

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Shiraz University of Medical Sciences, Shiraz, Iran

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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 indices 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

4**Description**

Quality of life

Timepoint

Before the start of interventions and a week after the interventions

Method of measurementWorld 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

Fateme Niknam

Street address

Shahid Faghihi Hospital, Next to Medical School, Zand Avenue, Shiraz, Iran

City**2****Recruitment center****Name of recruitment center**

Rehabilitation Clinic of the School of Rehabilitation

Full name of responsible person

Fateme 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

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Street address

Dastgheib Hospital, Next to National Garden, Hafez Street, Shiraz

City

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4**Recruitment center****Name of recruitment center**

Hafez hospital

Full name of responsible person

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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

Fateme niknam

Street address

Emam Reza Clinic, Reza Namazi Square, next to blood transfusion, Shiraz

City

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6**Recruitment center****Name of recruitment center**

Motahari Polyclinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shiraz University of Medical Sciences

Full name of responsible person

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

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

Name of organization / entity

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Position

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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