Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

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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