

The result of deep neck flexors training on disability and pain over upper back and neck muscles in patients with chronic neck pain

Submission date 19/11/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/01/2022	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Neck pain is a common problem that has various causes; sleeping in an awkward position, using a computer for a long period, anxiety, stress and straining a muscle to name a few. It is thought that 67% of the general population will experience neck pain. More women have been reported to have the condition than men (22% compared with 16%). It can cause problems for people trying to do their usual daily activities. Neck pain contributes significantly in the suffering of individuals and it is one of the most common problems that is seen in primary health care (for example, GP surgeries). Chronic neck pain of otherwise unknown (idiopathic) cause is often due to weak deep neck flexors (longus capitis and longus colli); these are muscles on the front of the neck that allow for simple movements such as nodding and turning the head. It is known that people who report the greatest neck pain have the weakest deep neck flexors. Myofascial trigger points, or simply trigger points, have been reported in many studies and it seems that they may be responsible for neck pain. Trigger points can be described as hypersensitive points within muscles that can cause pain if irritated or stimulated in some way. It is known that the deep neck flexors training reduces neck pain and disability caused by neck pain. However, whether or not this training can affect the sensitivity of myofascial trigger points (and therefore causing extra pain) has not been thoroughly investigated. The aims of this study were to investigate the effect of neck treatments (interventions) on disability to investigate the pain pressure thresholds over myofascial trigger points around the neck and upper back region for patients with chronic neck pain after the treatment.

Who can participate?

Adults aged 18-65 suffering from neck pain for at least the last three months.

What does the study involve?

The participants are randomly assigned into one of three treatment groups. Each group of participants are given different neck treatments twice a week for seven weeks. Each participant from all groups are assessed at the beginning of the study and after the end of treatment. This

includes assessing the extent of neck disability and pain, range of movement and whether the participants are satisfied with the treatment. All participants have a clinical examination and are taken through their medical history before they start the study.

What are the possible benefits and risks of participating?

Possible benefits from participating include diagnosing the cause of the neck pain and identifying the most appropriate treatment. Any participant that felt dizzy or any discomfort during their treatment stopped the treatment referred to the researchers physician.

Where is the study run from?

Technological Educational Institute of Western Greece, Branch Aigio

When is the study starting and how long is it expected to run for?

February 2014 to March 2015

Who is funding the study?

Technological Educational Institute of Western Greece, Department of Physiotherapy

Who is the main contact?

Mr Palvos Bobos

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The effect of neck muscles training on disability and pain in patients with chronic neck pain: a prospective single blind randomized controlled trial

Study objectives

There will be a difference in pain, disability, and pain pressure thresholds over myofascial trigger points after the neck muscles training in patients with chronic neck pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Technological Educational Institute of Western Greece (Aigio) committee, 26/03/2014, ref: 14075/26-3-14

Study design

Single-centre single-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Chronic neck pain

Interventions

All participants received instruction guidelines through written leaflet and digital video disk (duration 17 minutes recorded by the two physiotherapists) with ergonomic advices and exercise guidelines for neck for a fuller understanding of the execution of the therapeutic exercises. All therapeutic interventions from all groups were applied twice per week for 7 consecutive weeks with gradually increasing exercising difficulty depends on the level of each patient.

All the Individuals that met the inclusion criteria and signed the consensus form to participate in the study, they received an exercise leaflet guide (what to do at home) and a digital video disk

how to performed those exercises at home. More specifically, the leaflet instruction guide and the digital video disk had the following training program for the neck and shoulder region. The program was divided in 3 parts, the warm-up, the basic part and the ergonomic guidelines with stretching part. In the warm-up patients were instructed to do:

1. Slow rotations of the head in all directions 10 times/per rotation.
2. Movement of the shoulders and the back in all directions 10 times each movement
3. Rotation of the arms in all directions 10 times each movement Patients were instructed to breath normal during the warm-up period.

