

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Effect of mindfulness-based cognitive therapy on quality of Life , emotional symptom , dimensions of pain , dispositional mindfulness and disease activity in patients with inflammatory bowel disease

#### Protocol summary

##### Study aim

Determining the Effect of Mindfulness-Based Cognitive Therapy on quality of Life, Emotional symptom, Dimensions of pain, Dispositional mindfulness and Disease activity in patients with inflammatory bowel disease

##### Design

In this clinical trial the study population include patients with inflammatory bowel disease. First, a list of patients is prepared, then using simple randomization method, people are divided into intervention and control groups. The size of each sample was calculated based on the results of previous studies of 25 people. The grouping of people is parallel and the study is not blind.

##### Settings and conduct

Initially, those with diagnoses of inflammatory bowel disease and inclusion criteria will be selected in consultation with a physician. Then the psychological interview will be conducted by the researcher to investigate the psychological disorders. Initially, all participants (intervention and control group) will be asked to complete the tools used in the research, and after completion of the intervention, all participants will be asked to complete these tools again. This study is performed at Kashan University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmed diagnosis of Crohn's disease or ulcerative colitis. Exclusion criteria: Major psychiatric illness, Active alcohol or drug dependency, Exacerbation of symptoms, need for change in IBD medication during the study.

##### Intervention groups

People in the intervention group receive mindfulness-based cognitive therapy in addition to their usual medical treatment which is an eight-session psychological group program in two-hour weekly sessions. People in the control group receive only their

usual medical treatment.

##### Main outcome variables

Quality of Life, Depression, Anxiety, Stress, Severity of pain, pain catastrophizing, Dispositional mindfulness and Disease activity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200219046553N1**  
Registration date: **2020-04-03, 1399/01/15**  
Registration timing: **prospective**

Last update: **2020-04-03, 1399/01/15**

Update count: **0**

##### Registration date

2020-04-03, 1399/01/15

##### Registrant information

##### Name

Sara Hosseinpoor

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 4250 7777

##### Email address

hosseinpoor.sarah74@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-12-20, 1399/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of mindfulness-based cognitive therapy on quality of Life , emotional symptom , dimensions of pain , dispositional mindfulness and disease activity in patients with inflammatory bowel disease

**Public title**

Effect of mindfulness-based cognitive therapy in patients with inflammatory bowel disease

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

- Having informed consent to participate in research - Age 18-60 years - Confirmed diagnosis of Crohn's disease (CD) or ulcerative colitis (UC) (by a physician) - Patients should be in the active phase of IBD disease (Mild to moderate, moderate to severe) , not in the remission ,that accompanied by a decrease in symptoms - In the Anxiety, Depression, Stress DASS-21 questionnaire, the individual's score on the depression scale of 10 or higher and / or on the anxiety scale of 8 or higher and / or on the stress scale of 15 or higher - Ability to do light exercise (for example, to lift arms above the head or bend knees) because part of the practices in the program require this movement - Able to commit to attend the eight sessions (participants should consider their personal circumstances to assess if this is practical and feasible for them) - To be able to commit to do home practice of up to 45 minutes daily over the 8 weeks of the study (this is a core component of the program) - No change of antidepressants (dose or type) within the last 3 months

**Exclusion criteria:**

- Major psychiatric illness.(The treatment for a major psychiatric illness may interfere with the program) - Active alcohol or drug dependency -Scheduled for major surgery in the next 3 months - Participation in a pharmacological study or psychological intervention study within the last 6 months or intention to participate in a pharmacological study during the duration of this study - Have recently (within the last 3 months) been prescribed antidepressants - Exacerbation of symptoms and need for change in IBD medication (dose or type) during the study

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study people are placed in two groups, the intervention group and the control group, using simple randomization method. random number table is used for implement this method. First, the researcher determines the direction of reading the numbers. The researcher then considers even numbers for the intervention group and odd numbers for the control group. The researcher lays his hand on one of the numbers and moves in a predetermined direction, recording the numbers and assigning them to the groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

As the patients in this study are patients with inflammatory bowel disease are active phase , these patients are subdivided into mild to moderate and moderate to severe subgroups (the severity of symptoms and medications used varies). In this regard, intervention and control groups will be matched.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

**Street address**

Unit Three., Taban Building., Hedayati Ave., Takhti Blvd

**City**

Broujerd

**Province**

Lorestan

**Postal code**

6915735457

**Approval date**

2020-02-17, 1398/11/28

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1398.131

**Health conditions studied****1****Description of health condition studied**

Mindfulness-based cognitive therapy(MBCT)

**ICD-10 code****ICD-10 code description**

## 2

### **Description of health condition studied**

Crohn's disease

### **ICD-10 code**

K50

### **ICD-10 code description**

Crohn's disease [regional enteritis]

## 3

### **Description of health condition studied**

Ulcerative colitis

### **ICD-10 code**

K51

### **ICD-10 code description**

Ulcerative colitis

## 4

### **Description of health condition studied**

Depression

### **ICD-10 code**

F32.0

### **ICD-10 code description**

Major depressive disorder, single episode, mild

## 5

### **Description of health condition studied**

Anxiety

### **ICD-10 code**

F41.9

### **ICD-10 code description**

Anxiety disorder, unspecified

## **Primary outcomes**

## 1

### **Description**

quality of life

### **Timepoint**

Before the intervention, after the intervention

### **Method of measurement**

This variable is measured by the short form of the disease-specific IBD quality of life questionnaire (IBDQ-9)

## 2

### **Description**

Depression

### **Timepoint**

Before the intervention, after the intervention

### **Method of measurement**

This variable is measured by the depression, anxiety, stress questionnaire (DASS-21).

