

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Effect of an exercise program on neuropathic and musculoskeletal pain intensity in spinal cord injury patients

Protocol summary

Summary

This study is Randomized control trials that all of the spinal cord injury, who referred to khatam-al Anbia Hospital in Tehran Iran, was our statistical research community. 40 patients were selected Based on inclusion criteria such as consent to participate in research, Patients not participate in exercise programs in Last three months, have a history of spinal cord lesion for 6 months and more, the lack of other chronic diseases such as hypertension And epilepsy, lack of Vertebral disc prolapse, no history of severe trauma, lack of alcohol and drug addiction, paraplegic, not pregnant (For Women), earning a score of 4 or more a measure of pain intensity score and purposive sampling method. They were randomly divided into two groups of experimental and control. Experimental groups were performed intervention include exercise program for paraplegia spinal cord injury during twelve 45-60 minutes sessions, twice a week. Patient filled international spinal cord injury based pain data set. The analysis will be used as t-test, independent t-test, paired T, and analysis of variance.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051822311N1**

Registration date: **2015-08-01, 1394/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-01, 1394/05/10

Registrant information

Name

Naser Sedghi Goyaghaj

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3640 0459

Email address

sedghi.nurse@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, University of Social Welfare and Rehabilitation sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of an exercise program on neuropathic and musculoskeletal pain intensity in spinal cord injury patients

Public title

Effect of an exercise program on neuropathic and musculoskeletal pain intensity in spinal cord injury patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Consent to participate in research and cooperation necessar;Patients not participate in exercise

programs Last three months; history of spinal cord injury for 6 months and more; not having chronic disease as high blood pressure and epilepsy and...; not having Vertebral disc prolapse; not Having a history of severe trauma; Non- alcohol drug addiction; The level of spinal cord injury should be thoracic , lumbar or sacral that named paraplegia;Not pregnant (for women); All participants should be use of a same manual wheelchair to suit their own physical condition; Earn score of 4 or higher on a scale measuring pain intensity score;Ability to read manual by themselves or relatives and the ability to perform intervention. Exclusion criteria:Cancel the continued cooperation; The absence of more than 3 times the intervention meetings; intensifying of symptoms and spinal disorders; Defects of the nervous and cardiovascular disorders during the intervention

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

For randomization, the method of odd and even numbers will be used

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of University of Social Welfare and Rehabilitation sciences

Street address

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

City

Tehran

Postal code**Approval date**

2013-06-22, 1392/04/01

Ethics committee reference number

uswr.rec1392.93

Health conditions studied**1****Description of health condition studied**

Spinal cord injury

ICD-10 code

M84.1

ICD-10 code description

Injury to nerves and spinal cord

Primary outcomes**1****Description**

Neuropathic pain intensity

Timepoint

Before and 2 months after the intervention

Method of measurement

International Spinal Cord Injury Basic Pain Data Set

2**Description**

Musculoskeletal pain intensity

Timepoint

Before and 2 months after the intervention

Method of measurement

International Spinal Cord Injury Basic Pain Data Set

Secondary outcomes**1****Description**

Timepoint

Method of measurement

Intervention groups**1****Description**

Intervention group 1: The intervention consisted of 12 sessions of 45 to 60 minutes exercise program for patients with spinal cord injuries paraplegia caused by Canadian spinal cord injuries center and casa colina hospital of Australia is designed to be taught. The program includes 30 movements about the upper body and lower body includes warm-up, upper body endurance and stretching exercises, resistance exercises, lower body stretching exercises and stretching exercises for cool- up is done in 3 sets 10-8 repetitions with an exercise band by patient

Category

Treatment - Other

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-Al-anbia Hospital

Full name of responsible person

Naser Sedghi Goyaghaj

Street address

Rashid Yasemi Street, Above Mirdamad Blvd, Vali-Ye-Asr Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, University of Social Welfare and Rehabilitation sciences

Full name of responsible person

Dr.Hamidreza Khankeh

Street address

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

City

Tehran

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, University of Social Welfare and Rehabilitation 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

University of Social Welfare and Rehabilitation sciences

Full name of responsible person

Naser Sedghi Goyaghaj

Position

Master student of medical surgical nursing

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