

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Comparison of the effectiveness of preventive exercise therapy delivered by health care providers with the control group on the incidence of neck pain in adults

Protocol summary

Study aim

Comparison of the effectiveness of preventive exercise therapy delivered by health care providers with the control group on the incidence, prevalence, disability and costs of neck pain in adults

Design

A pragmatic trial including two groups (control and exercise). Single blinded with 4000 participants in total (2000 each group) and randomized on health centers level.

Settings and conduct

The training will be provided to the health care providers by a Sports Medicine specialist. The health care providers will then provide the training to the participants through pamphlets and interviews. The data will be collected by caregivers using questionnaires, after obtaining informed consent from the individuals. Considering the kind of intervention (exercise), the participants and educator (health care provider) can not be blinded. The data will be blinded using coding for the purpose of collection, analyses, and interpretation.

Participants/Inclusion and exclusion criteria

Inclusion: Participants under the coverage of rural health network of Tehran University of Medical Sciences 18 to 60 years old
Exclusion: Diagnosed neoplasm
Diagnosed remarkable psychiatric disorders
Diagnosed cognitive impairment
Unwillingness to participate/continue with participation

Intervention groups

Intervention group: Participants who, based on center randomization, are placed in intervention centers will be educated on preventive neck pain exercise by health care providers. Participants will be followed up on new episodes or changes in previous neck pain and will be compared with the control group.
Control group: Participants who, based on center randomization, are placed in control centers will only be followed up, without

any interventions, on new episodes or changes in previous neck pain, and will be compared with the intervention group.

Main outcome variables

Incidence, prevalence, disability, and costs of neck pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048058N1**

Registration date: **2020-08-02, 1399/05/12**

Registration timing: **prospective**

Last update: **2020-08-02, 1399/05/12**

Update count: **0**

Registration date

2020-08-02, 1399/05/12

Registrant information

Name

Amir Ahmadzadeh Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2293 0953

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of preventive exercise therapy delivered by health care providers with the control group on the incidence of neck pain in adults

Public title

Evaluation of the effectiveness of preventive exercise therapy on neck pain

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Participants under the coverage of rural health network of Tehran University of Medical Sciences 18 to 60 year-old participants

Exclusion criteria:

Diagnosed neoplasm Diagnosed remarkable psychiatric disorders Diagnosed cognitive impairment Unwillingness to participate/continue with participation

Age

From **18 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: **4000**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to prevent statistical contamination, randomization will be done in the cluster form at the level of health bases. Eight health bases with equal coverage population will enter simple randomization processes in Excel software and will be divided into two groups of control and exercise intervention. The randomization method is simple randomization, the unit is cluster randomization, and non-stratified randomization is used to better represent the reality of our target community. In this study, Excel statistical software will be used for randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, considering the type of intervention (exercise), blinding cannot be carried out on the participants and the health care providers (who are responsible for educating people and collecting data). The data analyst is blinded to the grouping of each individual.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Vice-chancellor in research affairs- Tehran University of Medical Sciences

Street address

Keshavarz Blv. Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416753955

Approval date

2018-05-22, 1397/03/01

Ethics committee reference number

IR.TUMS.VCR.REC.1397.039

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

Neck pain

ICD-10 code

M54.2

ICD-10 code description

Cervicalgia (Neck pain)

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

Neck pain incidence

Timepoint

after 12 months since first visit

Method of measurement

Translated Neck pain and disability score (NPDS) questionnaires and participants' electronic health records (SIB)

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

Disability caused by neck pain

Timepoint

after 3, 6, and 12 months since first visit

Method of measurement

NPDS questionnaire

2

Description

Treatment cost

Timepoint

after 12 months since first visit

Method of measurement

Participants' electronic health records (SIB)

3

Description

Prevalence of neck pain

Timepoint

after 3, 6, and 12 months since first visit

Method of measurement

NPDS questionnaire

Intervention groups

1

Description

Control group: Without exercise intervention. Participants will be followed by health care providers and relevant data (incidence, prevalence, disability and the costs of treating neck pain) will be collected from them.

Category

N/A

2

Description

Intervention group: Neck exercise group, a sum of 10 simple stretch and strength exercises to strengthen the neck muscles and stabilize the posture which are practicable by the public at home, without any tools, while standing, sitting, and laying down. The training will emphasize on the neck's motion in different directions and also necks stability against force. These exercises, which will be taught to primary health care providers by Sports medicine specialists before the trial begins, will be taught to the Intervention group by primary health care providers in one session interviews, and pamphlets. This study aims to assess the effectiveness of exercises taught by the primary care providers to the study population.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences Health Network

Full name of responsible person

Ramin Kordi

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District 6, Jalal-e-Al-e-Ahmad Hwy, No. 7

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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TUMS Central Organization, Keshavarz Blv.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

14

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

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

Position

Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Comparison of the effectiveness of preventive exercise therapy delivered by health care providers with the control group on the incidence of neck pain in adults

When the data will become available and for how long

Starting in January 2022 for 5 years

To whom data/document is available

Researchers and policymakers in the field of public health and sports medicine

Under which criteria data/document could be used

Systematic review/Meta-analysis

From where data/document is obtainable

Tehran University of Medical Sciences (TUMS) Sports Medicine Research Center (SMRC)

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

Contacting the author for correspondence with reasonable request

Comments