Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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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
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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
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Ghotbe ravandi Blv
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Kashan
Province
Isfehan
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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Person responsible for updating data

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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