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Impact of neck rehabilitation on temporomandibular joints and muscle functioning in patients with chronic neck pain

Submission date
27/08/2020

Recruitment status
No longer recruiting

Registration date
23/09/2020

Overall study status
Completed

Last Edited
19/10/2021

Condition category
Musculoskeletal Diseases

✓ Retrospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Cervical spine dysfunction is a cause of neck pain. Cervical spine dysfunction occurs in about 70% of the population. Both diagnosis and treatment of these problems are difficult, and in many cases, the effects of therapy are not satisfactory. Existence of jaw (temporomandibular joint) discomfort along with cervical spine disorders is quite common and is associated with many limitations and adverse symptoms for the patient. The exact relationship between neck ailments and temporomandibular dysfunction (TMD) is still unclear. This study aims to verify the functional relationship between the cervical spine and TMJ as well as check whether the therapy focusing only on the cervical region has a real impact on the structures located in the facial area. These tests have practical applications because they can indicate new directions in the diagnosis and therapy of neck and TMD

Who can participate?
Adults aged over 18 years, with chronic neck pain, and also healthy subjects.

What does the study involve?
Participants undergo a three-week rehabilitation program involving manual therapy, massages, exercise and education.

What are the possible benefits and risks of participating?
The benefits to those taking part are the chance to receive 3 weeks of rehabilitation, which may improve health and reduce chronic neck pain. The intervention is provided by qualified physiotherapists, so there is no risk for participants.

Where is the study run from?
1. Rzeszow University in Poland
2. University of Physical Education in Kraków (Poland)

When is the study starting and how long is it expected to run for?
April 2011 to December 2014

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Anna Mika, anna.mika@awf.krakow.pl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Protocol/serial number
Nil known

Study information

Scientific Title
Impact of cervical spine rehabilitation on temporomandibular joints functioning, and bioelectrical activity of cervical and masticatory system muscles in patients with idiopathic neck pain

Acronym
CRTMD

Study hypothesis
The aim of this study is to assess the impact of a 3-week neck-only rehabilitation programme without direct intervention in the craniofacial area on the bioelectric activity of both the cervical spine and muscles in the craniofacial area among patients with idiopathic neck pain. Experimental group undergo three-weeks rehabilitation program, which is individual for each patient and comprise the following standard treatments for chronic pain of the musculoskeletal system.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2012, Ethical Committee of Rzeszow University in Poland (al. Tadeusza Rejtana 16C, 35-310 Rzeszów, Poland; +48 17 872 19 20; komisjabioetur@gmail.com), ref: No 3/05/2012

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Condition
Idiopathic neck pain

Interventions
The experimental group undergo a 3-week rehabilitation program, which is individual for each patient and comprises the following standard treatments for chronic pain of the musculoskeletal system: manual therapy (soft tissue therapy of the neck and the shoulder girdle, trigger point therapy, manual cervical traction, classical massage, myofascial release); individual exercises with a therapist (weight free, respiratory, fit ball and body posture correction exercises); physical therapy (sollux lamp); education on the character of the dysfunction, body posture correction techniques, ergonomics and everyday mouth hygiene.

The rehabilitation was provided five times a week lasting each time for about 2 h.

Age-matched subjects (control group) who were cervical pain-free, had no cervical spine and TMJ dysfunctions or were not in the process of current orthodontic treatment did not undergo any therapy.

Intervention Type
Mixed

Primary outcome measure
Measured at baseline and 3 weeks:
1. Pain intensity measured using 10-point visual analogue scale (VAS)
2. Temporomandibular joints functioning measured using the Helkimo clinical dysfunction index (Di)
3. Head posture and range of motion in the cervical spine - measured with measuring tape
4. Cervical Spine and craniofacial muscles bioelectrical activity (sEMG) assessed by surface electromyography

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/04/2011

Overall study end date
22/12/2014

Eligibility

Participant inclusion criteria
Patient:
1. Chronic idiopathic neck pain
Patient and control:
2. Aged 18 years or above

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
60

Participant exclusion criteria
Patient:
1. Cervical spine injury 3 months prior to the therapy

2. Regular use of painkillers or steroids, without possibility to withdraw it for the whole duration of the therapy
3. Radiographically diagnosed developmental and degenerative abnormalities of the cervical spine as; spinal stenosis, subluxations, spinal disc herniation
4. Orthodontic treatment (braces, aligners); removable dentures

Control:
5. Cervical pain
6. Cervical spine and TMJ dysfunction
7. In the process of current orthodontic treatment

Recruitment start date
02/04/2012

Recruitment end date
22/12/2014

Locations

Countries of recruitment
Poland

Study participating centre
Rzeszow University in Poland
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Sponsor information

Organisation
Rzeszów University

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Sponsor type
University/education

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ROR
https://ror.org/03pfsnq21

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/04/2021	27/04/2021	Yes	No
Results article		07/10/2021	19/10/2021	Yes	No