

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Evaluating the effect of a theory-based educational program on healthy spine-related behavior among female fifth grade elementary school - Randomized Community Trial

#### Protocol summary

##### Study aim

The purpose of this study is "Designing an educational program based on theory and its impact on healthy spine-related behavior in female fifth grade elementary school in capital Tehran`s region 22".

##### Design

The study population included 102 public elementary schools fifth grade girls, Tehran 22nd District, has inclusion criteria, with the pre and post-test in the academic year 97-98. At first, two similar schools were selected and are randomly assigned to control and test group. Then in each school, two classes are randomly selected and in each group, 51 eligible people are enrolled in the study.

##### Settings and conduct

Before intervention, a localized questionnaire based on the four constructs of social cognitive theory (behavioral capability, self-efficacy, beliefs and behavior), validity and reliability of which were previously measured, will be completed by the two groups. After performing 6 educational intervention sessions in the test group, immediately, three and six months after the intervention, the questionnaire will again be filled in by the two groups. The effects of the intervention are compared with control group.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Fifth grade female student; parental written consent for student participation in the study; informed consent and voluntary; participation of the student in the study; ability to attend training sessions; no training in this area. Exclusion Criteria: having pain or disorder in the student's spine; disapproval of student's spine health by physiotherapist.

##### Intervention groups

Intervention group: Includes 51 people who receive instructional education based on 4 construct of social cognitive theory. The control group also includes 51

people who will not receive any intervention.

##### Main outcome variables

Healthy spine-related behavior

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180528039885N1**

Registration date: **2018-10-30, 1397/08/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-17, 1398/03/27**

Update count: **1**

##### Registration date

2018-10-30, 1397/08/08

##### Registrant information

##### Name

Zahra Akbari chehrehbargh

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4602 3277

##### Email address

z-akbari@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-22, 1397/06/31

##### Expected recruitment end date

2019-09-21, 1398/06/30

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluating the effect of a theory-based educational program on healthy spine-related behavior among female fifth grade elementary school - Randomized Community Trial

**Public title**  
Effectiveness of a theory-based educational program on healthy spine-related behavior

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Female fifth grade elementary school Parents informed consent Student informed consent and voluntary participation Ability to attend training sessions No training in this area

**Exclusion criteria:**

Receive back pain prevention programs before or outside of this study Any reports of pain or disorder in the student's spine by him or her, parents or school officials Report of student's spine unhealthy by physiotherapist

**Age**  
From **11 years** old to **11 years** old

**Gender**  
Female

**Phase**  
N/A

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

**Sample size**  
Target sample size: **102**

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

**Randomization description**  
Because the trial is done on the group and the community ,in the first stage of the sampling process, a list of schools in the study location was prepared which included nine schools in the study location. As the second step, two schools of 9 schools -which is similar In terms of social class and the number of students in the class- are randomly assigned to the intervention and control groups using the simple random sampling technique . As the final step, two classes of fifth grade in each school - 51 students regarding the inclusion and exclusion criteria - are randomly selected to enter the study .

**Blinding (investigator's opinion)**  
Not 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 in Tarbiat Modarres University

**Street address**

Tarbiat Modarres University, Jalal Ahmad Highway,

**City**

Tehran

**Province**

Tehran

**Postal code**

111-14115

**Approval date**

2018-03-17, 1396/12/26

**Ethics committee reference number**

IR.TMU.REC.1396.727

## Health conditions studied

### 1

#### Description of health condition studied

back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

## Primary outcomes

### 1

#### Description

Healthy spine-related behavior

#### Timepoint

before, Immediate, three and six months after the intervention

#### Method of measurement

Using a questionnaire

## Secondary outcomes

### 1

#### Description

Knowledge, Skill, Self-efficacy and Belief.

#### Timepoint

before, Immediate, three and six months after the intervention

#### Method of measurement

Using a performance checklist

## Intervention groups

### 1

#### Description

Intervention group: Includes 51 people who receive 6 sessions of instructional education program based on social cognitive theory. Two strategies( 3 sessions) are used to increase the behavioral capability(knowledge and skills):- Provide required knowledge to conduct recommended behavior using lecture, slide show and brain storm 2- Teaching essential skills for accepting the behavior and keeping it using the direct and vicarious experience and demonstration- re demonstration method In order to increase self-efficacy are used (2 sessions) , methods of mastering the practice, observing others' performance, receiving suggestions from others, and confronting emotions arising from thoughts of change . To enhance the fear-avoidance beliefs (1 sessions) are used the methods of discussing about benefit, brainstorm , and role playing .

#### Category

Prevention

### 2

#### Description

Control group: Includes 51 people (two classes) who are in the same school as the intervention group and do not receive any training.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Elementary School Girls in District 22 of Tehran

##### Full name of responsible person

District Education Management 5

##### Street address

District Education Department,Ferdowsi Avenue,  
Shahid Sattari Highway,

##### City

Tehran

##### Province

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##### Postal code

111-14115

##### Phone

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##### Email

z-akbari@modares.ac.ir

##### Web page address

<https://www.TEHRANEDUS.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Deputy of Tarbiat Modares University

##### Full name of responsible person

Ali Jafarian Dehkordi

##### Street address

Tarbiat Modarres University,Jalal Al-Ahmad Pol Nasr,

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<http://www.modares.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Research Deputy of Tarbiat Modares University

#### 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

Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University ,

##### Full name of responsible person

Sediqh al-Sadat Tawafian

##### Position

Professor of Health Education & Promotion

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Health Promotion

##### Street address

Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University, Jalal Al Ahmad, Paul Nasr

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Sediqh al-Sadat Tawafian  
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Professor of Health Education & promotion  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Department of Health Education, School of Medical Sciences, Tarbiat Modares University  
**Full name of responsible person**  
Zahra Akbari Chehrehbargh  
**Position**  
PhD student  
**Latest degree**

Master  
**Other areas of specialty/work**  
Health Promotion  
**Street address**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document When the data will become available and for how long

31/ 09/2020

### To whom data/document is available

The person who evaluates the outcome - Analytic person  
- Journal Reviewer - executor of plan

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

To evaluate the outcome, data analysis and validation of data - Under the conditions of the triple-blind

### From where data/document is obtainable

executor of plan

### What processes are involved for a request to access data/document

It is requested by e-mail to the project implementer with the address: tavafian@modares.ac.ir

### Comments