

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Country

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

AgeFrom **20 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget 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

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Shahid Beheshti University of Medical Sciences, Arabi Alley , Daneshjoo St, Velenjak.

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trhran

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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

عباس مسجدی آرانی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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