

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

A comparison study of the effect of routine physical therapy and routine physical therapy plus an exercise on the Wobble board on the pain, disability index and Paravertebral muscle endurance in women with chronic nonspecific low back pain

Protocol summary

Study aim

Study the effect of routine physical therapy and routine physical therapy plus an exercise on the wobble board on the pain, disability index and paravertebral muscles endurance time in women with chronic nonspecific low back pain

Design

clinical trial with control group , parallel group , randomized , phase 2 on 40 patient , using random number generator from Stat Trek website.

Settings and conduct

40 women with chronic nonspecific low back pain aged between 30-50 year old will inter in this study after checking the inclusion and exclusion criteria by a physician and by the researcher then they will complete a consent form so they will be divided into control or intervention group using randomized number table , patients in the first group will receive 8 session routine physical therapy and patients in the second group will receive 8 session routine physical therapy plus a wobble board exercise. This physical therapy interventions will be done in a private physical therapy clinic in Najafabad of Isfahan. Pain number, disability percentage and paravertebral muscle endurance time will be recorded before treatment , after treatment and 4 week after treatment.

Participants/Inclusion and exclusion criteria

- 30-50 years old females - Nonspecific low back pain more than 12 weeks - No serious pathologies such as vertebral fracture - No special causes such as spinal canal stenosis or large disc herniation

Intervention groups

Control group will receive routine physical therapy including TENS, hot pack and a series of stretching, strengthening and motor control exercise. Interventional group will receive routine physical therapy including

TENS , hot pack a series of stretching, strengthening and motor control exercise plus an exercise on the wobble board.

Main outcome variables

Pain. Disability percentage. Paravertebral muscle endurance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201108049302N1**

Registration date: **2020-11-28, 1399/09/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-28, 1399/09/08**

Update count: **0**

Registration date

2020-11-28, 1399/09/08

Registrant information

Name

Fateme Taghijarah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-01, 1399/08/11
Expected recruitment end date
2021-11-01, 1400/08/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

A comparison study of the effect of routine physical therapy and routine physical therapy plus an exercise on the Wobble board on the pain, disability index and Paravertebral muscle endurance in women with chronic nonspecific low back pain

Public title

A comparison study of the effect of routine physical therapy and routine physical therapy plus an exercise on the Wobble board on the pain, disability index and Paravertebral muscle endurance in women with chronic nonspecific low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

30_50 years old females feeling low back pain more than 12 weeks Ability of writing and reading Visual analogue scale : 4 to 8 in last week

Exclusion criteria:

Lumbar spine surgery Spinal canal stenosis Severe scoliosis(cob. angle >40) spondylolisthesis (>grade |) Ankylosing spondylitis Large disc herniation (extrusion and sequestration) Vertebral fracture Balance disorders Radiculopathy BMI>30 Using analgesics or drugs that disturb balance

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study simple randomization is used. For generating random sequence, table of random numbers generated by stat Trek website is used, there are 40 numbers in this table which are coding from 01 to 40. After writing the numbers by the researcher, she will read the randomized number from left to right, so the first 20 codes will be in the control group and the second 20 codes will be in the intervention group. Based on the time of reference , the participants are coding from 01, 02,...40 till the sample size being completed.

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 Isfahan medical university of science

Street address

No.190 , East Golbahar Ave., South 15 Khordad Ave., Najafabad.

City

Najafabad

Province

Isfahan

Postal code

8518668551

Approval date

2020-03-07, 1398/12/17

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.464

Health conditions studied

1

Description of health condition studied

Chronic nonspecific low back pain

ICD-10 code

G89.29

ICD-10 code description

Other chronic pain

Primary outcomes

1

Description

Pain number

Timepoint

before intervention, after intervention and 4 weeks after intervention

Method of measurement

Visual Analogue Scale

2

Description

Disability index percentage

Timepoint

before intervention, after intervention and 4 weeks after

intervention

Method of measurement

Oswestry Disability Index

3

Description

paravertebral muscle endurance time

Timepoint

before intervention, after intervention and 4 weeks after intervention

Method of measurement

Sorensen test

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 20 patient will be interred in this group and they will receive 8 session routine physical therapy including 20 minuet TENS,10 minute hot pack and a series of exercise including knee to chest and wall stretch as stretching exercises, posterior pelvic tilt and bridge as strengthening exercises and dead-bug and bird-dog as motor control exercises that they will be repeated every day in 3 set of 10 times.

Category

Rehabilitation

2

Description

Intervention group: 20 patient will be interred in this group and they will receive 8 session routine physical therapy including 20 minuet TENS,10 minute hot pack and a series of exercise including knee to chest and wall stretch as stretching exercises, posterior pelvic tilt and bridge as strengthening exercises and dead-bug and bird-dog as motor control exercises that they will be repeated every day in 3 set of 10 times. In addition, in this group exercise on the wobble board which is a sitting balance exercise will be done in the clinic for 3 minutes per session in first week progress to 9 minutes per session in 3rd week .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn Sina physical therapy clinic

Full name of responsible person

Navid Taheri

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No.190 , East Golbahar Ave., South 15 Khordad Ave., Najafababd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

فاطمه جراح

Position

student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measures only

When the data will become available and for how long

starting 1 year after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

No limitation

From where data/document is obtainable

fsayban@gmail.com n_taheri@rehab.mui.ac.ir

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

studying the request and the condition

Comments