Basic Part: Patients were instructed to do:

1. Posterior movement of the neck from sitting position 10 times
2. Posterior movement of the neck with towel or elastic belt from sitting position 10 times
3. Isometric contraction of neck muscles in all directions (flex-extension, side flexion-extension, rotation left-right and forward and backward the neck) by adding resistance with their hand 10 times per movement
4. Very slow rotary motion of the head 10 times

Stretching part: The patients were instructed to do:

1. Neck extension- flexion stretching 10 sec - 15 sec maximum to avoid possible dizziness
 2. Neck side flexion and rotation stretching 10 sec - 15 sec maximum to avoid possible dizziness
- Ergonomic directions: Patients were repeatedly instructed how to sleep, sit on the chair during their work, driving position and walk

Group (A)-Intervention Deep neck flexors Group

Deep neck Flexors group (A): Performed the following exercises:

1. The craniocervical Flexion Test (CCFT) with air pressure biofeedback
2. Nodding from supine position
3. Nodding from pronation position
4. Nodding from Stand position close to the wall All exercises were terminated if the patient activated the superficial neck muscles

Group (B)- Intervention Superficial Neck muscles Group

Superficial Neck muscles Group (B)

1. Posterior head movement from sitting position
2. Posterior head movement from supine position
3. Movement in all directions from pronation position
4. Basic "cat exercise" from knee positioning

Group (C)- Advice Group

Advice Group (C) The advice group performed the above mentioned exercises that were described in the leaflet and the digital video disk.

In the end all the groups performed stretching exercises (the group (A) and (B) with the help of the physiotherapist) except from the group (C) that performed the stretching part with the help of the DVD and the leaflet.

All the measurements (self-reported outcomes & clinician based outcomes) were done in the start and in the end of the therapeutic training programs. Also, patients were informed not participate in other therapeutic sessions and do not receive any medication. Thus, they were informed that they can leave from the study whenever they desire.

Intervention Type

Procedure/Surgery

Primary outcome measure

The Neck Disability Index (NDI) which measures the disability of the neck and the score ranging from 0"no disability" to 50"severe disability"

Measured at the beginning and the end of the training programme

Secondary outcome measures

1. The Numeric Pain Rating Scale (NPRS) an 11-pain scale which measures the pain intensity from 0"no pain" to 10"maximum pain"
2. The Short-Form 12 (SF-12) questionnaire which measures the quality of life
3. The Client Satisfaction Questionnaire-8 (CSQ-8) an 8 item questionnaire which measures the patient satisfaction ranging from 0"no satisfaction" to 32"maximum satisfaction"
4. The craniocervical flexion test (CCFT) tested with Chatanooga pressure biofeedback unit which measures the deep neck flexors muscle endurance
5. The pain pressure thresholds (PPTs) over Myofascial Trigger points of levator scapulae, upper trapezoid and splenius capitis muscles (both sides), tested with Wagner pressure pain algometer (FDK-20 model)
6. The thoracocervical angle which measures the angle from C-7-tragus-horizontal and tragus-eye-vertical for traction of the head with digital photo pictures (Nikon Coolpix p520) and analysis of angles with digital protractor

Measured at the beginning and the end of the training programme

Overall study start date

20/02/2014

Completion date

31/03/2015

Eligibility

Key inclusion criteria

1. All patients that had at least 3 months or more pain in the neck
2. Age range 18-65 years
3. Both genders

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

A power analysis was performed and the power sample size was calculated 59 individuals. The total recruitment was 92 individuals and 25 were excluded from the study. The trial started with 67 individuals and were randomly assigned in each of the 3 groups. The first (A) group had 23 , The second (B) group had 22 and the third (C) had 22 patients.

Total final enrolment

67

Key exclusion criteria

Individuals were excluded from the study if they had:

1. Cervical radiculopathy
2. Any systemic disease (e.g diabetes)
3. Previous neck surgery
4. Pregnancy
5. Diseases of central nervous system
6. Myopathy
7. Participation in neck treatment program for the last 6 months

Date of first enrolment

01/10/2014

Date of final enrolment

09/01/2015

Locations**Countries of recruitment**

Greece

Study participating centre

Technological Educational Institute of Western Greece, Branch Aigio

Psaron 6, Myrtia

Aigio

Greece

25100

Sponsor information**Organisation**

Technological Educational Institute of Western Greece

Sponsor details

Psaron 6, Myrtia
Aigio
Greece
25100

Sponsor type

University/education

Website

<http://physio.teiwest.gr/en/>

ROR

<https://ror.org/01mymm084>

Funder(s)

Funder type

University/education

Funder Name

Technological Educational Institute of Western Greece, Department of Physiotherapy

Results and Publications

Publication and dissemination plan

Intention to publish date

30/11/2015

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/11/2016	07/01/2022	Yes	No