Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Investigating the effect of massage on chronic low back pain in the elderly undergoing corrective movements

Protocol summary

Study aim
Effect of massage on chronic nonspecific low back pain in the elderly treated with corrective movements

Design
A randomized controlled clinical trial with parallel groups

Settings and conduct
Massage is done in each session before starting the movements. In this study, 12 sessions are considered every other day for the presence of each patient in the study to perform corrective movements and massage in the two physiotherapy centers of Novin and Bouali.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Elderly patients with nonspecific low back pain ranging in age from 60 to 80 years. • Not having specific chronic low back pain • No chronic diseases such as: respiratory, heart disease, malignant tumors, etc. Exclusion criteria: • Elderly unwillingness to continue working • Creating a specific problem that the patient cannot continue to study. • Missing more than two sessions • People who have had a lower back pain than they did during the corrective and massage exercises.

Intervention groups
Control samples only received corrective movements prescribed by the physiotherapist and the intervention group will receive massage in addition to the corrective exercises by the researcher who trained the massage before study or by the trained assistant.

Main outcome variables
Measurement of LBP and pain assessment in pre and post intervention and one month after intervention

General information

Reason for update
Enter the end time of the trial

Acronym

IRCT registration information
IRCT registration number: **IRCT20200125046246N1**
Registration date: **2020-04-09, 1399/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-20, 1399/05/30**
Update count: **1**

Registration date
2020-04-09, 1399/01/21

Registrant information

Name
leily shokrollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 4244 5375

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leily.shokrollahi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
2019-09-28, 1398/07/06

Actual recruitment end date
2020-04-13, 1399/01/25

Trial completion date
2020-05-29, 1399/03/09

Scientific title
Investigating the effect of massage on chronic low back pain in the elderly undergoing corrective movements

Public title
The effect of massage on the treatment of low back pain before corrective exercises

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Elderly with nonspecific chronic low back pain ranging in age from 60 to 80 years According to VAS measurements, their back pain score is greater than 3.
Exclusion criteria:
Lack of respiratory, heart disease, malignant tumors, tuberculosis, cutaneous lesions and severe skin allergies
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Actual sample size reached: **67**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization:7 blocks with 10 samples(5 samples in each intervention and control group) by www.sealedenvelop.com
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 Kashan University of Medical Sciences
Street address
Shahrdary Ave., NO.15 Khordad Square.,Kashan
City
Kashan
Province
Isfehan
Postal code
8715973474
Approval date
2019-09-02, 1398/06/11
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1398.035

Health conditions studied

1

Description of health condition studied
Non-specific chronic low back pain
ICD-10 code
Dorsalgia
ICD-10 code description
M54

Primary outcomes

1

Description
The effect of massage on Low back pain score in the Quebec and Vas questionnaire
Timepoint
Measurement of LBP before intervention for both sample and control groups and after intervention for both groups
Method of measurement
Quebec Back Pain Disability Scale and VAS(visual Analougue Scale)

Secondary outcomes

1

Description
Low back pain score
Timepoint
Low back pain score 1 month after intervention for both sample and control groups
Method of measurement
Quebec Back Pain Disability Scale and VAS(visual Analougue Scale)

Intervention groups

1

Description
Intervention group: Receiving 20 minutes of massage by the researcher and in each session for the patient before performing the corrective movements prescribed by the physiotherapist
Category
Prevention

2

Description
Control group: Physiotherapist received prescription corrective movements in 12 sessions according to intervention group.
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
BoAli
Full name of responsible person
Hamid Talak Abadi
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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Mohamad Afshar
Position
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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
Yes - There is 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
Title and more details about the data/document
The informed consent form is used to obtain patient consent to participate in the study, and each patient reads it before entering the study, and if so, signed and entered the study.
When the data will become available and for how long
Each patient is studied before entering the study.
To whom data/document is available
Supervisor as well as project visitors who rebel on site to monitor the project.
Under which criteria data/document could be used
To obtain patients' consent to enter the study and in case of unsatisfactory exit from the study.
From where data/document is obtainable
The forms of informed consent are in the hands of the researcher and one is in the hands of the University Research Institute.
What processes are involved for a request to access data/document
After completing the titles, the informed consent form is approved by the supervisor and then by the Vice President of Research and multiplied by the number of samples to be completed by the patients.
Comments