

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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)

Phone

+98 51 3734 4825

Email address

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 minutes. These 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
خافانی 19
City

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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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Postal code
9138813944
Phone
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Email
tafaghodim@gmail.com
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 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