

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study of the effectiveness of clinically-supervised and internet-based exercise therapy on pain, muscle thickness and endurance and head posture in females with chronic non-specific neck pain

Protocol summary

Study aim

Comparison of the effect of clinically-supervised and internet-based exercise therapy on pain, muscle thickness and endurance and forward head posture in female with chronic neck pain.

Design

Clinical trial, with a parallel control group, single-blind, randomized, will be performed on 44 women. Block randomization is performed.

Settings and conduct

This research will be performed in Hazrat Rasool Hospital. After signing the consent form, all female patients with neck pain are randomly divided into two groups; one group performs the exercises in the clinic and the second group performs the exercises online. Data are collected and analyzed in pre- and post-intervention evaluations.

Participants/Inclusion and exclusion criteria

inclusion criteria: Having non-specific chronic neck pain (persistent neck pain for at least three months and with an intensity of at least 3 according to VAS criteria). female. Age 65-18 years. BMI < 30. Balanced mood. Having access to the Internet Participant consent to participate in the trial. exclusion criteria: Existence of acute traumatic injury in the spine. Existence of a history of surgery or previous lesion of the neck. Pregnancy. Simultaneous pain in the shoulder joint. Fractures in the upper limbs over the past year. Malignant tumors. Inflammatory diseases Any therapy for neck pain during the last three months. Congenital spinal deformity.

Intervention groups

Intervention group 1: Supervised exercise therapy; Intervention group 2: Internet-based exercise therapy. The exercise protocol designed for patients is the same for all participants in both groups and includes a 6-week, 3 sessions per week, exercise therapy protocol. A specific group of exercise is designed for every 14 days.

Main outcome variables

neck pain; thickness of neck muscles; neck muscle endurance; head posture

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20181219042055N2**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Sara Lotfian

Name of organization / entity

Shaheed Rajaee Heart Research Center

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effectiveness of clinically-supervised and internet-based exercise therapy on pain, muscle thickness and endurance and head posture in females with chronic non-specific neck pain

Public title

Comparison of the effect of two methods of prescribing exercise on neck pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having non-specific chronic neck pain (persistent neck pain for at least three months and with an intensity of at least 3 according to VAS criteria) female Age 18- 65 years Body mass index equal to or less than 30 Balanced mood Ability to access the Internet and other communication tools Consent to participate in the trial

Exclusion criteria:

Existence of acute traumatic injury in the spine approved by a specialist Existence of a history of surgery or previous lesion of the neck and other joints of the upper limbs during a recent year Pregnancy Simultaneous pain in the shoulder joint Existence of new fractures in the upper limbs during a recent year Suffering from malignant tumors Inflammatory diseases such as ankylosing spondylitis, rheumatoid arthritis, fibromyalgia, myelopathy and cervical radiculopathy Participate in exercise therapy, manipulation, acupuncture and physiotherapy programs during the last three months Congenital spinal deformity

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Eligible patients were randomized in blocks of four, into the following groups: A: exercise therapy in clinic B: online exercise therapy Randomization tool: Random assignment in groups is done applying the website of "www.randomization.com" (seed 23226) and then in order of entering the study, the participant is allocated to one of the groups of A

(supervised exercise therapy) or B (Internet-based exercise therapy) as arranged above. The random sequence has been made online. For allocation concealment the above sequence is only at the disposal of the main researcher and the group assigned to each patient is determined by them after the participant has entered the study. In this study, in order for patients not to be informed about the other group's exercise therapy method, group A patients are treated on even days and group B patients are treated on odd days. It should be noted that the exercise therapy sessions are supervised by a sports medicine resident. Evaluations in hospital, before and after interventions, are performed by another resident who is unaware of the presence of patients in the groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Of the three main groups involved in researches, including participants, administrators and evaluators, there is only the possibility of blinding for the group of evaluators in this study. As it is not feasible to blind participants to the method of prescribing exercise therapy, the patient is aware of it (in clinic or online). The researcher who is in charge of prescribing and supervising the exercise therapy sessions also knows how people are assigned to different groups, and the researcher prescribes specific exercises to each participant. The third group, i.e. evaluators, including the initial and outcome assessor, data analyzer, as well as the data and safety monitoring board, will not be informed of the method of exercise training in this study; and the data will be provided to them in groups of A and B.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of School of Medicine of Iran University of Medical Sciences

