Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of nutritional education based on the precede-Proceed model and according to the food basket introduced by the Ministry of Health on improving the growth indicators and food intake of malnourished children aged 7-12 years

Protocol summary

Study aim

Determining the effect of nutritional education based on the PRECEDE-PROCEED model and according to the optimal food basket introduced by the Ministry of Health on improving the growth indicators and food intake of 7-12 year old children suffering from malnutrition in Kermanshah.

Design

The current study is a randomized controlled trial (clinical trial). Malnourished children aged 7 to 12 who meet the inclusion criteria are included in the study. After obtaining informed consent, 254 people were selected from among them and randomly divided into two intervention and control groups of 127 people.

Settings and conduct

This study will be conducted in primary schools of Kermanshah and on malnourished children. Malnourished children are identified using anthropometric indicators and growth monitoring charts, and they are enrolled and enrolled in the study considering the entry and exit criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to cooperate, suffering from mild, moderate and severe malnutrition (diagnosed using anthropometric assessments and growth percentiles), children's age in the range of 7 to 12 years, not using vitamin and mineral supplements, not having underlying, genetic diseases, acute gastrointestinal, respiratory infections, acute-chronic renal failure, active liver disease, red blood cell hemolysis, intestinal parasites, hyperactivity and attention deficit. Exclusion criteria: unwillingness to continue cooperation, hospitalization and accidents.

Intervention groups

127 malnourished children who are under nutrition education according to the PRECEDE- PROCEED model and according to the optimal food basket introduced by the Ministry of Health.

Main outcome variables

Average scores of predisposing factors, enhancing factors, enabling factors Average growth indices (height for age, weight for age, BMI for age)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181111041611N7**
Registration date: **2023-07-25, 1402/05/03**
Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**
Update count: **0**

Registration date

2023-07-25, 1402/05/03

Registrant information

Name

Mehnoosh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 83 3710 2009

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mehnoosh_samadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of nutritional education based on the precede-Proceed model and according to the food basket introduced by the Ministry of Health on improving the growth indicators and food intake of malnourished children aged 7-12 years

Public title

Investigating the effect of nutrition education on improving growth indicators and food intake in 7-12 year old children suffering from malnutrition

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate Suffering from mild, moderate and severe levels of malnutrition Children's age ranges from 7 to 12 years Not using vitamin and mineral supplements Not having underlying, genetic diseases Absence of acute digestive and respiratory infections, acute-chronic renal failure, attention deficit

Exclusion criteria:

Unwillingness to continue cooperation Hospitalization Accidents

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **254**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants of this study from public and non-profit primary schools in Kermanshah city were identified by student using anthropometric indicators and growth monitoring charts, and taking into account the entry and exit criteria, they were registered and enrolled. Then, using block randomization method, they are divided into intervention and control groups. The size of the blocks is not equal and is chosen randomly, which can include 10 blocks of 20, 5 blocks of 10 and 2 blocks of 2, and there are equal numbers of each group A and B in each block. A): intervention group and B: control group) Random numbers are generated by the statistical consultant and the random allocation of people to two groups of intervention and control will be done by the project manager (supervisor) and the student is not aware of this allocation. Coded boxes will also be used to hide random sequences.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

The current study is a randomized controlled trial (clinical trial) that will be conducted on 254 children aged 7 to 12 with malnutrition who are randomly divided into two groups of 127 intervention and control. The intervention group receives nutrition education and the control group does not receive any education.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No. 2, Research Council of Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Approval date

2023-07-09, 1402/04/18

Ethics committee reference number

IR.KUMS.REC.1402.137

Health conditions studied

1

Description of health condition studied

Malnutrition

ICD-10 code

E46

ICD-10 code description

Unspecified protein-calorie malnutrition

Primary outcomes

1

Description

Scores of predisposing factors including (score of awareness, attitude and self-efficacy), strengthening and

enabling factors

Timepoint

Before the intervention, 1 month and 3 months after the intervention

Method of measurement

PRECEDE questionnaire

2

Description

height-for-age

Timepoint

before the intervention, 1 month and 3 months after the intervention

Method of measurement

WHO height-for-age chart

3

Description

weight-for-age

Timepoint

before the intervention, 1 month and 3 months after the intervention

Method of measurement

WHO weight-for-age chart

4

Description

BMI for age

Timepoint

Before the intervention, 1 month and 3 months after the intervention

Method of measurement

BMI chart for age WHO

5

Description

Food intake

Timepoint

Before the intervention, 1 month and 3 months after the intervention

Method of measurement

Food record questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 127 children aged 7 to 12 suffering from malnutrition in the city of Kermanshah who have been subjected to the intervention of an educational program that, according to the information of the initial questionnaire, educational needs assessment, prioritization of these educations and determination of educational goals are carried out and these educations can include group education food, healthy eating, food variety, meat substitutes, protein sources, food containing vitamins, minerals such as iron, calcium and zinc, the amount of daily body needs from food groups and how to prepare food according to the child's interest, which It will be prepared from each training session. The trainings are weekly for 2 months and each session lasts 45 to 60 minutes in the form of face-to-face lectures, group discussions, worksheets, questions and answers, and educational videos, which will be conducted in the presence of students, their parents, and teachers.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nasim Primary school

Full name of responsible person

Soraya Yazdani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah 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
Kermanshah 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available