# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

# Randomised Clinical Trial of The Effect of Tele-Rehabilitation Technology on Pain, Functional Disability, Clinical Index of Balance and Quality of Life in Patients with Chronic Non-Specific Low Back Pain

## Protocol summary


**Summary**

The aim of this study is to determine the effect of tele-rehabilitation on pain, functional disability, clinical index of balance and quality of life in patients with chronic non-specific low back pain. The study population consists of all the subjects with non- specific low back pain. The inclusion criteria include subjects have experienced low back pain within the past three months without any pathologic cause, Age between 18-55 years, having smart phone or tablet and the exclusion criteria include subjects with past history of spine and herniation disk surgery. The study sample (n=20) will be selected purposively and voluntarily and allocated into two groups including intervention and control groups by block randomization method. The baseline measurements include the pain intensity and clinical indexes of balance, functional disability and quality of life. The exercise program will be sent to the intervention group through the application designed for this study during four weeks; however, the control group won't participate in any specific treatment plan and will receive only their usual care. Post-test will be performed within one week after the intervention period. Data will be collected using Oswestry disability index questionnaire, WHOQOL-100 questionnaire, balance test and NRS Pain. Expected outcome is the difference in the pain intensity, functional disability, clinical index of balance and quality of life of patients with chronic non-specific low back pain in intervention group to compare with control group.


## General information

**Acronym**

-

**IRCT registration information**

IRCT registration number: **IRCT2016070528809N1**
Registration date: **2016-12-30, 1395/10/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-12-30, 1395/10/10

**Registrant information**


**Name**

Fatemeh Niknam

**Name of organization / entity**

School of Management and Medical Informatics, Shiraz University of Medical Sciences, Shiraz, Iran

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for research of Shiraz University of Medical Sciences

**Expected recruitment start date**

2016-12-21, 1395/10/01

**Expected recruitment end date**

2017-03-20, 1395/12/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Randomised Clinical Trial of The Effect of Tele-

Rehabilitation Technology on Pain, Functional Disability, Clinical Index of Balance and Quality of Life in Patients with Chronic Non-Specific Low Back Pain

**Public title**
The Effect of Tele-Rehabilitation Technology on chronic non specific low back pain
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: male and female subjects with chronic non-specific low back pain; at the age of 18-55 years old; Having back pain for more than three months without any pathological cause; subjects should not have been any history of other illnesses (such as infection, cancer, inflammatory diseases, osteoporosis) or surgical interventions; back pain confirmed by orthopedic specialist; pain score less than 6 on numeric rating scale for pain (NRS Pain); Moderate disability score (25-50) based on Oswestry Low Back Pain disability questionnaire; internet access; having a smart phone or personal computer or laptop. Exclusion criteria: subjects with regular physical activity with 30 to 45 minutes duration, at least three times per week; subjects with past history of spine and herniation disk surgery; Pain in the spine corroborating fever and chills; morning stiffness; inflammatory diseases and fracture in the spine indicating the presence of osteoporosis; subjects with past history of fractures of vertebrae, pelvis and lower extremities; subjects with Malignancies, rheumatoid arthritis or systemic infectious diseases; subjects who regularly take pain killer medications and anti-inflammatory drugs; pregnancy or less than 6 months postpartum; body mass index of 30 or higher; presence of arthritis.
**Age**
From **18 years** old to **55 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Randomly allocated using block randomization method.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Shiraz University of Medical Sciences
**Street address**
Zand Av, The Central Building of Shiraz University of Medical Sciences, Shiraz, Iran
**City**
Shiraz
**Postal code**
**Approval date**
2016-10-09, 1395/07/18
**Ethics committee reference number**
IR.SUMS.REC.1395.123

## Health conditions studied

### 1

**Description of health condition studied**
chronic low back pain
**ICD-10 code**
M54.5
**ICD-10 code description**
Low back pain

## Primary outcomes

### 1

**Description**
Pain intensity
**Timepoint**
Before the start of interventions and one week after the interventions
**Method of measurement**
Numeric Rating Scale for Pain (NRS Pain)

### 2

**Description**
Clinical indicies of balance
**Timepoint**
Before the start of interventions and one week after the interventions
**Method of measurement**
single leg stand test and Star Excursion Balance Test to measure static balance and dynamic balance respectively.

### 3

**Description**
Functional Disability
**Timepoint**
Before the start of interventions and one week after the interventions
**Method of measurement**

Oswestry Disability Index (ODI)

### 4

**Description**
Quality of life
**Timepoint**
Before the start of interventions and a week after the interventions
**Method of measurement**
World Health Organization Quality of Life Questionnaire-100(WHOQOL-100)

## Secondary outcomes

### 1

**Description**
Patient satisfaction
**Timepoint**
1 week after completion of the intervention
**Method of measurement**
questionary

## Intervention groups

### 1

**Description**
Intervention group: 5 educational videos will be produced including the stages of exercise and the exercise program will be sent to the intervention group through 12 sessions during 4 weeks (3 sessions per week) based on the treatment protocol. Each session takes 30 to 45 minutes. Each session has been designed in four parts: warm-up, preform exercise programs, cooling, questions and answers.
**Category**
Rehabilitation

### 2

**Description**
Control group: the control group will not participate in any specific treatment plan and receive only their usual care.
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Faghihi Hospital
**Full name of responsible person**
Fatemeh Niknam
**Street address**
Shahid Faghihi Hospital, Next to Medical School, Zand Avenue, Shiraz, Iran
**City**
Shiraz

### 2

**Recruitment center**
**Name of recruitment center**
Rehabilitation Clinic of the School of Rehabilitation
**Full name of responsible person**
Fatemeh niknam
**Street address**
School of Rehabilitation, Abiverdi no 1 avenue, Chamran Blvd.
**City**
Shiraz

### 3

**Recruitment center**
**Name of recruitment center**
Dastgheib Hospital
**Full name of responsible person**
Fatemeh Niknam
**Street address**
Dastgheib Hospital, Next to National Garden, Hafez Street, Shiraz
**City**
Shiraz

### 4

**Recruitment center**
**Name of recruitment center**
Hafez hospital
**Full name of responsible person**
Fatemeh Niknam
**Street address**
Hafez hospital, at the beginning of Chamran Blvd, Shiraz.
**City**
shiraz

### 5

**Recruitment center**
**Name of recruitment center**
Emam Reza clinic
**Full name of responsible person**
Fatemeh niknam
**Street address**
Emam Reza Clinic, Reza Namazi Square, next to blood transfusion, Shiraz
**City**
Shiraz

### 6

**Recruitment center**
**Name of recruitment center**
Motahari Polyclinic
**Full name of responsible person**
Fatemeh Niknam
**Street address**
Motahari polyclinic, Namaze Square, next to Namaze

hospital, Shiraz.

**City**

Shiraz

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for Research of Shiraz University of Medical Sciences

**Full name of responsible person**

Fatemeh Niknam

**Street address**

School of Management and Medical Informatics, Almas Building, Allay 29,Qasrodasht Av, Shiraz, Iran

**City**

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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**

Vice Chancellor for Research of Shiraz 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**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Other areas of specialty/work**

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f_niknam1369@yahoo.com

**Web page address**

## 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*