

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of emotional awareness on symptoms of patients with irritable bowel syndrome

Protocol summary

Summary

The present study is based on the body of evidence which suggests awareness of internal emotions as important factors to relief from psychosomatic disorders which cannot be achieved without continuous attention toward internal emotions and challenge with their interpretation. The current study aims to actuate patients with irritable bowel syndrome to their emotions and decreasing somatization of the problem by effective expression of them. Sixty patients with irritable bowel syndrome will be enrolled from the clinic of Tabriz University of Medical Sciences. All patients will receive the proposed medical treatment by the gastroenterologist. A psychiatrist will explain the concept of arousal and the eight main emotions to the patients in the intervention group. These patients will analyze their arousal level and emotions once daily and record it in a chart. Both groups will be revisited one week and one month later by the gastroenterologist blinded to the intervention for assessment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810152999N1**

Registration date: **2010-05-15, 1389/02/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-05-15, 1389/02/25

Registrant information

Name

Alireza Farnam

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Liver and gastrointestinal diseases research center, Tabriz univeristy of medical sciences

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2010-06-21, 1389/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of emotional awareness on symptoms of patients with irritable bowel syndrome

Public title

Effect of emotional awareness on symptoms of patients with irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Educational level of high school diploma or higher. Exclusion criteria: Major psychiatric disorder, Substance dependence, suicidal ideations, history of psychosis, Pregnancy, Using OCP medications

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tabariz Univeristy of medical sciences

Street address

Univeristy Ave

City

Tabriz

Postal code

Approval date

2008-12-16, 1387/09/26

Ethics committee reference number

5/4/8073

Health conditions studied

1

Description of health condition studied

Irritbale bowel syndrome

ICD-10 code

K-58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Severity of pain

Timepoint

1 month

Method of measurement

Visual analouge scale

2

Description

Frequency of pain

Timepoint

one month

Method of measurement

interview

Secondary outcomes

1

Description

Quality of life

Timepoint

1 month

Method of measurement

questionnaire

Intervention groups

1

Description

The intervention group will be educated about the concept of the 8 basic emotions during a 0.5-hour session using examples and figures, as well as receiving the indicated medications. The participants will estimate the mixture of their emotions regarding their feelings and will sign them on the designated table during the study period every day on at given time. They may referre to solve any problem about the process as well.

Category

Other

2

Description

The control group will only receive indicated medications.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Univeristy Clinic, Tabriz univeristy of medical sciences

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Liver and gastrointestinal diseases research center

Full name of responsible person

Dr M H Somi

Street address

Imam Reza hospital, Golbad Ave;

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Liver and gastrointestinal diseases research center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Tabriz university of medical sciences

Full name of responsible person

Miss Mahdavi

Position

Master of psychology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Dr Sara Farhang

Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty