

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Development and evaluation of the effectiveness of gamification in self-care among children with celiac disease.

Protocol summary

Study aim

Development and evaluation of the effectiveness of gamification in self-care among children with celiac disease. In this study, a game is designed to help children and adolescents with celiac disease learn necessary care for the disease.

Design

This is a non-randomized, double-blind, parallel-group clinical trial that will be conducted on a total of 120 children with celiac disease in two groups of control and intervention.

Settings and conduct

This study aims to assist in learning celiac self-care and will be conducted in medical centers affiliated to Urmia University of Medical Sciences in Urmia city. A program is designed to educate children about necessary care for their disease through gaming, the effectiveness of which will be measured by its impact on the knowledge, performance, and attitudes of children and their families in the intervention group compared to the control group. Quantitative variables such as height, weight, and laboratory tests will be also measured. The final statistical analysis will be performed by a qualified statistical analyst.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with celiac disease in the 7-15 age group Children who have been diagnosed with celiac disease for at least six months Having a smartphone in the family Exclusion criteria: Children with celiac disease and type 1 diabetes in the 7-15 age group Children with celiac disease and Down syndrome in the 7-15 age group Children with celiac disease and thyroid dysfunction in the 7-15 age group

Intervention groups

The intervention group will use gamification, while the control group follows traditional methods.

Main outcome variables

Qualitative variables: Function Knowledge attitude
Quantitative variables: Weight height Anti TTG(IgA) &

Anti TTG(IgG) Abdominal pain frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230618058509N1**

Registration date: **2023-10-13, 1402/07/21**

Registration timing: **prospective**

Last update: **2023-10-13, 1402/07/21**

Update count: **0**

Registration date

2023-10-13, 1402/07/21

Registrant information

Name

sahar hadifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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hamanhadifar1995@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Development and evaluation of the effectiveness of gamification in self-care among children with celiac disease.

Public title

The effect of games on the self-care among children with celiac disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children with celiac disease in the 7-15 age group Having a smartphone Children who have been diagnosed with celiac disease for at least six months

Exclusion criteria:

Children with celiac disease and thyroid dysfunction in the 7-15 age group Children with celiac disease and Down syndrome in the 7-15 age group Children with celiac disease and type 1 diabetes in the 7-15 age group

Age

From **7 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is being developed and the executive researchers have decided to largely blind the participants after designing the intervention based on its capabilities. For statistical analysis, it was decided that the results of the study, which are collected in the form of a questionnaire, will be encrypted and only raw data will be available to the analyst. Moreover, the raw encrypted data (both qualitative and quantitative) will be classified and made available to the analyst in a two-group (A and B) form.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Vice Chancellor for Research, UMSU Central Site, Orjhans Street, Resalat Blvd, Urmia ,Iran

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Approval date

2023-09-20, 1402/06/29

Ethics committee reference number

IR.UMSU.REC.1402.178

2

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

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Postal code

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Approval date

2023-09-20, 1402/06/29

Ethics committee reference number

IR.UMSU.REC.1402.178

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

Anti TTG(IgA) & Anti TTG(IgG)level

Timepoint

Before and after the intervention

Method of measurement

laboratory test

2

Description

Performance

Timepoint

Before and after the intervention

Method of measurement

KAP study questionnaire

3

Description

Knowledge

Timepoint

Before and after the intervention

Method of measurement

KAP study questionnaire

4

Description

attitude

Timepoint

Before and after the intervention

Method of measurement

KAP study questionnaire

5

Description

Weight

Timepoint

Before and after the intervention

Method of measurement

Weight measurement

6

Description

Height

Timepoint

Before and after the intervention

Method of measurement

Height measurement

7

Description

Abdominal pain frequency

Timepoint

Before and after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 children with celiac disease who were randomly assigned to the intervention group and used a mobile-based program designed to help them learn self-care skills for six months. First, the quantitative and qualitative variables are measured in the intervention group before the intervention. Then, the same variables will be re-measured after the end of the intervention and the effectiveness of the program will be determined by comparing the results before and after the intervention.

Category

Behavior

2

Description

Control group: 30 children with celiac disease who were randomly assigned to the control group and used a routine and traditional educational program to learn self-care skills for six months. First, the quantitative and qualitative variables are measured in the control group before the intervention. Then, the same variables will be re-measured after the end of the intervention and the effectiveness of the program will be discussed by comparing the results before and after the intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia University of Medical Sciences

Full name of responsible person

Sahar Hadifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Urmia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Sahar Hadifar

Position

Master of health information technology

Latest degree

Bachelor

Other areas of specialty/work

Others

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Full name of responsible person

Sahar Hadifar

Position

Master of health information technology

Latest degree

Bachelor

Other areas of specialty/work

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Position

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable