Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of physical activity labeling which indicates the amount of physical activity needed to burn energy of chosen food, and traffic light labeling on food choice

Protocol summary

Study aim

The purpose of this study is to compare the existing food labels (traffic light label) with a new label which will be designed by the researchers.

Design

This study will be conducted in qualitative and quantitative phases. Step 1: Assessment of current status of labeling In this section, the strengths and weaknesses of existing labels will be explained. Step 2: designing a new label and testing interventions Number: 500 Mother Mothers randomly will enter into 5 groups. First group: without nutrition label, second group: traffic light label (without informing mothers) - Third group traffic light label (by informing mothers via brochures) - Group 4 physical activity labels (without informing mothers) - Group 5 physical activity labels (by Informing mothers via brochures). The brochures will be sent with an invitation.

Settings and conduct

Intervention in schools will take place. Mothers are not aware of the main purpose of the project, and the investigator is unaware of the division of mothers in each groups.

Participants/Inclusion and exclusion criteria

Include: Participants are mothers who can read and write. They also want to participate in the study. Exclude: Pregnant, lactating or diseases such as diabetes, allergies, etc. and diets.

Intervention groups

To assess the impact of new label, the school community will be used. They will be randomly selected from elementary schools from both sex groups.

Main outcome variables

Total calories of selected products in each groups are considered as the final result.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181002041201N1**
Registration date: **2018-10-25, 1397/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**
Update count: **0**

Registration date

2018-10-25, 1397/08/03

Registrant information

Name

Shirin Seyedhamzeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8898 4837

Email address

shirinseyedhamzeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-13, 1397/07/21

Expected recruitment end date

2019-03-16, 1397/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of physical activity labeling which indicates the amount of physical activity needed to burn energy of chosen food, and traffic light labeling on food choice

Public title
The effect of physical activity labeling and traffic light labeling on food choice
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Participants are mothers who can read and write and want to participate in the study.
Exclusion criteria:
Those individuals who are pregnant, lactating, or have diseases such as diabetes, allergies, etc., and those with diets will be excluded.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **500**
Randomization (investigator's opinion)
Randomized
Randomization description
To evaluate the effect of physical activity labeling, schools from Tehran will be assigned. Block randomization will be considered. Tehran will be divided into five regions: north, south, east, west and center. two schools from each region will be randomly selected. Preschool and elementary schools (girls or boys) will be included. Fifty mothers will be randomly enrolled from each school, Then selected mothers will be divided into five groups. A total of 500 mothers will be included.
Blinding (investigator's opinion)
Double blinded
Blinding description
Mothers will be not aware of the aim of the study, so their food choices will be not affected. The divisions will be done by an expert and the researcher will not aware of it.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Keshavarz boulevard, Ghods St
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2018-01-08, 1396/10/18
Ethics committee reference number
IR.TUMS.VCR.REC.1396.4160

Health conditions studied

1

Description of health condition studied
prevention of non-communicable diseases
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The total calories of selected products in each groups are considered as the final result.
Timepoint
Immediately after food choice
Method of measurement
observation and record

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group number1: physical activity labeling: After designing physical activity label in the first step, it will be produced by a printing office and will be fixed on products (dairy products- beverages- cakes and biscuits). It will be asked from mothers to assume that they are a supermarket and choose from the products that are available. This label will compare with the traffic light label which is currently in use. Mothers will only encounter this label once. one hundred mothers will participate in this group.
Category
Prevention

2

Description

Intervention group number 2: physical activity labeling via brochure: Physical activity label with brochure: In this group, an educational brochure for choosing healthy food will be given to one hundred mothers, so the effect of education on choice is taken into account. The results of this group will be compared with the traffic light label group via brochure.

Category

Prevention

3

Description

Intervention group number 3: traffic light labeling: In this group, 100 mothers will be included and they will select once from the products with a traffic light labels.

Category

Prevention

4

Description

Intervention group number 4: traffic light labeling via brochure: An educational brochure with healthy food choice information will be provided for the 100 mothers in this group to determine its impact on food choice.

Category

Prevention

5

Description

Control group: without nutrition labeling: 100 mothers will enter to this group, and will make their choices among products that do not have any nutritional labels so we can determine the impact of nutritional labels.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Elementary schools from Tehran

Full name of responsible person

Ahmadreza Dorosti Motlagh

Street address

No 44, Naderi St, Hojjat doost Alley, Keshavarz Blvd

City

Tehran

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Postal code

1416643931

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+98 21 8895 5975

Email

dorostim@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shokoufeh Nikfar

Street address

Ghods St, Keshavarz Boulevard

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Phone

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Email

Nikfar_sh@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shirin Seyedhamzeh

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

No 44, Hojjat-dost Alley, Naderi Street, Keshavarz Boulevard

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shirin Seyedhamzeh
Position
PhD candidate
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Full name of responsible person
Shirin Seyedhamzeh
Position
PhD candidate
Latest degree
Master
Other areas of specialty/work
Nutrition
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All information will be shared documented without the identity of the participants.
When the data will become available and for how long
Starting in 2021
To whom data/document is available
Researchers
Under which criteria data/document could be used
Results will be useful for policy makers.
From where data/document is obtainable
dorostim@tums.ac.ir
What processes are involved for a request to access data/document
After confirming the applicant, by Dr Dorosty the information will be provided.
Comments