## 3

### **Description**

Anxiety

## **Timepoint**

Before the intervention, after the intervention

### **Method of measurement**

This variable is measured by the depression, anxiety, stress questionnaire (DASS-21)

## 4

### **Description**

Stress

### **Timepoint**

Before the intervention, after the intervention

### **Method of measurement**

This variable is measured by the depression, anxiety, stress Questionnaire (DASS-21).

## 5

### **Description**

Abdominal pain

### **Timepoint**

Before the intervention, after the intervention

### **Method of measurement**

This variable is measured by the McGill Pain Questionnaire.

## 6

### **Description**

pain catastrophizing scale

### **Timepoint**

Before the intervention, after the intervention

### **Method of measurement**

This variable is measured by the Catastrophizing Pain Scale (PCS).

## 7

### **Description**

Dispositional mindfulness

### **Timepoint**

Before the intervention, after the intervention

### **Method of measurement**

This variable is measured by the mindful, attention, awareness scale (MAAS)

## 8

### **Description**

Disease activity

### **Timepoint**

Before the intervention, after the intervention

### **Method of measurement**

1\_Clinical index :Crohn's disease activity index (CDAI) and Simple clinical colitis activity index (SCCAI) 2\_ Blood sampling from each individual to measure each of the following: 1:CBC (Red blood cell count M/MCL, white blood cell count K/MCL, hematocrit) 2: CRP (C reactive protein level in the blood Mg/L) 3: ESR ( Erythrocyte sedimentation rate per unit time mm/h) 4: Albumin g/dL

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: These people receive mindfulness-based cognitive therapy in addition to their usual medical treatment. Mindfulness-based cognitive therapy (MBCT) is an evidence-based psychological group program designed to help manage stress and depressive symptoms. MBCT is an 8-week, facilitator-led, group-based psychological intervention. In addition to the 2-h weekly group sessions, there is a guided home practice component for up to 45 min a day. Within the 8 weeks, participants practice a series of mindfulness meditation, cognitive-behavioural therapy and stretching exercises within the group and at home. During the programme, participants become more aware of their body sensations, thoughts and emotions and their interrelatedness

#### Category

Treatment - Other

### 2

#### Description

Control group: People in the control group receive their usual medical treatment as before, and during the study period follow-up sessions are held to monitor the status of these patients (including the possibility of exacerbation of symptoms). The sessions also explain the inflammatory bowel disease and its complications, and participants discuss the symptoms they are experiencing

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid behshti hospital

##### Full name of responsible person

Dr.MohammadReza Molaghanbari

##### Street address

Ghotbe ravandi Blv

##### City

Kashan

##### Province

Isfahan

##### Postal code

8715981151

##### Phone

+98 31 5554 0026

##### Fax

##### Email

beheshtihospital@kaums.ac.ir

##### Web page address

http://beheshti.kaums.ac.ir/

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr. HamidReza Banafshe

##### Street address

Ghotbe ravandi Blv

##### City

Kashan

##### Province

Isfahan

##### Postal code

8715973474

##### Phone

+98 31 5544 3022

##### Email

info@kaums.ac.ir

##### Web page address

http://kaums.ac.ir/

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kashan 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

Kashan University of Medical Sciences

##### Full name of responsible person

Sara Hosseinpoor

##### Position

Master student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Psychology

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##### City

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Sara Hosseinpoor  
**Position**  
Master student  
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## Person responsible for updating data

### Contact

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Kashan University of Medical Sciences  
**Full name of responsible person**  
Sara Hosseinpoor  
**Position**  
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**Latest degree**  
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**Other areas of specialty/work**  
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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

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

Participant data file available after the people's identity was removed. This data includes consent, blood test and questionnaires completed by participants before and after the intervention. The study protocol and the results of the statistical analysis of the data and the results of the study are also published. How to perform the intervention will be available in the form of audio files from the sessions, if possible. The data dictionary will also be shared.

### When the data will become available and for how long

The start of the data access period is after the results are published

### To whom data/document is available

Researchers working in academic and scientific institutions, people working in health centers, participants in this study

### Under which criteria data/document could be used

Use of data from this study for new studies is permitted by citing the source. Also, The data from this study will be made available to health centers to improve treatment plans if necessary. Study results will also be made available to participants

### From where data/document is obtainable

Applicants should send an email to the following email address for the required documentation.  
hosseinpoor.sarah74@gmail.com

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

After submitting a request and reviewing how the study documentation and data will be used, the data will be made available to applicants.

### Comments