Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

"Comparative study of the effect of 12 weeks of monitored stability exercises combined with routine physiotherapy treatment with routine physiotherapy treatment alone on abdominal muscle size in patients with chronic non-specific back pain using ultrasonography"

Protocol summary

Study aim
Comparison of the effect of 12 weeks of supervised stability exercises with routine physiotherapy with routine physiotherapy treatment only on the size of abdominal muscles in patients with chronic non-specific back pain using ultrasonography

Design
Patients in the experimental group (n=30) received routine physiotherapy and supervised stabilization exercise,

Settings and conduct
Patients with chronic low back pain referred to the physiotherapy centers of Golestan University of Medical Sciences

Participants/Inclusion and exclusion criteria
The inclusion criteria were: subjects experienced chronic LBP with duration of more than three months aged between 18 to 55 years old, and were in a good general health and willing to take part in the study. The exclusion criteria any underlying disease such as malignancy, obvious disc herniation, osteoporosis, viscerogenic causes, infection or systemic disease of the musculoskeletal system, previous spinal manipulation therapy or ultrasound treatment; neurologic disease or sciatic nerve root compression, radicular pain, sensory disturbances, loss of strength and reflexes; previous back surgery; evidence of previous vertebral fractures or major structural abnormality; tumor of the spine; pregnancy; devices such as heart pacemakers that may be affected by electrical stimulation or receiving any physiotherapy treatments for their back pain within last three months.

Intervention groups
The aim of this group of exercises is to improve the function of the deep muscles of the spine, including the transverse abdomen, multifidus, diaphragm and pelvic floor muscles, as well as to control more cross-sectional movements of the vertebra.

Main outcome variables
Abdominal muscles (transversus abdominals, internal oblique and external oblique) thickness was measured before and immediately after intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220509054787N1**
Registration date: **2022-05-22, 1401/03/01**
Registration timing: **prospective**

Last update: **2022-05-22, 1401/03/01**
Update count: **0**

Registration date
2022-05-22, 1401/03/01

Registrant information

Name
javad khademi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"Comparative study of the effect of 12 weeks of monitored stability exercises combined with routine physiotherapy treatment with routine physiotherapy treatment alone on abdominal muscle size in patients with chronic non-specific back pain using ultrasonography"

Public title

The effects of 12 weeks supervised stabilization exercise on abdominal muscle thickness in patients with chronic low back pain: A single blind randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic low back pain of both sexes (between 20 and 55 years) Patients with low back pain for which no specific cause has been reported by the treating physician in clinical examinations and radiography Low back pain lasts for 12 weeks or more 4- Enjoying public health

Exclusion criteria:

Existence of numbness and decrease in muscle strength or possibly lack of urine control, which indicates the presence of horsetail syndrome History of spine surgery Pain in the spine area with Wellers fever, morning dryness, etc., which indicate the presence of infectious sponidopathy syndrome, malignancy, or inflammatory diseases, sponidylosis Presence of pressure fracture due to osteoporosis, spinal stenosis and spondylolysis or spondylolistosis, presence of fracture in the spine which indicates the presence of osteoporosis or other diseases . Pregnancy

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the restricted randomization method randomization (block type randomization) block randomization (we will use. blocking usually in order Balance the number of samples assigned to each group To be used in the study. This feature helps researchers to Items that require intermediate analyzes during the sampling process The number of samples assigned to each of the case groups Study is equal. The size of all the blocks is equal and we are in this Two-group trial of 6 blocks (including 3 participants) We will have an intervention group and 3 participants in the control group. Randomization tools are also used in sequence generation software Random allocation software is used Random sequence generation software in addition to simple randomization capable To generate random sequences by block generation method. For hiding Allocation concealment (Allocation concealment) We use the method used to execute the sequence Random refers to study participants, in a way That before the individual is assigned, the assigned group is not specified. With From opaque envelopes sealed in random sequence در که (Sequentially numbered, sealed, opaque envelopes) This method uses each of the random sequences created on a card It is registered and the cards are placed in the letter envelopes in order To be. In order to maintain a random sequence, also on the outer surface of the envelope The numbering is done in the same way. Finally the envelope lid The letters are pasted and placed in a box, respectively. At Time to start registration of participants, based on the order of entry of the company Eligible applicants to open one of the envelopes in order And the assigned group of the participant will be revealed

Blinding (investigator's opinion)

Single blinded

Blinding description

"Ultrasound evaluation is performed by a radiologist with 15 years of experience and a faculty member who had no knowledge of how to group patients."

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of golestan University of Medical Sciences

Street address

Faculty of Health, Golestan University of Medical Sciences, Gorgan, Iran »

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gorgan

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4934174515

Approval date
2022-04-17, 1401/01/28
Ethics committee reference number
IR.GOUMS.REC.1401.028

Health conditions studied

1

Description of health condition studied
LOW BACK PAIN
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Abdominal muscle thickness (TrA; IO; EO)
Timepoint
Before and after the intervention
Method of measurement
ultrasongraphy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Lumbar stabilization exercises consisted of 14 exercises that are performed with the aim of strengthening the deep lumbar stabilizing muscles (TrA, EO and IO). All 14 stabilization exercises will be performed once, in a row and in the same order. Before each exercise, the physiotherapist provides detailed oral explanations and visual instructions (images) about the start and end position. The training program will be applied to the knees in a four-point position using abdominal fire. Patients were asked to perform 10 exercise programs per session, three times a day (one in the clinic and two at home) for three sessions per week. In order for the number and frequency to be the same, each exercise will be performed ten times in the first session, and all patients were asked to refrain from strenuous physical activity during the treatment period.
Category
Rehabilitation

2

Description
Control group: Patients in the experimental group (n = 30) will receive routine physiotherapy and supervised stabilization exercises performed by an experienced independent physiotherapist.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
University Physiotherapy Centers
Full name of responsible person
Javad Khademi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology
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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
Deputy of Research and Technology
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

Gorgan University of Medical Sciences

Full name of responsible person

Javad Khademi

Position

Associated Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Its release schedule is not yet known.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available