

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study the effect of nutrition education via mobile-based game, on nutritional knowledge, dietary habits, dietary diversity and growth indices in 5-6 years old children

#### Protocol summary

##### Study aim

Determination of the educational effect of mobile-based nutrition education game on nutritional knowledge, dietary habits, dietary diversity and growth indices in 5-6 years old children

##### Design

Clinical trial with two groups of intervention and control in 5-6 years old-parallel, no blinded and randomized groups-Based on e-learning

##### Settings and conduct

Preschools in 4 educational areas of Shiraz, selected and divided into intervention and control groups randomly and eligible volunteers will be included in the study.

##### Participants/Inclusion and exclusion criteria

5-6 years old children, Shiraz resident, healthy and without any chronic, mental, motor or mental illnesses, Literate parents, access to Android mobile phone

##### Intervention groups

Intervention group: 5-6 years old children who play electronic games on their mobile phone or tablet one hour a day for six months. Control group: 5-6-year-old children who do not receive any nutritional education from the researcher during the six-month intervention period.

##### Main outcome variables

Anthropometric measurement, Dietary diversity score, Dietary habits, Nutritional Knowledge of children and parents.

#### General information

##### Reason for update

The sample size has been changed to 120 people (60 people in each group) after consulting again with the statistical consultant. In the inclusion criteria for the fourth item, the word (healthy) has been removed.

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190810044496N1**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **prospective**

Last update: **2022-12-09, 1401/09/18**

Update count: **1**

#### Registration date

2019-08-26, 1398/06/04

#### Registrant information

##### Name

Maryam al sadat Riasatian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3627 9629

##### Email address

maryam\_riasatian@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-10-22, 1398/07/30

#### Expected recruitment end date

2019-12-21, 1398/09/30

#### Actual recruitment start date

2021-08-23, 1400/06/01

#### Actual recruitment end date

2021-09-23, 1400/07/01

#### Trial completion date

2022-03-20, 1400/12/29

#### Scientific title

Study the effect of nutrition education via mobile-based game, on nutritional knowledge, dietary habits, dietary

diversity and growth indices in 5-6 years old children

### Public title

Study the effect of nutrition education via mobile-based game, on nutritional knowledge, dietary habits, dietary diversity and growth indices in 5-6 years old children

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

5 to 6 year old children Shiraz resident Healthy and without any chronic and mental , motor and psychological disease Literate parents Access to android mobile phone Willing to cooperate during the study period Obtaining written consent

#### Exclusion criteria:

Existence of any congenital, chronic diseases , motor and mental disorders Cancer Malignant diseases (kidney and liver disease, severe anemia, heart disease, pulmonary failure, type 1 and type 2 diabetes, neurological diseases, mental illness and behavioral disorders such as autism and attention deficit disorder and gastrointestinal inflammatory diseases Any disease with a specific diet therapy

### Age

From **5 years** old to **6 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **120**

Actual sample size reached: **120**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Cluster randomization based on 4 educational areas of Shiraz

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

The present study is the first study to teach nutrition as an e-game in this age group (inability to read and write), so the process of design and construction of the game should be step by step based on creativity, taste and charm, and the details designed for the original framework may undergo changes or modifications during the game construction process.

### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

,No 61,66 Ave,Pasdaran Blvd,

##### City

Shiraz

##### Province

Fars

##### Postal code

7184956516

#### Approval date

2019-05-20, 1398/02/30

#### Ethics committee reference number

IR.SUMS.REC.1398.332

## Health conditions studied

### 1

#### Description of health condition studied

Preschool children, nutritional knowledge, mobile-based education

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Nutritional knowledge

#### Timepoint

The beginning and the end of the intervention

#### Method of measurement

Researcher-made questionnaire

## Secondary outcomes

### 1

#### Description

Dietary habits

#### Timepoint

The beginning and the end of the intervention

#### Method of measurement

Three-day food record questionnaire

### 2

#### Description

Diet diversity

#### Timepoint

The beginning and the end of the intervention

#### Method of measurement

Three-day food record questionnaire

### 3

**Description**

Growth Indices

**Timepoint**

The beginning and the end of the intervention

**Method of measurement**

Scales and meter

## Intervention groups

### 1

**Description**

Intervention group: one hour of daily play with nutrition education electronic game installed on mobile phone or tablet for six months

**Category**

N/A

### 2

**Description**

Control group: Without any intervention from the researcher

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Preschools

**Full name of responsible person**

Maryam alsadat Riasatian

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Pasdarán Blvd

**City**

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**Province**

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**Phone**

+98 71 3627 9629

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maryam\_riasatian@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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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**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam alsadat Riasatian

**Position**

Student

**Latest degree**

Master

**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

**Name of organization / entity**  
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**Full name of responsible person**  
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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

Not applicable

### 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

Not applicable

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

Participants' general information and study protocol and informed consent form will be published in the thesis.

### When the data will become available and for how long

End of study

### To whom data/document is available

Students, professors and researchers

### Under which criteria data/document could be used

Through the text of the thesis and the articles that will be published

### From where data/document is obtainable

Authentic Journals and Library of Shiraz University of Medical Sciences

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

in-person

### Comments