

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2475

Email address

f.zargar@med.mui.ac.ir

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

Isfahan

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

Tamadon Bridge, Aghababaei Highway

City

Isfahan

Province

Isfahan

Postal code

8139946666

Phone

+98 31 3554 8158

Email

f.zargar@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

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

Other areas of specialty/work

Psychology

Street address

Department of Psychiatry, Khorshid Hospital

City

Isfahan

Province

Isfahan

Postal code

8199888945

Phone
+98 31 3222 2127
Email
f.zargar@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Zargar
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Psychology
Street address
Department of Psychiatry, Khorshid Hospital
City
Isfahan
Province
Isfahan
Postal code
8199888945
Phone
+98 31 3222 2127
Email
f.zargar@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person

Niloofer Nik Goftar
Position
Non-faculty general physician
Latest degree
Medical doctor
Other areas of specialty/work
Psychology
Street address
Department of Psychiatry, Khorshid Hospital
City
Isfahan
Province
Isfahan
Postal code
8199888945
Phone
+98 31 3222 2127
Email
nikgoftar@yahoo.com

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