

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The Ready-to-Use Supplementary Food 's impact on indicators of malnutrition in Mild and Moderately Wasted Children: a randomized controlled trial.

Protocol summary

Summary

This study is a randomized controlled clinical trial, and 106 children will be studied for eight weeks. Inclusion criteria are having age 24 to 59 months; mild and moderate malnutrition without edema (Anthropometric index of weight for height between the -1 and -3 z-score); filling a consent form. Exclusion criteria are being twins; food allergies and intolerance; severe anemia; liver-kidney disease; malabsorption syndrome; unwillingness to cooperate. After enrollment, children will be allocated into two groups (Intervention and Control groups) based on random number table. Intervention group will receive the formula and the control group on the other will not. At baseline and during examination sessions, caregivers will be trained about Childhood nutrition. Before initiating the intervention, we will ask caregivers to give 5 grams of sample to children in the intervention group in case of checking for food intolerance. In absence of food intolerance, we will measure and record their weight, height and weight for height anthropometric index. In addition, during examination sessions, we will ask questions about the frequency of symptoms such as diarrhea, anorexia and abdominal pain. Also, we will take two Food records from caregivers which will show food consumed by children. After intervention we will measure and record their weight, height and weight for height anthropometric index. The primary outcome will be recovery (Increment of children's weight for height anthropometric index to the top of -1 z-score). The Secondary outcomes will be average increment of weight gain, height gain, and incidence of fever and diarrhea among children.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021315536N6**

Registration date: **2017-04-07, 1396/01/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-07, 1396/01/18

Registrant information

Name

Mohammad Javad Hosseinzadeh

Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

Country

Iran (Islamic Republic of)

Phone

+98 21 8899 3059

Email address

mhosseinzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Ready-to-Use Supplementary Food 's impact on indicators of malnutrition in Mild and Moderately Wasted Children: a randomized controlled trial.

Public title

The Ready-to-Use Supplementary Food 's impact on indicators of Children malnutrition

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having age 24 to 59 months; Mild and moderate malnutrition without edema (Anthropometric index of weight for height between the -1 and -3 z-score); Filling a consent form. Exclusion criteria: Being twins; Food allergies and intolerance; Severe anemia; Liver-kidney disease; Malabsorption syndrome; Lack of cooperation.

Age

From **2 years** old to **4 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Children will be numbered, and randomly will be assigned into two groups (Control and Intervention groups) by random number tables.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

6th floor, Central Tehran University, Ghods street, Keshavarz Bolivar.

City

Tehran

Postal code

Approval date

2016-07-25, 1395/05/04

Ethics committee reference number

IR.TUMS.VCR.REC.1395.353

Health conditions studied

1

Description of health condition studied

moderate malnutrition

ICD-10 code

E44.0

ICD-10 code description

Moderate protein-energy malnutrition

2

Description of health condition studied

mild malnutrition

ICD-10 code

E44.1

ICD-10 code description

Mild protein-energy malnutrition

Primary outcomes

1

Description

recovery

Timepoint

Every two weeks after intervention

Method of measurement

Increase children's weight for height anthropometric index z-score to the top of -1 in weight-for-height tables Children's World Health Organization, Weight will be measured with scale, and height will be measured with meter.

Secondary outcomes

1

Description

weight gain

Timepoint

two month after intervention

Method of measurement

difference between New weight at the end of intervention and children's initial weight. Weight will be measured with scale.

2

Description

height gain

Timepoint

two month after intervention

Method of measurement

difference between New height at the end of intervention and children's initial height. height will be measured with meter.

3

Description

Fever

Timepoint

two month after intervention

Method of measurement

Counting the number of days of fever from the beginning to the end of the study. method of measurement is With question

4

Description

Diarrhea

Timepoint

two month after intervention

Method of measurement

Counting the number of days of Diarrhea from the beginning to the end of the study. . method of measurement is With question.

Intervention groups

1

Description

Control group: before and during intervention, in four half-hour sessions, caregivers will be trained about Childhood nutrition by face to face method. The subjects of education sessions will be the adequacy of feeding; the correct number of meals; type and amount of food each meal should have, based on the child's age; sensory characteristics and diversity of food; hygiene; and how to prepare energetic nutritious foods.

Category

Treatment - Other

2

Description

Intervention group: The Ready-to-Use Supplementary Food, which contains whey protein, egg white, soy, palm, starch, honey, sugar, oil and natural flavorings will be given to children as daily snacks for eight weeks. On average, each of them should consume one to three packs (100 grams), daily. Like control group, before and during intervention, caregivers will be trained about Childhood nutrition by face to face education. The subjects of education sessions will be the adequacy of feeding; the correct number of meals; type and amount of food each meal should have, based on the child's age; sensory characteristics and diversity of food; hygiene; and how to prepare energetic nutritious foods.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Abolfazl (AS) Comprehensive Rural Health Service Center

Full name of responsible person

Fatemeh Azimi

Street address

Hazrat Abolfazl (AS) Comprehensive Rural Health Service Center, Shour abad, Qhom old road, Shahr Rey.

City

Tehran

2

Recruitment center

Name of recruitment center

Bagher Shahr Comprehensive Urban Health Service Center

Full name of responsible person

Fatemeh Azimi

Street address

Bagher Shahr Comprehensive Urban Health Service Center, No. 82, Next to gas operated, St. Shahid Ismaili, Bagher shahr, Shahr Rey.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr.Masood Younesian

Street address

Room No 605, sixth floor, Ghods street, Keshvarz Blvd

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences Department of
Nutrition and Dietetic

Full name of responsible person

Mohamad Javad Hosseinzadeh

Position

MD PHD Clinical nutrition

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Azimi

Position

MSc student of Nutrition Sciences in disaster

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty