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

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

Pain self-efficacy; Pain intensity; Acceptance of pain

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

Country

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
Street address
Evin, Daneshjoo Blvd., Koodkiar impasse
City
Tehran
Province
Tehran
Postal code
1985713834
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
Street address
Shahid Yahya Nejad Hospital, Shahid Mostafa Khomeini St., Modares St.
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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3

Recruitment center
Name of recruitment center
Rohani Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Hamid reza Khoramkhorshid
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Second floor - Farabi building - University of Rehabilitation Sciences and
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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
University of social welfare and rehabilitation sciences
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Zahra Maghdoori
Position
Educational affairs expert
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Master
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Person responsible for updating data

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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