

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Aug 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

Country

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

AgeFrom **2 years** old to **6 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget 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.

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Tabriz

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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

Tabriz University of Medical Sciences

Full name of responsible person

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Research & Technology Dept, Third Floor, Tabriz University of Medical Sciences Central building No. 2, Golgasht 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

Contact

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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