Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of multidisciplinary and multimedia pain management education on the severity of disability in patients with chronic musculoskeletal pain and its mediating factors

Protocol summary

Study aim
Determining the effect of multidisciplinary and multimedia pain management education on the severity of disability inpatients with chronic musculoskeletal pain and its mediating factors

Design
A three-blind randomized clinical trial with a control group, pre-test-post-test design, with parallel groups. using random sequence generation software.

Settings and conduct
Clinics affiliated to Shiraz University of Medical Sciences. Intervention group will receive multidisciplinary and multimedia pain management educations and control group will receive routine educations. patients, evaluator and statistical analyzer will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age>18 years; Chronic musculoskeletal pain based on the specialist diagnosis; willingness to participate in the study; Literacy of reading, writing and speaking in Persian; Having a smart phone with WhatsApp social network; Internet access; Conscious consent. Not including Criteria: having other chronic physical or mental diseases or other chronic pains.

Intervention groups
Patients in the control group receive routine care. In addition to routine care, patients in the intervention group receive multidisciplinary and multimedia training in chronic pain management. 7 educational contents are delivered to patients in 7 sessions. Providing educational materials to the patients of the experimental group will be in the form of sending short videos, short texts, questions and answers and group discussions through the WhatsApp application. Sessions content includes: teaching the difference between acute pain and chronic pain and how psychological factors affect the experience of chronic pain, sports exercises, effective communication and assertiveness skills, stress management, positive thinking and anger coping skills.

Main outcome variables
pain intensity; depression; pain catastrophizing; pain disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201001048893N5**
Registration date: **2022-07-11, 1401/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-11, 1401/04/20**
Update count: **0**

Registration date
2022-07-11, 1401/04/20

Registrant information

Name
Maryam Shaygan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3626 7345

Email address
m2620.shaygan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multidisciplinary and multimedia pain management education on the severity of disability in patients with chronic musculoskeletal pain and its mediating factors

Public title

Effect of multidisciplinary and multimedia pain management education on the disability in patients with chronic musculoskeletal pain

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

-Age>18 years -Chronic musculoskeletal pain based on the specialist diagnosis - Willingness to participate in the study - Literacy of reading, writing and speaking in Persian - Having a smart phone with WhatsApp social network - Internet access - Conscious consent to participate voluntarily in the study

Exclusion criteria:

- Having other chronic physical diseases such as cancer and MS, according to the patient's own report -Suffering from known chronic mental illnesses, according to the patient's own report - Having other chronic pain such as chronic headache

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **132**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, all 132 patients required to participate in the study will be selected with using the available sampling method based on visits to the office of physicians (fellowships in pain, neurology, orthopedics, spine surgery and rehabilitation) located in clinics affiliated to Shiraz University of Medical Sciences and the basis for the inclusion criteria. Then, the selected individuals will be divided into two groups of control and intervention in a completely randomly available way using randomization software. 66 patients are assigned to each study group. To do this, random sequence generation software was used. In this way, a number is assigned to each selected patient from the available sampling stage, then the numbers are entered into the software and finally, by randomly selecting the numbers by the software, it is determined that each patient will be in which group. In order to reduce the possible bias, the randomization process will be performed by the assistant researcher who will not be involved in other stages of the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In order to blind the study and prevent possible bias, divided patients into two groups of intervention and control, interpretation of questionnaires, entering and analyzing data will be done by the assistant researcher and statistician out-of-study. In this way, the general introduction of the studied groups will be made for the participants, but they will be unaware of the allocation of the study groups. The evaluator and statistical analyst will not know which group’s data is interpreted or analyzed by.

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

Zavnd st.

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2022-05-30, 1401/03/09

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1401.034

Health conditions studied

1

Description of health condition studied

chronic musculoskeletal pain

ICD-10 code

G89.29

ICD-10 code description

Other chronic pain

Primary outcomes

1

Description
Pain disability
Timepoint
Before, immediately and 1 month after intervention
Method of measurement
Roland-Morris disability questionnaire (MRMDQ)

Secondary outcomes

1

Description
Pain intensity
Timepoint
Before, immediately and 1 month after intervention
Method of measurement
Numeric rating scale

2

Description
Depression
Timepoint
Before, immediately and 1 month after intervention
Method of measurement
Patient health questionnaire-9

3

Description
Pain catastrophizing
Timepoint
Before, immediately and 1 month after intervention
Method of measurement
Pain catastrophizing questionnaire

Intervention groups

1

Description
Intervention group: Intervention group: Receive seven training sessions per week including training on the difference between acute and chronic pain and how psychological factors affect the experience of chronic pain, exercise training, training of effective communication, assertiveness, stress management, positive thinking and anger coping skills.
Category
Other

2

Description
Control group: Receive routine cares.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Clinic
Full name of responsible person
Dr Mani Ramzi
Street address
Zand st.
City
Shiraz
Province
Fars
Postal code
71348714737
Phone
+98 71 1000 3612
Email
motahari@sums.ac.ir

2

Recruitment center
Name of recruitment center
Imam Reza Clinic
Full name of responsible person
Dr Mani Ramzi
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Zand st.
City
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Email
emamreza@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mahtab Memarpour
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Zand st.
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Postal code
71348-14336
Phone
+98 71 3235 7282
Email

memarpour@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

Hajar Haghshenas

Position

student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School, Namazi Squre, Zand St.

City

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Province

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Postal code

71936-13119

Phone

07136474254-8

Email

haghshenah@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Maryam Shaygan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hajar Haghshenas

Position

student

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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

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

Undecided - It is not yet known if there will be 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

Unidentifiable information of patients related to the effect of educational intervention on the main variables of the study will be published, including: pain intensity,

depression, pain catastrophe and pain-induced disability.

When the data will become available and for how long

1-2 months after the publication of the study results

To whom data/document is available

Researchers working in academic and scientific institutions as well as people working in industry.

Under which criteria data/document could be used

The use of study results by citing the source is not prohibited.

From where data/document is obtainable

Dr Maryam Shaygan 07136474254, Hajar Haghshenas 07136474254.

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

The applicant can access the requested information through the mentioned email address.

Comments