Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Examining the effectiveness of Unified Protocol on alleviating psychological distress and digestive symptoms in patients with irritable bowel syndrome

Protocol summary

Study aim

Determining the relationship between transdiagnostic mechanisms, mindfulness, cognitive flexibility, anxiety sensitivity, emotional avoidance, and behavioral avoidance in integrative treatment with psychological distress and severity of gastrointestinal symptoms in patients with irritable bowel syndrome.

Design

A controlled, parallel-group, single-blind, randomized clinical trial on 52 patients. A random number generator will be used for randomization.

Settings and conduct

The study will be conducted in a specialized gastroenterology clinic in Kermanshah. In addition to receiving standard treatments for irritable bowel syndrome, 26 patients in the intervention group will undergo integrated protocol treatment once a week by a clinical psychologist for eight 45-60 minute sessions; and will be compared with 26 patients receiving standard treatments for irritable bowel syndrome as the control group.

Participants/Inclusion and exclusion criteria

Patients with irritable bowel syndrome are a condition for inclusion of the study and bowel surgery is a condition for exclusion.

Intervention groups

The intervention group will receive the Integrated Protocol for Transdiagnostic Treatment. The control group will receive only standard treatments for irritable bowel syndrome, including drug treatments.

Main outcome variables

Severity of clinical symptoms of irritable bowel syndrome, based on scores obtained from the IBS-SSS questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260808070576N1**
Registration date: **2026-09-20, 1405/06/29**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-20, 1405/06/29**
Update count: **0**

Registration date

2026-09-20, 1405/06/29

Registrant information

Name

Hosna Mirzaasgari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-03, 1405/05/12

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Examining the effectiveness of Unified Protocol on alleviating psychological distress and digestive symptoms in patients with irritable bowel syndrome

Public title
Investigating the effectiveness of psychotherapy on reducing psychological distress and symptoms of the disease in patients with irritable bowel syndrome.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Have at least a high school diploma A cutoff score of 15 or more on the DASS-21 Depression and Anxiety subscale Having irritable bowel syndrome Willingness and consent to participate in the study

Exclusion criteria:
Receiving other psychological treatments in the past year History of intestinal surgery Psychotic features or suicidal thoughts Organic mental disorder History of drug abuse or drug dependence

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: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 52 eligible patients will be allocated to two intervention and control groups in a 1:1 ratio. The random allocation sequence will be prepared using the Block Randomization method with variable sizes of 4 and 6 and a 1:1 ratio. The allocation sequence will be generated by an individual independent of the recruitment and implementation of the intervention and placed in opaque, non-transparent, sealed, and sequentially numbered envelopes. After meeting the inclusion criteria, obtaining informed consent, and final entry of each patient into the study, the next numbered envelope will be opened by the person responsible for allocation and the patient group will be determined. Thus, group allocation cannot be predicted or selected before the patient's final entry.

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
Ethics committee of shahid beheshti University of Medical Sciences

Street address
No 30 Agha Razi avenue Golestan crossroad

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Postal code
6714763164

Approval date
2026-08-03, 1405/05/12

Ethics committee reference number
IR.SBMU.MSP.REC.1405.301

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome

ICD-10 code
K58

ICD-10 code description
Irritable bowel syndrome

2

Description of health condition studied
Mixed anxiety and depressive disorder

ICD-10 code
F41.2

ICD-10 code description
Mixed anxiety and depressive disorder

3

Description of health condition studied
Mild depressive episode

ICD-10 code
F32.0

ICD-10 code description
Major depressive disorder, single episode, mild

Primary outcomes

1

Description
Score obtained from the IBS-SSS questionnaire

Timepoint
For this purpose, participants must complete the previous module before starting a new module in order to be eligible for the next module intervention. Initially, psychological distress and severity of gastrointestinal symptoms and transdiagnostic mechanisms as mediators

(integrated protocol treatment modules) will be assessed as Baseline before the start of treatment (t0). All hypothesized mediators will also be assessed immediately after the module targeting the mechanism to ensure that participants have received the treatment (t1). For mechanisms that will be targeted early in treatment (mindfulness and cognitive flexibility), they will also be assessed after treatment to examine further changes (t2). We will not assess anxiety sensitivity and avoidance at post-treatment due to the close temporal proximity to the assessment of modules 6 and 7 (weeks 6 and 7). We assume that one module is completed each week. Accordingly, we will assess the meta-diagnostic mechanisms in the control group in the week that corresponded to the module number (i.e., we will assess mindfulness after module 3 in the treatment and after 3 weeks in the control group).

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group receives the Integrated Protocol treatment. The Integrated Protocol is a cognitive behavioral therapy with an emotion-focused approach. This treatment is designed to help patients learn how to deal with their unpleasant emotions and respond to their emotions in a more adaptive way. The treatment is delivered in 8 weekly sessions of 50 to 60 minutes. In the first session, the patient's motivation to participate in the treatment is increased. Patients weigh the advantages and disadvantages of change compared to staying the same and express their treatment goals. The topic of the second session is psychological education tracking emotional experiences. The nature of emotions and the main components of emotional experience are introduced to patients. In the third session, patients are taught emotion awareness. Patients become more aware of how they react and respond to emotions. The fourth session is Cognitive Appraisal and Change Appraisal: In this section, patients are taught to consider the role of maladaptive automatic appraisals in creating emotional experiences. Session 5: Avoiding Emotions and Emotional Behaviors: This section emphasizes the components of emotional experience behaviors. In this section of the treatment, therapists help patients identify patterns of avoiding emotions and maladaptive emotional behaviors. Session 6: Awareness of and Tolerance for Physical Feelings: This section emphasizes increasing awareness of the role of physical feelings in emotional experiences. Session 7: Facing Internal and External Triggers of Emotions: This section focuses on internal triggers, including physical and external feelings of emotions, and helps patients increase their tolerance for emotions. Session 8: Relapse Prevention: An overview of treatment concepts and discussion and exchange of opinions about the patient's progress are conducted. Before the start of treatment, in different sessions and at the end of treatment, depending on the topic, questionnaires are completed by the patient to measure psychological distress and digestive symptoms.

Category

Behavior

2

Description

Control group: 26 patients in the control group will receive only the usual medications for the treatment of irritable bowel syndrome and will not receive the psychological treatment of the integrated protocol. Before, during, and at the end of treatment, depending on the subject, questionnaires will be completed by the patient to measure psychological distress and digestive symptoms.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastroenterology Clinic

Full name of responsible person
Hosna Mirzaasgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?

No

Title of funding source

The budget has not been approved.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hosna mirzaasgari

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Psychology

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Latest degree

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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

Not applicable

Title and more details about the data/document

All data can be shared after de-identifying individuals.

When the data will become available and for how long

The period of access to data and documents will begin from 1406 onwards.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions, as well as to people working in industry, who can apply to receive them.

Under which criteria data/document could be used

They are authorized to receive information and documentation for literature review, data meta-analysis, or any other type of data analysis.

From where data/document is obtainable

To receive information about the corresponding author, Dr. Hosna Mirzaasgari, you can contact her at the following email addresses and phone numbers: h.m.asgari@hotmail.com hosna.mirzaasgari@sbmu.ac.ir 09126347604

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

It is possible to send a request via the mentioned emails, or by calling the mobile phone number, or by sending a message via WhatsApp messenger, and the information will be sent to them within a maximum of 3 weeks.

Comments