

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 413357580

##### Email address

abbasalizadm@tbzmed.ac.ir

**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](http://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

#### Street address

Tabriz - Golgasht St. - Attar Neyshabouri St. - Faculty of Nutrition and Food Sciences

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

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#### Phone

+98 41 3335 7580

#### Email

abbasalizadm@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr Parviz Shahabi

##### Street address

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

##### City

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5166614711

##### Phone

+98 41 3335 7310

##### Fax

+98 41 3334 4280

##### Email

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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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Professor

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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