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A therapeutic program combining massage and strengthening exercises can correct posture and improve the quality of life in patients with neck pain

Submission date
18/03/2020

Recruitment status
No longer recruiting

Registration date
19/03/2020

Overall study status
Completed

Last Edited
20/08/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Postural disorders like forward head posture (FHP) have been linked to cervical dysfunction and pain in patients with neck pain syndromes. Nevertheless, it remains unclear whether this can be corrected by specific therapeutic programs. The aim of this study is to evaluate the short- and long-term effects of the combined application of massage, soft-tissue stretching and strengthening exercises of the cervical and thoracic area of the spine on the improvement of quality of life in neck pain patients.

Who can participate?
Female patients with neck pain

What does the study involve?
Participants are randomly allocated to receive specific exercises combined with either targeted IASTM (instrument-assisted soft tissue mobilization) or classical massage for eight treatment sessions in 4 weeks (twice per week). The total duration of the follow-up is 2 months (8 weeks).

What are the possible benefits and risks of participating?
Benefits of the study include improvement of functionality in terms of strength, mobility, and disability. There is no risk for the patients because the procedures are light (massage-soft tissue techniques) and therapeutic (exercises).

Where is the study run from?
University of Patras (Greece)

When is the study starting and how long is it expected to run for?
September 2019 to June 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Konstantinos Fousekis
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A structured rehabilitation program combining targeted instrument-assisted soft tissues mobilization (IASTM) applications and neuromuscular exercises can correct forward head posture and improve functionality of patients with mechanical neck pain

Study objectives
The main study hypothesis is that the combined application of instrument-assisted soft tissues mobilization (IASTM) techniques and neuromuscular exercises of the cervical and thoracic area is better than the combined application of classical massage and same exercises on the improvement of the functionality of patients with mechanical neck pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/11/2019, ethical committee of the Department of Physiotherapy, University of Patras (Dr Charalambos Matzaroglou MD, Psaron 6, Egio PC 25100, Greece; +30 (0)26910 22058; orthopatras@yahoo.gr), ref: 29-10/11/2019

Study design
Single-centre interventional randomized control study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mechanical neck pain

Interventions
Randomization of the patients will be performed before assessment by computer-generated numbers, details of which will be concealed in sequentially numbered, sealed opaque envelopes.

20 female patients with diagnosed mechanical neck pain and FHP (>50) are randomized to receive specific exercises combined with either targeted IASTM applications (group A, n=10) or classical massage (Group B, n=10) for 8 treatment sessions in 4 weeks (2 x week).

The total duration of the follow-up will be 2 months (8 weeks).

Intervention Type
Other

Primary outcome(s)
Forward head posture in sitting and standing, measured by craniospinal angle measurement (Cervicalangle or Craniovertebralangle - CVA) before and after each treatment session and at 2 and 4 weeks after the end of treatment

Key secondary outcome(s))
Measured during treatment (before and after each treatment session) and at 2 and 4 weeks after the end of treatment:
1. Pain measured using the VAScale pain questionnaire
2. Cervical muscles strength measured using the Microfet 2 hand dynamometer
3. Cervical range of motion (ROM) measured using inclinometer (BubbleInclinometerBaseline)
4. Neck disability assessed using neck pain disability index (NDI) questionnaire

Completion date
20/06/2020

Eligibility

Key inclusion criteria

1. Female patients with diagnosed mechanical neck pain
2. Craniovertebral angle >50

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
20

Key exclusion criteria
1. Little or no forward head displacement (<50°)
2. Acute neck injuries
3. Intervertebral disc herniations
4. Vertebral slip
5. Concomitant neurological, musculoskeletal, and mental disorders
6. Medication administration

Date of first enrolment
10/01/2020

Date of final enrolment
15/02/2020

Locations

Countries of recruitment
Greece

Study participating centre
University of Patras
Lab of human assessment and rehabilitation
Psaron 6
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Sponsor information

Organisation
University of Patras

ROR
https://ror.org/017wvtq80

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Konstantinos Fousekis (kfousekis@upatras.gr) after the end of the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/02/2021	20/08/2021	Yes	No