, the specific data/document requested, and the intended use. The request will be reviewed for scientific merit and ethical compliance to ensure that use is strictly research-oriented and does not compromise participant confidentiality. If the request is approved, the requester will be asked to sign a confidentiality and non-disclosure agreement. After this agreement is signed, the shareable version of the data/document (with no identifying information) will be provided.

Comments