

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Effect of community-based health promotion interventions on nutritional behaviors of households in Hamadan city by applying the combined model

#### Protocol summary

##### Summary

This study is a randomized controlled trial. The aim of this study is to evaluate the effectiveness of community-based educational intervention on improving the nutritional behavior of households in Hamadan city. Methods: In the first stage of study by using qualitative and quantitative methods, nutritional problems will be determined. Fifth-grade students and their mothers are as the target group. Hamadan has two educational areas. One area will be considered as the intervention group and other as the control group randomly. According to socioeconomic status, schools will be divided into three categories: good, average and poor. Through a stratified, cluster sampling 842 subjects will be placed in two intervention and control groups (421 subjects in intervention group and 421 subjects in control group). Schools and two fifth-grade classes from each school will be selected randomly. Data gathering tools will be a questionnaire designed based on the health promotion and health education models and a food frequency questionnaire. Based on the evidence from initial survey, priorities nutritional problems and considering the conditions and needs of the target group, interventions will be designed and implemented. Finally, to evaluate the effectiveness of intervention, nutritional behaviors in the intervention and control groups will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014042315797N3**  
Registration date: **2014-07-12, 1393/04/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-07-12, 1393/04/21

##### Registrant information

###### Name

Seyed Mohammad Mahdi Hazavehei

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 1641

###### Email address

hazavehei@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2016-11-20, 1395/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of community-based health promotion interventions on nutritional behaviors of households in Hamadan city by applying the combined model

##### Public title

Effect of health promotion interventions on nutritional

behaviors

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
Inclusion criteria: Fifth grade student; mother or supervisor of the child who is charged with the responsibility of cooking in the family Exclusion criteria: Transferring student to another school.; lack of willingness of students to continue participating in the study; lack of willingness of mother or child supervisor to continue participating in the study; having specific diet due to illness or other reasons

**Age**  
From **7 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **842**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single 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 Hamadan University of Medical Sciences

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh A, Hamadan, Iran

##### City

Hamadan

##### Postal code

65178

##### Approval date

2014-05-17, 1393/02/27

##### Ethics committee reference number

16/30/9/715/پ/

## Health conditions studied

### 1

#### Description of health condition studied

nutritional behaviors

#### ICD-10 code

Z72.4

#### ICD-10 code description

Inappropriate diet and eating habits

## Primary outcomes

### 1

#### Description

Constructs of combined health education and promotion model

#### Timepoint

Before and after intervention

#### Method of measurement

Questionnaire

### 2

#### Description

Practice

#### Timepoint

Before and after intervention

#### Method of measurement

Questionnaire

### 3

#### Description

Knowledge

#### Timepoint

Before and after intervention

#### Method of measurement

Questionnaire

### 4

#### Description

Food consumption

#### Timepoint

Before and after intervention

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

BMI (Body Mass Index)

#### Timepoint

Before and after intervention

#### Method of measurement

Height and weight measurements

### 2

#### Description

WHR (Waist to hip ratio)

**Timepoint**

Before and after intervention

**Method of measurement**

Waist and hip circumferences

**Intervention groups****1****Description**

Interventions will be performed using Train to trainer strategy to promote nutritional behaviors of mothers and students. In this method, teachers and school health educators will be trained, to teach the students about healthy eating behaviors. Finally, mothers will be trained by students. Interventions for 3 months included: education about food groups and nutritional behaviors; providing educational aids including pamphlet, booklet, display video and banner installation; holding painting competitions and providing wallpaper to promote nutritional behaviors. To assess the rate of learning, mothers and students will write their homework in the logbook.

**Category**

Lifestyle

**2****Description**

For the control group will not perform any of the action that will be taken for the intervention group.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Elementary Schools of Hamadan

**Full name of responsible person**

Seyedeh Zeinab Hashemi

**Street address**

School of Public Health, Hamadan University of Medical Sciences, Hamadan, IRAN

**City**

Hamadan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Hamadan University of Medical Sciences

**Full name of responsible person**

Saeed Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Av, Hamadan, Iran

**City**

Hamadan

**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, Hamadan 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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Seyedeh Zeinab Hashemi

**Position**

Ph.D Student of Health Education and Promotion

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

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## Person responsible for updating data

### Contact

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Hamadan  
**Postal code**

## 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*