

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of Persian medicine's dietary recommendations on improving headaches in patients with both headaches and functional dyspepsia.

#### Protocol summary

##### Study aim

Determining the Effect of Dietary Recommendations in Persian Medicine on the Improvement of Headaches in Patients with Headache and Functional Dyspepsia.

##### Design

This clinical trial uses a parallel-group control design with single-blind methodology, involving 160 eligible patients. After assessing headache severity and functional dyspepsia in the pre-intervention phase, participants are categorized into four quartiles based on similar headache scores. They are then randomly assigned to two groups using a 40-block sequence, each marked with the letters A or B.

##### Settings and conduct

We will use convenience sampling from individuals referred to government hospitals affiliated with Babol University of Medical Sciences who have undergone endoscopy. In the intervention group, we'll provide training in both Iranian traditional medicine and conventional medicine to improve dyspepsia and associated headaches, while the control group will receive training in conventional medicine for the same purpose. Both groups will also receive their standard treatments. This approach creates a form of single-blind study design, as participants won't be aware of each other's training content.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Presence of functional dyspepsia 2. Age between 18 and 60 years 3. Presence of primary headaches Exclusion criteria: 4. Use of medications causing headaches or gastrointestinal damage 5. Presence of gastrointestinal diseases 6. Presence of secondary headaches

##### Intervention groups

1. In the intervention group, dietary and beverage practices will be instructed based on the fundamentals of Persian medicine in conjunction with conventional

medicine. 2. In the control group, dietary and beverage practices will be instructed based on conventional medicine principles.

##### Main outcome variables

Treating Dyspepsia-Related Headaches in Patients with Functional Dyspepsia.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220606055085N1**

Registration date: **2023-09-09, 1402/06/18**

Registration timing: **prospective**

Last update: **2023-09-09, 1402/06/18**

Update count: **0**

##### Registration date

2023-09-09, 1402/06/18

##### Registrant information

##### Name

Morteza Mojahedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 4730

##### Email address

mortazamojahedy@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2024-06-21, 1403/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of Persian medicine's dietary recommendations on improving headaches in patients with both headaches and functional dyspepsia.

**Public title**

The impact of dietary recommendations from Persian medicine on alleviating headaches caused by dyspepsia.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The presence of functional dyspepsia, determined by the use of diagnostic tools and the assessment of a gastroenterologist, including endoscopy. At least 3 months of gastrointestinal symptoms have elapsed. Age should be between 18 and 60 years old. The presence of primary headaches, including tension-type headaches and migraines, based on the ICHD3 criteria, confirmed by a physician. The presence of a minimum of 3 headache attacks per month. The patient should have had headaches for at least 3 months.

**Exclusion criteria:**

The patient should have been using medications regularly or daily, either currently or during the past 3 months, that can lead to gastrointestinal damage, such as aspirin and non-steroidal anti-inflammatory drugs (NSAIDs). The regular and daily use of medications that can potentially trigger headaches, such as nitroglycerin, type 5 phosphodiesterase inhibitors (such as sildenafil), and others. The presence of other gastrointestinal conditions such as gastric ulcers, inflammatory gastrointestinal diseases, or malignant gastrointestinal diseases confirmed through endoscopy. The presence of secondary headaches confirmed by a specialist. (Secondary headaches are one of the symptoms of another underlying primary condition that the patient has, such as malignancies, cerebral aneurysms, hypertension, meningitis, etc.). The presence of progressive or malignant diseases related to the central nervous system. The presence of other chronic conditions such as diabetes, uncontrolled and advanced hypertension, chronic obstructive pulmonary disease (COPD), etc.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals are randomly block-assigned to two groups, intervention and control. After assessing the severity of headaches and functional dyspepsia in the pre-intervention phase and placing them in quartiles based on headache severity, they are then assigned to two groups (A and B) within each quartile using a random sequence of 40 quartet blocks.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Both groups receive separate instructions, and individuals are unaware of the educational content delivered to the other group, creating a form of single-blind study design.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Babol University of Medical Science

**Street address**

Sargord Ghasemi Avenue

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Approval date**

2023-08-06, 1402/05/15

**Ethics committee reference number**

IR.MUBABOL.HRI.REC.1402.062

**Health conditions studied**

1

**Description of health condition studied**

Headache caused by indigestion

**ICD-10 code**

G44.2

**ICD-10 code description**

Tension-type headache

## 2

### **Description of health condition studied**

Headache caused by indigestion

### **ICD-10 code**

G43

### **ICD-10 code description**

Migraine

## **Primary outcomes**

### 1

#### **Description**

Headache Improvement Due to Dyspepsia.

#### **Timepoint**

At the study's outset and then every two weeks until the eighth week.

#### **Method of measurement**

1. Headache Severity Assessment Checklist 2. Visual Analog Scale (VAS)

## **Secondary outcomes**

### 1

#### **Description**

Improve functional dyspepsia

#### **Timepoint**

At the study's initiation, and subsequently every 2 weeks up to the 8th week.

#### **Method of measurement**

Dyspepsia Severity and Frequency Questionnaire.

## **Intervention groups**

### 1

#### **Description**

Intervention Group: This group comprises 80 patients with headache caused by dyspepsia. These individuals undergo a 30-minute in-person training session conducted by a researcher. The educational content in Persian medicine includes dietary and beverage practices drawn from rich Persian medical sources. This material is presented in text and video formats for the participants' convenience. Additionally, individuals in this group continue their standard treatments and also receive conventional medical instructions for reducing dyspepsia. Follow-up assessments involve monitoring the severity of both headaches and dyspepsia.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control Group: This group consists of 80 patients with headache caused by dyspepsia. These individuals receive a 30-minute, in-person training session with a researcher. The educational content for this group includes conventional medical instructions for reducing

dyspepsia. The instructional materials are provided to patients in text and video formats. Participants in this group also continue to receive their standard treatments. Follow-up assessments involve monitoring the severity of both dyspepsia and headaches.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rouhani Hospital

##### **Full name of responsible person**

Morteza mojahedi

##### **Street address**

Sargord Ghasemi Avenue

##### **City**

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##### **Province**

Mazandaran

##### **Postal code**

4717647745

##### **Phone**

+98 11 3223 8284

##### **Email**

mortazamoghedy@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Babol University of Medical Sciences

##### **Full name of responsible person**

Morteza Mojahedi

##### **Street address**

Sargerd Ghasemi St. - Keshavarz Blvd

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##### **Email**

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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**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Morteza Mojahedi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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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**

There is no further information 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