Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Tehran
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
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak
City
Tehran
Province
Tehran
Postal code
۱۹۸۵۷۱۷۴۱۳
Phone
+98 21 2243 2560
Fax
Email
info@sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Modarres Hospital
Full name of responsible person
Nahid Bahadoriyan
Street address
Kaj Sq., Sadat Abad St
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2207 4087
Email
pr_modarres@sbmu.ac.ir

3

Recruitment center
Name of recruitment center
Cancer Institute- Imam Khomeini Hospital
Full name of responsible person
Nahid Bahadoriyan
Street address
Keshavarz Bulvard
City
Tehran
Province
Tehran
Postal code
158-13145
Phone
+98 21 6658 1638
Email
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

City
Tehran

Province
Tehran

Postal code
193954631

Phone
+98 21 2243 9982

Email
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

Street address
arabi St, Taleghani Hospital

City
Tehran

Province
Tehran

Postal code
193954631

Phone
+98 21 2243 9872

Email
nahidbahadoriyan@gmail.com

Person responsible for scientific 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

Street address
Arabi St, Taleghani hospital

City
Tehran

Province
Tehran

Postal code
193954631

Phone
+98 21 2243 9770

Email
nahidbahadoriyan@gmail.com

Person responsible for updating data

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

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Street address
arabi St, Taleghani Hospital

City
Tehran

Province
Tehran

Postal code
193954631

Phone
+98 21 2243 9770

Email
nahidbahadoriyan@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

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