

# 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**