Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of Feldnkaris method and core stability exercise on pain and disability of patients with Non specific Low Back Pain

Protocol summary

Study aim

Investigating the efficacy of Core Stability Exercise therapy and Feldenkaris Method in Patients with CNSLBP

Design

This study was designed as a double-blind randomized controlled trial. 60 patients with diagnosis of CLBP for at least 3 months were randomly allocated to the (FG) or (CSEG) (mean age 38.8 years). Pain was assessed using the McGill Pain Questionnaire (MPQ), disability was evaluated with the Oswestry Disability Index (ODI), quality of life was measured with the WHOQOL-BREF, and mind–body interactions were studied by the Multidimensional Assessment of Interoceptive Awareness Questionnaire (MAIA). Abdominal transverse muscle (TrA) diameter at rest and draw-in maneuver were assessed by ultrasonography before and after the intervention. Data were collected at baseline, at the end of treatment.

Settings and conduct

The study was performed at the sport medicine center of MAZUMS. The study was a double-blind, parallel, randomized clinical trial. Both participants and evaluators were unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • History of low back pain: at least for three months • Clinical Diagnosis of nonspecific low back pain: • Pain severity in pain assessment questionnaire: between 3 and 6 out of 10 • Patients of 18 to 60 years old Exclusion criteria: Patients under 18 or above 68 yrs Diagnosis of acute or specific low back pain

Intervention groups

The study constituted of two interventing exercise therapy, the gropus of core stability exercise and and Feldenkaris, performed on patients with chronic non-specific low back pain.

Main outcome variables

This study investigates the impacts of the two types of exercise therapy on pain, disability, body awareness, quality of life, and transverse abdominal muscle diameter in patients with CNSLBP.

General information

Reason for update

Acronym

NSLBP

IRCT registration information

IRCT registration number: **IRCT20200117046160N1**
Registration date: **2020-03-08, 1398/12/18**
Registration timing: **retrospective**

Last update: **2020-03-08, 1398/12/18**
Update count: **0**

Registration date

2020-03-08, 1398/12/18

Registrant information

Name

Hanieh Adib

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-19, 1397/12/28

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date

2019-04-04, 1398/01/15

Actual recruitment end date

2019-11-19, 1398/08/28

Trial completion date
2019-11-21, 1398/08/30

Scientific title
Comparing the effect of Feldnkaris method and core stability exercise on pain and disability of patients with Non specific Low Back Pain

Public title
Exercises impacts on patients with chronic low back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clinical diagnosis of CNSLBP (Chronic non specific low back pain) Patients age:18-68

Exclusion criteria:
Patients with diagnosis of specific or acute low back pain Patients under 18 or above 68 yrs

Age
From **18 years** old to **68 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **66**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Systematic random allocation of patients will be done using "Random allocation Generation web site"

Blinding (investigator's opinion)
Double blinded

Blinding description
The survey was double blinded. Both participants and valuator were not aware of the allocation method of study groups. although participants were unaware of two different exercise groups of study, they knew about their own group of exercise therapy group. the final valuator was not informed about the course of exercise therapy in each particiapnt

Placebo
Not used

Assignment
Parallel

Other design features
Patients have inclusion criteria were randomly divided into two groups: Feldenkrais and Core stability exercise therapy. They received exercise therapy for 5 weeks. At the beginning and the end of the study same measurements were evaluated for both groups. for both groups were evaluated.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences, Imam Hospital

Street address
Imam Hospital, Amir Mazandarani St, Imam Sq, Sari

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Sari

Province
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Postal code
4816633131

Approval date
2019-03-19, 1397/12/28

Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1397.108

Health conditions studied

1

Description of health condition studied
Chronic low back pain

ICD-10 code
M54.5

ICD-10 code description
Chronic low back pain

Primary outcomes

1

Description
Low back pain score in McGill questionnaire

Timepoint
Before and after intervention

Method of measurement
McGill questionnaire

Secondary outcomes

1

Description
Low Back Pain Disability Score in Oswestry questionnaire

Timepoint
Before and after intervention

Method of measurement
Oswestry questionnaire

Intervention groups

1

Description
Core stability exercises group were performed for 5 weeks. Patients were trained every two weeks in the clinic and were required to perform the exercise three times a day, ten times each, with a 10-second isometric contraction. Patients were followed up by a researcher over the phone for two weeks. If the pain rises to above three score, exercises were stopped or they would be taken to the previous stage, if physician agreed. The exercises were progressive in two models on the ground and sport ball.

Category
Treatment - Other

2

Description
The Feldnkaris is a body-mind exercise method, included from 5 weeks of treatment protocol based exercises. All the exercises were taught under the supervision of the researcher, in groups of 10, twice a week and 1 to 2 hours each session. the exercises consisted of: breathing techniques, cervical, thoracic, lumbar spine mobilization, shoulder and hip joint range of motion, concentration and body awareness and relaxation exercises, correction of posture in lying, sitting, standing, and stretching exercises and improved flexibility and reduce motor resistance were in the aforementioned joints and muscles and spine.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Sports Medicine Center of Imam Khomeini Hospital

Full name of responsible person
Hanieh Adib

Street address
No6, 3th Ave, Razi St,Sport center of Mostafavian Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
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Grant name
1290004

Grant code / Reference number
1602001000

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Sari 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
Mazandaran University of Medical Sciences

Full name of responsible person
Hanieh Adib

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

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Person responsible for scientific inquiries

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Assistant of Sport Medicine

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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

All recorded data will be reachable for clinical and academic researchers for one year after the article publications as non-identifiable files.

When the data will become available and for how long

Accessibility to the data will be possible 6 months after the article publication for the applicants, for one year.

To whom data/document is available

Clinical and academic researchers

Under which criteria data/document could be used

Using the documents only under the permission of the head researcher, providing participation in the ongoing research.

From where data/document is obtainable

1.Hanieh Adib by Email Address: Hanieadib@gmail.com
2. Hanieh Ahmadi by Email Address: Hani.medico@gmail.com

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

The request should be emailed to corresponding author, identifiable ID card and reason of request must be noted . After confirmation of their documents, data would be emailed within a week.

Comments