Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
Phone
+98 34 3281 9168
Email address
fateme.saghaie@ens.uk.ac.ir

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

City

Kerman

Province

Kerman

Postal code

7616913911

Phone

+98 34 3325 7470

Fax

Email

paafzali@kmu.ac.ir

Web page address

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
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

City
Kerman

Province
Kerman

Postal code
7616913911

Phone
+98 34 3325 7470

Email
paafzali@kmu.ac.ir

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

Street address
No. 4, Alley 44, Rezvan Blvd., Jomhuri Blvd., Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7618988565

Phone
+98 34 3281 9168

Email
fateme.saghaie@gmail.com

Person responsible for scientific 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

Street address
No. 4, Alley 44, Rezvan Blvd., Jomhuri Blvd., Kerman, Iran

City
کرمان

Province
Kerman

Postal code
7618988565

Phone
+98 34 3281 9168

Email
fateme.saghaie@gmail.com

Person responsible for updating data

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

Street address
No. 4, Alley 44, Rezvan Blvd., Jomhuri Blvd., Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7618988565

Phone
+98 34 3281 9168

Email
fateme.saghaie@gmail.com

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