

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Study of the effect of group- based education of gluten-free diet on knowledge, quality of life, clinical signs and body mass index in patients with Celiac disease

Protocol summary

Study aim

Determination of the effect of group- based education of gluten-free diet on knowledge, quality of life, clinical signs and body mass index in patients with Celiac disease

Design

The study will be conducted in a controlled clinical trial with parallel and randomized groups and participants will be randomly divided into two groups based on their age and sex.

Settings and conduct

This interventional study will be conducted on 140 patients with Celiac disease aged 18-55 years who are referred to Imam Reza Medical Center. After obtaining written informed consent, if there are necessary inclusion criteria, they will be included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Volunteers with celiac disease diagnosed with biopsy. 2-Age 18-55 years 3-Compliance with gluten-free diet for more than three months 4-Ability to read and write
Exclusion criteria: Types of malignancies Autoimmune diseases such as type 1 diabetes and thyroid disease Intestinal diseases Metabolic bone diseases Liver disease

Intervention groups

Intervention group :In the intervention group, in addition to the usual education provided at the Celiac clinic by a nutritionist aware of the gluten-free diet, people in groups of 10 will also receive 3 group education sessions.
Control group:In the control group, patients with Celiac disease, referring to the Celiac clinic, they will benefit from individual counseling provided by a nutritionist who is aware of the gluten-free diet and gluten-free diet .

Main outcome variables

1-Knowledge 2-Quality of life 3-Clinical signs 4-Body mass index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080904001197N21**

Registration date: **2019-05-23, 1398/03/02**

Registration timing: **prospective**

Last update: **2019-05-23, 1398/03/02**

Update count: **0**

Registration date

2019-05-23, 1398/03/02

Registrant information

Name

Reza Mahdavi

Name of organization / entity

Faculty of Health & Nutrition, Tabriz Univ. of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7584

Email address

mahdavir@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-28, 1398/03/07

Expected recruitment end date

2019-06-28, 1398/04/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of group- based education of gluten-free diet on knowledge, quality of life, clinical signs and body mass index in patients with Celiac disease

Public title

The effect of group- based education of gluten-free diet in patients with Celiac disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Volunteers with Celiac disease diagnosed with biopsy
Volunteers with Celiac disease diagnosed with biopsy
Compliance with gluten-free diet for more than three months
Ability to read and write

Exclusion criteria:

Types of malignancies
Autoimmune diseases such as type 1 diabetes and thyroid disease
Intestinal diseases
Metabolic bone diseases
Liver disease

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be divided into two groups based on age and sex using random blocks.

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614776

Approval date

2019-04-25, 1398/02/05

Ethics committee reference number

IR.TBZMED.REC.1398.075

Health conditions studied

1

Description of health condition studied

Celiac disease

ICD-10 code

K90.0

ICD-10 code description

Celiac disease

Primary outcomes

1

Description

Knowledge of patients with Celiac Disease

Timepoint

Before the intervention After the end of the intervention
Three months after the end of the intervention

Method of measurement

Knowledge questionnaire designed by the researcher

2

Description

Quality of life in patients with Celiac disease

Timepoint

Before the intervention After the end of the intervention
Three months after the end of the intervention

Method of measurement

SF-36 (Short Form Health Survey) questionnaire

3

Description

Clinical signs of patients with Celiac disease

Timepoint

Before the intervention After the end of the intervention
Three months after the end of the intervention

Method of measurement

Gastrointestinal Symptom Rating Scale (GSRS) questionnaire

4

Description

Body mass index of patients with Celiac disease

Timepoint

Before the intervention After the end of the intervention
Three months after the end of the intervention

Method of measurement

Dividing the weight in kilograms by squared height in meters

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to the usual education provided at the Celiac clinic by a nutritionist aware of the gluten-free diet, people in groups of 10 will also receive 3 group education sessions. Educational contents include generalized Celiac disease, gluten-free diet, and checking problems and at the end of each session, there will be a question and answer. Educational topics will include the definition of the disease, the causes of disease, symptoms, diagnosis, treatment, the definition of gluten, gluten-free diet and its importance, nonconformity of gluten-free diet complications, how to read the food label and the choice of gluten-free foods.

Category

Treatment - Other

2

Description

Control group: In the control group, patients with Celiac disease, referring to the Celiac clinic, they will benefit from individual counseling provided by a nutritionist who is aware of the gluten-free diet and gluten-free diet and how to comply with it, nonconformity of gluten-free diet complications and how to read food labels and select gluten-free products will be taught.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Medical Research and Training Hospital

Full name of responsible person

Zahra Akbari Namvar

Street address

Golgasht Ave., Tabriz Town

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3337 6923

Email

info@imamreza.tbzmed.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Akbari Namvar

Street address

Golgasht Ave., Azadi Ave ., Tabriz Town

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 7581

Fax

Email

nut-rc@tbzmed.ac.ir

Web page address

http://tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Akbari Namvar

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Nutrition & Food Sciences Faculty, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 7580

Email

zahranamvar1993@gmail.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Prof. Reza Mahdavi

Position

Ph.D of Nutrition, Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Nutrition Research Center, Nutrition & Food Sciences Faculty, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 7580

Email

mahdavir@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Akbari Namvar

Position

student

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East Azarbaijan

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5166614711

Phone

+98 41 3335 7580

Email

zahranamvar1993@gmail.com

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