Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 psychologicall 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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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
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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
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