

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Mohammadreza Pourahmadi

###### Name of organization / entity

Rehabilitation Research Center, Department of Physiotherapy

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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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 worst 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

#### 1

##### 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

#### 1

##### 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

#### 1

##### Description

Range of motion

##### Timepoint

before and after 16 treatment sessions

##### Method of measurement

Motion capture system and conducting analysis

#### 2

##### Description

Angular velocity

##### Timepoint

before and after 16 treatment sessions

##### Method of measurement

Motion capture system and conducting analysis

#### 3

##### Description

Phase angle

##### Timepoint

before and after 16 treatment sessions

##### Method of measurement

Motion capture system and conducting analysis

#### 4

##### 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

#### 1

##### 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

#### **Street address**

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

#### **City**

Tehran

## **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.

**City**

Tehran

**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

**Position**

MSc, PT, Currently PhD Candidate in Physical Therapy

**Other areas of specialty/work**

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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*