Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of balance practice and stability exercises on kinetic factors of balance, pain intensity and disability in patients with non-specific chronic low back pain

Protocol summary

Study aim

Comparison of the effect of balance practice and stability exercises on kinetic factors of balance, pain intensity and disability in patients with non-specific chronic low back pain

Design

Clinical trial with 3 parallel groups, single-blind, randomized, phase 3 on 60 patients. use roll ofdie method for randomization.

Settings and conduct

People are randomly divided into 3 groups (1- stability exercises, 2- balance exercises, 3- control).At the beginning and end of the study We measure the following variables , to check the balance (displacement of the center of pressure and the time to reach stability by force plate - time in the Stork test - distance in Star test), to check pain (score of vas) to check disabilityare (score of oswestery), finally the comparison between groups and within groups ،will be made. Studies are conducted at Semnan Neuromuscular Rehabilitation Research Center

Participants/Inclusion and exclusion criteria

inclution criteria :Patients who have been diagnosed as non-specific back pain with or without referring pain to the leg that lasts at least three months. The pain intensity should be at least 3 according to the pain questionnaire, their age should be between 20 and 60 years. Exclution criteria:- pregnancy-History of back surgery- Cancer- Vestibular problems- Neurological problems - pathology in the spin- Nerve root disorders- Vertebral fracture- ankle or knee Arthritis Congenital foot and ankle deformities - Ankle sprains, knee and leg ligament injuries

Intervention groups

Group 1: clinical exercises (6 weeks-3 times a week) Group 2:stabilityexercises (6 weeks-3 times a week)Group 3: no exercise

Main outcome variables

Fluctuations of the center of pressure - time to stability - time in the Stork test - distance in Star test - the score of VAS - the score of oswestry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230612058468N1**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-19, 1402/05/28**
Update count: **0**

Registration date

2023-08-19, 1402/05/28

Registrant information

Name

susan shahhosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8839 2182

Email address

shahhosseiniali@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2023-09-17, 1402/06/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of balance practice and stability exercises on kinetic factors of balance, pain intensity and disability in patients with non-specific chronic low back pain

Public title

Comparison of the effect of balance practice and stability exercises on kinetic factors of balance, pain intensity and disability in patients with non-specific chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have been diagnosed as non-specific back pain with or without referring pain to the leg that lasts at least three months. . The pain intensity should be at least 3 according to the pain questionnaire their age should be between 20 and 60 years

Exclusion criteria:

People who are pregnant . People who have a history of back surgery. People who have cancer. People who have vestibular system problems. People who have neurological problems. People who have pathology in the spinal cord. People who have nerve root disorders . People who have fractured vertebra. People who have arthritis in the ankle or knee. People who have congenital deformities of the foot and wrist such as genovalgum genovarum genu recuratum. People who have ankle sprains And those who have knee and leg ligament injuries.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization Individual randomization unit Dice randomization tool How to make a random sequence: In this study, there are three groups. Numbers 1-2 are used for the first group, numbers 3-4 are used for the second group, and numbers 5-6 are used for the third group. Concealment using non-transparent sealed envelopes: based on the sample size, a number of envelopes are prepared and each of the random sequences created is recorded on the card, and the card is placed inside the envelope and the lid of the envelopes is glued and It is placed in the box, according to the order of arrival of the participants, one of the envelopes is opened and the participating group is revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient does not know which of the research groups he/she is placed in, so our study is single blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of semnan university of medical sciences

Street address

No29, east 4th ave, seyed jamaledin asad abadi , tehran town

City

Tehran

Province

Tehran

Postal code

1431684316

Approval date

2023-06-25, 1402/04/04

Ethics committee reference number

IR.SEMUMS.REC.1402.039

Health conditions studied

1

Description of health condition studied

non-specific low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

evaluation of static balance by measuring time during standing stork test - evaluation of static balance by measuring the speed of changes in the center of pressure -evaluation of static balance by measuring the displacement of changes in the center of pressure .

Timepoint

Before the intervention and 1 week after the end of the intervention

Method of measurement
Static balance checking tool: Force .plate. Static balance checking tool: standing Stork test.

2

Description
evaluation of dynamic balance by measuring the covered distance during Star excursion balance test - evaluation of dynamic balance by measuring time to stability .
Timepoint
Before the intervention and 1 week after the end of the intervention
Method of measurement
Dynamic balance checking tool: Force plate. Dynamic balance checking tool: Star excursion balance Test.

3

Description
Examining the level of pain through the visual analogue scale's scores.
Timepoint
Before the intervention and 1 week after the end of the intervention
Method of measurement
Pain assessment tool: Visual analogue Scale.

4

Description
- Examining the level of disability through the oswestry disability questionnaire's scores.
Timepoint
Before the intervention and 1 week after the end of the intervention
Method of measurement
- Disability assessment tool: oswestry Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1 is a group that receives balance exercises that include eleven exercises for 60 minutes (15 minutes of warming up - 15 minutes of cooling down - 30 minutes of main exercise), .three times a week for 6 weeks .
Category
Rehabilitation

2

Description
Control group: They do not receive any treatment, only the studied variables are measured for them once at the beginning of the study and once at the end of the study and compared with the other groups.
Category
N/A

3

Description
Intervention group: is a group that receives stability exercises that include eight exercises for 60 minutes (15 minutes of warm-up - 15 minutes of cooling down - 30 minutes of main exercise), three times a week for 6 weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuromuscular Rehabilitation Research Center of Semnan
Full name of responsible person
Banafsheh Mansori
Street address
Neuromuscular Rehabilitation Research Center of Semnan,Tabatabayi Clinic,next to Nemat Ice Cream ,Ghods Blvd,Semnan Town
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Semnan
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9837535196
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+98 23 3365 4180
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nmrrc@semums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
kamran Qods
Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran.
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Semnan
Postal code
35147-99442
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Fax
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Email
info@semums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Susan Shahhosseini
Position
Student-master degree
Latest degree
Bachelor
Other areas of specialty/work
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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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Student-master degree
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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No.29 4th street chehelsotoon ave . jahad square .teheran town
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Province
Tehran
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1431684316
Phone
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Fax
Email
shahhosseiniali@ymail.com

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
Not applicable
Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after de-identifying individuals, including: background information. The amount of changes in the center of pressure - the amount of changes in the time to reach stability - the amount of changes in the distance traveled in the Star test - the amount of changes in the time in the Stork test - the amount of changes in the score of the visual scale analogue - the amount of changes in the score of the oswestry questionnaire

When the data will become available and for how long

One month after publication

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions, and people working in industry can apply to receive them

Under which criteria data/document could be used

Students who are doing a research and people working in the field of treatment

From where data/document is obtainable

Sosan Shah Hosseini- Phone: 09121243936 Email: shahhosseinisousan@gmai.com

What processes are involved for a request to access data/document

The request and its reason should be registered via e-mail and the data will be sent within five working days

Comments