Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Laughter Yoga and anti-anxiety medication on anxiety and gastrointestinal symptoms of patients with irritable bowel syndrome

Protocol summary

Study aim

The aim of the study is to determine the comparison of laughter yoga and anti anxiety medication on anxiety and gastrointestinal symptoms of patients with irritable bowel syndrome

Design

In this research, 60 eligible patients with irritable bowel syndrome referring to gastrointestinal clinic were chosen purposefully and were randomly divided into three groups of interventions with laughter yoga, anti anxiety medication and symptomatic treatmentby closed packets.

Settings and conduct

This study which will be conducted in gastrointestinal clinic of valiasr hospital birjand. patients will be divided into three groups randomly with 20 members and in the end of interventions, efficacy will be evaluated with IBS severity scoring system and beck anxiety inventory.

Participants/Inclusion and exclusion criteria

Patients aged between 18 and 50 years old؛ patients who accepted to participate in the study after explaining the purposes of the study and advantages and disadvantages of the interventions؛ Patients who do not have any other anatomical or functional gastrointestinal disorders.

Intervention groups

60 eligible patients with irritable bowel syndrome were randomly divided into three groups of interventions with laughter yoga, anti anxiety medication and symptomatic treatment by closed packets.

Main outcome variables

Irritable Bowel Syndrome severity؛ Anxiety severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170829035966N1**

Registration date: **2018-01-17, 1396/10/27**

Registration timing: **prospective**

Last update: **2018-01-17, 1396/10/27**

Update count: **0**

Registration date

2018-01-17, 1396/10/27

Registrant information

Name

Navid Davoody

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Birjand University of Medical Sciences

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-04-20, 1397/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Laughter Yoga and anti-anxiety medication on anxiety and gastrointestinal symptoms of patients with irritable bowel syndrome

Public title
Efficacy of Laughter Yoga and anti-anxiety drugs on irritable bowel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged between 18 and 50 years old Patients who accepted to participate in the study after explaining the purposes of the study and advantages and disadvantages of the interventions There should be the possibility to keep the type and dose of the medications fixed during the study Patients who do not have psychotic or personality disorders Patients who do not have alarm signs including gastrointestinal bleeding, blood in stool, fever, weight loss, anemia, diarrhea at night, severe abdominal pain and so on
Exclusion criteria:
Patients who receive psychological treatments before entering the study Patients who have any other anatomical or functional gastrointestinal disorders
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomizashin by sealed envelope
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 Birjand University of Medical Sciences
Street address
Faculty of medicine, Birjand University of Medical Sciences, Ghaffari street, Birjand
City
Birjand
Province
South Khorasan
Postal code
9187874151
Approval date
2017-06-21, 1396/03/31
Ethics committee reference number
Ir.bums.REC.1396.82

Health conditions studied

1

Description of health condition studied
Irritable Bowel Syndrome
ICD-10 code
K58.9, K58
ICD-10 code description
Irritable bowel syndrome without diarrhoea ,Irritable bowel syndrome with diarrhoea

Primary outcomes

1

Description
Irritable Bowel Syndrome severity
Timepoint
Before and right after the end of intervention
Method of measurement
Irritable Bowel Syndrome severity score system designed by Francis CY in 1997: mild (8 to 18) - moderate (18 to 30) - severe (more than 30)

Secondary outcomes

1

Description
Anxiety severity
Timepoint
Before and right after the end of intervention
Method of measurement
Anxiety score from beck anxiety inventory

Intervention groups

1

Description
Intervention in the first intervention group:Laughter Yoga:Laughter Yoga combines unconditional laugh with yoga breathing and yoga stretching exercises, and people laughing without any jokes. Meetings will be held once a week. there are seven Meetings of stress management therapy by Laughter Yoga, each meetings duration are one hour, a first meeting is justification of Laughter Yoga for participants, and the next five meetings are training and practice of laughing techniques, and the last meeting is practice and repetition of training of the previous one will be. Severity scorring system of irritable bowel syndrome designed by

Francis CY in 1997. Mild (score 8 to 18), moderate (score 18 to 30) and severe (above 30)

Category

Behavior

2

Description

Intervention in the second intervention group: Anti-anxiety treatment: Sertraline, 50 mg orally once a day for seven weeks

Category

Treatment - Drugs

3

Description

Control group: Symptomatic treatment with loperamide and hyoscine Loperamide: 2 mg orally three to four times a day for seven weeks Hyoscine: 20 mg orally four times a day for seven weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinic, Vali-e-Asr hospital, birjand

Full name of responsible person

Dr Tavakoli Tahmine assistant professor and gastroenterologist

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Birjand University of Medical Sciences

Full name of responsible person

Vice Chancellor for research of Birjand University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Birjand 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

Faculty of medicine, Birjand University of Medical Sciences, Birjand, South Khorasan, Iran.

Full name of responsible person

Dr Davoody Navid

Position

Internist

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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