Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Cognitive behavioral therapy (CBT) on behavioral responses and anxiety for patients with irritable bowel syndrome (IBS)

Protocol summary

Study aim
To evaluate the effect of cognitive behavioral therapy on behavioral responses and anxiety for patients with irritable bowel syndrome.
Design
Quasi-experimental design, two groups pre-test/ post-test, intervention and control group with blind randomization
Settings and conduct
The study will be carried out at Al Shatra General Hospital.
Participants/Inclusion and exclusion criteria
Patients with irritable bowel syndrome
Intervention groups
investigate effect of cognitive behavioral therapy sessions on behavioral responses and anxiety for IBS patients.
Main outcome variables
In this study the instruments that will be use are scales used in cognitive behavioral therapy for irritable bowel syndrome that presented below: 1. The Visceral Sensitivity Index is a unidimensional 15- item scale that measures gastrointestinal symptom–specific anxiety (e.g., “I often fear that I will not be able to have normal bowel movements”). 2. The Irritable Bowel Syndrome-Behavioral Responses Questionnaire includes 26 items with responses ranging from 1 (never) to 7 (always), and its total score ranges from 26 to 182. to investigate the effect of cognitive behavioral therapy on behavioral responses and anxiety for patients with irritable bowel syndrome.

General information

Reason for update
Acronym
CBT (Cognitive behavioral therapy)
IRCT registration information
IRCT registration number: **IRCT20240529061950N1**
Registration date: **2024-11-03, 1403/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-03, 1403/08/13**
Update count: **0**
Registration date
2024-11-03, 1403/08/13

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-15, 1403/07/24
Expected recruitment end date
2025-02-15, 1403/11/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Cognitive behavioral therapy (CBT) on behavioral responses and anxiety for patients with irritable bowel syndrome (IBS)

Public title

Cognitive behavioral therapy for patients with Irritable Bowel Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

An adult patients with underlying IBS. Fulfillment of Rome III criteria for IBS Male and female patients patients who accepted to participate in the CBT

Exclusion criteria:

Blood in stool without benign medical explanation Rapid weight loss without benign medical explanation Ongoing alcohol or drug abuse Patients with colon cancer or Inflammatory Bowel diseases

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization is simple randomization method and the tools used in randomization is computer software.

Blinding (investigator's opinion)

Single blinded

Blinding description

All participants in the study do not know (blinds) whether they are in the intervention group or the control group. Only the researcher, who is himself a provider of cognitive behavioral therapy, is the one who knows that.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baghdad University /college of Nursing

Street address

al adil street

City

Al shatra

Postal code

313

Approval date

2024-09-22, 1403/07/01

Ethics committee reference number

Session 8

Health conditions studied

1

Description of health condition studied

patients with irritable bowel syndrome

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

behavioral responses and anxiety, the primary outcomes: Changes in behavioral responses and anxiety levels, measured using validated anxiety scales and behavioral assessment tools.

Timepoint

before intervention and 8 weeks after intervention.

Method of measurement

1. The Visceral Sensitivity Index is a unidimensional 15-item scale that measures gastrointestinal symptom–specific anxiety (e.g., “I often fear that I will not be able to have normal bowel movements”). 2. The Irritable Bowel Syndrome-Behavioral Responses Questionnaire includes 26 items with responses ranging from 1 (never) to 7 (always), and its total score ranges from 26 to 182.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Intervention Name: Cognitive Behavioral Therapy (CBT). Details: Treatment Method: Psychological therapy. Procedures: Includes cognitive restructuring, stress management, relaxation exercises, and exposure therapy. Number of Sessions: 4 sessions Content: Each session will cover cognitive restructuring, stress management, relaxation techniques, and graded exposure exercises tailored to IBS. Duration of Sessions: Each session will last for 45 minutes. Frequency: once weekly. Method of Use: Conducted by licensed therapist face-to-face interview. Duration of Intervention: 4 weeks. Control Group: Intervention Name: Standard Care / Placebo. Details: Treatment Method: Usual care without any additional psychological therapy. Procedures: Regular follow-up visits with the primary care provider or

gastroenterologist. Number of Sessions: As per the usual care. schedule Content: Standard medical treatment for IBS, which may include dietary advice, medication management, and regular monitoring of symptoms. Duration of Sessions: Typically 30 minutes, depending on the care provider. Frequency: As recommended by the primary care provider. Method of Use: In-person visits with medical professionals

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Al Shatra General Hospital
Full name of responsible person
Mustafa alhelali
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Sponsors / Funding sources

1

Sponsor

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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
Personal Finance
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
University of Baghdad, college of Nursing
Full name of responsible person
Mustafa R. Waheed Alhelali
Position
PhD student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
To preserve patients privacy and adhere to the terms of the Ethics Committee

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