

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect of education based on the theory of self-efficacy on health literacy, self efficacy of eating habits and physical activity in the second secondary school students

#### Protocol summary

##### Summary

at first a cross-sectional study was done. The sample consisted of 425, 18-15 year-old female student that are studying at The secondary public schools in 2016, selected by stage randomly sampling. After determining the initial sample size, students height and weight will be measured .also The questionnaire containing demographic information, self-efficacy of eating habits and physical activity, and health literacy NVS (Newest vital signe ) , for them is completed. Before the study ,the localization and adaptation of self-efficacy of eating habits and self efficacy of regular physical activity questionnaires with cultural and social characteristics of the community, will be done. After the first stage students who have low levels of health literacy, self-efficacy of eating habits and physical activity behavior and eligible to enter the intervention stage and with no problem and a specific disease, and have a desire to participate in the study, divided into two experimental and control groups. The number of samples in each group in education and intervention phase, on the basis of Ezzati Article at least 40 people were calculated. With regard to the possible lack of random assignment on an individual basis, randomized intervention and control groups at the school level is done. School,taking into consideration social, economical and cultural Conditions assigned to two experimental and control groups. Training methods to groups with role-plays, practical work and lectures are given and before training, immediately after training and three months later followed up and compared to the control group

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016101628863N6**  
Registration date: **2017-07-10, 1396/04/19**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-10, 1396/04/19

##### Registrant information

###### Name

Nooshin Peyman

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 915 502 6195

###### Email address

peymann@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

##### Expected recruitment start date

2016-12-04, 1395/09/14

##### Expected recruitment end date

2017-01-30, 1395/11/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of education based on the theory of self-efficacy on health literacy, self efficacy of eating habits and physical activity in the second secondary school students

#### Public title

The effect of education based on the theory of self-efficacy on health literacy, self efficacy of eating habits and physical activity in the second secondary school students

#### Purpose

Health service research

#### Inclusion/Exclusion criteria

Inclusion criteria: 1. The second secondary school students who have completed consent and are willing to cooperate 2. The second secondary school students who do not have physical health problems 3. The second secondary school students that do not have a particular disease, disability and mental health problems 4. Having Iranian nationals Exclusion criteria: 1-absence over a meeting attended training courses 2. Do not complete the post-test questionnaire 3-occurrence of certain events during the study in student that lead to diseases that affect the study

#### Age

From **15 years** old to **18 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **425**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

-

## Secondary Ids

### 1

#### Registry name

ندارد

#### Secondary trial Id

ندارد

#### Registration date

empty

### 2

#### Registry name

no

#### Secondary trial Id

no

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mashhad University of Medical Sciences School of Health

##### Street address

School of Health, Mashhad University of Medical Science, Mashhad, Iran

##### City

mashhad

##### Postal code

#### Approval date

2017-03-15, 1395/12/25

#### Ethics committee reference number

IR.MUMS.REC.1395.623

## Health conditions studied

### 1

#### Description of health condition studied

health literacy, Self-Efficacy to Regulate Eating Habits and Self-Efficacy to Regulate Exercise

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

health literacy

#### Timepoint

Before the intervention, immediately after the intervention and three months after intervention

#### Method of measurement

Complete the questionnaire

### 2

#### Description

Self-Efficacy to Regulate eating habits

#### Timepoint

Before the intervention, immediately after the intervention and three months after intervention

#### Method of measurement

Complete the questionnaire

### 3

#### Description

Self-Efficacy to Regulate Exercise

#### Timepoint

Before the intervention, immediately after the

intervention and three months after intervention

**Method of measurement**

Complete the questionnaire

**Secondary outcomes**

**1**

**Description**

Weight

**Timepoint**

Before the intervention, immediately after the intervention and three months after intervention

**Method of measurement**

Digital scales Seca

**2**

**Description**

Height

**Timepoint**

Before the intervention, immediately after the intervention and three months after intervention

**Method of measurement**

Tape measure

**3**

**Description**

Body Mass Index

**Timepoint**

Before the intervention, immediately after the intervention and three months after intervention

**Method of measurement**

Weight divided by height squared

**4**

**Description**

Regular physical activity per week

**Timepoint**

Before the intervention, immediately after the intervention and three months after intervention

**Method of measurement**

Self-report questionnaire

**5**

**Description**

Watching TV, using computers and mobile phones during the day

**Timepoint**

Before the intervention, immediately after the intervention and three months after intervention

**Method of measurement**

Self-report questionnaire

**Intervention groups**

**1**

**Description**

In the intervention group, six 45-minute sessions based on the theory of self-efficacy will be conducted

**Category**

Lifestyle

**2**

**Description**

In control group we do not give them the instructions in intervention group. But in this group training is given with different topics of the experimental group educational topics.

**Category**

Lifestyle

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mashhad University of Medical Sciences School of Health

**Full name of responsible person**

nooshin peyman

**Street address**

School of Health, Mashhad University of Medical Science, Mashhad, Iran

**City**

Mashhad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Mashhad University of Medical Sciences

**Full name of responsible person**

nooshin peyman

**Street address**

School of Health, Mashhad University of Medical Science, Mashhad, Iran

**City**

Mashhad

**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, Mashhad 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**

School of Health, Mashhad University of Medical  
Science

**Full name of responsible person**

Nooshin Peyman

**Position**

Associate Professor Management & Social  
Determinants of Health Research Center, Department  
of He

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

Management & Social Determinants of Health  
Research Center School of Health, Mashhad  
University of Medical Science, Mashhad, Iran

**City**

Mashhad

**Postal code****Phone**

+98 51

**Fax****Email**

peymann@mums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

School of Health, Mashhad University of Medical

Science

**Full name of responsible person**

nooshin peyman

**Position**

Associate Professor

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

School of Health, Mashhad University of Medical  
Science

**City**

Mashhad

**Postal code****Phone**

+98 51 3854 4643

**Fax****Email**

peymann@mums.ac.ir

**Web page address****Person responsible for updating data****Contact****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*