# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Aug 2026

## The effectiveness of lifestyle intervention based on Iranian traditional medicine prespective in patient with functional bloating

## Protocol summary

**Study aim**
Determining the efficacy of lifestyle interventions based on thetraditional Iranian medicine in improving functional bloating

**Design**
Clinical trial with control group, with parallel groups, without blindness, simple randomized, with a sample size of 40 patients.

**Settings and conduct**
The research sample includes 40 patient with functional bloating. They will be randomly divided into intervention and control groups. Teachings of the life style based on Iranian medicine will be conducted during the sessions for the intervention group in the health center of traditional medicine of Fasa University of Medical Sciences. The Control group will not be received any intervention during the study.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients with functional bloating symptoms consistent with ROME III criteria Exclusion criteria: gastrointestinal disorders such as irritable bowel syndrome; severe mental illness; severe uncontrolled systemic diseases such as cardiac, pulmonary, and hepatic impairment; taking aspirin or nonsteroidal anti-inflammatory drugs, corticosteroids, antibiotics, proton pump inhibitor drugs; pregnancy or breastfeeding; severe weight loss, black stool or bitumen color.

**Intervention groups**
The intervention includes modifying the lifestyle of patients with functional bloating and includes eating, drinking, physical activity, sexual activity and sleep patterns based on traditional Iranian medicine. Patients in the control group should not change their lifestyle.

**Main outcome variables**
The score of the functional bloating complications questionaire, the intensity of rectal gas (flatulence), the amount of abdominal distension, the amount of burping (eructation)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20180623040211N1**
Registration date: **2019-05-28, 1398/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-15, 1398/03/25**
Update count: **1**

**Registration date**
2019-05-28, 1398/03/07

**Registrant information**

**Name**
Ahmadreza Sharifi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-01-15, 1397/10/25

**Expected recruitment end date**
2019-07-21, 1398/04/30

**Actual recruitment start date**
2019-01-15, 1397/10/25

**Actual recruitment end date**
2019-06-05, 1398/03/15

**Trial completion date**
2019-08-06, 1398/05/15

**Scientific title**

The effectiveness of lifestyle intervention based on Iranian traditional medicine prespective in patient with functional bloating

**Public title**
The effectiveness of Iranian traditional medicine in functional bloating
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with functional bloating symptoms consistent with ROME III criteria include: 1.Recurrent feeling of bloating or visible distension at least 3 days/month in the last 3 months; 2.Insufficient criteria for a diagnosis of functional dyspepsia, irritable bowel syndrome, or other functional GI disorder. Criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis
**Exclusion criteria:**
Existing gastrointestinal ulcer diagnosis by internal medicine specialist; Acute abdominal pain; Gastrointestinal organ diseases such as inflammatory bowel disease, peptic ulcer or duodenal ulcer and functional constipation are recognized by an internal medicine specialist; Severe mental illness; Severe uncontrolled systemic diseases such as cardiac, pulmonary, and hepatic impairment; Taking aspirin or nonsteroidal anti-inflammatory drugs, corticosteroids, antibiotics, proton pump inhibitor drugs; Pregnancy or breastfeeding; Severe weight loss, black stool or bitumen color;
**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: **40**
Actual sample size reached: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The patients were randomly divided into intervention and control groups using a lottery method. As the names of all participants are placed inside the container. The names are drawn out from the container, respectively, and placed in the intervention and control groups. At the end, the papers containing the names are opened and different groups are determined.
**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**
The Ethics Committee of Baqiyatallah University of Medical Sciences
**Street address**
Baqiyatallah University of Medical Sciences, Shahid Nasrati Alley, South Sheikh Bahayi St, Mulla Sadra St, Vank Square, Tehran.
**City**
Tehran
**Province**
Tehran
**Postal code**
1435916471
**Approval date**
2017-03-13, 1395/12/23
**Ethics committee reference number**
IR.BMSU.REC.1395.329

## Health conditions studied

### 1

**Description of health condition studied**
Functional Bloating
**ICD-10 code**
R14
**ICD-10 code description**
Flatulence and related conditions

## Primary outcomes

### 1

**Description**
The score of the functional bloating complications questionaire
**Timepoint**
At the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Functional bloating complications questionnaire

## Secondary outcomes

### 1

**Description**
The amount of epigastric distension after the usual meal
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**

Visual analogue scale

## 2

**Description**
The amount of distension and bulging in the lower abdomen
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 3

**Description**
The intensity of rectal gas (flatulence)
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 4

**Description**
The amount of burping (eructation)
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 5

**Description**
The intensity of abdominal rumbling
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 6

**Description**
The intensity of early satiety in eating (The inability to finish the usual meal)
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 7

**Description**
The severity of postprandial fullness after a typical meal
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 8

**Description**
The intensity of bloating after bloatable food eating
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 9

**Description**
The intensity of bloating in hunger and without food
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 10

**Description**
The intensity of bloating during menstruation
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 11

**Description**
The intensity of nausea after eating
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## 12

**Description**
The intensity of nausea in hunger and without food
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

### 13

**Description**
The intensity of retching
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

### 14

**Description**
The intensity of epigastric pain
**Timepoint**
To evaluate the severity of the complication at the beginning of the study (before the intervention) and two months after the intervention
**Method of measurement**
Visual analogue scale

## Intervention groups

### 1

**Description**
Intervention group: Functional bloating patients are taught the teachings of the style of life based on Iranian medicine. These fifteen trainings have already been prepared and standardized by a group of traditional medicine specialists and include eating, drinking, sleeping, physical and sexual activity, such as avoiding overeating, avoiding eating several types of foods together, and so on. Standardized recommendations can be provided if required.
**Category**
Lifestyle

### 2

**Description**
Control group: A number of patients with functional bloating are placed in the control group. These patients are requested to make no changes to their lifestyle, eating and drinking habits during the two months of the clinical trial.
**Category**
Lifestyle

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Health Center of Traditional Medicine of Fasa University of Medical Sciences
**Full name of responsible person**
Alireza Moulazade
**Street address**
No. 8, Fayazbakhsh St, Poste darabi square, Fasa town
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Bagheiat-allah University of Medical Sciences
**Full name of responsible person**
Ahmad reza Sharifi Alun-abadi
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Shahid Nosrati alley, Sheikh Bahaee St, Mollasadra St, Vanak square, Tehran
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a-sharifi@shahed.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Bagheiat-allah 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**
Bagheiat-allah University of Medical Sciences
**Full name of responsible person**
Ahmad Reza Sharifi Alun-abadi
**Position**
Assistant Professor
**Latest degree**

Ph.D.

**Other areas of specialty/work**
Traditional Medicine

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## Person responsible for scientific inquiries

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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