Street address

3th Floor of School of Medicine, Shahid Hemmat Highway (between Sheikh Fazlollah and Shahid Chamran Intersection)

City

Tehran

Province

Tehran

Postal code

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.IUMS.FMD.REC.1400.506

Health conditions studied**1****Description of health condition studied**

Chronic non-specific neck pain

ICD-10 code

M54.2

ICD-10 code description

Cervicalgia

Primary outcomes**1****Description**

Neck pain

Timepoint

Before and after the intervention (6 weeks)

Method of measurement

Visual analogue scale

2**Description**

Thickness of neck muscles

Timepoint

Before and after the intervention (6 weeks)

Method of measurement

Ultrasound device

3**Description**

Neck muscle endurance

Timepoint

Before and after the intervention (6 weeks)

Method of measurement

Cervical flexor and extensor muscles endurance tests

4**Description**

Head posture

Timepoint

Before and after the intervention (6 weeks)

Method of measurement

measurement of craniovertebral angle

Secondary outcomes**1****Description**

neck disability

Timepoint

Before and after treatment intervention (6 weeks later)

Method of measurement

Neck Disability Index Questionnaire

Intervention groups**1****Description**

Intervention group 1: Exercise therapy under the supervision in the sports medicine clinic that includes 18 training sessions, 3 days a week for 6 weeks; and will be done in 3 different phases based on progressive increase of workload. Each phase lasts two weeks and at the end the second week, the exercises of the next phase is added. All sessions start with a warm-up in the form of walking and simultaneously moving the head and neck to the sides, flexion and extension, and rotating the neck to both sides. Step 1 (1-The participant, while sitting, tries to performed the chin tuck without raising her head and maintaining this position for 10 seconds. 2- The participant, while lying down in a supine position, places a towel in the form of a tube in the space between the neck and the table and try to squeeze the towel and maintain this position for 10 seconds). step 2 (1-The participant, lying in supine position, performs the chin tuck position then lifting the head off the table and holding it for 10 seconds. 2- The participant is placed on all fours and flex her head and look at their knees and hold for 10 seconds, then raise the head up to 30 degrees extension and stare at the point between the two hands and hold this position for 10 seconds). step 3 (1- Using an elastic band, while applying a force from back to front, the person moves the head to the extension position and holds for 10 seconds. 2- The person uses an elastic band while applying a force from the front of the head to back, moves the head to the flexion position and holds for 10 seconds) Each set includes 10 repetitions.

Category

Treatment - Other

2**Description**

Intervention group 2: Internet-based exercise therapy that initially internet and mobile messaging applications access will be checked. For the IET group, exercise therapy guidelines with videos of how to perform exercises are made ready; the first phase of which will be delivered to them after pre-intervention evaluation. Each phase lasts two weeks and at the end of the second week, the exercises of the next phase is added. They will be asked to perform their exercise therapy protocol three days a week for six weeks (18 sessions totally) similar to the other group. If the patient has any questions about the exercises, she can ask online. The details and sequence of prescribing exercises are the same as in intervention group 1.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasoole Akram Hospital

Full name of responsible person

Sara Lotfian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Hossein Keyvani

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5th floor of headquarters building, Iran University of
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Web page address

<https://vcr.iums.ac.ir/fa?sid=22>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Sara Lotfian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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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

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

All results, except for Individual Participant Data, can be shared after participants become unrecognizable.

When the data will become available and for how long

Start access after publishing results

To whom data/document is available

There is no limit.

Under which criteria data/document could be used

There is no limit.

From where data/document is obtainable

Sara Lotfian- By sending an email

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

The received email will be replied.

Comments