

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Study the effect of interactive education on adherence to diet ,quality of life and functional indicators in patients with celiac disease

Protocol summary

Study aim

Determining the effect of interactive education on adherence to diet, quality of life and performance indicators in patients with celiac disease

Design

Controlled clinical trial, community-based and pragmatic, parallel groups, randomized

Settings and conduct

The study will be performed after obtaining research approval from the ethics committee. The eligible participants will be invited to the Celiac center of Buali Hospital. After selecting the subjects of the study, the demographic information of participants, as well as the necessary data about their quality of life, diet adherence, functional index, and body mass index, will be recorded. The intervention will include 4 sessions of classes (90 min each session) for the experimental group. On the other hand, those in the control group will receive the usual care services. Before and after three months, participants will be asked to fill out the quality of life and diet adherence questionnaires. Furthermore, there will be an assessment of their body mass index and functional index.

Participants/Inclusion and exclusion criteria

Inclusion criteria: above 18 years old, no chronic disease (e.g., diabetes), hypothyroidism, hyperthyroidism, no mental disorders, no problem in communication (e.g., blindness or deafness), and non-pregnant women
Exclusion criteria: special and incurable diseases, inability to learn

Intervention groups

Intervention group: This group will receive 4 sessions of interactive education (90 min each session). Control group: This group will have a booklet on Celiac after the intervention.

Main outcome variables

Gluten free diet adherence, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170926036426N4**

Registration date: **2019-04-09, 1398/01/20**

Registration timing: **retrospective**

Last update: **2019-04-09, 1398/01/20**

Update count: **0**

Registration date

2019-04-09, 1398/01/20

Registrant information

Name

fatihe kermansaravi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 1415

Email address

kermansaravi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-09, 1397/06/18

Expected recruitment end date

2019-01-08, 1397/10/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of interactive education on adherence to diet ,quality of life and functional indicators in patients with celiac disease

Public title

The effect of interaction education on patients with celiac disease

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Celiac disease, the diagnosis of celiac disease, is documented by a specialist in the medical records of the patient no chronic disease (e.g., diabetes), hypothyroidism, hyperthyroidism no mental disorders no problem in communication (e.g., blindness or deafness) non-pregnant women above 18 years old

Exclusion criteria:

special and incurable diseases inability to learn

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients referring to the celiac center of Buali hospital will be randomly selected and divided into two groups of experimental and control. In doing so, two cards were assigned as A and B, where A refers to the experimental group and B denotes control group. The subjects of the study will be asked to choose a card, and accordingly participants will be randomly placed in the control and experimental groups.

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 Zahedan University of Medical Sciences

Street address

Campus Office Complex, Zahedan University of Medical Sciences and Health Services,Khalig Phars Blvd,Doctor Hesabi square,Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2018-07-14, 1397/04/23

Ethics committee reference number

IR.ZAUMS.REC.1397.185

Health conditions studied**1****Description of health condition studied**

Celiac

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Compliance with a gluten-free diet

Timepoint

Before the intervention and 4 weeks after providing interactive education

Method of measurement

Dietary compliance questionnaire

2**Description**

Quality of Life

Timepoint

Before the intervention and 4 weeks after providing interactive education

Method of measurement

Quality of life questionnaire for patients with celiac disease

3**Description**

Serum iron

Timepoint

Measurement of serum iron before intervention and four months after intervention

Method of measurement

Perform a test with a fully automatic B.T 3000 machine

4**Description**

Serum vitamin D

Timepoint

Measurement of serum vitamin D before intervention and four months after intervention

Method of measurement

Performing the experiment with FOMO ELITE ARIDER

5

Description

Body mass index

Timepoint

Measurement of height and weight before intervention and four months after intervention

Method of measurement

Height and weight measurements with HBMI PLUS-CR device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Providing interactive education on the diet of patients with celiac disease who provided this training for four sessions of 90 minutes over a period of four weeks in groups of 7 to 9 with active participation of the patient in the formulation of content based on the content of the training, discussion and the exchange of ideas and questions and questions will be provided by the researcher.

Category

Behavior

2

Description

Control group: Receive no training about gluten free diet, they will receive a booklet on the topic of celiac disease after the intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Celiac Counseling Center of Buali Hospital in Zahedan

Full name of responsible person

Rostam Shahraki

Street address

Boali Hospital, Amiralmomenin Street, Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

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Campus Administration Complex, Zahedan University of Medical Sciences and Health Services,,-Persian Gulf Blvd-Dr. Hassabi Square

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Fateme Gharebaghi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Information about individuals without the name and last name

When the data will become available and for how long

Three months after the publication of the results, access to the documentation will be available.

To whom data/document is available

This will be available for researchers working in academic and scientific institutions and industry professionals.

Under which criteria data/document could be used

For use in scientific papers

From where data/document is obtainable

Use the person's email Fatemeh gharebaghy as f.gharebaghi@yahoo.com

What processes are involved for a request to access data/document

Send an e-mail for permission from authors

Comments