Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Street address
Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran
City
Tehran
Postal code
Phone
+98 21 3640 0459
Fax
Email
sedghi.nurse@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
University of Social Welfare And Rehabilitation sciences
Full name of responsible person
Masoud Fallahi khoshknab
Position
PhD of nursing
Other areas of specialty/work
Street address
Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran
City
Tehran
Postal code
Phone
+98 21 2218 0036
Fax
Email
msflir@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
University of Social Welfare and Rehabilitation sciences
Full name of responsible person
Naser Sedghi Goyaghaj
Position
Master Student Of Nursing
Other areas of specialty/work
Street address
Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran
City
Tehran
Postal code
Phone
+98 21 3840 0459
Fax

Email
sedghi.nurse@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