Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

Designing a smart phone application for celiac patients and evaluate the effect of this application on patients knowledge and the rate of adherence to gluten free diet compared with conventional education in clinic

Protocol summary

Study aim
Designing a smart phone application for celiac patients and evaluate the effect of this application on patients knowledge and the rate of adherence to gluten free diet compared with conventional education in clinic

Design
Two arm parallel group randomized trial

Settings and conduct
Target population in the present study is adults with celiac disease in Tabriz. At first an application will be designed and its reliability and validity will be checked using 10 expert panel and also 10 patients. Then the patients will divided two groups; one group will received regular education in clinic plus application, the second group will only receive education in clinic. after 3 months patients knowledge (using questionnaire) and also their adherence to gluten free diet (using CDAT and serum tTG) will be evaluated.

Participants/Inclusion and exclusion criteria
Being as a member of celiac association; biopsy proven celiac patients; aged >18 years old; educated and can use phone application. Exclusion criterion: disease that affect study outcomes.

Intervention groups
Education using application

Main outcome variables
Knowledge; adherence rate to diet

General information

Reason for update
considering the assessment of gastrointestinal symptoms as a secondary outcome, the "secondary outcome section" is updated.

Acronym

IRCT registration information
IRCT registration number: **IRCT20170117032004N2**
Registration date: **2019-06-29, 1398/04/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-21, 1399/04/01**
Update count: **1**

Registration date
2019-06-29, 1398/04/08

Registrant information

Name
Zeinab Nikniaz

Name of organization / entity
Liver and gastrointestinal disease research center, Tabriz University of medical sciences-Tabriz_Ir

Country
Iran (Islamic Republic of)

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+98 41 3336 7473

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Designing a smart phone application for celiac patients and evaluate the effect of this application on patients knowledge and the rate of adherence to gluten free diet compared with conventional education in clinic

Public title
Smart phone application for celiac patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being as a member of celiac association, , Biopsy proven celiac patients Aged>18 years old Educated and can use phone application
Exclusion criteria:
Disease that affect study outcomes
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using randomization softwares
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Approval date
2018-12-03, 1397/09/12
Ethics committee reference number
IR.TBZMED.REC.1397.697

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
Timepoint
At first and 3 months after intervention
Method of measurement
Questionnaire

2

Description
adherance to diet
Timepoint
At first and 3 months after intervention
Method of measurement
CDAT questionnaire and serum tTg

Secondary outcomes

1

Description
gastrointestinal symptoms
Timepoint
Before intervention and 3 months post intervention
Method of measurement
using GSRS questionnaire

Intervention groups

1

Description
Intervention group: Education with smart phone application
Category
Other

2

Description
Control group: usual education in clinic
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital, Tabriz University of medical sciences

Full name of responsible person
Zeinab Nikniaz

Street address
Golgasht St, Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Abolghasem Jouyban

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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
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
Zeinab Nikniaz

Position
Assistant proffessor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable