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Manual therapy vs tactile sensory training in patients with neck pain

Submission date
24/03/2021

Recruitment status
No longer recruiting

Registration date
26/04/2021

Overall study status
Completed

Last Edited
10/05/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Neck pain is a major musculoskeletal condition with a great impact on people's lives worldwide in modern society. It is reported that more than 60% of the population will suffer from it at least once over the course of their lifetime.
Neck pain is managed by a plethora of treatment options, mostly delivered in primary care settings, including non-pharmacological treatments(self-management advise and pain education, exercise therapy, manual therapy and psychosocial interventions)complementary treatments (i.e. acupuncture), pharmacological therapies and more rarely surgical options in severe cases.
Recently greater attention has been given to factors, like patients' beliefs and expectations placebo effect and pain education which provide input into the nervous system, as well as activate the brain to modulate pain experience.
The purpose of the present study was to investigate the outcomes of neck pain treatment and compare the immediate effects of manual therapy versus localization training by the tactile stimulus on pain intensity and mobility of the neck, after a single treatment session.

Who can participate?
Eligible patients had to present with neck pain for at least 1 week prior to their recruitment in the trial
Patients were excluded if they could not read or understand spoken /written Greek, were under the age 18 and over 65, had undergone spinal surgery in the area of focus, had any skin condition preventing them from receiving tactile stimuli, had any contraindications to manual therapy (vertebral arteries insufficiency, spinal instability, steroid medication use, malignancy) present any symptoms related to neurological conditions altering sensation (i.e. peripheral neuropathy, multiple sclerosis, diabetes), had a diagnosis of radiculopathy with high irritability. All participants were required to completed and pass, a health questionnaire

What does the study involve?
Volunteer adults suffering from neck pain and meeting the inclusion criteria were asked to complete a consent form prior to the commencement and participants were reminded at this point that they were free to withdraw from the study at any point.
Then the assessor assessed the level of pain and neck mobility of the participants using the

equipment before and right after the one session treatment which is painless and its duration is less than 5 minutes.
The participants were randomly assigned into either the tactile sensory stimulation group or the manual therapy group, with mobilizations.

What are the possible benefits and risks of participating?
The possible benefits after your participation in the current trial are the decrease in the level of pain and the improvement of cervical spine mobility. But even if there is no immediate benefit from this one single treatment session you would have contributed to further investigate the aspects and treatment of neck pain.
If the participant meets the inclusion criteria to the experimental procedure there are no risks from the application of the therapeutic techniques as the interventions are painless and safe.

Where is the study run from?
The study was run by the University of Patras, Department of Physiotherapy and took place in Aigion Campus (Greece)

When is the study starting and how long is it expected to run for?
February 2019 to December 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Eleftheria Thomaidou, elethom@gmail.com
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
University of Patras 7922/26022019

Study information

Scientific Title
Manual therapy vs localization (tactile sensory training) in patients with neck pain: a randomized clinical trial

Study objectives
1. There is a significant difference in the interventional effect between manual therapy and localization group (Group Factor)
2. There is a significant difference in pain levels and cervical range of motion between pre and post-intervention to cervicothoracic spine (Time Factor)

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 01/04/2019, TEI Western Greece University of Patras Bioethics Committee (University Campus 26504 Rio Achaia, Greece; +30 2610 996683; rectorate@upatras.gr), ref:12144

Study design
Single-blind interventional randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files (in Greek)

Health condition(s) or problem(s) studied
Neck pain

Interventions
Thirty eligible volunteers, with neck pain, consented and were randomly allocated to a Manual Therapy or to a motionless, localization (tactile sensory training) group.
A single three-minute treatment session was delivered to each group's cervico-thoracic area by two therapists (one for each group).
Localization involved tactile sensory stimulation, applied randomly in one out of a nine-block grid. Subjects were asked to identify the number of the square being touched.
Manual therapy involved three-minute anteroposterior glides and SNAG techniques, applied to hypo-mobile levels.
Pre- and post-intervention pain intensity, using a pressure pain threshold (PPT) algometer and numeric pain rate scale (NPRS), was assessed. Neck ROM was recorded with a bubble inclinometer.

Randmoization
Randomized number table designed by an online software (www.randomizer.org) in a private room in the Clinical Rehabilitation lab.

Intervention Type
Behavioural

Primary outcome measure
1. Self-reported neck and thoracic pain intensity was evaluated using 0-10 Numeric Pain Scale (NPRS) pre and immediately post-treatment
2. Pain Pressure Threshold (PPT) measured through an algometer pre and immediately post-

treatment
3. The range of motion of the cervical spine was measured through a bubble inclinometer pre and immediately post-treatment

Secondary outcome measures
1. Neck Disability was measured using Neck Disability Index (questionnaire) only at baseline
2. Anxiety and Depression was measured using the Hospital Anxiety and Depression Scale (HADS) only at baseline
3. Patient's improvement or deterioration over time, was measured using the Global Rating of Change Scale (GRoC)only at baseline

Overall study start date
26/02/2019

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Participants should suffer from neck pain for at least 1 week
2. Participants must be between the ages of 18-65, including both males and females
3. Participants able to understand spoken and written Greek
4. Participants must be able to give informed consent
5. No previous adverse effects to manual therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
A sample of 30 patients with neck pain, who met the inclusion criteria were randomly assigned into 2 equal groups(n=15)

Total final enrolment
30

Key exclusion criteria

1. Trauma/surgery to the CxTx in past
2. Skin allergies/ irritation/ dermatological conditions (dermatitis, eczema)
3. Neurological disorders such as altered sensation, peripheral neuropathy, multiple sclerosis
4. Vertebral arteries insufficiency
5. Steroid medication use
6. Spinal instability
7. High irritability
8. Radiculopathy
9. Malignant neoplasm
10. Cervical myelopathy
11. Those who answered YES to any of the questions in the health screening questionnaire, suggesting having contraindication on treatment

Date of first enrolment
01/11/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Greece

Study participating centre
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University/education

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ROR
https://ror.org/017wvtq80

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
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/05/2021	No	Yes
Protocol file			04/05/2021	No	No
Thesis results		01/05/2020	13/01/2022	No	No
Results article		11/05/2023	10/05/2024	Yes	No