

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of virtual reality and conventional proprioceptive training in neck region on pain, functional variables and balance in patients with cervical radiculopathy

Protocol summary

Study aim

Comparison of the effect of virtual reality and conventional proprioceptive training in neck region on pain, functional variables and balance in patients with cervical radiculopathy

Design

A randomized clinical trial Sampling allocated in 3 groups with 15 subjects, assessor blind and block randomization

Settings and conduct

45 patients will be randomly assigned to conventional or virtual reality based exercises group or control group. The virtual reality group will perform the computer game. The stages of the game are designed easy to hard sequentially. Movement and position sense, gaze stability, head-eye coordination exercises will be performed by patients in conventional group. all groups will perform control group exercises in 2 sets of 8 repetitions and will mark in their daily check list. Exercise regimes are of 10 sessions each lasting 20 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 40-60 years old with more than 3 month history of pain between 30-60 out of 100 according to visual analogue scale in neck or upper limb with numbness or tingling or weakness in one or two hand whom referred by specialist Neck disability index 15-25 score out of 50 At least 4/5 degree head repositioning error in 4 direction Exclusion criteria: Positive vertebral artery Steroidal injection History of surgery Upper motor neuron lesion Medical red flags People with thoracic outlet syndrome, tennis elbow and carpal tunnel syndrome

Intervention groups

3 Groups: Virtual reality training, Conventional proprioception training and control

Main outcome variables

Pain, Disability, Proprioception (position sense)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181209041897N1**

Registration date: **2019-04-10, 1398/01/21**

Registration timing: **prospective**

Last update: **2019-04-10, 1398/01/21**

Update count: **0**

Registration date

2019-04-10, 1398/01/21

Registrant information

Name

sara shabakhti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5333 4984

Email address

stud2560308071@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of virtual reality and conventional proprioceptive training in neck region on pain, functional variables and balance in patients with cervical radiculopathy

Public title

Comparison of the effect of computer game and conventional proprioceptive training in neck region on pain, disability and balance in patients with cervical radicular pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

40-60 years old pain history more than 3 month The average of the highest and lowest pain in the past day was at least 30 to a maximum of 60 out of 100 mm according to Visual Analogue Scale in neck or upper limb with numbness or tingling or weakness in one or two hands referred by specialist with cervical radiculopathy diagnosis 3 out of 4 tests become positive: spurling test, distraction test, upper limb tension test 1. cervical rotation less than 60 degree have moderate disability according to neck disability index between 15 to 25 out of 50 score have at least 4.5 degree head repositioning error in 4 directions(Flexion, Extension, Rotation to right and left)

Exclusion criteria:

Positive Vertebral Artery test Steroidal injection in recent two past weeks history of neck or thoracic surgery myelopathy Upper motor neuron lesion sign & symptom for example: stroke ,Multiple sclerosis and amyotrophic lateral sclerosis medical red flags like: tumor, fracture, Rheumatoid arthritis and Long-term use of steroid medications People with thoracic outlet syndrome, tennis elbow and carpal tunnel syndrome Taking effective balance medication over the past 72 hours Vestibular problems People who Regularly used analgesic and anti-inflammatory drugs due to neck problem.

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

People through Block Randomization and sealed opaque envelopes concealment fall into three groups

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor as well as data analyzer will be blinded to the group allocation

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shiraz School of Rehabilitation Sciences

Street address

School of Rehabilitation Sciences - Abiverdi 1 St. - Chamran Blvd. - Shiraz - Iran

City

shiraz

Province

Fars

Postal code

33669-71947

Approval date

2018-12-08, 1397/09/17

Ethics committee reference number

IR.SUMS.REHAB.REC.1397.002

Health conditions studied

1

Description of health condition studied

Cervical Radiculopathy

ICD-10 code

M50.1

ICD-10 code description

Cervical disc disorder with radiculopathy

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, 48 hr after intervention & a month later

Method of measurement

Visual Analogue Scale

2

Description

Disability

Timepoint

Before intervention, 48 hr after intervention & a month later

Method of measurement

Neck Disability Index questionnaire

3

Description

Head Reposition Error

Timepoint

Before intervention, 48 hr after intervention & a month later

Method of measurement

Laser pointer & Graded page

Secondary outcomes

1

Description

Balance

Timepoint

Before intervention, 48 hours after intervention & a month later

Method of measurement

Modified Star Excursion Balance test

2

Description

Kinesiophobia

Timepoint

Before intervention, 48 hours after intervention & a month later

Method of measurement

Tampa Scale of Kinesiophobia questionnaire

3

Description

Neuromuscular control of head and neck movements

Timepoint

Before intervention, 48 hours after intervention & a month later

Method of measurement

Time of movement duty

Intervention groups

1

Description

Control group: This group do the isometric neck exercise, deep neck flexor strengthening exercise, shoulder and scapular strengthening exercise for 10 sessions, three times a week in home. It will check by the physiotherapist once weekly.

Category

Rehabilitation

2

Description

First intervention group: This group do home exercises

plus a computer game designed to improve cervicocephalic kinesthesia, eye-head coordination, reflexes related to head and neck, eye and vestibular system with their head and neck movements. The stages of the game are designed easy to difficult sequentially. Ten exercise sessions each lasted 20 minutes is programmed. 5 minutes warm up exercises will be performed at the beginning of each session.

Category

Rehabilitation

3

Description

Second intervention group: This group do home exercises plus conventional neck proprioceptive exercises including: The combination of joint position sense and movement sense training (by using laser beam fixed on the head), gaze stability training, eye and head coordination training will be performed in each session and they will be progressed in the next sessions. The duration of each training session and the number of training sessions are the same as first intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals of Shiraz university of medical sciences

Full name of responsible person

Sara Shabakhti

Street address

School of Rehabilitation Sciences - Abiverdi 1 St. - Chamran Blvd. - Shiraz - Iran

City

Shiraz

Province

Fars

Postal code

71947-33669

Phone

+98 35 3624 0227

Email

sara.shabakhti@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ghasemi Unes

Street address

Floor 7, Center Bilding of Shiraz Univercity of Medical Science, beside Helale Ahmar, Zand street

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3235 7282

Fax

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Web page address<http://research.sums.ac.ir/fa/contact-information/index.html>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohsen Razeghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation Sciences - Abiverdi 1 St. - Chamran Blvd. - Shiraz - Iran

City

Shiraz

Province

Fars

Postal code

1733-71345

Phone

+98 71 3627 1551 ext. 213

Email

RazeghM@Sums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohsen Razeghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, Abiverdi 1 St., Chamran Blvd., Shiraz, Fars, Iran

City

shiraz

Province

Fars

Postal code

1733-71345

Phone

+98 71 3627 1551 ext. 213

Email

RazeghM@Sums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Sara Shabakhti

Position

Master student of physical therapy

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation Sciences - Abiverdi 1 St. - Chamran Blvd. - Shiraz - Iran

City

Shiraz

Province

Fars

Postal code

7194733669

Phone

+98 71 3626 1081

Email

sara.shabakhti@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available