Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of cervical proprioceptive exercises in addition to conventional physiotherapy with isolated conventional physiotherapy on relative proprioceptive weighting of the cervical spine and postural control in chronic non-specific neck pain individuals.

Protocol summary

Study aim
Investigating of the effect of Adding Exercises focused on neck proprioception to conventional physical therapy on relative proprioceptive weighting of the cervical spine and postural control in Patients with non-specific chronic neck pain.

Design
A randomized clinical trial, consisting of two parallel, double-blind, groups. Sample size will be calculated using G * power software based on mean difference and standard deviation of the main study variables to be obtained in the pilot study (n = 5).

Settings and conduct
Accessible population is adult men and women with non-specific chronic neck pain will refer to USWR outpatient clinics. Patients should not contact with each other.The assessor will not be aware of the grouping and treatment plan of the subjects. Both groups will be treated by experienced physiotherapist. Subjects will practice twice daily for 5 weeks.

Participants/Inclusion and exclusion criteria
Individuals with nonspecific chronic neck pain with a duration of at least 3 months (either permanent or episodic).The pain should be experienced in the sub-occipital (to T1) and/or the upper trapezius muscle. They should not have received physiotherapy in the past 6 months to treat neck pain. They should stand upright and their neck range of motion should not limited.

Intervention groups
We should have two treatment groups. One group will receive conventional physical therapy and the other group will receive cervical proprioceptive exercises in addition to the conventional treatment. In both groups, participants will receive PT treatment 3 sessions/week for a duration of 5 weeks. They'll all be asked to do their home exercise twice a day and record exercises performance in their schedule sheet.

Main outcome variables
Sway Velocity, Sway Range, Relative Proprioceptive Weighting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191130045552N1**
Registration date: **2020-01-12, 1398/10/22**
Registration timing: **prospective**

Last update: **2020-01-12, 1398/10/22**
Update count: **0**

Registration date
2020-01-12, 1398/10/22

Registrant information

Name
Leila Goudarzi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2218 0146

Email address
le.goudarzi@uswr.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of cervical proprioceptive exercises in addition to conventional physiotherapy with isolated conventional physiotherapy on relative proprioceptive weighting of the cervical spine and postural control in chronic non-specific neck pain individuals.

Public title

Comparison of the effect of cervical proprioceptive exercises in addition to conventional physiotherapy with isolated conventional physiotherapy on relative proprioceptive weighting of the cervical spine and postural control in chronic non-specific neck pain individuals.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with nonspecific chronic neck pain with a duration of at least 3 months (either permanent or episodic).The pain should be experienced in the sub-occipital area and/or the upper trapezius muscle. The average pain intensity during 3 weeks prior to testing session should be between 3.5 and 6.5 and pain intensity in the testing day should be less than 6.5. based on the patient's physician's diagnosis, the neck pain should not be associated with any specific lesion or injury, with no symptoms of radicular pain and upper limbs and no pathoanatomic diagnosis. By asking the patient, we make sure that patients do not receive any physical therapy or exercise therapy for the neck during the study. The patient should have passed at least primary school level of education. Included patients should have at least 60 degrees of neck extension without sever symptom exacerbation. In the past 6 months, they have not received physiotherapy for neck pain. Ability to stand upright. The patients know Persian language. The patients did not perform Jaw-Temporal surgery. The patients should not have Severe mental illnesses requiring medication. Not participating regular exercising.

Exclusion criteria:

Positive Dix Hallpike test that indicates vestibular system dysfunction. Dissatisfaction with continuing tests. Inability to perform or complete study tests due to exacerbation of symptoms.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated into two groups of proprioceptive (PT) and conventional physiotherapy treatment with Randomization.com software through Random Permutations. This method provides the researcher with a predetermined random order by the software, thus prior to recruitment, the allocation of every participant is determined. Each subject will enter the study based on the order of their entry (number 1, subject 2 and ...). Randomization will be done on subjects who are all patients with neck pain and are not different in all group characteristics and independent variables, so none of our independent variables play a role in randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Grouping is associated with the patient kept unaware of being in the case or control group and the treatment regimen of the other group. The assessor will not be aware of the grouping and treatment plan of the subjects.

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 Social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences, Koodakyar Ave, Daneshjoo Blve, Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2019-10-21, 1398/07/29

Ethics committee reference number

IR.USWR.REC.1398.095

Health conditions studied

1

Description of health condition studied
Non-specific chronic neck pain
ICD-10 code
M54. 2
ICD-10 code description
Pain, cervical (neck), chronic, more than 3 months. Discomfort or more intense forms of pain that are localized to the cervical region. This term generally refers to pain in the posterior or lateral regions of the neck.

