

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The comparison between the effectiveness of mindfulness-based cognitive therapy (MBCT) and cognitive behavioral therapy (CBT) on anxiety, depression and fatigue in cancer patients.

#### Protocol summary

##### Study aim

(1) Comparison of the effectiveness of mindfulness-based cognitive therapy (MBCT) and (CBT) on the level of anxiety, depression and fatigue in cancer patients (2) Determining the effectiveness of (MBCT) on the level of anxiety, depression and fatigue in cancer patients (3) Determining the effectiveness of (CBT) on the level of anxiety, depression and fatigue in cancer patients (4) Comparison of the effectiveness of (MBCT) and (CBT) on the level of anxiety in cancer patients (5) Comparison of the effectiveness of (MBCT) and (CBT) on the level of depression in cancer patients (6) Comparison of the effectiveness of (MBCT) and (CBT) on the level of fatigue in cancer patients

##### Design

Randomization method with a random number table. The sampling method is available sampling, are randomly divided into three groups

##### Settings and conduct

. In order to achieve this sample size, the researcher has referred to two hospitals. Subjects are asked to complete the tests of the depression, beck anxiety, and the fatigue severity scale. The members of the group that were under (MBCT) and (CBT) received eight sessions of therapeutic interventions. The third group members did not receive any treatment. The members of the three groups are again evaluated at the end of the treatment using the relevant questionnaire

##### Participants/Inclusion and exclusion criteria

Entry Criteria 1- Age between 18 and 50 years 2- Minimum Cycle Degree .Ability to attend meetings 3- Ability and informed consent of the company in the scheme 4- Minimum duration of cancer for 6 months 5- Not receiving psychological help at diagnosis Exit criteria 1- No history of mental illness specifically 2- Lack of physical illness other than the study

##### Intervention groups

The group mindfulness based cognitive therapy The group cognitive behavioral therapy The group didnot receive any treatment

##### Main outcome variables

anxiety, depression, fatigue

#### General information

##### Reason for update

##### Acronym

درمان شناختی رفتاری - (MBCT) شناخت درمانی مبتنی بر ذهن آگاهی (CBT)

##### IRCT registration information

IRCT registration number: **IRCT20180503039509N1**

Registration date: **2018-10-30, 1397/08/08**

Registration timing: **prospective**

Last update: **2018-10-30, 1397/08/08**

Update count: **0**

##### Registration date

2018-10-30, 1397/08/08

##### Registrant information

##### Name

Masoumeh Sheikhzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5522 4569

##### Email address

sheikhzadehpsychology@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-01, 1397/08/10

**Expected recruitment end date**

2019-01-30, 1397/11/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison between the effectiveness of mindfulness-based cognitive therapy (MBCT) and cognitive behavioral therapy (CBT) on anxiety, depression and fatigue in cancer patients.

**Public title**

The comparison between the effectiveness of mindfulness-based cognitive therapy (MBCT) and cognitive behavioral therapy (CBT) on anxiety, depression and fatigue in cancer patients.

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 18 and 50 years Minimum Cycle Degree (Given the active nature of the species and the contribution of the therapist and doing the homework to a degree, the energy and superhuman motivation of the ability to identify thoughts and emotions is needed). Ability to attend meetings Ability and informed consent of the company in the scheme Minimum duration of cancer for 6 months Not receiving psychological help at diagnosis

**Exclusion criteria:**

No history of mental illness specifically Lack of physical illness other than the study

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be performed through a table of random figures and allocation concealment will be performed by sealed envelopes which will be kept by the hospital reception. Based on these the participants will be assigned to CBT, MBCT and the control group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study the participant, the evaluator of the outcome and analyzer of data will not be aware how the individuals are allocated to mbct and cbt groups and

control group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Committee on Ethics in Mashhad University of Medical Sciences

**Street address**

University of research and technology assistance, second floor , Qoreishi building, Daneshgah ST

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2018-04-21, 1397/02/01

**Ethics committee reference number**

ir.mums.rec.1397.025

**Health conditions studied****1****Description of health condition studied**

colon, rectosigmoid and rectum cancer

**ICD-10 code**

C19

**ICD-10 code description**

Malignant neoplasm of rectosigmoid junction

**2****Description of health condition studied**

breast cancer

**ICD-10 code**

C50.4

**ICD-10 code description**

Malignant neoplasm of upper-outer quadrant of breast

**3****Description of health condition studied**

Lymphatic cancer

**ICD-10 code**

C96.9

**ICD-10 code description**

Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified

## Primary outcomes

### 1

#### Description

anxiety - depression

#### Timepoint

Before and immediately after the intervention

#### Method of measurement

Using Beck Anxiety and Depression Inventory

## Secondary outcomes

### 1

#### Description

Fatigue

#### Timepoint

before and after intervention

#### Method of measurement

Ocuyama Cancer Fatigue Questionnaire (2000)

