

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effects of an exergame on the pain and muscle strength in people with neck osteoarthritis

Protocol summary

Study aim

The aim of this pilot study was to design an exergame and clinical evaluation of its effect on pain sensation and muscle strength in people with cervical osteoarthritis

Design

This was a parallel-group clinical study. Subjects were randomly divided into two groups by drawing a concealed envelop from a bag.

Settings and conduct

This study was a parallel-groups clinical trial. Participants were allocated into two groups using a stratified randomization method (the severity of the lesion was the stratification factor). Participants were recruited through a convenience sampling method and from outpatient clinic of the Shariati Hospital, Isfahan, Iran. There was no blinding for participants and assessor.

Participants/Inclusion and exclusion criteria

Patients with a history of clinical symptoms such as mild and moderate spondylosis, neck pain (at least score 3 for pain intensity based on the visual analog scale, muscle spasm in the neck or shoulder and the numbness in the hands were included in this study. Individuals with severe neck spondylosis, spinal stenosis, history of neck fracture or spine surgery, cervical osteoarthritis(grade 4), spinal canal stenosis, history of spinal fracture or surgery, severe osteoporosis, neurological disease, cardiovascular dysfunction, pregnancy, and spinal deformities were excluded .

Intervention groups

Intervention group received the conventional physiotherapy modalities that were delivered with isometric exercise through the computerized game (exergame). Control group received The conventional physiotherapy protocols for neck pain followed with hand-resisted isometric exercise.

Main outcome variables

Neck function, pain intensity, and isometric strength of neck muscles were measured before and after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N6**

Registration date: **2020-02-06, 1398/11/17**

Registration timing: **retrospective**

Last update: **2020-02-06, 1398/11/17**

Update count: **0**

Registration date

2020-02-06, 1398/11/17

Registrant information

Name

Ebrahim Sadeghi-Demneh

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

2019-05-10, 1398/02/20

Actual recruitment end date

2019-07-21, 1398/04/30

Trial completion date

2019-07-21, 1398/04/30

Scientific title

The effects of an exergame on the pain and muscle strength in people with neck osteoarthritis

Public title

Effects of therapeutic game for neck pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

People with clinical symptoms of mild and moderate neck osteoarthritis Neck pain (if pain is scored at least 3 on visual analogue scale) Muscle spasm Sensory loss in the arm Shoulder or scapular muscles pain

Exclusion criteria:

People with severe neck osteoarthritis Canal stenosis A history of vertebral fracture Severe osteoporosis Rheumatoid arthritis Neurological disease Cardiovascular disease Pregnancy Spinal deformities

Age

From **27 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization was stratified by severity of the lesion (mild/moderate) to pursue equal distribution of the degrees of severity for both intervention and control groups. Randomization in each stratum was carried out by having a piece of paper that has the phrase "intervention (exergame+physiotherapy)" and "control (hand exercise+physiotherapy)" placed inside an envelope. The outside of the envelopes were sequentially numbered. After participants have been enrolled in the study and consented, a sequence number envelope on the stack will be randomly drawn and opened to determine the study group that the participant will enter.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Esfahan

Street address

Daneshgah Blvd

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Isfahan

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Isfahan

Postal code

8174673441

Approval date

2019-11-06, 1398/08/15

Ethics committee reference number

IR.UI.REC.1398.047

Health conditions studied

1

Description of health condition studied

People with grade 2 (mild) and grade 3 (moderate) cervical spondylosis

ICD-10 code

M43.02

ICD-10 code description

Spondylolysis, cervical region

Primary outcomes

1

Description

Neck function

Timepoint

The outcome was measured in three time intervals: before starting the exercise, after the last session of the exercise, and one month after finishing the exercise sessions.

Method of measurement

Neck was assessed using the "Neck disability index".

2

Description

Pain intensity

Timepoint

The outcome was measured in three time intervals: before starting the exercise, after the last session of the exercise, and one month after finishing the exercise sessions.

Method of measurement

Pain intensity was measured using "visual analogue scale".

3

Description

Isometric strength of neck muscles

Timepoint

The outcome was measured in three time intervals:

before starting the exercise, after the last session of the exercise, and one month after finishing the exercise sessions.

Method of measurement

The isometric strength of neck muscles were measured using a digital force dynamometer.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The conventional physiotherapy modalities were delivered with isometric exercise through the computerized game (exergame). The conventional physiotherapy included heating through a towel at 74 degrees of Celsius, transcutaneous electrical stimulation (pulse duration:100-110 ms; frequency: 70-80 Hz), ultrasound modality (pulse wave with intensity of 1.25-1.5 W/cm²; duration: 5 min), and stretching of the upper trapezius muscle (10-30 seconds; 3-5 repeats). The exergame included software and a glove as a controller of the game. The isometric neck exercises are carried out while the patient was playing the game. The hand pressure against the head was applied in four directions. This pressure was holding 10 seconds to control the motion of the game character in the game's path.

Category

Rehabilitation

2

Description

Control group: The conventional physiotherapy protocols for neck pain followed with hand-resisted isometric exercise. The conventional physiotherapy was the same as explained for the exergame group. The participants were instructed to apply pressure by their hand against the head and hold it for 10 s in four directions. Each pressure repeated five times, and two minutes rest was given after each exercise set. People carried out the exercise three times a day and repeated it every other day.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Mehdi Naghosi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Houshang Talebi

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Grant name

Postgraduate studies

Grant code / Reference number

1398.047

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of Isfahan

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

Esfahan University of Medical Sciences

Full name of responsible person

Ebrahim Sadeghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physical Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study data (excluding the personal details) can be shared with other researchers or systematic reviewers.

When the data will become available and for how long

No limit was set.

To whom data/document is available

No specific limitation is considered.

Under which criteria data/document could be used

No terms and conditions is considered for sharing the data.

From where data/document is obtainable

People can send their request to the correspondence and obtain the data.

What processes are involved for a request to access data/document

Request can be sent through an email.

Comments

