

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effect of educational intervention on the prevention of Musculoskeletal Pain (MSP) in elementary school students

Protocol summary

Study aim

Design, implementation and evaluation of an interventional program for preventing Musculoskeletal Pain (MSP) among primary school students

Design

The design of the study is in two stages: descriptive-analytical and interventional. The sample size in the first stage is 670 students and their parents, and in the second stage 222 students with high prevalence of musculoskeletal pain eligible to enter the study.

Settings and conduct

Interventions will be taken to prevent and reduce Musculoskeletal pain(MSP) in Hamadan and in the school environment. Participants are randomly divided into two groups of intervention and control, and Interventions will be provided in the intervention group

Participants/Inclusion and exclusion criteria

Inclusion criteria Elementary students (1st to 6th grades), completion of informed consent by parents, Students' tend to participate in the stud; exclusion criteria:Students who have birth defects, Students who are affected by reason of secondary cause such as accidents and else.

Intervention groups

Intervention group: 111 primary school students who will use educational intervention. Control group: 111 primary school students without interventional intervention

Main outcome variables

Musculoskeletal Pain: posture: bag weight: knowledge: perceived sensitivity: perceived severity: perceived benefits: perceived barriers: Reinforcing Factors: Enabling Factors and self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171218037935N1**

Registration date: **2018-02-01, 1396/11/12**

Registration timing: **prospective**

Last update: **2018-06-13, 1397/03/23**

Update count: **1**

Registration date

2018-02-01, 1396/11/12

Registrant information

Name

elham gheysvandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0360

Email address

e.ghiasvand@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of educational intervention on the prevention of Musculoskeletal Pain (MSP) in elementary school students

Public title

Design, implementation and evaluation of an

interventional program for preventing Musculoskeletal Pain (MSP) among primary school students

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Elementary School Students (First to Sixth Grades)
 Complete informed consent by parents
 Students tend to participate in the study
Exclusion criteria:
 Students who have birth defects. Students who are affected by reason of secondary cause such as accidents and else.

Age
From **7 years** old to **13 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **222**

Randomization (investigator's opinion)
Randomized

Randomization description
Multi-stage cluster sampling will be used. The sample classes are selected based on the socioeconomic levels (high, middle and low), gender (girls and boys), and the students' educational base. Then the list of schools and the number of elementary students in the city of Hamedan was taken from the Department of Education. According to the required sample size and according to the number of schools in each district, randomly, according to the random number table, six schools in district one (three girls' schools and three male schools) and seven schools in district two (four schools Girls and 3 male boys) will be selected. Then from each school, all the grades (from the first to sixth) and from each grade of a class will be randomly selected, and from each class the required sample will be selected randomly according to the number of students in each grade on the list of students

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 of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmided st

City

Hamadan

Province

Hamadan

Postal code

6517838736

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR.UMSHA.REC.1396.641

Health conditions studied

1

Description of health condition studied

Musculoskeletal pain

ICD-10 code

M95-M99

ICD-10 code description

Other disorders of the musculoskeletal system and connective tissue

Primary outcomes

1

Description

Musculoskeletal pain

Timepoint

3 and 6 months after the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Posture

Timepoint

Before intervention, 3 and 6 months after the intervention

Method of measurement

Observation based on the standard checklist RULA

2

Description

Bag weight

Timepoint

Before intervention, 3 and 6 months after the intervention

Method of measurement

Measuring the weight of the bag with a scales

3

Description

knowledge

Timepoint

Before intervention, and 6 months after intervention

Method of measurement

Researcher made questionnaire

4

Description

Perceived Susceptibility

Timepoint

Before intervention, and 6 months after intervention

Method of measurement

Researcher made questionnaire

5

Description

Perceived Severity

Timepoint

Before intervention, and 6 months after intervention

Method of measurement

Researcher made questionnaire

6

Description

Perceived Benefits

Timepoint

Before intervention, and 6 months after intervention

Method of measurement

Researcher made questionnaire

7

Description

Perceived Barriers

Timepoint

Before intervention, and 6 months after intervention

Method of measurement

Researcher made questionnaire

8

Description

Reinforcing Factors

Timepoint

Before intervention, and 6 months after intervention

Method of measurement

Researcher made questionnaire

9

Description

Self-efficacy

Timepoint

Before intervention, and 6 months after intervention

Method of measurement

Researcher made questionnaire

10

Description

Enabling Factors

Timepoint

Before intervention, and 6 months after intervention

Method of measurement

Researcher made questionnaire

Intervention groups

1

Description

Intervention group: 3 Educational sessions;educational booklet;educational film;pamphlet and stretching

Category

Behavior

2

Description

Control group:This group does not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Elementary schools in Hamadan

Full name of responsible person

Elham Gheysvandi

Street address

Hamadan University of Medical Sciences, Shahid Fahmided st

City

Hamadan

Province

Hamadan

Postal code

6517838736

Phone

+98 81 3838 0360

Email

elhamgheysvandi65@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Saied Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmided st

City
Hamadan

Province
Hamadan

Postal code
6517838736

Phone
+98 81 3838 0717

Email
s_bashirian@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Elham Gheysvandi

Position
Ph.D Student, Health Education and Health Promotion

Latest degree
Master

Other areas of specialty/work
Health Promotion

Street address
Hamadan University of Medical Sciences, Shahid Fahmided st

City
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Province
Hamadan

Postal code
6517838736

Phone
+98 81 3838 0360

Email
elhamgheysvandi65@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Elham Gheysvandi

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Phone
+98 81 3838 0360

Email
elhamgheysvandi65@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Elham Gheysvandi

Position
PhD student in health education and health promotion

Latest degree
Master

Other areas of specialty/work
Health Promotion

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Hamadan University of Medical Sciences, Shahid Fahmideh st

City
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Province
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Postal code
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Phone
+98 81 3838 0360

Email
elhamgheysvandi65@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to
make this available
Analytic Code

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