Clinical Trial Protocol
Iranian Registry of Clinical Trials
11 Nov 2019

A comparative study of the effects of virtual reality based exercises versus conventional exercises in the neck region on sensorimotor function and postural control of patients with nonspecific chronic neck pain

Protocol summary

Summary
The aim of this study is to compare the effects of virtual reality based exercises versus conventional exercises in the neck region on sensorimotor function and postural control of patients with nonspecific chronic neck pain. This is a double-blinded randomized clinical trial. Inclusion criteria are non-traumatic neck pain with a duration between 3 months and 12 months and age between 20 to 55 years. Exclusion criteria are history of cervical and upper thoracic trauma in the 6 months before examination, neurological signs and symptoms in upper extremities, nerve injury, spinal cord compression, any disorders in which exercise therapy is contraindicated, scored more than 15 (out of possible 50) on the neck disability index, cervical spine pathology or surgery and cancer. 42 patients will be randomly assigned to conventional or virtual reality based exercises 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. Exercise regimes are of 8 sessions each lasting 20 minutes. The main outcomes are pain intensity, disability score, neuromuscular control and max range of motion of the head and neck and postural control. The participants will be assessed before and after 8 sessions of training.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2014040817177N1
Registration date: 2014-12-09, 1393/09/18
Registration timing: prospective

Registrant information
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Iman Rezaei
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Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2014-12-11, 1393/09/20
Expected recruitment end date
2015-04-21, 1394/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effects of virtual reality based exercises versus conventional exercises in the neck region on sensorimotor function and postural control of patients with nonspecific chronic neck pain

Public title
A comparative study of the effects of virtual reality based exercises versus conventional exercises in the neck region on sensorimotor function and postural control of patients with nonspecific chronic neck pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: non-traumatic neck pain with a
duration between 3 months and 12 months; age between 20 to 55 years. Exclusion criteria: History of cervical and upper thoracic trauma in the 6 months before examination; neurological signs and symptoms in upper extremities; nerve injury, spinal cord compression; cervical spine pathology or surgery; cancer; cervical instability; forward head posture; sever osteoporosis; cervical or thoracic spine or upper extremities fracture; pregnancy; history of brain or vestibular system injury; congenital anomaly of the cervical spine; cervical spine physiotherapy intervention in the preceding 6 months; scored more than 15 (out of possible 50) on the neck disability index; any disorders in which exercise therapy is contraindicated; otolaryngeal disorders that affect postural control; hearing problem; inability to clearly see any number with size 14 of Calibri font on monitor screen with or without glasses; the participant does not have required cervical range of motion to see computer screen during the game.

Age
From 73 years old to 37 years old

Gender
Both

Phase
N/A

Groups that have been masked
None

Sample size
Target sample size: 42

Randomization (investigator's opinion)
Randomized

Randomization description
Double blinded

Blinding (investigator's opinion)
None

Blinding description
None

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Ave.
City
Shiraz
Postal code
7134814336
Approval date
2014-02-23, 1392/12/04
Ethics committee reference number
CT-92-6895

Health conditions studied

1
Description of health condition studied
Nonspecific chronic neck pain

ICD-10 code
M54.2

ICD-10 code description
Cervicalgia

Primary outcomes

1
Description
Pain intensity

Timepoint
Before and after training

Method of measurement
Visual analoge scale

2
Description
Neuromuscular control of the head and neck movements

Timepoint
Before and after training

Method of measurement
Movement time of fit's task

3
Description
Functional disability

Timepoint
Before and after training

Method of measurement
Neck disability index questionnaire

4
Description
Head and neck proprioception (position sense)

Timepoint
Before and after training

Method of measurement
Head repositioning error

5
Description
Maximum range of motion of the head and neck

Timepoint
Before and after training

Method of measurement
Kinematic assessment

6
Description
Postural control

**Timepoint**
Before and after training

**Method of measurement**
Systematic balance assessment

Secondary outcomes
empty

Intervention groups

1
**Description**
Control group (conventional training): 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. Eight exercise sessions each lasted 20 minutes is programmed. 5 minutes warm up exercises will be performed at the beginning of each session.

Category
Treatment - Other

2
**Description**
Intervention group: (virtual reality training) the computer game is designed to improve cervicocephalic kinesthesia, eye-head coordination, reflexes related to head and neck, eye and vestibular system. The stages of the game are designed easy to difficult sequentially. The duration of each training session and the number of training sessions are the same as conventional group.

Category
Treatment - Other

Recruitment centers

1
**Recruitment center**
The hospitals of Shiraz University of Medical Sciences

Sponsors / Funding sources

1
**Sponsor**
Shiraz University of Medical Sciences

Person responsible for general inquiries

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School of Rehabilitation
Full name of responsible person
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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