## Intervention groups

### 1

#### Description

intervention group one: mindfulness-based cognitive therapy group Content of interventional sessions of mindfulness-based cognitive therapy1- Introduction of the program, structure and goals of the group, familiarity with cancer and anxiety, depression, and fatigue of patients having this disease, familiarity with mindfulness and expression of its logic and presentation of homework for the consolidation of educational materials2- Education and practice of mindfulness or breathing awareness techniques to increase attention and concentration capacity include 45 minute meditation of body care, ten minutes of breathing along with mindfulness and expressing the logic of each of these techniques, thinking about exercises and accurate sensation of each of them and a three-minute breathing space and expressing its logic3- Implementation of muscular relaxation technique, practicing conscious movement, keeping thoughts and minds widespread through pursuit of meditative exercises and focusing on conscious breathing and body organs, familiarity with mindfulness (the concept of automatic guide and mind states), familiarity with logic and the goals of this therapy (communication with the world in a different way) and the practice of mindfulness technique, three-minute breathing4- 45-minute training and practice, sitting meditation technique and expressing its logic, three-minute breathing exercise and providing simulated exercises for use in times of emotion, recognizing Beck's cognitive model on anxiety and depression based on ABC and understanding negative spontaneous thoughts on cancer, training how the table creates emotional thoughts and training ten-minute breathing along with mindfulness5- 45-minute body check practicing, training and exercising of discovering reactions to common patterns and applying the potential talents of

mindfulness skills to ease the reaction to the present time experiences (control of the wanderer mind), teaching and practicing meditation to accept and evaluate spontaneous thoughts and identification of common cognitive errors in cancer6-45-minute sitting meditation practicing, reviewing patients' problems during home exercise, emotions and anxieties during exercises, teaching techniques to respond to negative spontaneous thoughts, practicing three-minute body check technique and conscious breathing and making awareness the reactions against anxiety, depression and fatigue7- Performing meditation exercises, practicing three-minute breathing + designing a problem during the exercise and discovering their effects on the body and mind, discussing how best continue to move and order created in the last few weeks, a list of pleasurable symptoms and skillfulness and exercising body check8- Summation and reviewing the program, receiving feedback from group members, applying lessons for dealing with future creation, closing ceremonies, and post-test implementation.

#### Category

Behavior

### 2

#### Description

Intervention group two: Cognitive behavioral therapy group First sessionFamiliarization, introduction of rules and treatment process, acquaintance of the patient with the nature of their illness and the role of psychological factors in the emergence and exacerbation of symptoms and the introduction of cognitive behavioral therapy method and education of the relaxation technique (relaxation training is performed in all treatment sessions)The second session and the third sessionEducation of cognitive pattern for patients, introducing spontaneous thoughts, providing sheets to record invalid thoughts, identifying emerging thoughts of illnesses and unpleasant senses, investigating possible problems in recording thoughts and identifying emotions and helping them solveFourth and fifth sessionsMeet the challenge of irrational thoughts and beliefs, introducing challenges as a way to fight the irrational thoughts and beliefs that the patient wrote over the course of the week, delivering profits and losses, and Socratic questioning of thoughts that created unpleasant emotions.Sixth and seventh sessionsProblem-solving training, self-expression training, and education of planning for activities, and discussing problem solving methods as a way to cope with worries, training three passive, daring and aggressive behavioral styles in communication situations to strengthen self-expression and teaching time setting and planning for doing activitiesEighth sessionSummarizing and summation the contents of the past session, introducing several books in order to become more familiar with cognitive therapy, make the patient to pay attention to the intermediate beliefs and underlying assumptions, taking feedback from the patient towards treatment sessions.

#### Category

Behavior

### 3

#### Description

Control group third group : The group didnot receive any treatment.

#### Category

Behavior

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Qaem Hospital of Mashhad

###### Full name of responsible person

Masoumeh Sheikhzadeh

###### Street address

Shariati SQ

###### City

Mashhad

###### Province

Razavi Khorasan

###### Postal code

9919991766

###### Phone

+98 51 3840 0000

###### Email

Qaem.medical.center@mums.ac.ir

#### 2

##### Recruitment center

###### Name of recruitment center

Imam Reza Hospital of Mashhad

###### Full name of responsible person

Masoumeh Sheikhzadeh

###### Street address

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###### City

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###### Province

Razavi Khorasan

###### Postal code

9137913316

###### Phone

+98 51 3854 3031

###### Email

Emamreza@mums.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Islamic Azad University of Qom

###### Full name of responsible person

Mahboube Sadat Sharif

###### Street address

Islamic Azad University of Qom, University Blvd,  
Pardisan, Qom

###### City

Qom

###### Province

Ghoush

###### Postal code

3749113191

###### Phone

+98 25 3280 8080

###### Email

sharif44m@yahoo.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Islamic Azad University of Qom

##### 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

Mashhad University of Medical Sciences

###### Full name of responsible person

Masoumeh Sheikhzadeh

###### Position

Student

###### Latest degree

Bachelor

###### Other areas of specialty/work

Psychology

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###### Phone

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### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Islamic Azad University of Qom

###### Full name of responsible person

Masoumeh Sheikhzadeh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic Azad University of Qom

**Full name of responsible person**

Masoumeh Sheikhzadeh

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Student

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Bachelor

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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