

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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)

Phone

+98 71 3630 3391

Email address

vojdanimir@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

lr.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, With 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 hospital

Full name of responsible person

Nasrin Ahmadiqaragezlou

Street address

No. 11, Shahid Rajaei Blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3632 3731

Fax

+98 71 3632 5655

Email

amirhp@sums.ac.ir

2**Recruitment center****Name of recruitment center**

Shahid Motahari clinic

Full name of responsible person

Nasrin Ahmadiqaragezlou

Street address

Namazi Square, Shiraz

City

Shiraz

Province

Fars

Postal code

71348714737

Phone

+98 71 3612 1000

Email

motahari@sums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Reza Vojdani

Street address

Zand Stret, Central Department of Shiraz University of Medical Science

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3230 5410

Email

president@sums.ac.ir

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
Street address
Namazi Square, Shahid Motahari Clinic, Shiraz
City
Shiraz
Province
Fars
Postal code
71348714737
Phone
+98 71 3612 1000
Email
vojdani@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
The University of Semnan
Full name of responsible person
Issac Rahimian Boogar
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Semnan University
City
Semnan
Province
Semnan
Postal code
3513119111
Phone
+98 23 3365 4100
Fax
+98 23 3332 1005
Email
l_rahimian@semnan.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Nasrin Ahmadiqaragezlou

Position
Ph.D. Student of Health Psychology
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No.30, Alley 31/2, Shahid Rajaei Blvd. Shiraz
City
Shiraz
Province
Fars
Postal code
7185954679
Phone
+98 71 3633 3091
Email
ahmadiqaragezlou@gmail.com

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, Data 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