Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 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
Yasouj
Province
Kohgilouyeh-va-Boyrahmad
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., Yasouj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Amir-Hossain Doosti Motlagh
Street address
Motahari Blvd., Yasouj
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7591875114
Phone
+98 74 3334 6078
Email
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
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
janmohamad Malekzadeh
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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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