Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The impact of short-term psychological training on the ability of mindfulness, anxiety sensitivity, and symptoms of irritable bowel syndrome

Protocol summary

Study aim
Determining the short-term psychological training on the ability of mindfulness, anxiety sensitivity, and symptoms of irritable bowel syndrome

Design
A randomized single-blinding clinical trial, with the parallel groups, Phase 2-3 on 30 patients

Settings and conduct
In this study, 30 patients with irritable bowel syndrome referred to Poursina Center in Isfahan will be included in the study and will be randomly divided into two groups. All patients will receive routine treatment. There is no other intervention in the first intervention group, but in the second intervention group, patients will receive psychological training for 5 sessions. Then their symptoms are evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being literate, lack of active psychiatric diseases, diagnosis of irritable bowel syndrome with the diagnosis of a gastroenterologist, and based on Roman-2 criteria. Exclusion criteria: No willingness to participate in the study, having severe psychiatric diseases, substance or alcohol use during the past year, receiving psychological treatment during the past three months, taking psychiatric medications, and any medication effects on irritable bowel syndrome.

Intervention groups
Patients in the control group will receive only routine treatments. Patients in the intervention group, in addition to the usual treatments, undergo five sessions of face-to-face group psychological training. Also, muscle relaxation training will be performed according to the shortened protocol, and at the end of the sessions, the voice of the therapist and in accordance with the sessions, a CD will be provided to the participants and will be followed in cyberspace for 3 weeks.

Main outcome variables
Gastrointestinal allergies, gastrointestinal symptoms, mindfulness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180909040974N4**
Registration date: **2021-02-02, 1399/11/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-02, 1399/11/14**
Update count: **0**

Registration date
2021-02-02, 1399/11/14

Registrant information

Name
Fatemeh Zargar
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of short-term psychological training on the ability of mindfulness, anxiety sensitivity, and symptoms of irritable bowel syndrome

Public title

The impact of short-term psychological training on symptoms of irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy for reading and writing Lack of active psychiatric diseases Diagnosis of irritable bowel syndrome according to Roman-2 criteria, with the diagnosis of a gastroenterologist

Exclusion criteria:

Unwillingness to participate in the study Having severe psychiatric diseases Consumption of drugs or alcohol over the past year Receive psychological therapies during the last three months Use of psychiatric drugs and any drugs effective in irritable bowel syndrome

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

30 eligible patients will be simple randomly selected. Then, using computer software called "Random Allocation" random numbers are generated and automatically divided into two parts. The generated random numbers are assigned to the patients in the study. Then, as numbers assigned to patients using the software, it is determined that which patient belongs to a specific group. In this way, patients are divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Considering that in this study, in addition to the usual treatments, training sessions are held for one group and the other group receives only the usual treatments. Therefore, the researcher and the patient are aware of the type of intervention. However, the data analyzer and the data collector will not be aware of the type of study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University Of Medical Sciences;Hezarjarib Blvd

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2020-10-12, 1399/07/21

Ethics committee reference number

IR.MUI.MED.REC.1399.575

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

Mindfulness score

Timepoint

Before the intervention, 4 and 10 weeks after the intervention

Method of measurement

Freiburg Mindfulness Inventory-Short Form (FMI-SF)

2

Description

Digestive sensitivity score

Timepoint

Before the intervention, 4 and 10 weeks after the intervention

Method of measurement

Visceral Sensitivity Index (VSI)

3

Description
Gastrointestinal symptoms score
Timepoint
Before the intervention, 4 and 10 weeks after the intervention
Method of measurement
Gastrointestinal Syndrome Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Patients in the this group will receive only routine treatments.
Category
Treatment - Other

2

Description
Second intervention group: Patients in the intervention group, in addition to the usual treatments, undergo five sessions of face-to-face group psychological training. Also, muscle relaxation training will be performed according to the shortened protocol, and at the end of the sessions, the voice of the therapist and in accordance with the sessions, a CD will be provided to the participants and will be followed in cyberspace for 3 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Center of Isfahan
Full name of responsible person
Fatemeh Zargar
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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?
No
Title of funding source
Isfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Zargar
Position
Associate Professor
Latest degree
Specialist
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Person responsible for updating data

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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available