

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effectiveness of brief Mindfulness-based Cancer Recovery intervention on physical and psychological symptoms of gastrointestinal cancer patients

Protocol summary

Study aim

Investigating the effectiveness of brief mindfulness based cancer recovery on psychological distress, demoralization syndrome, pain, fatigue, sleep disturbance and quality of life of patients with gastrointestinal cancer.

Design

A randomized clinical trial with a parallel control group, single blind. Excel software rand function was used for randomization. The sample size includes 52 patients

Settings and conduct

The study will be conducted in Taleghani, Imam Khomeini (RA) and Modares hospitals. After giving the necessary explanations to the participants and receiving informed consent, the relevant questionnaires will be provided to them at first, and then the intervention will be implemented in groups in 4 sessions, and the questionnaires will be completed again after the test. Follow-up procedures will be 2 and 6 months.

Participants/Inclusion and exclusion criteria

Patients with gastrointestinal cancer stage 1 and 2, whose age is above 18 years and who can read and write and who do not have medical disease and psychological disorder at the same time.

Intervention groups

People in the intervention group will receive a 4-session group intervention, mindfulness based cancer recovery by a clinical psychologist under the supervision of a supervisor. The control group will not receive any intervention at the same time, but after the follow-up period, the control group will also receive this treatment.

Main outcome variables

Psychological distress, Demoralization Syndrome, Pain, Fatigue, Sleep disturbance, Quality of life

General information

Reason for update

Acronym

MBCR

IRCT registration information

IRCT registration number: **IRCT20231101059926N1**

Registration date: **2023-11-10, 1402/08/19**

Registration timing: **prospective**

Last update: **2023-11-10, 1402/08/19**

Update count: **0**

Registration date

2023-11-10, 1402/08/19

Registrant information

Name

Nahid Bahadoriyan lotf abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6540 1748

Email address

bahadoriyan.n@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of brief Mindfulness-based Cancer Recovery intervention on physical and psychological symptoms of gastrointestinal cancer patients

Public title

Effectiveness of Mindfulness-based Cancer Recovery in gastrointestinal cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 and above Definitive diagnosis of stage 2 and 3 gastrointestinal cancer by an oncologist Having minimum reading and writing literacy to complete the questionnaires Not participating in any yoga and meditation classes or courses in the last 6 months Not participating in any mindfulness intervention at the same time

Exclusion criteria:

Not continuing mindfulness sessions for more than 2 sessions Disease recurrence or metastasis Failure to complete questionnaires Having a medical illness at the same time having a serious psychiatric disorder such as psychotic spectrum disorders, bipolar disorder, and substance abuse via self-report

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be simple randomization method and the random unit is individuals. 52 patients with gastrointestinal cancer will be divided into intervention and control groups by Microsoft Excel software using Rand function. In this way, a table of random numbers will be prepared and the Randbetween function will be created and the patients will be divided into two groups of 26 people respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor in data collection after the intervention and the data analyst will be unaware of the objectives of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

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Postal code

19395-4631

Approval date

2023-10-28, 1402/08/06

Ethics committee reference number

IR.SBMU.MSP.REC.1402.393

Health conditions studied

1

Description of health condition studied

Gastrointestinal Cancer

ICD-10 code

(C15-C26)

ICD-10 code description

Malignant neoplasms of digestive organs

Primary outcomes

1

Description

Psychological distress

Timepoint

In the per-intervention and post-intervention stages for 2 and 6 months for follow up

Method of measurement

The Kessler Psychological Distress Scale (K10)

2

Description

Demoralization Syndrome

Timepoint

In the per-intervention and post-intervention stages for 2 and 6 months for follow up

Method of measurement

Demoralization Scale(DS)

3

Description

Pain

Timepoint

In the per-intervention and post-intervention stages for 2 and 6 months for follow up

Method of measurement

Numeric Pain Rating Scale (NPRS)

4

Description

Fatigue

Timepoint

In the per-intervention and post-intervention stages for 2 and 6 months for follow up

Method of measurement

Brief Fatigue Inventory (BFI)

5

Description

Sleep disturbance

Timepoint

In the per-intervention and post-intervention stages for 2 and 6 months for follow up

Method of measurement

Insomnia Severity Index (ISI)

6

Description

Quality of Life

Timepoint

In the per-intervention and post-intervention stages for 2 and 6 months for follow up

Method of measurement

World Health Organization Quality of Life (WHOQOL)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mindfulness Based Cancer Recovery will be implemented in 4 sessions, as a group and in 90-minute sessions.

Category

Treatment - Other

2

Description

Control group: After the follow-up period, Mindfulness Based Cancer Recovery will be implemented in 4 sessions, as a group and in 90-minute sessions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleqani Hospital

Full name of responsible person

Nahid Bahadoriyan

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2

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Cancer Institute- Imam Khomeini Hospital

Full name of responsible person

Nahid Bahadoriyan

Street address

Keshavarz Bulvar

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Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Velenjak St. , Shahid Chamran Highway

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193954631

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taleghani@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nahid Bahadoriyan Lotf abadi

Position

PHD student of Clinical psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Participant data will be shared in the SPSS file using the participant code (not using first and last name).

When the data will become available and for how long

Access to the data will be after the articles are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Request from the journals where the articles related to this research are going to be published.

From where data/document is obtainable

By receiving confirmation via email to the main promoter or promoters of the project

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

By sending an email to the main promoter or other project promoters and receiving written confirmation from them

Comments