

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)

Phone

+98 31 4244 5375

Email address

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

Isfahan

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 Analogue 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 Analogue 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
Novin
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
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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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