

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effects of core stability versus general trunk exercises on the kinematics and joint coordination of the lumbar spine and hip during sit-to-stand and stand-to-sit in patients with chronic non-specific low back pain: A randomised double-blind clinical trial

Protocol summary

Summary

Following the recruitment process, 30 patients with chronic non-specific low back pain and 15 demographically matched asymptomatic participants will be included in this randomized double-blind clinical trial. The kinematics and joint coordination of the lumbar spine and hips will be evaluated during the sit-to-stand (STS) and its reverse using a motion capture system (Qualisys). The participants will be asked to sit in their usual posture on an adjustable stool. Reflective markers will be placed on the T12, L3, S2, anterior superior iliac spines, posterior superior iliac spines, greater trochanters, and lateral femoral epicondyles on the right and left legs. The participants will be instructed to stand up at their natural speed, remain a comfortable and erect posture for 3 seconds; and then, sit down on the chair at their own comfortable speed. maximum flexion and extension range of motion, the timing of their occurrence, angular velocity of the lumbar spine, right/ left hips, the ratios of the total movements of the lumbar spine to those of the right/ left hips, upper and lower lumbar maximum flexion and extension, and their angular velocity, and relative phase angles will be computed. Afterward, the chronic non-specific low back pain participants will be allocated at random to receive one of 2 interventions: core stability exercises or general exercises. Treatment sessions will be held 3 times per week for 16 sessions. After the intervention period, all chronic non-specific low back pain participants will be assessed again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080812953N2**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

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Name of organization / entity

Rehabilitation Research Center, Department of Physiotherapy

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences and Health Services

Expected recruitment start date

2016-09-30, 1395/07/09

Expected recruitment end date

2017-10-20, 1396/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of core stability versus general trunk exercises on the kinematics and joint coordination of the lumbar spine and hip during sit-to-stand and stand-to-sit in patients with chronic non-specific low back pain: A randomised double-blind clinical trial	
Public title	The effect of exercise on lumbar and hip joints coordination in patients with chronic low back pain
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: 1- Chronic non-specific low back pain (low back pain persisting for more than 3 months in the absence of an underlying pathology); 2- Age between 18 and 40 years; 3- Pain between 3 and 6 on a 0- to 10-point pain visual analogue scale (VAS), where 0 represents no pain and 10 is the worse pain imaginable; 4- No contraindication for exercise; 5- No obvious deformity of the spine, pelvis, and lower extremities; 6- No autoimmune diseases (e.g. rheumatoid arthritis); and 7- Pregnancy. Exclusion criteria: 1- Absence for 3 consecutive, or a total of 5 sessions; and 2- Participant's request for termination of participation
Age	From 18 years old to 40 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 15
Randomization (investigator's opinion)	Randomized
Randomization description	
Blinding (investigator's opinion)	Double blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Research Ethics Committee at Iran University of Medical Sciences and Health services
Street address	Iran University Campus, Hemmat freeway, next to Milad tower
City	

Tehran	
Postal code	
Approval date	2016-07-27, 1395/05/06
Ethics committee reference number	IR.IUMS.REC 1395.9211342207
Health conditions studied	
<u>1</u>	
Description of health condition studied	Chronic non-specific low back pain
ICD-10 code	M54.5
ICD-10 code description	Loin pain, Low back strain, Lumbago NOS
Primary outcomes	
<u>1</u>	
Description	Range of motion
Timepoint	before and after 16 treatment sessions
Method of measurement	Motion capture system and conducting analysis
<u>2</u>	
Description	Angular velocity
Timepoint	before and after 16 treatment sessions
Method of measurement	Motion capture system and conducting analysis
<u>3</u>	
Description	Phase angle
Timepoint	before and after 16 treatment sessions
Method of measurement	Motion capture system and conducting analysis
<u>4</u>	
Description	Lumbar spine to right/left hip ratio
Timepoint	before and after 16 treatment sessions
Method of measurement	Motion capture system and conducting analysis
Secondary outcomes	
<u>1</u>	
Description	Pain

Timepoint

before and after 16 treatment sessions

Method of measurement

Visual analogue scale

2

Description

Disability

Timepoint

before and after 16 treatment sessions

Method of measurement

Roland-Morris Disability and Oswestry Low Back Disability Questionnaires

Intervention groups

1

Description

Patients with chronic non-specific low back pain will be divided into 2 groups: one group will receive core stability exercises and the other group will receive general trunk exercises: The first intervention group: core stability exercises: Core stability exercises or motor control exercises are designed to re-educate the co-activation pattern of abdominals, paraspinals, gluteals, pelvic floor muscles, and diaphragm. The biological rationale for core stability exercises is primarily based on the idea that the stability and control of the spine are altered in patients with low back pain. A core stability exercise programme begins with recognition of the natural position of the spine (mid-range between lumbar flexion and extension range of motion), considered to be the position of balance for improving performance in various sports. Initial low-level sustained isometric contraction of trunk stabilising muscles and their progressive integration into functional tasks is the requirement of core stability exercises. To ensure correct activation of the transversus abdominis muscle, it will be emphasized to chronic non-specific low back pain participants that the lower part of the anterior abdominal wall below the umbilical level is needed to be "drawn in" during contraction of this muscle. Furthermore, bulging action of the multifidus muscle is needed to be felt under the physical therapist's fingers when they are placed on either side of the spinous processes of the L4 and L5 lumbar vertebral levels, directly over the belly of the muscle. The second intervention group: general exercises: General exercises are an umbrella term that can involve strengthening exercises for all the main muscle groups with or without the addition of weights. In addition, this umbrella term can consist of exercises improving coordination, stretching, and aerobic fitness training. In our study, exercises activating the extensor (paraspinals) and flexor (abdominals) muscle groups will be performed. They will be conducted in a lying position initiating with simple movements and progressing to more difficult exercises (eg, on a gym ball). The same frequency (3 times per week [Saturday, Monday, Wednesday]) and duration (5 weeks [16 sessions]) will be provided for both groups. In each session, participants

will be instructed to perform their exercises as many times as they can with rest periods in the same session. The holding time and then the number of contractions will be progressively increased up to 10 contraction repetitions × 10-second duration each. Finally, exercises set will be increased from 3 to 5 sets. Chronic non-specific low back pain participants in the core stability exercise group will be asked to activate their muscles at about 30% of their maximum activation level during the performance of stabilization exercises and chronic non-specific low back pain participants in the general exercise group will be asked to activate their muscles at about 60% to 70% during the performance of general exercises. In this study Shamsi et al. (2015) exercise programme will be used. All these exercises will be performed under supervision of an experienced physical therapist. Moreover, to control confounding variables and creating a standard and homogeneous condition for all chronic non-specific low back pain participants, they will be instructed not to perform exercises at home between the treatment sessions

Category

Rehabilitation

2

Description

In this study, the control group will include demographically matched healthy participants and the kinematic variables of chronic non-specific low back pain participants will be compared with healthy participants before and after intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy clinic located at the school of rehabilitation sciences, Iran University of Medical Sc

Full name of responsible person

Mohammad reza Pourahmadi

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Madadkaran All., Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research in school of rehabilitation sciences of Iran University of Medical Sciences

Full name of responsible person

Azam Bayat

Street address

Madadkaran All., Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran, Iran.

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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 in school of rehabilitation sciences of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences and Health Services

Full name of responsible person

Mohammad Reza Pourahmadi

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MSc, PT, Currently PhD Candidate in Physical Therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty