Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of affect regulation treatment on the treatment outcomes of patients with irritable bowel syndrome

Protocol summary

Study aim
Comparing the effectiveness of affect regulation therapy and cognitive behavioral therapy on the severity of gastrointestinal symptoms, visceral sensitivity, executive function, emotional processing and psychological disturbance in patients with irritable bowel syndrome.

Design
Clinical trial, with parallel groups, double-blind, randomized, on 32 patients, with a follow-up period of three months. The permuted random blocking method is used to do randomization.

Settings and conduct
Patients are included in the study with the referral of a gastroenterologist and with the inclusion criteria. affect regulation therapy and cognitive behavioral therapy is implemented in the form of weekly two-hour sessions at the clinic of the Faculty of Behavioral Sciences and Mental Health in Tehran. The study is double blind. after a general explanation about the goals and obtaining informed consent, the participants are randomly assigned to two intervention groups and will not be informed of which treatment will be implemented for them until the end of the study. Then the data obtained from the research is coded and provided to the analyst.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosing irritable bowel syndrome Age between 18 and 55 years Literacy level above middle school Exclusion criteria: manic states or psychotic symptoms severe depression Having a drug addiction Severity of disease symptoms high and medium risk level of suicide

Intervention groups
For the first intervention group, affect regulation therapy is performed based on Professor Berking's protocol, and for the second intervention group, cognitive behavioral therapy is performed based on Toner's protocol. Both interventions are weekly sessions.

Main outcome variables
Severity of gastrointestinal symptoms, visceral sensitivity, executive function, emotional processing and psychological disturbance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240602061987N1**
Registration date: **2025-01-20, 1403/11/01**
Registration timing: **prospective**

Last update: **2025-01-20, 1403/11/01**
Update count: **0**

Registration date
2025-01-20, 1403/11/01

Registrant information

Name
Samane Soltanabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3734 4825

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-19, 1403/12/01

Expected recruitment end date
2025-05-22, 1404/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of affect regulation treatment on the treatment outcomes of patients with irritable bowel syndrome

Public title
Effectiveness of affect regulation treatment on the treatment outcomes of patients with irritable bowel syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosing irritable bowel syndrome by a gastroenterologist based on the Rome IV criteria Age between 18 and 55 years Literacy level above middle school

Exclusion criteria:
Suffering from manic states or having psychotic symptoms based on SCID (SCID-5-CV) Suffering from severe depression that prevents effective processing of educational concepts according to SCID Having a drug addiction based on the SCID The severity of the disease and symptoms related to irritable bowel syndrome should be such that the person is unable to participate in the sessions (such as bleeding or severe pain), which is measured through a clinical interview. The existence of high and medium risk level of suicide which is measured through interview.

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
The permuted random blocking method is used to do randomization. In this method, 8 blocks of 4 will be randomly selected from a combination of letters A and B. These blocks are as follows AABB, ABBA, BBAA, BAAB, ABAB, and BABA. Allocating the letters A and B to the intervention and control groups will be done randomly before randomization and the data analyst will be unaware of the intervention and control groups. The researcher, having a list of people (a list of 48 people who are going to participate in the project), assigns a numeric code to each person. It then offers the anonymous list of members (containing only the numeric code) to the sample assignor to the groups. First, the sample assignor organizes the selected blocks as described, writes them on separate sheets of paper (8 separate sheets), and places them in sealed envelopes. Then s/he randomly selects the envelopes and, based on the previously selected codes, A and B, determines the numerical code number of the individuals assigned to A and B interventions and provides it to the researcher. For instance, if the BABA block is selected first, the first person on the list will be assigned to group B, the second person to group A, the third person to group B, and the fourth person to group A. Likewise, participants 5 to 32 will be assigned to groups A and B.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the participants, after the general explanation of the treatment and the purpose of the research and obtaining informed consent, the participants are randomly divided into two intervention groups, but they will not be informed of which intervention group they are in until the end of the treatment Explanations are given about the interventions. In order to blind the analyzer, a code is assigned to each data.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences

Street address
Tehran, Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2024-03-11, 1402/12/21

Ethics committee reference number
IR.IUMS.REC.1402.1148

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
Severity of gastrointestinal symptoms
Timepoint
beginning and end and three months after the end of treatment
Method of measurement
Gastrointestinal Syndrome Rating Scale of Revicki (1998)

2

Description
Visceral Sensitivity
Timepoint
beginning and end and three months after the end of treatment
Method of measurement
Visceral Sensitivity Index of Labus et al

3

Description
Executive Function
Timepoint
beginning and end and three months after the end of treatment
Method of measurement
Behavior Rating Inventory of Executive Function (BRIEF)

4

Description
Emotional Processing
Timepoint
beginning and end and three months after the end of treatment
Method of measurement
Emotional Processing Scale (EPS) Baker et al

5

Description
Psychological disturbances
Timepoint
beginning and end and three months after the end of treatment
Method of measurement
Depression Anxiety Stress Scales-Short Form (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: Weekly two-hour sessions of affect regulation therapy are conducted according to the protocol of affect regulation therapy (ART) based on the study of Berking and Whitley, 2014.The content of these sessions includes teaching skills such as muscle and breathing relaxation, non-judgmental awareness, acceptance and tolerance, compassionate self-support, emotion analysis and emotion change.
Category
N/A

2

Description
The second intervention group: 12 weekly two-hour sessions of cognitive behavioral therapy are performed based on the Toner protocol.The content of these sessions includes examining thoughts and challenging them and teaching skills such as problem solving and assertiveness.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology doctor's office
Full name of responsible person
Samane Soltanabadi
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South Punak St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Samane Soltanabadi
Position
Ph. D. Candidate
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
Not applicable
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
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Informed consent and clinical study report will be shared.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

All people

Under which criteria data/document could be used

Using the results to improve the quality of life of patients

From where data/document is obtainable

Samane Soltanabadi Email: samane.soltanabadi@gmail.com Number: 09384701029

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

Send email or message

Comments