

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Nursing Counseling on knowledge and Practice Dietary Compliance in Patients with Celiac Disease

Protocol summary

Study aim

main objective The Effect of Nursing Counseling on Knowledge and Practice in Adherence to the Diet of Patients with Celiac Disease

Design

Clinical trials with control group, with parallel groups, one-on-one blind, randomized

Settings and conduct

The Celiac Community Center of Isfahan In this study, the outcome assessor was kept blind to randomized appropriation, either parallel or single-blind design.

Participants/Inclusion and exclusion criteria

The Desire to Participate in the Study Individuals Diagnosed with Celiac Disease by Gastroenterologist and Confirmed by Biopsy and Blood Positive Serology Test People Who have been Gluten-Free Diet for more than 6 Months People Over 18 Years of Age Disinclination to Continue to Participate in Research

Intervention groups

(Intervention group)) to Nursing Counseling and (Control Group) based on the Celiac Center Routine Care

Main outcome variables

Celiac Disease, Knowledge, Practice, Adherence to Gluten Free Diet, Nursing Counseling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190528043742N1**

Registration date: **2019-07-17, 1398/04/26**

Registration timing: **retrospective**

Last update: **2019-07-17, 1398/04/26**

Update count: **0**

Registration date

2019-07-17, 1398/04/26

Registrant information

Name

Tahere Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3680 1309

Email address

taherekarimi@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-12-13, 1397/09/22

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2018-12-27, 1397/10/06

Trial completion date

2018-12-27, 1397/10/06

Scientific title

The Effect of Nursing Counseling on knowledge and Practice Dietary Compliance in Patients with Celiac Disease

Public title

The Effect of Nursing Counseling on knowledge and Practice Dietary Compliance in Patients with Celiac Disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The Desire to Participate in the Study Individuals Diagnosed with Celiac Disease by Gastroenterologist and Confirmed by Biopsy and Blood Positive Serology Test

People Who have been Gluten-Free Diet for more than 6 Months People Over 18 Years of Age

Exclusion criteria:

Disinclination to Continue to Participate in Research

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **100**

Actual sample size reached: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Throw Coin (Tap and Line) Individual Non-Transparent, Sealed Envelopes Randomize Sequence Hiding

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor was kept blind to randomized appropriation, either parallel or single-blind design.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan Islamic Azad University (Khorasgan)

Street address

Islamic Azad University, Isfahan Branch (Khorasgan), University Blvd, Arghavaniyeh, East Jey St.

City

Esfahan

Province

Isfahan

Postal code

81551-39998

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.153

Health conditions studied

1

Description of health condition studied

Celiac disease

ICD-10 code

K55-K63

ICD-10 code description

A chronic Intestinal discomfort associated with malabsorption due to gluten intolerance.

Primary outcomes

1

Description

Level of knowledge in Dietary Compliance in Patients with Celiac Disease

Timepoint

Before starting the study and 5, 8, 10 weeks after the nursing consultation

Method of measurement

Dietary Compliance about knowledge Questionnaire (Researcher)

2

Description

Level of Practice in Dietary Compliance in Patients with Celiac Disease

Timepoint

Before starting the study and 5, 8, 10 weeks after the nursing consultation

Method of measurement

Dietary Compliance about Practice Questionnaire (Researcher)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 49 patients were interviewed by nursing counseling method in the form of seven, verbally and face-to-face groups in the Celiac Center. Two weeks after the intervention sessions, a supplementary counseling session was organized to assess possible dietary problems. Then one week after the supplementary counseling session, the questionnaires were filled out by knowledge and practice by telephone and in person by him and supervised by a research colleague who did not know the type of study group.

Category

Behavior

2

Description

Control group :(50 patients) were studied based on routine care of the association.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Celiac Community Center and Poursina Hakim Gastrointestinal Diseases Research Center

Full name of responsible person

Tahere Karimi

Street address

Third Floor,Noor Integrated, North Ordibehesht St,Taleghani St.

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Email

info@celiacngo.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

I did not have financial support

Street address

No. 7,Milad 7,Milad Integrated,Azad Street,Baharestan

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Province

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381-893-9117

Phone

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Email

Karimitahere63@gmail.com

Grant name

I did,nt get a budget

Grant code / Reference number

هیچ گرنتی اعطا نشد

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Tahere karimi

Position

Master of Science in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Marzieh Ziaeirad

Position

Associated Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Latest degree
Master
Other areas of specialty/work
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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

Only the Original outcome Can be Shared. The Main Consequence of my Study is Adherence of Gluten-free diet in two Groups of Test and Control, and Only the Difference Outcome is Reported in the two Groups.

When the data will become available and for how long

The article in the journal is available within 1 month.

To whom data/document is available

Only Available Working Scholars in Academic Institutions

Under which criteria data/document could be used

Due to the fact that ownership of the data with the Association, Celiac Special Clinic and Islamic Azad University of Isfahan (Khorasgan) is not possible to transfer data to other research groups.

From where data/document is obtainable

Poursina Hakim Gastrointestinal Diseases Research Center, Poursina Hakim Clinic, Third Floor, Phase I, Health Center, Sepehr Blvd, AghaBabaei Road, Isfahan.

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

Step 1: Visit the site of the Iranian Celiac Association or Poursina Hakim Research Center or by visiting the relevant research expert. Step Two: Contract Collaboration Step 3: Operate the data under the supervision of these centers

Comments