

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of self-care on the quality of life of children with celiac disease

Protocol summary

Study aim

Determine the effect of self-care program implementation on the quality of life of children with celiac disease

Design

In the first stage, consecutive sampling was performed and in the next stage, the samples were randomly assigned to intervention and control groups.

Settings and conduct

The purpose of this study was to determine the effect of self-care program implementation on the quality of life of children with celiac disease in Isfahan Celiac Society. The samples were randomly divided into intervention and control groups. For the intervention group, four sessions were held. The control group They were also followed up by telephone.

Participants/Inclusion and exclusion criteria

Children with celiac disease who have been diagnosed with a doctor by their physician. Children with celiac disease aged 20-8 years old living in the city of Isfahan In the past six months, there is no stressful incident such as divorce or the death of parents;Unwilling to attend or continue to study During the research, stressful events are close to death.

Intervention groups

In coordination with the samples in the intervention group, weekly training sessions were held once in four sessions by researcher, psychologist and nutrition expert. After completing the sessions in the intervention group, self-care checklist was provided to the samples for marking each activity in front of it. At the end of each month, the previous checklist was taken and the new checklist for that month was given to the samples. After the end of the three months, the checklist was collected in the intervention group and for the final stage, the quality of life questionnaire was given to all the units in the two groups to complete.

Main outcome variables

Self-care, quality of life.

General information

Reason for update

Acronym

I.R.C.S.S

IRCT registration information

IRCT registration number: **IRCT20170916036219N1**

Registration date: **2018-11-06, 1397/08/15**

Registration timing: **retrospective**

Last update: **2018-11-06, 1397/08/15**

Update count: **0**

Registration date

2018-11-06, 1397/08/15

Registrant information

Name

Shohreh Ziaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3673 0123

Email address

ziaei@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

2016-08-22, 1395/06/01

Actual recruitment end date

2016-11-20, 1395/08/30

Trial completion date

2017-03-05, 1395/12/15

Scientific title

The effect of self-care on the quality of life of children with celiac disease

Public title

The effect of self-care in celiac disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Children with celiac disease who have been diagnosed with the disease by their physician. Children with celiac disease aged 20-8 years old living in the city of Isfahan have read and write literacy. have Persian dialect. Do not have psychological disorders. Do not have mental retardation. In the last 6 months, there is no stressful incident such as divorce or the death of parents.

Exclusion criteria:

Unwilling to attend or continue to study During the research, stressful events are close to death

Age

From **8 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The samples were divided into intervention and control groups, which were held only for the intervention group of the classes. The control group was only used for answering the possible questions and not coming out of the telephone follow-up study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hazar Jarib St., Faculty of Nursing and Midwifery

City

Isfahan

Province

Isfahan

Postal code

۷۳۴۶۱۸۱۷۴۶

Approval date

2016-04-30, 1395/02/11

Ethics committee reference number

ir.mui.rec.1395.3.269

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

Self-care

Timepoint

Self-care effects were examined at the end of the first month, the end of the second month and the end of the third month after the implementation of the training classes.

Method of measurement

Self care checklist

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before the intervention, one month, two months and three months after the intervention

Method of measurement

Quality of life questionnaire for children with celiac disease

Intervention groups

1

Description

Intervention group: In this intervention, first, the quality of life questionnaire was completed and then the classes were conducted in 4 sessions of two hours. The samples were filled for three months by completing the quality of life questionnaire at the end of each month and self-care checklist Which were completed during the month by samples and were delivered at the end of the month.tracking samples using self-care checklist.

Category
Lifestyle

2

Description

Control group: The control group in this study only completed quality of life questionnaires before the beginning of the study and completed for three months at the end of each month. The control group was followed up by telephone and responded to the question of study and celiac disease.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian Celiac Association
Full name of responsible person
Dr. Mohammad Hassan Emami
Street address
Sheikh Moufid St, Iranian Celiac Association
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shohreh Ziaei
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Email
Jazb@mui.ac.ir
Web page address
Grant name
Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Shohreh Ziaei
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is 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

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Get started since 2020

To whom data/document is available

For scholars working in academia

Under which criteria data/document could be used

The use of data with the name of the collector's name is authorized.

From where data/document is obtainable

zahraezadi796@yahoo.com

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

After receiving the email with the subject of requesting documentation, send it for 2 weeks.

Comments