Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Designing a mobile application for educating mothers of preschool children with undernutrition and comparing its efficacy with the usual method of clinical education on the level of knowledge, attitude and nutritional practices of mothers and nutritional status of children aged 2 to 6 years

Protocol summary

Study aim
Design, implementation and evaluation of the effect of educational undernutrition management application in preschool children

Design
Clinical trial with control group, with parallel group design of 100 patients, non-blind, randomized groups. Simple randomization will be carry out, groups will be matched based on age, sex and degree of malnutrition, as well as supplement or drug use.

Settings and conduct
To conduct the study, an application with contents of child growth charts, healthy nutrition education and the necessary instructions to improve the nutritional status of children will be designed and will be provided to the intervention group. The level of knowledge, attitude and practice of mothers of children with malnutrition will be assessed using a questionnaire. Anthropometric and weights for age, weight for height and BMI for age z-scores will be used to measure the effectiveness of education for mothers on the improvement of child malnutrition at the beginning and end of the study.This study will be conducted in Iran, Tabriz.

Participants/Inclusion and exclusion criteria
Smartphone accessibility, being 2 to 6 years old, being malnourished and underweight

Intervention groups
In this study, individuals will be divided into two intervention groups, including virtual training by the application and the group receiving the usual method of clinical training. The educational materials provided to both groups will be the same. After 3 months of using the application or providing face-to-face training anthropometric indices, weight for age and weight for height z-scores (at the beginning and end of the study) will be used to measure the effectiveness of education to mothers of children with malnutrition on the improvement of children malnutrition.

Main outcome variables
Weight; Height; weight for age, weight for height and BMI for age z-scores; Knowledge, attitude and practice of mothers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140907019082N11**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date
2022-02-19, 1400/11/30

Registrant information

Name
Mahdieh Abbasalizad Farhangi

Name of organization / entity
Department of Community Nutrition School of Nutrition

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-02-05, 1400/11/16
Expected recruitment end date
2022-03-11, 1400/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Designing a mobile application for educating mothers of preschool children with undernutrition and comparing its efficacy with the usual method of clinical education on the level of knowledge, attitude and nutritional practices of mothers and nutritional status of children aged 2 to 6 years

Public title
Effect of mobile application on children's undernutrition
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study and signature of written consent by mothers Smartphone accessibility Being 2 to 6 years old confirmation of being malnourished and underweight using growth charts Mother's literacy
Exclusion criteria:
Reluctance to continue participation Having a specific disease that affects the results of the study
Age
From **2 years** old to **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **116**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals enter the study through convenience sampling from pediatrician's office and will be divided into two groups of intervention and control using simple randomization and will be matched based on age, sex and degree of malnutrition as well as supplementation or medication. In this study, we will use block randomization. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups in cases where intermediate analyzes are required during the sampling process. The size of all the blocks is the same and we will have 4 blocks in this four-group experiment. The randomization tool is also used from the site www.sealedenvelope.com, which is a site for generating random sequences, in addition to simple randomization, is able to generate random sequences by blocking method. For concealment, we use allocation concealment, which is the method used to execute a random sequence on study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with a random sequence (Sequentially numbered, sealed, opaque envelopes) in which in this method each random sequence is recorded on a card and the cards are placed in the envelopes respectively. Are placed. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, participants will be unaware of the type of intervention received (application or routine consultation) by each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Faculty of Nutrition and Food Sciences, Attar Neyshabouri St., Golgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2022-01-29, 1400/11/09
Ethics committee reference number
IR.TBZMED.REC.1400.1090

Health conditions studied

1

Description of health condition studied
Undernutrition
ICD-10 code
R63.6
ICD-10 code description
Underweight

Primary outcomes

1

Description
Weight for age z-score
Timepoint
Baseline and 3 months after intervention
Method of measurement
Digital weighing scale and growth chart

2

Description
Weight for height z-score
Timepoint
Baseline and 3 months after intervention
Method of measurement
Digital weighing scale, stadiometer and growth chart

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: includes face-to-face instructions in the clinic and providing nutrition education mobile application
Category
Behavior

2

Description
Control group: Receive only in-clinic instructions
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Nutrition, Tabriz University of Medical Sciences
Full name of responsible person
Dr Mahdieh Abbasalizad Farhangi
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Tabriz - Golgasht St. - Attar Neyshabouri St. - Faculty of Nutrition and Food Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Street address
Research & Technology Dept,Third Floor,Tabriz University of Medical Sciences Central building No. 2, Gulgasht St
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research-vice@tbzmed.ac.ir
Web page address
https://researchvice.tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Mahdieh Abbasalizad Farhangi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available