Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the efficacy of schema therapy and mindfulness-based cognitive therapy on symptoms, anxiety sensitivity and sleep quality in patients with irritable bowel syndrome.

Protocol summary

Study aim
Comparison of the efficacy of schema therapy and mindfulness-based cognitive therapy on symptoms, anxiety sensitivity and sleep quality in patients with irritable bowel syndrome

Design
Clinical trial with control group, randomized, on 45 patients. Lottery

Settings and conduct
10 sessions of schema therapy were conducted at the research center for an experimental group of 15 people, and 10 sessions of mindfulness-based cognitive therapy were conducted at the research center for another experimental group of 15 people.

Participants/Inclusion and exclusion criteria
Diagnosis of irritable bowel syndrome based on Rome IV criteria with confirmation from a gastroenterologist Lack of history of psychotherapy and lack of use of psychiatric medications

Intervention groups
intervention groups with schema therapy and mindfulness based on cognitive therapy and a waiting list control group

Main outcome variables
irritable bowel syndrome symptoms, anxiety sensitivity, sleep quality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250604066062N1**
Registration date: **2025-07-22, 1404/04/31**
Registration timing: **prospective**

Last update: **2025-07-22, 1404/04/31**
Update count: **0**

Registration date
2025-07-22, 1404/04/31

Registrant information
Name
Shaghayegh Bazargan
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-08-01, 1404/05/10
Expected recruitment end date
2025-08-21, 1404/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of schema therapy and mindfulness-based cognitive therapy on symptoms, anxiety sensitivity and sleep quality in patients with irritable bowel syndrome.

Public title
Comparison of the efficacy of schema therapy and mindfulness-based cognitive therapy on symptoms, anxiety sensitivity and sleep quality in patients with

irritable bowel syndrome.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

patients with irritable bowel syndrome

Exclusion criteria:

History of psychotherapy Taking psychiatric drugs

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization - will be randomly assigned to intervention and control groups, and patients will be randomly assigned to three groups of 15 after meeting the entry criteria. The random selection method will be done by lottery and a number will be assigned to each of the sample people, and then the numbers will be randomly selected with the help of Excel software, which will form the test 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 Islamic Azad University- Najafaba Branch

Street address

no.8,homa alley,north towhid st

City

esfahan

Province

Isfehan

Postal code

8173655463

Approval date

2024-08-22, 1403/06/01

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1403.134

Health conditions studied

1

Description of health condition studied

Irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

High score on the Irritable Bowel Symptom Severity Questionnaire

Timepoint

Before the start of the intervention, after the end of the intervention, and 3 months after the end of the intervention

Method of measurement

Francis et al. Irritable Bowel Syndrome Severity Questionnaire

2

Description

Revised Anxiety Sensitivity Inventory

Timepoint

Before the start of the intervention, after the end of the intervention, and 3 months after the end of the intervention

Method of measurement

Taylor and Cox's Revised Anxiety Sensitivity Inventory

3

Description

Score on the sleep quality questionnaire

Timepoint

Before the start of the intervention, after the end of the intervention, and 3 months after the end of the intervention

Method of measurement

Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 group schema therapy sessions of Jeffrey Young's schema therapy protocol every week for 90 minutes. The intervention was designed according to the principles of the cognitive-emotional model of schema therapy and included the identification and

modification of early maladaptive schemas, activation of maladaptive coping styles, and enhancement of adaptive coping strategies using cognitive, emotional, experiential (e.g., empty-chair technique, guided imagery), behavioral, and interpersonal techniques.

Category
Treatment - Other

2

Description
Intervention group: 10 sessions of cognitive-based mindfulness group training each week for 90 minutes. The program included practices such as body scan, mindful breathing, mindful walking, thought meditation, and emotional acceptance. Sessions were conducted in groups and facilitated by a therapist trained in the MBCT approach. To enhance the effectiveness of the program, daily home practice (30 to 45 minutes per day) was also assigned to participants.

Category
Treatment - Other

3

Description
Control group: waiting list. After the completion of the study, participants in this group will be given the opportunity to take part in one of the intervention programs.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
alzahra hospital

Full name of responsible person
Maryam soheilipor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Gholamreza Asgari

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Hezar Jarib St, Esfahan University of Medical Sciences

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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
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
Shaghayegh Bazargan

Position
PH.d.student

Latest degree
Master

Other areas of specialty/work
Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available