Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of emotion regulation skills training on gastrointestinal sensitivity, disease perception, anxiety sensitivity and quality of life in patients with irritable bowel syndrome

Protocol summary

Study aim
Evaluation of the effectiveness of emotion regulation skills training on gastrointestinal sensitivity, disease perception, anxiety sensitivity and quality of life in patients with irritable bowel syndrome

Design
Quasi-experimental intervention with pre-test and post-test with control group. With a sample size of 48 people.The permuted random blocking method is used to do randomization

Settings and conduct
The statistical population is outpatients with irritable bowel syndrome.With the referral of Dr. Elham Mokhtari, an internal medicine specialist and gastroenterologist, they enter the study with the inclusion criteria.They are randomly divided into control and intervention groups.The experimental group is trained in emotion regulation skills.These skills are held according to the Gross protocol and in 8 sessions in Mashhad University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Irritable bowel syndrome with diagnosis of gastroenterologist and diagnostic criterion Romm-III Age 20 to 55 years Have at least 8 literacy classes Having informed consent to enter the research Have at least some insight into the psychological cause of your illness

Intervention groups
Emotion adjustment skills training for the experimental group. The control group did not intervene.

Main outcome variables
Digestive sensitivity, disease perception, anxiety sensitivity, quality of life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210515051300N1**
Registration date: **2021-07-20, 1400/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-20, 1400/04/29**
Update count: **0**

Registration date
2021-07-20, 1400/04/29

Registrant information

Name
Samane Soltanabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3734 4825

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soltanabadis981@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-19, 1400/04/28

Expected recruitment end date
2021-07-23, 1400/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of emotion regulation skills training on

gastrointestinal sensitivity, disease perception, anxiety sensitivity and quality of life in patients with irritable bowel syndrome

Public title
The effectiveness of emotion regulation skills training on gastrointestinal sensitivity, disease perception, anxiety sensitivity and quality of life in patients with irritable bowel syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Irritable bowel syndrome with diagnosis of gastroenterologist and diagnostic criterion Romm-III Age 20 to 55 years Have at least 8 literacy classes Having informed consent to enter the research Have at least some insight into the psychological cause of your illness

Exclusion criteria:
Severe physical condition (such as bleeding and severe pain) Acute psychiatric illness that makes it difficult to participate in treatment (such as psychotic disorders, bipolar disorder, major depression, suicide attempt) Absence for more than two sessions.

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
The permuted random blocking method is used to do randomization. In this method, 12 blocks of 4 will be randomly selected from a combination of letters A and B. These blocks are as follows AABB, ABBA, BBAA, BAAB, ABAB, and BABA. Allocating the letters A and B to the intervention and control groups will be done randomly before randomization and the data analyst will be unaware of the intervention and control groups. The researcher, having a list of people (a list of 48 people who are going to participate in the project), assigns a numeric code to each person. It then offers the anonymous list of members (containing only the numeric code) to the sample assignor to the groups. First, the sample assignor organizes the selected blocks as described, writes them on separate sheets of paper (12 separate sheets), and places them in sealed envelopes. Then s/he randomly selects the envelopes and, based on the previously selected codes, A and B, determines the numerical code number of the individuals assigned to A and B interventions and provides it to the researcher. For instance, if the BABA block is selected first, the first person on the list will be assigned to group B, the second person to group A, the third person to group B, and the fourth person to group A. Likewise, participants 5 to 48 will be assigned to groups A and B.

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 Mashhad University of Medical Sciences

Street address
Khaghani 19, No. 192

City
Mashhad

Province
Razavi Khorasan

Postal code
66373_91949

Approval date
2021-04-13, 1400/01/24

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.125

Health conditions studied

1

Description of health condition studied
Gastrointestinal sensitivity, disease perception, anxiety sensitivity and quality of life in patients with irritable bowel syndrome

ICD-10 code
K58.9, k58

ICD-10 code description
Irritable bowel syndrome with diarrhoea, Irritable bowelsyndrome without diarrhoea

Primary outcomes

1

Description
Gastrointestinal allergies

Timepoint
Beginning and end of the study

Method of measurement
Labas Digestive Sensitivity Questionnaire et al.

2

Description

Perception of disease

Timepoint

Beginning and end of the study

Method of measurement

Disease Perception Broadbent et al

3

Description

Anxiety sensitivity

Timepoint

Beginning and end of the study

Method of measurement

Taylor and Cox Anxiety Sensitivity Questionnaire

4

Description

Quality of Life

Timepoint

Beginning and end of the study

Method of measurement

Patrick and Dorsman Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

8 sessions of emotion regulation skills training are held twice a week for 90 minutesThese meetings are based on the Gross protocol.The content of the sessions includes familiarity with the concept of emotion and types of emotions,Talk about emotion performance and its benefits, introduce the Gross emotion regulation model and learning how to regulate emotion based on this protocol.

Category

Other

2

Description

Control group: They do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of a gastroenterologist

Full name of responsible person

Elham Mokhtari

Street address

19 خاقانی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Taqfadi

Street address

Khorasan Razavi, Mashhad

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Mashhad

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9138813944

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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

.

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

Mashhad University of Medical Sciences

Full name of responsible person

Samane Soltanabadi

Position

Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology
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Person responsible for scientific inquiries

Contact
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Mashhad University of Medical Sciences
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Position
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
.
When the data will become available and for how long
.
To whom data/document is available
.
Under which criteria data/document could be used
.
From where data/document is obtainable
.
What processes are involved for a request to access data/document
.
Comments