Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

effectiveness of mindfulness Based Cancer Recovery on depression, anxiety, stress, pain and quality of life in colon and stomach cancer patients

Protocol summary

Study aim
Reducing Depressive Symptoms by Mindfulness - Based cancer recovery Reducing Anxiety Symptoms by Mindfulness - Based cancer recovery Reducing stress syndrome through Mindfulness - Based cancer recovery Reducing pain through Mindfulness - Based cancer recovery Improving quality of life through Mindfulness - Based cancer recovery

Design
Clinical trial, randomization of 40 patients in two groups of intervention and control by lot

Settings and conduct
Patients are taken from Taleghani Hospital and Amir Alam Hospital by oncologists. patients is evaluated according to the inclusion and exclusion criteria, and after obtaining the necessary characteristics then enters one of the intervention or waiting groups by drawing lots

Participants/Inclusion and exclusion criteria
inclusion: Age over 20 years and under 65 years Have a minimum education in reading and writing in order to answer the questionnaires Definitive diagnosis of one of the stomach or intestinal cancers Simultaneous administration of chemotherapy moderate depression and anxiety scores Do not participate in any yoga and meditation classes in the last 6 months Willingness to complete intervention sessions Physical ability to attend 45-minute sessions exclusion: Existence of a severe mental illness comorbid of a severe physical illness Consumption of psychiatric drugs Receive any other type of psychotherapy at the same time Occurrence of an important stressful event in life (such as the death of a loved one) during treatment Two recurrent absences in treatment sessions

Intervention groups
In the intervention group, patients receive Mindfulness - Based cancer recovery (MBSR Approach)based on chemotherapy. But in the control group only chemotherapy is used.

Main outcome variables
depression; anxiety; stress; the pain ; Quality of life is associated with gastrointestinal cancer in people with the disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200211046458N1**
Registration date: **2021-01-27, 1399/11/08**
Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**
Update count: **0**

Registration date
2021-01-27, 1399/11/08

Registrant information

Name
Ahmad Yousefi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-03, 1399/11/15

Expected recruitment end date
2021-06-05, 1400/03/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
effectiveness of mindfulness Based Cancer Recovery on depression, anxiety, stress, pain and quality of life in colon and stomach cancer patients

Public title
The effect of mindfulness therapy on psychological problems of patients with gastrointestinal cancers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 20 years and under 65 years Have a minimum education in reading and writing in order to answer the questionnaires Definitive diagnosis of one of the stomach or intestinal cancers Simultaneous administration of chemotherapy moderate depression and anxiety scores Do not participate in any yoga and meditation classes in the last 6 months Willingness to complete intervention sessions Physical ability to attend 45-minute sessions
Exclusion criteria:
Existence of a severe mental illness (presence of any period of mania or hypomania, psychotic disorder and substance use disorders) comorbid of a severe physical illness (other than gastrointestinal cancers) Consumption of psychiatric drugs Receive any other type of psychotherapy at the same time Occurrence of an important stressful event in life (such as the death of a loved one) during treatment Two recurrent absences in treatment sessions
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
At first, the available patients referred to the cancer clinics of Taleghani and Amir Alam hospitals are selected by the oncologist and interviewed. And after obtaining the necessary conditions to enter the research, they are included in the list of patients. Finally, based on the list of patients, sampling is done by random selection by throwing dice. The numbers ... are assigned to assign the patient to the treatment group and the numbers ... are assigned to assign the patient to the control 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
کمیته اخلاق در پژوهش دانشکده پزشکی - دانشگاه علوم پزشکی شهید بهشتی
Street address
Shahid Beheshti University of Medical Sciences, Arabi Alley , Daneshjoo St, Velenjak.
City
trhran
Province
Tehran
Postal code
1985717443
Approval date
2020-12-28, 1399/10/08
Ethics committee reference number
IR.SBMU.MSP.REC.1399.542

Health conditions studied

1

Description of health condition studied
gastric cancer
ICD-10 code
C16
ICD-10 code description
Malignant neoplasm of stomach

2

Description of health condition studied
Colon Cancer
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

Primary outcomes

1

Description
Quality of Life
Timepoint
Before the intervention, after the intervention (60days after the first evaluation), 60 days after the intervention
Method of measurement

Quality of Life Questionnaire (EOROTC QLQ-C30)

2

Description
pain
Timepoint
Before the intervention, after the intervention (60 days after the first evaluation), 60 days after the intervention
Method of measurement
West Hawn-Yale Multidimensional Pain Questionnaire

3

Description
Psychological problems (depression, anxiety and stress)
Timepoint
Before the intervention, after the intervention (60 days after the first evaluation), 60 days after the intervention
Method of measurement
Depression, Anxiety, and Stress Scale (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Includes chemotherapy and psychological intervention. In Psychological intervention will use mindfulness - Based Cancer Recovery (MBSR), which is an 8-session intervention. Each session is 45 minutes, which includes a combination of therapy and training in the field of emotions, thoughts and behaviors.
Category
Treatment - Other

2

Description
Control group: Chemotherapy only without psychological intervention
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان طالقانی و بیمارستان امیر اعلم
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Seyed Ali Ziai
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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
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Abbas Masjedi Arani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Results, tables and treatment protocol

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Eligible applicants (general practitioners, medical professionals, psychiatrists, psychologists)

Under which criteria data/document could be used

repeated measure analysis

From where data/document is obtainable

ahmadyousefi, ahmadyousefi7676@gmail.com

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

The applicant should send his application to the responsible person by university email, the application will be reviewed within a week and if approved, it will be sent.

Comments