Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of low-FODMAPs (fermentable oligosaccharides, disaccharides, monosaccharides, and polyols) diet on clinical symptoms and quality of life in patients with non-ulcer dyspepsia: a randomized controlled trial

Protocol summary

Study aim

Investigating the Effect of a Low-FODMAP Diet on Clinical Symptoms and quality of life in patients with Non-Ulcer Dyspepsia

Design

This single-blind randomized trial evaluates the effect of a low-FODMAP diet on clinical symptoms and quality of life. The study includes 50 patients with non-ulcer dyspepsia, randomly assigned to either a low-FODMAP or standard diet group. Patients will be followed for 12 weeks. Randomization is performed using the RAND function in Excel.

Settings and conduct

The study will be conducted at the Behbood Gastroenterology and Hepatology Clinic in Tehran. Eligible patients will be enrolled after screening by a gastroenterology specialist and obtaining informed consent. Baseline data will be collected, and patients will be randomly assigned to either the intervention group (low-FODMAP diet) or the control group (standard diet). The intervention group will receive dietary guidance from a nutritionist, while the control group will follow a regular diet. Patients will be monitored every 4 weeks over 12 weeks for symptom severity, quality of life, and diet adherence. The study will be single-blind, with symptom assessors and data analysts unaware of group assignments.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age over 18 years Diagnosis of functional dyspepsia based on Rome IV criteria History of dyspeptic symptoms for at least 6 months Willingness and ability to adhere to a low-FODMAP diet (LFD) Absence of other gastrointestinal diseases No regular use of nonsteroidal anti-inflammatory drugs Not pregnant or breastfeeding Exclusion Criteria Unwillingness to participate in the study Non-adherence to the intervention Diagnosis of a new gastrointestinal disease Regular use of NSAIDs

Intervention groups

Low-FODMAPs diets

Main outcome variables

Clinical symptoms and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N41**
Registration date: **2025-03-24, 1404/01/04**
Registration timing: **prospective**

Last update: **2025-03-24, 1404/01/04**
Update count: **0**

Registration date

2025-03-24, 1404/01/04

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences, National Institute of Nutrition Research

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-05, 1404/01/16

Expected recruitment end date
2025-10-08, 1404/07/16
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of low-FODMAPs (fermentable oligosaccharides, disaccharides, monosaccharides, and polyols) diet on clinical symptoms and quality of life in patients with non-ulcer dyspepsia: a randomized controlled trial

Public title
The Effect of low-FODMAPs (fermentable oligosaccharides, disaccharides, monosaccharides, and polyols) diet on clinical symptoms and quality of life in patients with non-ulcer dyspepsia: a randomized controlled trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Diagnosis of functional dyspepsia based on Rome IV criteria History of dyspeptic symptoms for at least 6 months Willingness and ability to adhere to the Low FODMAP Diet (LFD) No other gastrointestinal diseases, such as Crohn’s disease, ulcerative colitis, or celiac disease No regular use of nonsteroidal anti-inflammatory drugs (NSAIDs) Not pregnant or breastfeeding
Exclusion criteria:
Unwillingness to continue the study Non-adherence to the intervention The occurrence of any serious adverse effects Becoming pregnant Development of any new gastrointestinal disease Regular use of NSAIDs
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
For the random allocation of participants into the intervention and control groups, each individual will be assigned a numerical code, which will then be entered into a table of random numbers. Based on the first randomly selected number from the table, participants will be sequentially assigned to one of the two groups. This process will continue until all participants have been allocated to either group. Randomization will be conducted by an individual independent of the intervention team to ensure impartiality.
Blinding (investigator's opinion)
Single blinded
Blinding description
Collected data will be coded (e.g., Group A and Group B) before being provided to the data analysts. Statistical analyses will be conducted without knowledge of group allocation. This approach prevents potential bias in the interpretation of results.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of National Nutrition and Food Technology Research Institute (NNFTRI)
Street address
#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2025-01-22, 1403/11/03
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1403.075

Health conditions studied

1

Description of health condition studied
non-ulcer dyspepsia
ICD-10 code
K30
ICD-10 code description
Functional dyspepsia

Primary outcomes

1

Description
Clinical symptoms
Timepoint
At the beginning of the study, the first month, and the third month

Method of measurement
GSRS Scale for Functional Dyspepsia

2

Description
Quality of life
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
Short-Form Nepean Dyspepsia Index (SF-NDI)

Secondary outcomes

1

Description
Upper Abdominal Pain
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
GSRS Scale for Functional Dyspepsia

2

Description
Bloating
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
GSRS Scale for Functional Dyspepsia

3

Description
Early Satiety
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
GSRS Scale for Functional Dyspepsia

4

Description
Nausea
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
GSRS Scale for Functional Dyspepsia

5

Description
Belching
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
GSRS Scale for Functional Dyspepsia

