

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The Impact of Educational Intervention by Interactional Multi Media based on Health belief model on preventive behavior about pediculosis in primary school students

#### Protocol summary

Registration timing: **prospective**

#### Study aim

Determining the Effect of Educational Intervention Using Interactive Multimedia Method Using Health Belief Model on Pediculosis Preventive Behavior in Primary School Students in First and Second Periods in Bavanat, 1397

Last update: **2019-02-15, 1397/11/26**

Update count: **0**

#### Registration date

2019-02-15, 1397/11/26

#### Design

In this study, 300 primary school students who are eligible to enter the study are selected. Participants are randomly divided into intervention and control groups and each participant is assigned a code.

#### Registrant information

##### Name

zahra keshtkaran

##### Name of organization / entity

Shiraz university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5233 7546

##### Email address

zkeshtkar@sums.ac.ir

#### Settings and conduct

This double-blind clinical trial is conducted in elementary girl schools in the Bavanat city. In this trial one session will be conducted by multimedia for the intervention group and no intervention will be conducted for the control group.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Written consent from students' parents; Students own desire and willingness to participate in the study; no previous involvement with lice related training. Non inclusion criteria: having affected by skin disease and fungi before; Change the place of residence or education

#### Expected recruitment start date

2019-02-20, 1397/12/01

#### Expected recruitment end date

2019-05-22, 1398/03/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

For the intervention group, 1 session will be held in an interactive and multimedia format. No intervention will be conducted for the control group.

#### Scientific title

The Impact of Educational Intervention by Interactional Multi Media based on Health belief model on preventive behavior about pediculosis in primary school students

#### Main outcome variables

Preventive behaviors of pediculosis

#### Public title

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180806040715N2**

Registration date: **2019-02-15, 1397/11/26**

The Effect of Training on Lice pediculosis

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Obtain written consent from parents of students  
Satisfaction and desire of students to participate in the study  
Students studying at elementary girl schools  
No participation of students in sessions on prevention of head lice

#### **Exclusion criteria:**

Skin and fungus diseases  
Change the student's residence or school

### **Age**

From **6 years** old to **12 years** old

### **Gender**

Female

### **Phase**

3

### **Groups that have been masked**

- Participant
- Data analyser

### **Sample size**

Target sample size: **300**

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

Randomized

### **Randomization description**

The method of assigning samples to the test and control groups is based on the randomized block method in which we select letter "A" for control group and letter "B" for intervention group. In this way, we will consider block of size 2 with two modes including "AB" and "BA".

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

Participants are not aware of which group they are involved with and control. The data analyzer does not know who the participants are in.

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

##### **Street address**

Central Building of Shiraz University of Medical Sciences, Zand Blvd

##### **City**

Shiraz

### **Province**

Fars

### **Postal code**

71348-14336

### **Approval date**

2018-11-27, 1397/09/06

### **Ethics committee reference number**

IR.SUMS.REC.1397.800

## **Health conditions studied**

### 1

#### **Description of health condition studied**

The Effectiveness of a Health Education Program Based on the Health Belief Model on Students

#### **ICD-10 code**

Z55.8

#### **ICD-10 code description**

Other problems related to education and literacy

## **Primary outcomes**

### 1

#### **Description**

Perceived susceptibility

#### **Timepoint**

Before, after the intervention, two months later

#### **Method of measurement**

Researcher made questionnaire

### 2

#### **Description**

Perceived severity

#### **Timepoint**

Before, after the intervention, two months later

#### **Method of measurement**

Researcher made questionnaire

### 3

#### **Description**

Perceived Barriers

#### **Timepoint**

Before, after the intervention, two months later

#### **Method of measurement**

Researcher made questionnaire

### 4

#### **Description**

Perceived benefits

#### **Timepoint**

Before, after the intervention, two months later

#### **Method of measurement**

Researcher made questionnaire

**5**

**Description**

Efficacy

**Timepoint**

Before, after the intervention, two months later

**Method of measurement**

Researcher made questionnaire

**6**

**Description**

Cues to action

**Timepoint**

Before, after the intervention, two months later

**Method of measurement**

Researcher made questionnaire

**7**

**Description**

Preventive Behaviors

**Timepoint**

Before, after the intervention, two months later

**Method of measurement**

Researcher made questionnaire

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

In the intervention group: A training session is conducted using an interactive multimedia method in which female students are trained lice prevention behaviors

**Category**

Prevention

**2**

**Description**

In the control group, there is no intervention and they will be provided with educational materials at the end of the study.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

primary schools students in Bavanat

**Full name of responsible person**

Kadijeh Kiani

**Street address**

Nursing and Midwifery School, Namazi square

**City**

Shiraz

**Province**

Fars

**Postal code**

71936-13119

**Phone**

+98 71 3647 4258

**Email**

kh.kiani.nurse85@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Basir Hashemi

**Street address**

Central building of Shiraz University of Medical Sciences, Zand Blvd

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**Email**

Vcrdep@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Khadijeh Kiani

**Position**

Bachelor

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Nursing and Midwifery school, Namazi Square

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

kh.kiani.nurse85@gmail.com

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Nursing and Midwifery school, Namazi Square

**City**

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**Province**

Fars

**Postal code**

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**Phone**

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**Email**

kh.kiani.nurse85@gmail.com

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Zahra Keshtkaran

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Nursing and Midwifery school, Namazi Square

**City**

Shiraz

**Province**

Fars

**Postal code**

71936-13119

**Phone**

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**Email**

zkeshtkar@sums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Khadijeh Kiani

**Position**

Bachelor of science

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidentiality of the participants' information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available

**Title and more details about the data/document**

Information on the main consequences

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

If requested, the researchers will be provided by the first moderator

**Under which criteria data/document could be used**

Presenting articles at prestigious seminars and presenting articles in prestigious scientific journals

**From where data/document is obtainable**First performer Dr. Zahra Keshtkaran  
zkeshtkar@sums.ac.ir**What processes are involved for a request to access data/document**

By Email

**Comments**