Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of lifestyle modification treatment and dietary change on the quality of life, severity of gastrointestinal symptom and the level of anxiety, and depression in patients with irritable bowel syndrome

Protocol summary

Study aim

Determining the effect of therapeutic intervention of lifestyle modification and dietary change on the quality of life and anxiety and depression in patients with irritable bowel syndrome

Design

A clinical trial, before and after comparison, without a control group, an intervention group with a sample size of 55 patients by available sampling method, phase 2, unblinded. Randomization does not apply at this study

Settings and conduct

Before and after study in the field of psychiatry and gastroenterology. 55 patients with irritable bowel syndrome, male and female, aged 15 to 65 years in the gastrointestinal clinic of Taleghani Hospital in Tehran, with available sampling and obtaining consent. First, patients completed the Beck Anxiety and Depression Standard Questionnaire, the Irritable Bowel Syndrome Symptoms Severity Questionnaire, and the Quality of Life Questionnaire. After training by a nutritionist and psychologist and performing two months of lifestyle and diet modification intervention, the above questionnaires were completed again.Blindness does not apply at this study

Participants/Inclusion and exclusion criteria

Patients with IBS who consent to participate in the scheme. Patients who do not follow the therapeutic intervention or are treated for psychiatric disorders will be excluded from the study.

Intervention groups

IBS patients After an initial evaluation with standard questionnaires for quality of life, anxiety, depression, and IBS symptoms severity, Lifestyle modification intervention was performed. (Interventions include adequate physical activity training as 150 minutes per week, medium speed walking, no smoking and alcohol, and low FODMAP diet). After the intervention period of 2 months, patients were re-evaluated with the above questionnaires.

Main outcome variables

Severity of gastrointestinal symptoms, quality of life, anxiety and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220329054367N1**
Registration date: **2022-04-25, 1401/02/05**
Registration timing: **retrospective**

Last update: **2022-04-25, 1401/02/05**
Update count: **0**

Registration date

2022-04-25, 1401/02/05

Registrant information

Name

Seyed Shahab Banihashem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2540

Email address

shb_banihashem@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date
2018-06-05, 1397/03/15
Actual recruitment end date
2020-09-22, 1399/07/01
Trial completion date
2020-11-21, 1399/09/01

Scientific title
The effect of lifestyle modification treatment and dietary change on the quality of life, severity of gastrointestinal symptom and the level of anxiety, and depression in patients with irritable bowel syndrome

Public title
The effect of lifestyle and diet modification on psychological symptoms in patients with irritable bowel syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Has IBS diagnosis based on ROM IV criteria Satisfaction with participation in the project
Exclusion criteria:
Patients receiving therapy due to underlying psychiatric problem
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **55**
Actual sample size reached: **55**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Velenjak
City
Tehran
Province
Tehran
Postal code
1985711151
Approval date
2018-03-21, 1397/01/01
Ethics committee reference number
IR.sbmu.msp.rec.1397.333

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome (IBS)
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Severity of gastrointestinal symptoms in irritable bowel severity scoring system-questionnaire (primary outcome)
Timepoint
Before starting the intervention and 2 months after the intervention
Method of measurement
irritable bowel severity scoring system-questionnaire

2

Description
quality of life score in quality of life -IBS questionnaire (primary outcome)
Timepoint
Before starting the intervention and 2 months after the intervention
Method of measurement
quality of life -IBS questionnaire

3

Description
Depression severity score in Beck Depression Inventory (primary outcome)
Timepoint
Before starting the intervention and 2 months after the intervention
Method of measurement
Beck Depression Inventory questionnaire

4

Description
Anxiety severity score in Beck Anxiety Inventory (primary

outcome)

Timepoint

Before starting the intervention and 2 months after the intervention

Method of measurement

Beck Anxiety Inventory questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lifestyle modification intervention was performed for two months. (Interventions include: adequate physical activity training as 150 minutes per week –medium speed walking-no smoking, and alcohol psychology consultants).

Category

Lifestyle

2

Description

Intervention group: Diet change to LOW FODMAP for two months period. The training was done by a dietician, and written protocol

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Afrooz Ahmadi Ghadikolaee

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Sadeghi

Position

Associate professor

Latest degree

Subspecialist

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inquiries

Contact

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Person responsible for updating data

Contact

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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
In order to maintain the research information, the data will not be published, but only in the form of articles and the result of the analysis
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
No - There is not 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
Not applicable
Data Dictionary
Not applicable