Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparative study of the impact of educational programs, self-hypnosis, and web-based bioenergy economics on the severity of symptoms, awareness, quality of life anxiety and depression in patients with irritable bowel syndrome

Protocol summary

Study aim

This study purpose is to investigate the effectiveness of web-based training programs, self-hypnosis and bioenergy economy on awareness, quality of life, anxiety and depression and severity of symptoms in IBS patients

Design

The randomized clinical trial, with two factorial groups, blinded outcome assessment, phase 3 on 120 patients, that were randomized by the Random Allocation Software

Settings and conduct

In this trial, 120 eligible patients were selected among referring cases to the gastroenterology and psychiatry clinics of Isfahan Al-Zahra hospital and will be randomly divided into 3 groups. All patients are assessed before and after training by standard relative questionnaires. The researcher assessing the outcomes will not be aware of randomization.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diagnosis of moderate to severe IBS based on ROME III criteria and exclusion of potential organic causes by gastroenterology specialists Basic literacy skills Ability to work with and access software applications. Exclusion Criteria: Depression disorders, bipolar disorders, or psychotic disorders based on DSM-V diagnostic criteria Suicidal ideation or plans Antidepressant or antianxiety medications Participation in psychotherapeutic programs Pregnancy or breastfeeding History of bowel surgery Substance abuse

Intervention groups

All participants undergo a 6-week training on various aspects of Irritable Bowel Syndrome (IBS). The first group, designated as the control group, receives only basic training. The second group, in addition to basic training, simultaneously undergoes Gut-Directed Hypnotherapy, through audio files and educational brochures. The third group, apart from basic training, also receives weekly training on bioenergy economics for IBS, using audio files and brochures.

Main outcome variables

Symptom severity, depression, anxiety, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190404043159N6**
Registration date: **2024-01-08, 1402/10/18**
Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**
Update count: **0**

Registration date

2024-01-08, 1402/10/18

Registrant information

Name

Mohammad Reza Sharbafchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date
2024-05-20, 1403/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the impact of educational programs, self-hypnosis, and web-based bioenergy economics on the severity of symptoms, awareness, quality of life anxiety and depression in patients with irritable bowel syndrome

Public title
Impact of educational programs, self-hypnosis, and web-based bioenergy economics on patients with irritable bowel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Both male and female participants aged 18 to 65 years Diagnosis of moderate to severe IBS based on ROME III criteria and exclusion of potential organic causes by gastroenterology specialists Basic literacy skills (reading and writing) Ability to work with and access software applications Satisfaction to participate in the study
Exclusion criteria:
Diagnosis of any organic disease during the study period that renders continued participation impossible Diagnosis of depression disorders, bipolar disorders, or psychotic disorders based on DSM-V diagnostic criterias assessed by a psychiatrist and psychiatric assistant Serious suicidal thoughts or plans at the time of study entry Use of antidepressant or antianxiety medications within 2 weeks prior to study entry Participation in psychotherapeutic programs within 2 months prior to study entry Pregnant or breastfeeding History of bowel surgery Substance abuse since the onset of symptoms
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study randomization performs based on the blocked randomization method. Information such as the number of study groups (3 main groups: 2 intervention groups (for example A,B) and a control group (for example (C), block size (a multiple of the number of groups that will be chosen in this study to reduce the complexity of the work, size 4) and the total number of patients (sample size 120 people), were enter into the online software machines specific for this calculation (for example available at https://www.sealedenvelope.com/simple-randomiser/v1/lists) and according to the codes that it is obtained by the final analysis (for example (group B 1, 4, 1), each of the patients being studied is given a specific code respectively. Blocking is usually used in order to create a balance in the number of samples assigned to each of the studied groups. In this method, equal blocking will be used. In this way, the samples are randomized in two groups as much as possible.
Blinding (investigator's opinion)
Double blinded
Blinding description
One researcher performs randomization of individuals into three groups and then sets up the receipt of web-based programs. The second researcher, who is unaware of the group assignments, evaluates patients using the questionnaires.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan university of Medical sciences
Street address
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan
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Postal code
۸۱۳۷۸۶۶۵۱۵
Approval date
2023-07-15, 1402/04/24
Ethics committee reference number
IR.MUI.MED.REC.1402.149

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
Severity of Irritable Bowel Syndrome symptoms
Timepoint
Before and after 6 weeks training
Method of measurement
The irritable bowel severity scoring system (IBSSS)

2

Description
Depression
Timepoint
Before and after 6 weeks training
Method of measurement
Hospital Anxiety and Depression Scale (HADS)

3

Description
Anxiety
Timepoint
Before and after 6 weeks training
Method of measurement
Hospital Anxiety and Depression Scale (HADS)

4

Description
Quality of life
Timepoint
Before and after 6 weeks training
Method of measurement
Irritable Bowel Syndrome Quality of Life (IBS-QOL-34)

5

Description
Awareness level
Timepoint
Before and after 6 weeks training
Method of measurement
Which number from 0 to 100 rates your awareness level of your disease?

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: in addition to basic training, simultaneously undergoes Gut-Directed Hypnotherapy training, through audio files. These audio files include self-hypnosis training, which are recorded by the hypnotherapist and patients practice them at home between weekly sessions. According to the standard, the hypnotherapy process includes the following stages: induction, relaxation, deepening, therapeutic suggestions focused on the GI system, ego strengthening and emergence.
Category
Treatment - Other

2

Description
Second intervention group: apart from basic training, also receives weekly training on bio-energy economics for IBS, using audio files and brochures.These part include mental and behavioral, and motor techniques that reduce psychosomatic symptoms by regulating body movements and ergonomics and proportional distribution of biological energy. The 6-week IBS program is the abbreviated form of this program, which includes four sections relating to the body, thoughts, others, and existence.
Category
Treatment - Other

3

Description
Control group: undergo a 6-weeks basic training on various aspects of Irritable Bowel Syndrome (IBS) such as disease definition, signs and symptoms, diagnosis, lab tests, medical and non medical treatments, and prognosis.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospial
Full name of responsible person
Mohammad Reza Sharbafchi
Street address
Department of Psychiatry, Al-Zahra Hospital, Hezar Jarib Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?
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
Mohammad Reza Sharbafchi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

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Other areas of specialty/work
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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
Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data

Comments