Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 analoge scale in neck or upper limb with numbness or tingling or weakness in one or two hand whom refered by specialist Neck disability index 15-25 score out of 50 At least 4/5 degree heag repositioning error in 4 direction Exclusion criteria: Positive vertebral artery Steroidal injection History of surgery Upper motor neuron lesion Medical red flags People with thorasic outlet syndrom, tennis elbow and carpal tunnel syndrom

Intervention groups
3Groups: 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)

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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 Analoge Scale in neck or upper limb with numbness or tingling or weakness in one or two hands refered by specialist with cervical radiculoathy 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 reposistioning error in 4 directions(Flextion, Extension, Rotation to right and left)

Exclusion criteria:
Positive Vertebral Artery test Steroidal injection in recent two past weeks history of neck or thorasic 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 thorasic 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 Analoge 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
Kinsiophobia
Timepoint
Before intervention, 48 hours after intervention & a month later
Method of measurement
Tampa Scale of Kinsiophobia 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 computar 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 programed. 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Full name of responsible person
Mohsen Razeghi
Position
Associate professor
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Person responsible for updating data

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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