

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Surveying the effects of increasing meals frequency intake on the growth of 2-5 year old children with failure to thrive

Protocol summary

Study aim

Investigating the effect of increasing the frequency of meals on children weight growth compared to the usual method of nutritional counseling including three meals a day

Design

A clinical trial without blinding, with a control group, randomly assigned to parallel groups, phase 2 of 64, 2-5 years children with failure to thrive (low weight for height and low weight for age) will be conducted. Excel software will be used for randomization.

Settings and conduct

The research will be conducted in the form of a controlled clinical trial at Clinics of Yasuj University of Medical Sciences on 64 children aged 2-5 years with low weight for age/low weight for height. The research is not blinded, in the intervention and control groups. In addition to the usual training, the intervention group will be advised to receive breakfast, lunch, dinner, 2 snacks in the morning and evening, and a late night meal. Only breakfast, lunch and dinner will be recommended to children in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with low weight for age and weight for height; two and five years of age; Parents agreement Exclusion criteria: Failure to receive 5 meals or more in the intervention group; Receiving diet and advice from other authorities; Receiving more than 4 meals in the control group

Intervention groups

group of children with underweight or wasting who will be randomly selected from eligible children to enter the study and will be trained to receive 5 meals or more per day.

Main outcome variables

Weight for height, Weight for Age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230820059190N2**

Registration date: **2023-09-03, 1402/06/12**

Registration timing: **prospective**

Last update: **2023-09-03, 1402/06/12**

Update count: **0**

Registration date

2023-09-03, 1402/06/12

Registrant information

Name

Janmohamad Malekzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 3505

Email address

malekjmd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Surveying the effects of increasing meals frequency intake on the growth of 2-5 year old children with failure to thrive

Public title

Investigating the effect of food frequency on children's growth

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

2-5 years old child suffering from low weight for age and low weight for height First refer

Exclusion criteria:

receiving drug and dietary supplements Previous visit and receiving previous dietary advice

Age

From **24 months** old to **60 months** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In case of child's parents' agreement to participate in the project, the children will be randomly assigned to one of two intervention groups and control. The randomization method is to generate 32 random numbers from 1 to 64 by Excel software to be assigned to the intervention group and then assigning the remaining 32 numbers to the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yasuj University of Medical Sciences

Street address

Motahari Blvd

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591875114

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.YUMS.REC.1402.004

Health conditions studied**1****Description of health condition studied**

Failure to thrive

ICD-10 code

R62.8

ICD-10 code description

Other lack of expected normal physiological development

Primary outcomes**1****Description**

Weight for age

Timepoint

At the beginning of the study, two weeks and one month after the intervention

Method of measurement

Weight measurement with an accurate scale with an accuracy of 0.1 kg

2**Description**

Weight for height

Timepoint

At the beginning of the study, two weeks and one month after the intervention

Method of measurement

Measuring weight with an accurate scale with an accuracy of 0.1 kg and height with a caliper with an accuracy of 0.5 cm

3**Description**

Body Mass index

Timepoint

At the beginning of the study, and a month after the intervention

Method of measurement

The ratio of weight in kilograms to the square of height in meters

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group of underweight or low weight for height children who receive 5 or more meals a day

Category

Treatment - Other

2

Description

Control group: A group of underweight or low weight for height children who receive 3-4 meals a day

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh clinic of Yasuj

Full name of responsible person

Janmohamad Malekzadeh

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No. 15, Golestan., Pasdaran Blvd., Yasuj

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75918-38165

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Email

malekjmd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Amir-Hossain Doosti Motlagh

Street address

Motahari Blvd., Yasuj

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research@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

janmohamad Malekzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 15, Golestan., Pasdaran Blvd, Yasuj School of Health

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information related to the main outcome, and its statistical details will be available to researchers in the form of articles or otherwise, in case of YUMS Agreement.

When the data will become available and for how long

The start of the access period will probably be from June 2024 if the data is completed on time

To whom data/document is available

The data will be available to researchers of medical sciences, social sciences and managers of healthcare departments

Under which criteria data/document could be used

The data will be available for those who are in line with the provision of children's health. Such as planning to improve nutrition, education

From where data/document is obtainable

Contact through email, malekjmd@yahoo.com

What processes are involved for a request to access data/document

First, contact my email with full affiliation and reasons for requesting information, I will discuss the matter with the vice president of technology of the university and request a decision and permission. The minimum required time will be 30 working days

Comments