Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the Effect of Mindfulness-Based Cognitive Therapy and Progressive Muscle Relaxation on Symptoms, Fatigue, and Visceral Hypersensitivity in Inflammatory Bowel Disease Patients

Protocol summary

Study aim

A Comparative Study of The Effects of Mindfulness-Based Cognitive Therapy and Progressive Muscle Relaxation on Symptoms, Fatigue, and Visceral Hypersensitivity in Inflammatory Bowel Disease Patients

Design

This Study is a Randomized Block Clinical Trial with Two Intervention Groups and Three Stages of Pre-Test, Post-Test and Follow-Up. It Will be Conducted in an Unblinded Manner on 72 Patients with Inflammatory Bowel Disease (2 Intervention Groups of 36). Patients Will be Included in The Study if They Agree and are Eligible and Will be Randomly Assigned to The Two Intervention Groups. (Randomized)

Settings and conduct

The Trial Will be Conducted on Patients with Inflammatory Bowel Disease at The Porsina Hakim Clinic, Isfahan. Individuals Participating in The Intervention Groups Will Receive Mindfulness-Based Cognitive Therapy and Progressive Muscle Relaxation in a Group Setting for 8 2-Hour Sessions (2 Months).

Participants/Inclusion and exclusion criteria

Entry conditions: 1) Possessing Minimum Age of 18 Years and a Maximum Age of 65 Years 2) Definitive Diagnosis of Crohn's Disease or Ulcerative Colitis by a Specialist physician, 3) Ability to Participate in 8 Treatment Sessions, 4) Having at Least a High School Diploma, 5) Completing the Informed Consent Form 6) Ability to Perform Light Exercise Non-entry conditions: 1) Having Major Psychiatric Disorders, 2) Participation in Other Psychosocial Trials

Intervention groups

Intervention Group One: They Will Receive Mindfulness-Based Cognitive Therapy. This Treatment Will Consist of 8 Two-Hour Sessions and Will be Delivered in a Group Setting. Intervention Group Two: They Will Receive Progressive Muscle Relaxation. This Will Consist of 8 Two-Hour Sessions and Will be Delivered in a Group Setting.

Main outcome variables

Symptoms, Fatigue, and Visceral Hypersensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260225068949N1**
Registration date: **2026-04-27, 1405/02/07**
Registration timing: **prospective**

Last update: **2026-04-27, 1405/02/07**
Update count: **0**

Registration date

2026-04-27, 1405/02/07

Registrant information

Name

Sara Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3346 7012

Email address

sa.ahmadi.9731@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2026-10-23, 1405/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Mindfulness-Based Cognitive Therapy and Progressive Muscle Relaxation on Symptoms, Fatigue, and Visceral Hypersensitivity in Inflammatory Bowel Disease Patients

Public title

Comparison the Effect of Mindfulness-Based Cognitive Therapy and Progressive Muscle Relaxation on Inflammatory Bowel Disease Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Possessing Minimum Age of 18 Years and a Maximum Age of 65 Years Definitive Diagnosis of Crohn's Disease or Ulcerative Colitis by a Specialist physician Ability to Participate in 8 Treatment Sessions Having at Least a High School Diploma Completing the Informed Consent Form Ability to Perform Light Exercise Like Raising Arms Above Head or Bending Knees

Exclusion criteria:

Having Major Psychiatric Disorder Such as Psychotic Disorders, Substance Use Disorders, Mood disorders Participation in Other Psychosocial Trials

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

This Study is a Block Randomization Clinical Trial with Two Intervention Groups and is Conducted in an Unblinded Manner. The Sample of This Design Includes 72 Patients with Inflammatory Bowel Disease. After Reviewing and Evaluating the Files of the Affected Patients and also Evaluating the Patients Diagnosed with Inflammatory Bowel Disease by a Specialist Physician and after Their Agreement to Participate in this Design and also Evaluating the Entry Conditions; with the Help of a Statistical Consultant and Based on Statistical Software; Blocks of 9 Sizes are Created, Which will Ultimately Create 8 Blocks of 9 and 36 Patients will be Placed in Each Group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address

Building No. 3, Isfahan University of Medical Sciences, Hezar Jerib Street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2026-02-08, 1404/11/19

Ethics committee reference number

IR.MUI.MED.REC.1404.453

Health conditions studied

1

Description of health condition studied

Inflammatory Bowel Disease (IBD)

ICD-10 code

K50

ICD-10 code description

Crohn's disease [regional enteritis]

2

Description of health condition studied

Inflammatory Bowel Disease (IBD)

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Symptoms

Timepoint

Before the Intervention, After the Intervention, 3 Months After the Intervention

Method of measurement

Inflammatory Bowel Disease Questionnaire-Short Form

2

Description
fatigue
Timepoint
Before the Intervention, After the Intervention, 3 Months After the Intervention
Method of measurement
Multidimensional Fatigue Inventory

3

Description
Visceral Hypersensitivity
Timepoint
Before the Intervention, After the Intervention, 3 Months After the Intervention
Method of measurement
Visceral Sensitivity Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: This Group of Patients with Inflammatory Bowel Disease (IBD) Received Mindfulness-Based Cognitive Therapy in a Group Setting Over 8 Two-Hour Sessions. Session 1: Introduction and Explanation of the Sessions' General Content and Awareness and Automatic Guidance Session 2: Living in Our Minds (Paying Attention to Breathing) Session 3: Gathering the Wandering Mind Session 4: Recognizing Aversion Session 5: Allowing/Coping Session 6: Thoughts are not Reality. Session 7: How can I Best Take Care of Myself? Session 8: Retaining and Expanding New Learning. Also, at the End of Each Session, There are a Series of Exercises That are Given to The Patient to Study and Do for The Next Session.
Category
Lifestyle

2

Description
Intervention group 2: This Group of Patients with Inflammatory Bowel Disease (IBD) Received Progressive Muscle Relaxation in 8 Two-Hour Sessions as a Group. Session 1: Justification of The Treatment Logic and Breathing Relaxation Session 2: Relaxation of 16 Muscle Groups Session 3: Relaxation of 7 Muscle Groups Session 4: Relaxation of 4 Muscle Groups Session 5: Relaxation Through Reminders Session 6: Relaxation Through Reminders with Counting Session 7: Relaxation Through Counting Session 8: Final Feedback on The Intervention Process and Post-Test At The Beginning of Each Session, Questions from Individuals about the Previous Session are Answered, and at The End of The Sessions, Guidance is Provided on How to Complete Assignments.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Hakim clinic & lab
Full name of responsible person
Sara Ahmadi
Street address
3rd Floor, Isfahan Health Town, Sepehr Street, Aghababaei Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Askari
Street address
Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib Street
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8174673461
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+98 31 3668 8138
Email
askari@mui.ac.ir
Web page address
https://mui.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Sara Ahmadi

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Associate Professor

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Sara Ahmadi

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

All Data about Participants Can be Shared After Individuals are De-identified.

When the data will become available and for how long

Access Period Starts 6 Months After Results are Published

To whom data/document is available

Researchers Working in Academic and Scientific Institutions

Under which criteria data/document could be used

The Data is Provided Solely for The Purpose of Better Understanding The Research Methodology. Therefore, Analysis of The Data is not Permitted.

From where data/document is obtainable

Sara Ahmadi: Sa.Ahmadi.9731@gmail.com Phone: 09367581699 Dr. Fatemeh Zargar:

fatemehzargar@gmail.com

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

First, Send an Email to Ms. Ahmadi. If You do not Receive a Response from The University Email, Send a Message to Her Personal Email. Otherwise, Send a Message to Dr. Fatemeh Zargar's Email. We Will Try to Respond Within a Week.

Comments