Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effect and durability of corrective exercises and manual therapy focused on the back and hip on disability, function, pressure pain, pain map, health and psychological status of the elderly with chronic back and hip pain

Protocol summary

Study aim

comparison the effect and durability of corrective exercises and manual therapy focused on the back and hip on disability, function, pressure pain, pain mapping, health status and psychological status of the elderly with chronic back and hip pain.

Design

Clinical trial with three training groups, with parallel groups, randomized, single-blind, phase 2 on 75 patients. Blocking and using the site will be used for randomization.

Settings and conduct

This study will be conducted in Iran, Tehran city, Kahrizak Central Hospital. Assessors and data analysts will be blinded to the participants in each group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: men and women 60 to 85 years old with back and leg pain for more than three months and hip rotation strength less than 0.26. Exclusion criteria: hip fracture, repair or replacement. Spine injuries except for osteoarthritis and spinal canal stenosis and severe movement disorder

Intervention groups

Rehabilitation intervention on the pelvis consists of fundamental lumbar spine-guiding techniques with hip-focused rehabilitation procedures. Spine-focused rehabilitation intervention: It is a comprehensive rehabilitation program of the lumbar spine. Rehabilitation intervention focused on the pelvis and spine: exercises from both exercise groups are included in this rehabilitation intervention for the pelvis and spine. For eight weeks, every workout lasts one hour, twice a week.

Main outcome variables

Disability and performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220911055941N1**
Registration date: **2023-07-22, 1402/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-22, 1402/04/31**
Update count: **0**

Registration date

2023-07-22, 1402/04/31

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-18, 1402/04/27

Expected recruitment end date

2023-09-16, 1402/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect and durability of corrective exercises and manual therapy focused on the back and hip on disability, function, pressure pain, pain map, health and psychological status of the elderly with chronic back and hip pain

Public title
Investigation of manual therapy and strengthening of the back and hip joints in elderly people suffering from chronic back and hip pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Low back pain > 3months for at least ½ of the days in the last 6months Moderate low back pain intensity (>3 on a scale of 0-10) Normalized isometric hip internal rotation strength <0.26 Hip Disability and Osteoarthritis Outcome Score >5 on pain relateditems P4-P8

Exclusion criteria:
Previous hip fracture with repair Hip fracture within the last 15 years without repair Known spinal pathology other than spinal stenosis and/or osteoarthritis Severely impaired mobility (ie, requires the use of a wheelchair) Folstein Mini-Mental State Examination Score <24 Severe visual or hearing impairment Red flags such as fever, significant unintentional weight loss > 10 pounds pain that awakens or keeps one awake at night trauma that preceded the onset of pain signs and symptoms of cauda equina Significant pain in the legs greater than the back Acute illness (eg, COVID-19) Receipt of manual or exercise therapy for low back or hip within thelast 3 months

Age
From **60 years** old to **85 years** old

Gender
Both

Phase
2

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Using random permuted blocks randomization (16 blocks with size 8), four treatment combinations are independently allocated to participants by1:1:1 ratio (after the initial assessment). The random sequence list was generated by computer (Pocock SJ. Clinical Trials: A Practical Approach. Wiley; 1983), and using (https://www.randomizer.org) This step will be guaranteed by a blind assessor.

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessor will be blind to group allocation. Participants will not be blind to the study and grouping; however, they were not aware which treatment will be considered as therapeutic (There is an unavoidable risk of bias in this study where the intervention cannot be blinded to interventionists, patients). Before the evaluation, the necessary training will be given to the outcome assessor in relation to how to measure the outcomes in order to prevent any questions and answers between the assessor and the participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
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Approval date
2022-07-20, 1401/04/29

Ethics committee reference number
IR.SSRC.REC.1401.052

Health conditions studied

1

Description of health condition studied
Hip disorders (osteoarthritis) and back pain

ICD-10 code
N8103. M54

ICD-10 code description
Hip ImpairmentsLow back pain

Primary outcomes

1

Description
Disability

Timepoint
Before intervention, after 8 weeks of intervention, and after 6 months of follow-up

Method of measurement

The way of measuring back disability by the Quebec Back Pain Disability Scale and hip disability through the Osteoarthritis Outcome Score questionnaire will be investigated.

2

Description
Function
Timepoint
Before intervention, after 8 weeks of intervention, and after 6 months of follow-up
Method of measurement
The 30-second chair test, the geriatric physical fitness exam, and the walking speed test will be used to assess performance.

Secondary outcomes

1

Description
Pressure pain
Timepoint
Before intervention, after 8 weeks of intervention, and after 6 months of follow-up
Method of measurement
The pressure will be measured using a manual pressure gauge with a stimulation surface of one square centimeter. Then the pain level is done by visual analog scale

2

Description
Pain map
Timepoint
Before intervention, after 8 weeks of intervention, and after 6 months of follow-up
Method of measurement
In this research, the lumbar region will be measured at 27 points by an ergometer

3

Description
Health
Timepoint
Before intervention, after 8 weeks of intervention, and after 6 months of follow-up
Method of measurement
A self-confidence test will be used to assess health status

4

Description
Psychological status
Timepoint
Before intervention, after 8 weeks of intervention, and after 6 months of follow-up
Method of measurement
The psychological variable will be assessed using the health questionnaire, the self-efficacy for exercise, the modified scale of walking efficiency, and the short scale of falling efficiency.

Intervention groups

1

Description
Intervention group: Thigh-focused exercises are divided into two on-site training sessions and two home training sessions for eight weeks, and the participants undergo functional exercises and manual therapy of both thighs for 45 minutes, and home exercises to be performed daily Exercises that do not include hip stretching, hip strengthening, and trunk muscle exercises are performed for 15 minutes.
Category
Rehabilitation

2

Description
Intervention group: The exercises focused on the spine were also divided into two sessions of on-site training and two sessions of training at home for eight weeks, where the on-site training includes functional exercises, manual treatment of the lumbar spine, and a stationary bike without resistance for 45 minutes, and the training At home, back flexibility exercises are done for 15 minutes
Category
Rehabilitation

3

Description
Intervention group: Spinal and hip focused exercises include both previous exercise protocols, two sessions per week for eight weeks of 90-minute on-site training and 30-minute home training.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
kharazmi University
Proportion provided by this source
100
Public or private sector
Private
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Only part of the data, such as the dependent variables and the mean of all samples, can be shared in scientific papers.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Personal information is confidential and general results are available to everyone in the article
Under which criteria data/document could be used
The information is not available to anyone. General results are available to all in the article.
From where data/document is obtainable
Mobina Khabiri 0098 9157709654. Email: mobinakhabiri@khu.ac.ir
What processes are involved for a request to access data/document
6 months after printing the results, the applicant can have the data by sending an email.
Comments