

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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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

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District Education Department,Ferdowsi Avenue,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tarbiat Modares University

Full name of responsible person

Ali Jafarian Dehkordi

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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

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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)

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