Primary outcomes

1

Description
Sway Velocity
Timepoint
Up to one week before and after the intervention
Method of measurement
Force Plate

2

Description
Sway Range
Timepoint
Up to one week before and after the intervention
Method of measurement
Force Plate

3

Description
Relative Proprioceptive Weighting
Timepoint
Up to one week before and after the intervention
Method of measurement
Force Plate

Secondary outcomes

1

Description
Pain Intensity
Timepoint
Up to one week before and after the intervention
Method of measurement
Visual Analog Scale

2

Description
Disability
Timepoint
Up to one week before and after the intervention
Method of measurement
Neck Disability Index

3

Description
Fear Avoidance
Timepoint
Up to one week before and after the intervention
Method of measurement
Tampa Scale for Kinesiophobia

4

Description
Sway Area
Timepoint
Up to one week before and after the intervention
Method of measurement
Force Plate

5

Description
Sway Path Length
Timepoint
Up to one week before and after the intervention
Method of measurement
Force Plate

6

Description
Maximum Lyapunov Exponent
Timepoint
Up to one week before and after the intervention
Method of measurement
Force Plate

Intervention groups

1

Description
Control group: The control group will receive convential physical therapy program (CPT). Each treatment session takes 60 minutes. Patients are asked to perform conventional physiotherapy exercises at home, twice a day for 5 weeks, and record their exercises in a structural scheduled. They will receive electrotherapy intervention at clinic sessions.
Category
Rehabilitation

2

Description
Intervention group: The intervention group will be received proprioceptive training (PT) in addition to the conventianal program. Each treatment session takes 120 minutes. Patients are asked to perform conventional physiotherapy exercises at home, twice a day for 5 weeks, and record their exercises in a structural scheduled. They will receive electrotherapy intervention

at clinic sessions. The PT group will be additionally trained by proprioceptive exercises at clinic sessions. The patients in this group will practice head relocating exercise under supervision of a trained physical therapist.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Rofeide Rehabilitation Hospital
Full name of responsible person
Amir Hossein Kahlaee
Street address
Physiotherapy Clinic, Rofeide Hospital, Nemati Alley, East Soleiman Street, Gheytarieh
City
Tehran
Province
Tehran
Postal code
1935973476
Phone
+98 21 2357 0146
Fax
Email
amir_h_k@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Khodaee Ardakani Mohammad Reza
Street address
University of Social Welfare and Rehabilitation Sciences, Koodakyar Ave, Daneshjoo Blve, Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 2218 0083
Fax
+98 21 2218 0109
Email
Kh.ardakani@uswr.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Amir Hossein Kahlaee
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Room 522, Floor 5, Farabi Building, University of Social Welfare and Rehabilitation Sciences, Koodakyar Ave, Daneshjoo Blve, Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Phone
+98 21 2218 0083
Fax
+98 21 2218 0109
Email
amir_h_k@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Amir Hossein Kahlaee
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Room 522, Floor 5, Farabi Building, University of Social Welfare and Rehabilitation Sciences, Koodakyar Ave, Daneshjoo Blve, Evin
City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0083

Email

amir_h_k@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Leila Goudarzi

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Floor 3, No 66, West Ramin Malakooti Ave, Patris Lomomba Street, Satarkhan Street

City

Tehran

Province

Tehran

Postal code

1443883364

Phone

+98 21 6642 7472

Email

leilaagoudarzi@gmail.com

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

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

Title and more details about the data/document

Intervention protocol and pre- and post-study tests, statistical methods, and informed consent forms will be shared prior to the intervention.The results of the statistical tests and the report of possible exit from the study will be reported after the end of the sampling and data analysis.

When the data will become available and for how long

Intervention protocol and pre- and post-study tests, statistical methods and informed consent forms will be shared in December 2019. Results of statistical tests and reports of possible withdrawal of subjects from study will be report winter 2021.

To whom data/document is available

It will be available to the public.

Under which criteria data/document could be used

The results of the study can only be used with reference to the present study. In order to perform any new statistical analysis on the data, a written authorization from the responsible researcher will be required.

From where data/document is obtainable

Interested in accessing study information can be reached by email at amir_h_k@yahoo.com or am.kahlaee@uswr.ac.ir or correspondence with Postal Address of Farabi Building, 5th Floor, Room 522 at Farabi Building, 5th Floor, Room 522

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

Contacting the responsible researcher will be sufficient to access the data of this study.If the responsible researcher agrees to provide the information, this process will take a maximum of one week.

Comments