# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)
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**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*