Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of mobile-based pain management education on the pain and quality of life of adolescents with chronic pain in Shiraz, 1397

Protocol summary

Study aim

Comparison of the effect of pain management training on face-to-face mobile-based methods on pain and quality of life in adolescents with chronic pain in Shiraz (1397)

Design

A clinical trial with two intervention groups and a control group in which 192 patients will be assigned by random numbers. Blind double-sided.

Settings and conduct

Research Areas: Secondary Schools for Girls and Boys in 4 Education area in Shiraz. Patients will be randomly assigned to one of the three mobile education groups, face-to-face training, and control group. In the mobile-based education group, the software will provide educational materials to the patients. In face-to-face training, students will attend four sessions. There is no training in the control group. The current study is two-way blind. The companies themselves do not know which group will be placed and the researcher It also does not recognize this issue and is used to help researcher.

Participants/Inclusion and exclusion criteria

inter: Age between12 to 18 years Secondary education Teen Access to Mobile Having chronic pain diagnosis based on ICD 11 criteria Exit: Having other chronic non-painful physical illnesses (such as MS, diabetes, cancer, etc.), according to a person According to a person, he has chronic mental illness

Intervention groups

Intervention group 1: Mobile education Intervention group 2: face to face training Control group: Just fill in the questionnaires without any training.

Main outcome variables

Changes in quality of life score after receiving pain management training in both face-to-face and mobile-based methods, changes in pain severity score from receiving pain management training in both face-to-face and mobile-based methods.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180808040744N2**
Registration date: **2019-04-12, 1398/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-12, 1398/01/23**
Update count: **0**

Registration date

2019-04-12, 1398/01/23

Registrant information

Name

Zahra Jahandide

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4254

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jahandide@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mobile-based pain management education on the pain and quality of life of adolescents with chronic pain in Shiraz, 1397

Public title

The effect of mobile-based pain control education on the pain and quality of life of adolescents with chronic pain in Shiraz

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 12 to18 years Secondary education Access to smart phone Having chronic pain diagnosis based on ICD 11 criteria

Exclusion criteria:

According to a person, he has chronic mental illness According to one's own opinion, the presence of other non-painful physical, chronic physical illnesses

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **640**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, secondary schools from the four educational districts of Shiraz city are randomly selected, and from each district two girls and boys' state schools will be selected by systematic random sampling and then from each school in a randomized, three classes (From each base, a class will be selected. After obtaining informed consent, demographic information, pain intensity and quality of life are provided to them, and adolescents who have the criteria for entering the study are selected to enter the study. And these adolescents are randomly assigned to three groups of pain management training in person, mobile education and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

To prevent contamination, all adolescents selected in a school are in the same category. The companies themselves do not know which group will be placed in, and the researcher will also not be aware of this. The purpose of the researcher's assistance is to use it and completely randomly place each sample in one of the intervention groups or control group. This study is a double-blind study.

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

Faculty of Nursing and Midwifery of Hazrat Fatemeh, Namazi Square, Shiraz

City

Shiraz

Province

Fars

Postal code

7193613119

Approval date

2019-01-31, 1397/11/11

Ethics committee reference number

IR.SUMS.REC.1398.091

Health conditions studied

1

Description of health condition studied

chronic pain

ICD-10 code

G89.2

ICD-10 code description

Chronic pain, not elsewhere classified

Primary outcomes

1

Description

Quality of life score in pediatrics quality of life questionnaire

Timepoint

At the beginning of the study, immediately and 3 months after the end of the intervention

Method of measurement

Pediatrics Quality of life questionnaire

2

Description

Pain severity score in pain intensity questionnaire

Timepoint

At the beginning of the study, immediately and 3 months after the end of the intervention

Method of measurement

Numeic rating scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In the mobile-based education group, the software will provide educational materials to the patients. For this purpose, patients in this group receive weekly instructional materials and encourages the use of the contents of the educational content provided in the software and will receive educational pamphlets.
Category
Rehabilitation

2

Description
Intervention group: Second intervention group: In face-to-face training, patients will attend four training sessions. These meetings will be held weekly (weekly by one meeting) and each session will last for 60 to 90 minutes. Face-to-face education will be done in groups of 8 to 10 people.
Category
Rehabilitation

3

Description
Control group: The control group will not receive any intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Secondary schools in Shiraz
Full name of responsible person
jahandide zahra
Street address
Faculty of Nursing and Midwifery of Hazrat Fatemeh, Namazi Square, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
dr. ghasemi , younes
Street address
Faculty of Nursing and Midwifery of Hazrat Fatemeh, Namazi Square, Shiraz
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Email
nurs_midwif@sums.ac.ir
Web page address
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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
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
Jahandide zahra
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

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SHAYGAN MARYAM

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Assistant Professor

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
Psychiatrics

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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