

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparing the Effectiveness of Mindfulness Based Stress Reduction and Acceptance and Commitment Therapy on Physiological and Psychological Symptoms in Inflammatory Bowel Disease

Protocol summary

Study aim

The aim of this study was to determine and compare the effectiveness of Acceptance and Commitment Therapy (ACT) and Mindfulness-Based Stress Reduction (MBSR) on the physiological and psychological symptoms of inflammatory bowel disease.

Design

Subjects were selected by the convenience sampling method and randomly entered each of the experimental and control groups. Each of the two treatments was presented to the experimental groups in 8 sessions and the control group did not receive treatment

Settings and conduct

In this research project that is done in Kerman Gastroenterology and Liver Center, two psychological methods are tested as a group on people with colitis, which aims to improve their psychological and physiological status. This intervention is one-way blind and participants do not know how to intervene and the number of groups.

Participants/Inclusion and exclusion criteria

The target population included all patients with inflammatory bowel disease in Kerman province in Iran who have a medical record in the hospitals of this city.

Intervention groups

Each of the two treatments of ACT and mindfulness based-stress reduction was presented to the experimental groups in 8 sessions and the control group did not receive treatment.

Main outcome variables

Improving the psychological and physiological dimensions of people with colitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044156N1**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **retrospective**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Fateme Sheikh Ali Saghaie

Name of organization / entity

The University of Shahid Bahonar Kerman

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-21, 1398/03/31

Expected recruitment end date

2020-03-04, 1398/12/14

Actual recruitment start date

2019-08-27, 1398/06/05

Actual recruitment end date

2020-07-13, 1399/04/23

Trial completion date

2020-08-12, 1399/05/22

Scientific title

Comparing the Effectiveness of Mindfulness Based Stress

Reduction and Acceptance and Commitment Therapy on Physiological and Psychological Symptoms in Inflammatory Bowel Disease

Public title

effective of mindfulness and ACT on inflammatory bowel disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

inflammatory bowel disease patients who have inactive and under control disease

Exclusion criteria:

Patients under 18 years Patients over 65 years pregnant females patients currently attending psychiatric services patients currently receiving antidepressant medication patients who have received steroid medications in the past three months patients who have previously undergone a stress management programme (relaxation techniques, psycho dynamic psychotherapy, cognitive behavioral therapy, hypnosis)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **160**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

in this study, we will use simple random sampling. participants get an identification number and after lottery, they will be in intervention number 1, intervention number 2 and control group

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding is used in this method of the first type, and the research is one-side blind, and we don't say to patients that they are in which groups study, and it is not necessary to tell patients how many groups in this study is there.

Placebo

Not used

Assignment

Parallel

Other design features

Each of the two treatments was presented to the experimental groups in 8 sessions. The Control group didn't receive any kind of treatment.

Secondary Ids

empty

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

Kerman University of Medical Sciences ethics committee

Street address

Kerman Medical Sciences Research Center, kerman, Somayeh Crossroads, at the beginning of Jihad Boulevard, at the beginning of Ibn Sina Street

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2019-08-24, 1398/06/02

Ethics committee reference number

IR.KMU.REC.1398.252

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

Inflammatory bowel disease

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes**1****Description**

Colitis physiological symptoms

Timepoint

before intervention, after intervention and 60 days after intervention

Method of measurement

Partial Mayo Scoring Index Assessment

2**Description**

Stress

Timepoint

before intervention, after intervention and 60 days after intervention

Method of measurement

Depression, Anxiety and Stress Scale questionnaire (DASS-21)

3**Description**

Anxiety

Timepoint

before intervention, after intervention and 60 days after intervention

Method of measurement

Depression, Anxiety and Stress Scale questionnaire (DASS-21)

4

Description

Depression

Timepoint

before intervention, after intervention and 60 days after intervention

Method of measurement

Depression, Anxiety and Stress Scale questionnaire (DASS-21)

5

Description

quality of life

Timepoint

before intervention, after intervention and 60 days after intervention

Method of measurement

world health quality of life questionnaire (BREF form)

6

Description

General Health

Timepoint

before intervention, after intervention and 60 days after intervention

Method of measurement

general health questionnaire (GHQ-28)

7

Description

pain perception

Timepoint

before intervention, after intervention and 60 days after intervention

Method of measurement

Mcgill pain perception questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

first Intervention group called "Acceptance and commitment therapy": it includes 8 psychological training sessions in 1.5 hours. each session is included one of these subjects: ACT introduction, creative hopelessness, acceptance, cognitive defusion, being in the present moment, self as a context, values, and committed action.

Category

Treatment - Other

2

Description

The second Intervention group called " Mindfulness-based stress reduction": includes 8 psychological training sessions in 1.5 hours. each session is included one of these subjects: MBSR introduction, creative perception, and reaction being body and mind in the present moment, the effect of perception conditioning on momentary and original experiences, stress and its communication with mindfulness, stressful communication, bringing practices to life texture, and continue with mindfulness.

Category

Treatment - Other

3

Description

Control group: Here we have 15 people who are pre-tested and post-tested but no intervention is done to compare with the experimental group.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and Hepatology Research Center

Full name of responsible person

Bijan Ahmadi

Street address

Gastroenterology and Hepatology Research Center, Afzali-pour Educational and Therapeutic Center, Next to the Shahid Bahonar University, Emam Khomeini Highway, Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences, Deputy of

Research, Gastroenterology Research Center

Full name of responsible person

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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

Kerman University of Medical Sciences, Deputy of
Research, Gastroenterology Research Center

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

Bahonar University of Kerman, Iran

Full name of responsible person

Fateme Sheikh-ali Saghaie

Position

M.A 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

Undecided - It is not yet known if there will be 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

The data obtained from the questionnaires each have a score that only the individual's score in the primary variables with its secondary variables is published and does not refer to the identity of the individual.

When the data will become available and for how long

The onset of the date of access to the information is 6 months after complete treatment and publication of the results.

To whom data/document is available

Only those who are in the field of gastrointestinal diseases and psychology researchers as well as educational centers in these fields and academic fields as well as those who want to complete this plan have the right to receive data and information.

Under which criteria data/document could be used

Researchers in the field of inflammatory bowel disease and all psychologists who seek a change in the brain wave of these individuals through with psychological approach.

From where data/document is obtainable

Refer to Kerman Physiological Research Science Center and Afzalipour Research Center.

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

After 6 months of the complete process of treatment, if the person requesting the information was among the people who could provide information to him, by asking questions about the impact of this information on the scientific study process or raising his level of knowledge, Its provided to him/her, By consulting with another person who contributing in this schema.

Comments