

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Assessing the effect of nutrition education on the "My plate" guide on anthropometric indices and some biochemical parameters compared to the usual education in children and adolescents with type 1 diabetes

Protocol summary

Study aim

The Effect of Nutrition Education Based on My plate Guide Compared to Normal Training in Type 1 Diabetes

Design

The total number of samples was randomly assigned to two groups by random allocation method, Experimentation Clinical control and intervention group with parallel and one-blind groups

Settings and conduct

This study was conducted at the Imam Hussein Hospital in Diabetes Clinic. The participants have been blinded.

Participants/Inclusion and exclusion criteria

No other illness other than type 1 diabetes, Infectious diseases and diseases other than diabetes

Intervention groups

A group was trained on "My plate" and group of control group was under regular training.

Main outcome variables

The mean of cholesterol, LDL, fasting blood glucose, systolic blood pressure and diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039665N1**

Registration date: **2018-11-05, 1397/08/14**

Registration timing: **retrospective**

Last update: **2018-11-05, 1397/08/14**

Update count: **0**

Registration date

2018-11-05, 1397/08/14

Registrant information

Name

Zahra Behrouz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3778 1686

Email address

zahra.behrouz@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-03-16, 1395/12/26

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2017-03-16, 1395/12/26

Trial completion date

empty

Scientific title

Assessing the effect of nutrition education on the "My plate" guide on anthropometric indices and some biochemical parameters compared to the usual education in children and adolescents with type 1 diabetes

Public title

Study the effect of nutrition education on the "My plate" guide on type 1 diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Girl and boy, aged 8 to 14 years old There is no other illness other than type 1 diabetes Over the past month,

They have not followed a particular diet The disease is newly diagnosed and has not followed a specific exercise program Not taking medications that affect serum lipids and high blood pressure

Exclusion criteria:

Infectious diseases and diseases other than diabetes

Age

From **8 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done based on random assignment and blocked

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in the study were kept blind to the study groups and the participants did not meet and contact the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Azadi Square, hazar Jarib St.

City

Esfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2016-01-25, 1394/11/05

Ethics committee reference number

IR.MUI.REC.1394.3.965

Health conditions studied

1

Description of health condition studied

Diabetes type 1

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Hemoglobin A1C

Timepoint

3 months

Method of measurement

Blood tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Learn "My plate" :The intervention group received my plate and my plate and diet training. The duration of the intervention was three months

Category

Lifestyle

2

Description

Control group: "Routine training" :The control group received routine training based on substitution lists and diet. The study included two intervention and control groups.The duration of the intervention was three months

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Zahra Behrouz

Street address

Imam Hossein Hospital, Imam Khomeini Street

City

Esfahan

Province

Isfahan
Postal code
۸۱۹۵۱۶۳۳۸۱
Phone
+98 31 3386 6266
Email
zahra.behrouz@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Doctor Shaghayegh Hagh Joy Javanmard
Street address
Isfahan University of Medical Sciences and Health
Services, No. 4, Tehran, Iran. Headquarters - Deputy
of Research and Technology of the University
City
Esfahan
Province
Isfahan
Postal code
۷۳۴۶۱-۸۱۷۴۶
Phone
+98 31 3668 5149
Email
research@mui.ac.ir
Web page address
<http://research.mui.ac.ir>

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

90

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
Zahra Behrouz
Position
Student
Latest degree

Master
Other areas of specialty/work
Nutrition
Street address
Hezar jarib street,Azadi Square
City
Esfahan
Province
Isfahan
Postal code
۷۳۴۶۱-۸۱۷۴۶
Phone
+98 31 3668 0048
Email
zahra.behrouz@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Behrouz
Position
Student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
University of medical science of Esfahan,Hezar jarib
street ,Azadi square
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3778 1686
Fax
Email
zahra.behrouz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Behrouz
Position
Student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Medical of science university of Esfahan, Hezar jarib
street,Azadi square
City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3778 1686

Fax

Email

zahra.behrouz@yahoo.com

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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

Information about the primary and secondary outcome is shared.

When the data will become available and for how long

Get started 6 months after printing results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

For those working in this field

From where data/document is obtainable

zahra.behrouz@yahoo.com

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

Documentation regarding the ongoing work

Comments