Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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No. 144 ,Nineteenth Alley , North Kargar Street -
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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?

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

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Latest degree

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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

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