

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of implementing pain self-management program on pain self-efficacy, pain intensity and pain acceptance in the elderly with chronic low back pain referred to clinics affiliated to Babol University of Medical Sciences in 2020

Protocol summary

Pain self-efficacy; Pain intensity; Acceptance of pain

Study aim

The overall aim of the self-management program is to help participants maintain their health and manage their illnesses.

Design

The present study is a randomized, controlled clinical trial. In this study, 100 participants would be randomly assigned to the intervention and control groups by permuted block randomization method.

Settings and conduct

The intervention group is divided into subgroups of 10 people, and they will be informed about the class schedule. Furthermore, the place of training will be in the school of medicine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Age over 60 years 2) The ability to read and write 3) Cognitive health based on the Abbreviated Mental Test (AMT) criteria Exclusion criteria: 1) Any history of back surgery 2) Any mobility disorders and disability

Intervention groups

After randomly dividing the participants into intervention and control groups, the intervention group completes the questionnaires before the intervention starts. Immediately after ending the intervention, the questionnaires will be completed for the second time. Then the intervention group will be given a one-month period to implement the training at home and be contacted via phone for further follow-up. At the end of the one-month period, the questionnaires will be completed for the third time. The control group will receive only routine care. This group will complete the questionnaires in parallel with the intervention group before the start, immediately after the end, and one month after the intervention.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210613051569N1**

Registration date: **2021-07-12, 1400/04/21**

Registration timing: **prospective**

Last update: **2021-07-12, 1400/04/21**

Update count: **0**

Registration date

2021-07-12, 1400/04/21

Registrant information

Name

Zahra Maghdoori

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementing pain self-management program on pain self-efficacy, pain intensity and pain acceptance in the elderly with chronic low back pain referred to clinics affiliated to Babol University of Medical Sciences in 2020

Public title

The effect of implementing pain self-management program on pain self-efficacy, pain intensity and pain acceptance in the elderly with chronic low back pain referred to clinics affiliated to Babol University of Medical Sciences in 2020

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 60 years Capable of reading and writing Have cognitive health based on the Abbreviated Mental Test (AMT) criteria Willing to participate in the study Live in the city of Babol and related countryside areas Back pain for more than 3 months (12 weeks) Capable of exercise according to a physicians opinion

Exclusion criteria:

Any history of back surgery Any mobility disorders and disability Any history of psychiatric disorders Any history of malignancies Any history of participation in similar interventions

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Unit randomization is done by block method with a block size of 4. For each of the 6 possible scenarios for the quadruple block, the numbers are assigned as follows AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5), BAAB (6). The numbers between 1 and 6 are selected, and the treatment allocation list is determined according to each number. In this method, the cans are numbered in a random sequence. Inside the boxes, the desired intervention or a sheet on which the random allocation is written is provided to the executor with the condition that the boxes are completely sealed. Finally, the researcher assigns patients to the control and intervention groups based on patients' admission orders. Tools: Create random sequences of 4 random blocks Concealment to execute random sequences on study participants will be done. How to make blocks:

Randomly select the block and read the letters from right to left. Hiding will be done by the method of cans that are numbered in random sequence. The cans are the same weight and shape and will be prepared by an independent researcher.

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**

Research Ethics Committees of University of Social Welfare and Rehabilitation Sciences

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Evin, Daneshjoo Blvd., Koodkiar impasse

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Approval date

2021-05-12, 1400/02/22

Ethics committee reference number

IR.USWR.REC.1400.026

Health conditions studied**1****Description of health condition studied**

chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

Pain self-efficacy

Timepoint

Before the beginning of the intervention, immediately after the end of the intervention and one month after the end of the intervention.

Method of measurement

Pain self-efficacy questionnaire

2

Description

Pain intensity

Timepoint

Before the beginning of the intervention, immediately after the end of the intervention and one month after the end of the intervention.

Method of measurement

Visual scale of pain

3

Description

Pain acceptance

Timepoint

Before the beginning of the intervention, immediately after the end of the intervention and one month after the end of the intervention.

Method of measurement

Chronic Pain Acceptance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After randomly dividing patients into intervention and control groups, the intervention group first completes the questionnaires and then is scheduled to receive self-management program training. Educational items include: pain control methods that include physical methods, psychological methods and medication methods and exercise. It should be noted that the educational content of the self-management program is in the form of a CD and an educational booklet whose content has been approved by experts, professors of orthopedics and neurosurgeons of Babol University of Medical Sciences, professors of geriatrics and physiotherapy, University of Rehabilitation Sciences and Social Health. Will be prepared and provided to patients in the intervention group. Patients will be given exercises to perform functional exercises and other sports exercises in coordination and under the supervision of a physiotherapist. Immediately after the intervention, the questionnaires will be completed for the second time and then the intervention group will be given a month to implement the training given at home and will be contacted by phone to follow up with patients. At the end of one month, the questionnaires are completed again (for the third time) by the members of the intervention group.

Category

Rehabilitation

2

Description

No intervention was performed on the control group. The

control group will receive only routine care. This group will complete the questionnaires in parallel with the intervention group before, after and one month after the intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahya nejad hospital

Full name of responsible person

Mohammad Saleki

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2

Recruitment center

Name of recruitment center

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

University of social welfare and rehabilitation 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
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Position
Educational affairs expert
Latest degree

Master

Other areas of specialty/work

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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