

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the Effectiveness of Cognitive- Behavioral Therapy and Emotion- Focused Therapy on Resiliency, Tolerance of Distress and Quality of Life in Patients with Irritable Bowel Syndrome

#### Protocol summary

##### Study aim

Comparison of the efficacy of emotion-focused and cognitive-behavioral therapy in resilience and distress tolerance and quality of life in patients with irritable bowel syndrome

##### Design

The clinical trial has a parallel and control intervention group, not blinded and randomized.

##### Settings and conduct

At Masoud Gastroenterology Clinic, patients who were diagnosed with a Quarterly Doctor with Irritable Bowel Syndrome were asked to complete the questionnaires if they were satisfied with the conditions of the trial. In the three stages of pre-test, post-test, and follow-up, the impact of protocol on emotional and cognitive behavioral therapies is examined

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: having diagnostic criteria for irritable bowel syndrome with the approval of a gastroenterologist; lack of psychological drugs over the past three months; tendency to participate in the program; have a high school diploma; over 20 years of age; no drug addiction; commitment to attending therapy sessions; low Assessment of Resiliency Questionnaire and Tolerance and Quality of Life Questionnaire in patients with irritable bowel syndrome. Exclusion criteria: having a family history of colon cancer; taking psychiatric drugs; having colon cancer; not wanting to participate in the research project.

##### Intervention groups

Cognitive-behavioral treatment protocol to the first experimental group to enhance resilience and tolerance of distress and improve quality of life in patients with irritable bowel syndrome. She has irritable bowel syndrome. Control group without any intervention.

##### Main outcome variables

Resilience based on Connor-Davidson Resilience Scale;

Distress Tolerance based on Simmons & Ganer Distress Tolerance Scale; Quality of Life based on Quality of Life Questionnaire for Irritable Bowel Syndrome Patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200207046399N1**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **retrospective**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

##### Registration date

2020-04-14, 1399/01/26

##### Registrant information

##### Name

Mitra Jahangirrad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8822 3620

##### Email address

m.jahangirrad@iaukishint.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-23, 1398/08/01

##### Expected recruitment end date

2020-03-18, 1398/12/28

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the Effectiveness of Cognitive- Behavioral Therapy and Emotion- Focused Therapy on Resiliency, Tolerance of Distress and Quality of Life in Patients with Irritable Bowel Syndrome

**Public title**

Comparison of Cognitive Behavioral Therapy and Emotional Therapy in Patients with Irritable Bowel Syndrome

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having diagnostic criteria for irritable bowel syndrome with the approval of a gastroenterologist No use of psychological drugs and psychological therapies within three months Willingness to participate in the scheme High school diploma Being over 20 years old No addiction to any drug Commitment to attend therapy sessions Low Resiliency Questionnaire and Quality of Life Questionnaire for Patients with Irritable Bowel Syndrome

**Exclusion criteria:**

Having a history of colon cancer in the family Having a psychiatric illness and taking psychiatric drugs Having Colon Organ Disease Unwillingness to participate in research project

**Age**

From **20 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**

Subjects will be selected by purposeful sampling. In the first consultation session after structured clinical interview with patients and considering inclusion and exclusion criteria, eligible patients will be asked to complete Connor-Davidson Resilience Scale, Simmons & Ganer Distress Scale. The quality of life of patients with irritable bowel syndrome respond. After the initial evaluation of the patients, the patients who received the lowest mean in these questionnaires, 45 patients were selected and randomly divided into three groups of 15 experimental subjects, the first group cognitive behavioral therapy, the second group emotional therapy and control group. They will be divided. Then the first and second groups will be given eight sessions of 90 minutes once a week, and the control group will receive no intervention. After the intervention sessions, the questionnaires will be given to the patients as post-test

and 3 months later for follow up in all 3 groups and the results of the groups will be compared again.

**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 Hormozgan University of Medical Sciences

**Street address**

Shahid Chamran Blvd., Hormozgan University of Medical Sciences

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Approval date**

2019-12-07, 1398/09/16

**Ethics committee reference number**

IR.HUMS.REC.1398.331

**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**

Resilience

**Timepoint**

Before the intervention, after the intervention and 3 months follow up

**Method of measurement**

Conner & Davidson Resilience Scale

## 2

### **Description**

Tolerance of distress

### **Timepoint**

Before the intervention, after the intervention and 3 months follow up

### **Method of measurement**

Simmons& Gaher Distress Tolerance Scale

## 3

### **Description**

Quality of Life

### **Timepoint**

Before the intervention, after the intervention and 3 months follow up

### **Method of measurement**

Quality of Life Scale in Patients with Irritable Bowel Syndrome

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Cognitive behavioral therapy intervention group. The treatment model used in Cognitive-Behavioral Therapy was based on a general pattern of available resources, considering the nature and nature of irritable bowel syndrome in Iranian patients, and applied behavioral and educational methods. Treatment sessions consist of 8 sessions of once a week for one hour and a half with the purpose of identifying unpleasant thoughts and cognitive errors, reducing stress, increasing resiliency, increasing distress tolerance, improving patients' quality of life and ultimately preventing relapse. It was a disease. Overall Session 1 includes focusing on evaluating, identifying and articulating the goals of Cognitive Behavioral Therapy, and Sessions 2 to 8 including feedback from the previous session, assignment review, discussion of assignment, goal setting, key issues presentation, information on IBS related problems, Identifying and introducing behaviors that affect the severity of IBS symptoms and related cognitive strategies, training stress management techniques and skills were required. At the end of each session, patients were given a summary of the same session and homework assignments.

#### **Category**

Treatment - Other

### 2

#### **Description**

Emotion-focused intervention group: first session Introducing clients, communicating and communicating the general principles of an emotion-focused approach. Second session: Creating therapeutic alliance,

discovering highlights of the third session: Examining past traumas and identifying attachment type, naming emotionally, identifying emotions Fourth Session: Running an Empty Chair Fifth Session: Relaxation Technique Sixth Session: Reopening Symbols and Emotional Problems Seventh Session: Describing and Talking about Mood, Inconvenience, Anger, Tests, and Ecclesiastes Post-test sessions after three months in the paging phase Ray will repeat the tests

#### **Category**

Treatment - Other

### 3

#### **Description**

Control group: no intervention in this group.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Massoud Internal Gastroenterology and Liver Clinic

##### **Full name of responsible person**

Dr. Reza Irani Rad

##### **Street address**

No. 144 ,Nineteenth Alley , North Kargar Street -

##### **City**

tehran

##### **Province**

Tehran

##### **Postal code**

1439963553

##### **Phone**

+98 21 8833 6300

##### **Email**

contact@masoudclinic.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Dr Alireza Rosta

##### **Street address**

Sanai Boulevard, Free Zone Organization Square, Islamic Azad University, Kish International Branch

##### **City**

Kish Island

##### **Province**

Hormozgan

##### **Postal code**

7941775883

##### **Phone**

+98 76 4442 2720

##### **Fax**

+98 76 4442 3957

**Email**

Info@lakishInt.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**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**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mitra Jahangirrad

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No. 33, East Twentieth Alley, North Kargar Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1437647790

**Phone**

+98 21 8822 3620

**Email**

m.jahangirrad@iaukishint.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Adis Keraskian Mojmenari, Ph.D.

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

NO. 79, Unit 28 St., Shahid Dastgerdi St., Shariati St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1911817639

**Phone**

+98 21 2226 7303

**Email**

Adis.Kraskian@Kiau.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Mitra jahangirrad

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

No33, No20 ( East Abtahi),North amirabad St.

**City**

tehran

**Province**

Tehran

**Postal code**

1437647790

**Phone**

+98 21 8822 3620

**Email**

m.jahangirrad@iaukishint.ac.ir

## 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**

Not applicable

**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