Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effectiveness of Acceptance and Commitment Therapy on Lifestyle, Psychological Flexibility, and Severity of Symptoms among People with Irritable Bowel Syndrome

Protocol summary

Study aim

Determining the Efficacy of Acceptance and Commitment Therapy on Lifestyle, Psychological Flexibility, and Symptom Severity in Individuals with Irritable Bowel Syndrome

Design

A randomized , controlled, parallel- group, phase 2 clinical trial on 42 patients. A table of random numbers is used for randomization.

Settings and conduct

The study is conducted at the specialized gastroenterology clinic of Shahid Beheshti Hospital, where the intervention group receives Acceptance and Commitment Therapy.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:Diagnosis of Irritable Bowel Syndrome (IBS) based on the ROME IV criteria. Age between 18 and 65 years, A minimum of a high school diploma for education. Willingness to maintain a stable type and dosage of current medications throughout the study period, Willingness and provision of informed consent to participate in the study, No current suicidal ideation, No current substance abuse or dependenc , No prior history of psychotherapy. Exclusion Criteria:Receiving any psychological treatment interventions within the last year or during the period of the study, Onset of an acute psychiatric or physical illness during the study, Three or more absences or irregular attendance in sessions,The individual's unwillingness to continue with the study.

Intervention groups

The intervention and control groups will consist of individual with Irritable Bowel Syndrome , diagnosed by a gastroenterologist according to the ROME IV criteria

Main outcome variables

This study examines whether Acceptance and Commitment Therapy can change psychological flexibility , lifestyle, and symptom severity in individuals with IBS. it is expected that lifestyle and psychological flexibility will increase and the symptom severity score will decrease.

General information

Reason for update

Acronym

irritable bowel syndrome

IRCT registration information

IRCT registration number: **IRCT20250630066306N1**
Registration date: **2025-07-15, 1404/04/24**
Registration timing: **prospective**

Last update: **2025-07-15, 1404/04/24**
Update count: **0**

Registration date

2025-07-15, 1404/04/24

Registrant information

Name

Bahar Shafizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-21, 1404/04/30

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effectiveness of Acceptance and Commitment Therapy on Lifestyle, Psychological Flexibility, and Severity of Symptoms among People with Irritable Bowel Syndrome

Public title

The Efficacy of Acceptance and Commitment Therapy in the Treatment of Irritable Bowel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis IBS based on the criteria of ROME IV Aged between 18 and 65 years Satisfaction and commitment to participate in the study Absence of suicidal thoughts No prior history of psychotherapy

Exclusion criteria:

Get interventions psychological treatment in the past year and the time of the study Three sessions of absence for each patient. Oncet of an acute psychological or somatic condition The individual's unwillingness to continue the session

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: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, to allocate participants to the experimental and control groups, a simple randomization method was used with a table of random numbers. First, a list of eligible participants was prepared, and each individual was assigned a number. Then, by randomly selecting a starting point in the table of random numbers, the numbers were read in sequence. Based on whether the numbers were even or odd, individuals were allocated to the experimental or control group (even numbers for the experimental group and odd numbers for the control group). This method was implemented to prevent bias in allocation and to increase the internal validity of the research.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Individuals are randomly assigned to two intervention and control groups using a random number table. The groups are also matched in terms of the type of medication used and the type of IBS. Patients are asked not to change their lifestyle during the implementation of this intervention and to continue their medical treatment. Then, acceptance and commitment therapy is implemented in 8 sessions of 90 minutes on the experimental group and is not performed on the control group. Finally, the treatment method is compared with the control group in terms of symptom reduction. All participants complete lifestyle and psychological flexibility questionnaires and IBS symptom severity before and after the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashanپ

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Kashan

Province

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Approval date

2025-06-08, 1404/03/18

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1404.047

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

Lifestyle

Timepoint

Before and after intervention

Method of measurement
Health-Promoting Lifestyle Profile

2

Description
Psychological Flexibility
Timepoint
Before and after intervention
Method of measurement
Cognitive flexibility inventory

3

Description
Severity Symptoms
Timepoint
Before and after intervention
Method of measurement
IBS-SSS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the intervention group received eight-90 minute sessions of Acceptance and Commitment Therapy
Category
Behavior

2

Description
Control group: Receives no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology Specialty Clinic of Shahid Beheshti Hospital
Full name of responsible person
Bahar Shafizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kashan 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
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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