6

Description
Has your general emotional well-being been disturbedby your stomach problems in the last 2 weeks?
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
Short-Form Nepean Dyspepsia Index (SF-NDI)

7

Description
Have you been irritable, tense or frustrated in thelast 2 weeks because of your stomach problems?
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
Short-Form Nepean Dyspepsia Index (SF-NDI)

8

Description
Has your ability to engage in things you usually do for fun (recreations, going out, hobbies, sports, etc.) been disturbed by your stomach problems in the last 2 weeks?
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
Short-Form Nepean Dyspepsia Index (SF-NDI)

9

Description
Has your enjoyment of things you usually do for fun (recreations, going out, hobbies, sports, etc.) been disturbed by your stomach problems in the last 2 weeks?
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
Short-Form Nepean Dyspepsia Index (SF-NDI)

10

Description
Has your ability to eat or drink (including when, what, and how much) been disturbed by your stomach problems in the last 2 weeks?
Timepoint
At the beginning of the study, the first month, and the third month
Method of measurement
Short-Form Nepean Dyspepsia Index (SF-NDI)

11

Description

Has your enjoyment of eating and/or drinking been disturbed by your stomach problems in the last 2 weeks? (Please also include your appetite, and howyou feel after food or drink).

Timepoint

At the beginning of the study, the first month, and the third month

Method of measurement

Short-Form Nepean Dyspepsia Index (SF-NDI)

12

Description

Have you wondered whether you will always have these stomach problems, in the last 2 weeks?

Timepoint

At the beginning of the study, the first month, and the third month

Method of measurement

Short-Form Nepean Dyspepsia Index (SF-NDI)

13

Description

Have you thought that your stomach problems might be due to a very serious illness (e.g. cancer or a heart problem), in the last 2 weeks?

Timepoint

At the beginning of the study, the first month, and the third month

Method of measurement

Short-Form Nepean Dyspepsia Index (SF-NDI)

14

Description

Has your ability to work or study been disturbed by your stomach problems in the last 2 weeks?

Timepoint

At the beginning of the study, the first month, and the third month

Method of measurement

Short-Form Nepean Dyspepsia Index (SF-NDI)

15

Description

Has your enjoyment of work or study been disturbed by your stomach problems in the last 2 weeks?

Timepoint

At the beginning of the study, the first month, and the third month

Method of measurement

Short-Form Nepean Dyspepsia Index (SF-NDI)

Intervention groups

1

Description

Control group: The control group will continue their regular weight-maintenance diet without any restrictions on FODMAP intake for 12 weeks. Clinical symptoms and quality of life will be assessed at baseline and after 4 weeks using standardized questionnaires. This diet includes the following guidelines: 1. Eat slowly and regularly. 2. Reduce fat intake. 3. Follow a diet that closely resembles the Mediterranean diet or increase the consumption of fresh foods while reducing ultra-processed foods. 4. Avoid triggers such as spicy foods, carbonated drinks, tea, coffee, alcohol, smoking, and NSAIDs. 5. Consume small, frequent meals.

Category

Other

2

Description

Intervention group: The intervention group will follow a weight-maintenance diet with low fermentable oligosaccharides, disaccharides, monosaccharides, and polyols (Low FODMAP), designed by a registered dietitian. This diet includes restrictions on foods high in FODMAPs, such as legumes, dairy products, certain fruits, and vegetables. In **Phase I (Weeks 0–4)**, patients in both groups will receive comprehensive oral and written dietary instructions from a trained dietitian. These instructions will include detailed recommendations on which foods to avoid or reduce and suitable alternatives. The dietitian will contact patients at the end of weeks 1, 4, and 12 to address any questions or concerns and to collect 3-day food records. Additionally, patients will have unlimited access to the dietitian for further consultation. In **Phase II (Weeks 5–12)**, after four weeks, a 3-day food record and symptom assessment will be collected. Patients will also complete the **Short-Form Nepean Dyspepsia Index (SF-NDI) for quality of life** and the **Gastrointestinal Symptom Rating Scale (GSRS) for functional dyspepsia symptoms, including the functional dyspepsia module**. Patients whose 3-day dietary recall shows a FODMAP intake of less than 20 grams will proceed to Phase II. The intervention group will receive revised instructions for continuing the low FODMAP diet, while the control group will continue following their initial dietary guidelines. At the **end of the study (Week 12)**, a 3-day food record and symptom assessment will again be collected, and patients will complete the **SF-NDI and GSRS (functional dyspepsia and dyspepsia module)**. Dietary compliance and any adverse effects will be recorded.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Behbood Gastroenterology and Hepatology Clinic

Full name of responsible person

Azita Hekmatdoost

Street address

Behbood Gastroenterology and Hepatology Clinic, No. 2, Corner of Alley 14, Beginning of North Mofatteh,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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1981619573

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a_hekmat2000@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Azita Hekmatdoost

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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