Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of neurofeedback on the severity of gastrointestinal symptoms, depression, anxiety, stress and quality of life in patients with irritable bowel syndrome (IBS)

Protocol summary

Study aim

Determining the effectiveness of neurofeedback on the severity of gastrointestinal symptoms, Depression, Anxiety, Stress and Quality of life in patients with irritable bowel syndrome.

Design

Clinical trial with double-blind, randomized, and parallel group design of 45 patients, random allocation rule type is used by lottery balls.

Settings and conduct

Clinical trial is performed in the Clinic of Gastrointestinal Functional Disorders with randomized double blind parallel groups. patients are not aware of the treatment of other group, Therapists are unaware of other groups treatment and assessment, and evaluators are unaware group types . patients are assessed by assessors for quality of life , IBS symptom severity, anxiety and depression. At the end of the course, all groups will be assessed .

Participants/Inclusion and exclusion criteria

Inclusion criteria :Having diagnostic full criteria of IBS based on Rome III criteria, age between 18 to 45 years. Non-inclusion criteria: dissatisfaction to participate , having bloody stools, family history of colon cancer, Unstable weight loss, anemia and eosinophilia, rectosigmoid, abnormal scoping, and concomitant psychiatric and neurological diseases

Intervention groups

For the intervention group, neurofeedback method from the unipolar protocol of anxiety on the PZ point and for depression at point F3 will be done .for placebo group, the Active Electrodes are placed in the middle of the skull at point CZ and the Grand Electrode is attached to the softness of the patient's ear. The control group receives only routine gastrointestinal drug treatment.

Main outcome variables

Reduce the severity of gastrointestinal symptoms, reduce depression, anxiety, stress and increase quality of life In patients with irritable bowel syndrome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191215045743N1**
Registration date: **2020-12-23, 1399/10/03**
Registration timing: **retrospective**

Last update: **2020-12-23, 1399/10/03**
Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2020-11-15, 1399/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of neurofeedback on the severity of gastrointestinal symptoms, depression, anxiety, stress and quality of life in patients with irritable bowel syndrome (IBS)

Public title

Evaluation of the effectiveness of neurofeedback on irritable bowel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having diagnostic criteria for IBS based on Rome III criteria , all three types of IBS included: C, D and M kind age between 18 and 45 years education: at least second level at middle school degree

Exclusion criteria:

patients who refused to participate in study positive Family history of colon cancer WBC, parasites and blood in the stool History of thyroid disorders and abnormal thyroid test, Patients with unstable weight loss, anemia and eosinophilia, rectosigmoid and abnormal scoping Having diagnostic Criteria of Severe psychiatric and neurological disorders based on psychiatrist diagnosis. Having bloody stools

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants include 45 people who are randomly assigned to three groups. Our method of randomization will be Random allocation rule that is a simple way of randomization. The randomization unit is the patient who is assigned to one of the groups A, B and C by the law of random allocation. In this way, the code of each person is recorded inside a lottery ball and is randomly removed from the container without any replacement and the created sequence is created. In this process, the person who assigns patients to the groups is not aware of the type of treatment groups. and does not know what intervention the next group is related to.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, those who randomly assign participants to treatment groups do not know the nature of the groups. Therapists are also unaware of the type of treatment of other groups. Evaluators are also unaware of the type of groups.

Placebo

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

Hezarjirib,Isfahan University of Medical Sciences

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ISFAHAN

Province

Isfehan

Postal code

7346181746

Approval date

2020-11-04, 1399/08/14

Ethics committee reference number

IR.MUI.REC.1396.2.129

Health conditions studied

1

Description of health condition studied

Irritable Bowel Syndrom

ICD-10 code

K58

ICD-10 code description

Irritable bowel syndrome

Primary outcomes

1

Description

Severity of gastrointestinal symptoms of irritable bowel syndrome based on IBS Symptom Severity Questionnaire,Symptoms of depression, anxiety and stress based on the score in DASS-42,Quality of life based on score in IBS-QOL-34 questionnaire

Timepoint

Before the intervention, the severity of gastrointestinal symptoms, depression, anxiety, stress and quality of life are measured. The list of alpha and beta waves is saved after each session. At the end of the sessions, the rate of gastrointestinal symptoms, psychological symptoms and

quality of life are measured.

Method of measurement

IBS-SSS Intensity of Gastrointestinal Symptoms Questionnaire, DASS-42 Questionnaire - Quality of Life Assessment QOL-34. Record brain waves of alpha and beta waves.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Neurofeedback:For the intervention group, the neurofeedback method is performed from the unipolar protocol of anxiety at point PZ and for the treatment of depression at point F3. Treatment plan include 20 sessions which is done three times a week.

Category

Treatment - Other

2

Description

Intervention group: Placebo (quasi-neurofeedback): for the placebo control group where the Active Electrodes are placed in the middle of the skull at point CZ and the Grand Electrode is attached to the softness of the patient's ear.similar to intervention group, placebo Treatment plan include 20 sessions which is done three times a week.

Category

Placebo

3

Description

Control group: Routine gastrointestinal medications:This group receives only routine gastrointestinal medication according to the opinion of the gastroenterologist. Simultaneous evaluation is performed before and after the intervention of the intervention groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychosomatic Research Center

Full name of responsible person

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Sponsors / Funding sources

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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

Esfahan 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

Amrollah Ebrahimi

Position

Associate professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Findings and data including the severity of gastrointestinal symptoms, anxiety, depression, stress and quality of life before and after the intervention can be shared.
When the data will become available and for how long
Access starts 4 months after the article is published
To whom data/document is available
Data and documentation are available to academic researchers and medical staff.
Under which criteria data/document could be used
Citing the source and preserving the rights of the researchers in this study
From where data/document is obtainable
Refer to the Vice Chancellor for Research, Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
The applicant can write a letter to the Vice Chancellor for Research of Isfahan University of Medical Sciences and request to receive the file. With the coordination of the executors, the files will be provided to the applicant
Comments