Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of mindfulness based stress reduction on self management strategies, fatigue, fear of cancer recurrence, and cognitive impairment in colorectal and breast cancer patients

Protocol summary

Study aim
Determining the effectiveness of mindfulness based stress reduction on fatigue, self management strategies, fear of cancer recurrence, and cognitive impairment in colorectal and breast cancer patients

Design
Clinical trial with control group, community based and pragmatic, randomized.

Settings and conduct
38 patients with colorectal and breast cancer were randomly assigned to control and intervention groups. Both groups were evaluated in the pretest using the scales (fatigue questionnaire, fear of cancer recurrence inventory, Wechsler memory scale revised، SAT(Smart Management Strategy for Health Assessment Tool) questionnaire), of the study. They also completed their personal consent form and the demographic questionnaire. Then the intervention group received the MBSR program for eight weeks in the rehabilitation College of Shiraz university of Medical Science. After completing the intervention, both groups were evaluated in the post test, and data were analyzed by using descriptive, multivariate and univariate covariance analysis statistics.

Participants/Inclusion and exclusion criteria
Infected with breast and colorectal cancer, and receive diagnosis by an oncologist Not participating in a mindfulness based stress reduction program before the study.

Intervention groups
The intervention group receives a mindfulness based stress reduction program for eight weeks, but control group doesn't receive any intervention.

Main outcome variables
Fear of cancer recurrence, cancer related cognitive impairment, self management strategies, and fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180331039163N1**
Registration date: **2018-11-22, 1397/09/01**
Registration timing: **retrospective**

Last update: **2018-11-22, 1397/09/01**
Update count: **0**

Registration date
2018-11-22, 1397/09/01

Registrant information

Name
Nasrin Ahmadiqaragezlou

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3630 3391

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vojdanir@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-05, 1397/02/15

Expected recruitment end date
2018-06-05, 1397/03/15

Actual recruitment start date
2017-11-22, 1396/09/01

Actual recruitment end date
2018-04-21, 1397/02/01

Trial completion date
2018-06-22, 1397/04/01

Scientific title
The effectiveness of mindfulness based stress reduction on self management strategies, fatigue, fear of cancer recurrence, and cognitive impairment in colorectal and breast cancer patients

Public title
The effectiveness of Mindfulness based stress reduction in cancer patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Getting a diagnosis of colorectal and breast cancer and approved by an oncologist Patients who have completed treatment or still receiving treatment Bing over 18 to 65 years of age

Exclusion criteria:
Having more than two absentee sessions Participate in yoga classes and meditation before implementing the plan Problem in hearing and speaking Participating in the mindfulness based stress reduction program Getting psychotherapy by a psychologist or psychiatric Participate in other psychosocial programs

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**
Actual sample size reached: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
One methods of randomization in studies is random blocking, in this way, the number of people assigned to each group is usually approximately the same. In this method, blocks are formed based on the desired variables, and within each block, half of the intervention and half as the control are considered.The main object of this method is to balance the number of participants in each group.

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 Shiraz University of Medical Sciences

Street address
No. 52, West Hedayat Ave., Shiraz

City
Shiraz

Province
Fars

Postal code
713451978

Approval date
2018-03-04, 1396/12/13

Ethics committee reference number
Ir.sum.rec.1396.192

Health conditions studied

1

Description of health condition studied
Colorectal cancer and breast cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cancer related fatigue

Timepoint
Pre test and post test

Method of measurement
Fatigue questionnaire

2

Description
Cancer related cognitive impairment

Timepoint
Pre and post test

Method of measurement
Wechsler memory scale-Revised

3

Description
Fear of cancer recurrence

Timepoint
Pre and post test

Method of measurement
Fear of cancer recurrence inventory

4

Description
Self management strategies

Timepoint
Pre and post test

Method of measurement
Smart

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group receives mindfulness-based stress reduction(MBSR). This is an eight-week group training program, Whit a meeting held every week for two hours, in which patients experientially practice body scan, sitting media, mindful walking, hatta yoga, mindful eating.
Category
Behavior

2

Description
Control group doesn't receive any intervention. The group to the questionnaires in Pre test and post test.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir oncology hosputal
Full name of responsible person
Nasrin Ahmadiqaragezlou
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2

Recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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
Shiraz University of Medical Sciences
Proportion provided by this source
50
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
Shiraz University of Medical Sciences
Full name of responsible person
Reza Vojdani
Position
Associate professor
Latest degree

Subspecialist

Other areas of specialty/work
Hematology

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Person responsible for scientific inquiries

Contact

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The University of Semnan

Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Demographic data, methodical data, Dara analysis

When the data will become available and for how long
As the results are published

To whom data/document is available
Researchers, research centers, academic institutions, therapeutic centers for cancer patients

Under which criteria data/document could be used
Using the data to improve the psychological distress, fatigue, cognitive impairment, fear of cancer recurrence in cancer patients

From where data/document is obtainable
By sending email to the writers

What processes are involved for a request to access data/document
By sending email to writers

Comments