Effect of shoulder and neck exercises on improving neck disability of middle-aged and older adults with chronic neck pain.

Submission date 27/12/2018	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 10/01/2019	Overall study status Completed	 Statistical analysis plan Results
Last Edited 11/01/2019	Condition category Musculoskeletal Diseases	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

People with neck pain often also have, neck disability and limited neck range of movement. Exercises are widely recommended for the improvement of pain in adults with persistent neck pain, but it is not agreed what the most effective exercises are. This study aimed to investigate whether shoulder and neck exercises can improving the neck disability of middle-aged and older adults with persistent neck pain.

Who can participate? Men and women aged over 45 years with neck pain.

What does the study involve?

Participants were randomly allocated to one of two groups. All participants received interferential current therapy (a type of electrical stimulation therapy) for 15 minutes, intermittent (on and off) neck traction (pulling/stretching) for 17 minutes per time and heat pack for 15 minutes, 3 times a week for 6 weeks. Participants in the intervention group were also asked to participate in a 6-week training program of shoulder and neck exercises performed with supervision 3 times a week.

What are the possible benefits?

Participants might experience improvement in pain, disability and range of motion. They might find some of the treatments uncomfortable or time-consuming.

Where is the study run from? Wan-Fang Hospital (Taiwan)

When is the study starting and how long is it expected to run for? December 2015 to September 2016

Who is funding the study? Wan Fang Medical Center (Taiwan) Who is the main contact? I-Hsien Lin, 88262@w.tmu.edu.tw

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N201508012

Study information

Scientific Title

Effect of shoulder and neck exercises on improving neck disability of middle-aged and older adults with chronic neck pain.

Acronym

shoulder and neck exercises on improving neck disability.

Study objectives

This study explored the effectiveness of 6-week shoulder and neck exercises on improving the neck disability of middle-aged and older adults with chronic neck pain.

Ethics approval required Old ethics approval format

Ethics approval(s)

The Institutional Review Board of Taipei Medical University, 18/12/2015, ref: N201508012

Study design

Randomized controlled assessor-blinded trial

Primary study design Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Chronic neck pain

Interventions

All participants attended physical therapy for 6 weeks. The therapy was composed of interferential current therapy (a type of electrical stimulation therapy) for 15 minutes, intermittent cervical traction for 17 minutes per time and heat pack for 15 minutes, 3 times per week for 6 weeks.

Participants in the intervention group also received a shoulder and neck exercises program consisting of craniocervical flexion exercises and progressive elastic-band resistance exercises. They performed these exercises with one-on-one supervision performed 3 times per week for 6 consecutive weeks.

Intervention Type

Other

Primary outcome measure

Pain measured using a visual analogue scale (VAS) before and after the 6-week intervention.

Secondary outcome measures

1. Neck disability measured using a neck disability index (NDI) before and after the 6-week intervention.

2. Neck flexibility measured using cervical range of motion (CROM) instrument (CROM Deluxe, Performance Attainment Associates, Lindstrom, MN) before and after the 6-week intervention. The participants were seated on a chair with back support and were asked to perform the maximum angles of flexion, extension, and side bending and rotation until they felt pain. In each direction, the mean CROM derived from the 3 angles was obtained.

Overall study start date

18/12/2015

Completion date

04/11/2016

Eligibility

Key inclusion criteria

- 1. Aged 45 years or older
- 2. Have experienced neck pain for more than 3 months
- 3. Neck pain exceeding 30 mm on a visual analogue scale (VAS)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants 72

Key exclusion criteria

- 1. Aged younger than 45 years
- 2. History of spine surgery
- 3. Major cardiovascular diseases
- 4. Rheumatoid arthritis
- 5. Pregnancy
- 6. Shoulder impingement syndrome
- 7. Spinal tumor
- 8 Participated in a neck exercise program in past 12 months.

Date of first enrolment

20/12/2015

Date of final enrolment 17/09/2016

Locations

Countries of recruitment Taiwan

Study participating centre Wan-Fang Hospital 111 Hsing-Long Road, Section 3 Taipei Taiwan 116

Sponsor information

Organisation Wan Fang Medical Center

Sponsor details No.111, Sec. 3, Xinglong Rd Wenshan District Taipei City Taipei Taiwan 116

Sponsor type Hospital/treatment centre

ROR https://ror.org/058y0nn10

Funder(s)

Funder type Hospital/treatment centre

Funder Name Wan Fang Medical Center

Results and Publications

Publication and dissemination plan Planned publication of study results in a peer reviewed journal.

Intention to publish date 31/12/2019

Individual participant data (IPD) sharing plan

The data sets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary Other