Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparision 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

شناخت درمانی مبتنی بر ذهن آگاهی (MBCT) - درمان شناختی رفتاری (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 comparision 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 comparision 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
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2

Recruitment center
Name of recruitment center
Imam Reza Hospital of Mashhad
Full name of responsible person
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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
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Ghoum
Postal code
۳۷۴۹۱۱۳۱۹۱
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
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Person responsible for updating data

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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