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What is the most effective number of sets of neck mobilisations to reduce pain?

Submission date
14/10/2014

Recruitment status
No longer recruiting

Registration date
26/11/2014

Overall study status
Completed

Last Edited
13/03/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Neck pain can have a serious effect on a person's quality of life. It can limit their ability to perform everyday tasks, lead to loss of range of movement and the pain can spread to other areas such as the shoulder, arm or hand. Joint mobilisation techniques can provide relief from these symptoms and are a safe and good way to improve neck movements. This involves a physiotherapist gently moving bone or individual vertebrae to relieve pain, stiffness and increase range of movement. Here, we are carrying out a study to compare different number of sets of a manual therapy intervention (treatment) for the neck (mobilisations). We want to find out the optimum number of mobilisation sets which produces the greatest pain relieving effect. We will want to look at whether one longer set should be used or several shorter sets (up to 5) to produce these effects. The study's findings should help to improve the clinical recommendations for manual therapies for neck pain.

Who can participate?
Healthy volunteers, aged at least 18 and from a sample of second and third year sports therapy students currently studying at University College Birmingham (UK).

What does the study involve?
Participants are randomly allocated into one of four groups. Those in group 1 receive one sustained oscillatory mobilisation technique (one per second) for five minutes. Those in group 2 receive up to five repeated mobilisation sets (one per second for one minute). Those in groups 3 and 4 are 'control' groups and are left in same position (prone) but no manual contact is made. Group 3 will receive the same outcome measurement timings as Group 1, and Group 4 the same as group 2 respectively. At the end of study, we will compare the number of mobilisation sets with changes in pain and neural mechanosensitivity.

What are the possible benefits and risks of participating?
Participants will view primary research first hand and it is anticipated that this will help with their own future research. There should not be benefits beyond the short term changes in range of movement or altered pain relief. The main risk is a short term localised discomfort which should disappear within 24 hours or dizziness, double vision, difficulty swallowing, speaking or fainting which should disappear, if present, very quickly after the treatment. It should be noted

that this would be extremely rare however, the researchers will ensure that a medical questionnaire has been filled in before participation begins and these symptoms will be assessed at the beginning and end of the treatment with only those considered safe allowed to proceed. The participants will be asked to sit for a period of ten minutes before leaving. The mobilisations will only be administered by therapists with post graduate level training in manual therapy techniques and principles.

Where is the study run from?
The sports injury clinic at University College Birmingham (UK).

When is the study starting and how long is it expected to run for?
March 2015 to April 2016.

Who is funding the study?
Funding is provided by the lead researcher and University College Birmingham (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of different number of posterior-anterior mobilisation sets on cervical pressure pain threshold and upper limb neurodynamic mechanosensitivity

Acronym
N/A

Study objectives
It is hypothesised that the pain pressure threshold will increase and the peripheral neurodynamic mechanosensitivity will decrease with an increased number of sets of cervical mobilisation until a natural threshold is reached. It is not known if increasing number of mobilisation sets (up to five) will increase pain pressure thresholds or decrease peripheral neural mechanosensitivity to a greater degree than using one longer, equivalent set of mobiisations. The null hypothesis is that there will be no difference in pain pressure threshold or upper limb neurodynamic mechanosensitivity between groups; this may arise if changes are solely down to the amount of mobilisation repetition. Asymptomatic participants used. Results should help inform care of people with neck and upper limb musculoskeletal disorders.

On 15/09/2015 the following changes were made to the trial record:
1. The overall trial start date was changed from 22/10/2014 to 15/3/2015.
2. The overall trial end date was changed from 25/03/2015 to 25/03/2016.
3. The target number of participants was changed from 80 to 60.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College Birmingham, 01/10/2014, ref. AR/01/09/STethics

Study design
Randomised single-blind within-subject repeated measures study design

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Neck and upper limb musculoskeletal disorders

Interventions
Current interventions as of 15/09/2015:
Grade 3 mobilisations will be applied to subjects C5-6 right articular pillar in a posterior-anterior direction post randomisation at a frequency of 1 Hertz. Grade three mobilisations have been used on previous randomised trials involving the cervical spine.

1. Group 1: 5 sets x 60 repetitions
2. Group 2: 300 repetitions
3. Control group 1 - No manual contact- Outcomes measured at baseline and every minute for five minutes (equivalent to 5 sets x 60 reps)
4. Control Group 2- No Manual contact - Outcomes measured at baseline and after five minutes (equivalent to 1 x 300 reps)

A script will be used to standardise verbal instructions. A metronome will be used to maintain pace.

Previous interventions:
Grade 3 mobilisations will be applied to subjects C5-6 right articular pillar in a posterior-anterior direction post randomisation at a frequency of 1 Hertz. Grade three mobilisations have been used on previous randomised trials involving the cervical spine.

1. Group 1: 5 sets x 60 repetitions
2. Group 2: 300 repetitions
3. Group 3: No manual contact

A script will be used to standardise verbal instructions. A metronome will be used to maintain pace.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain Pressure Algometer will be measured by a blind assessor and noted to assess pain pressure threshold (PPT) in four separate predetermined locations based on signature zones. These locations will be marked with a water soluble pen and measured in the same order each time.

The objective tests will be repeated after each intervention set. The mean of three measurements will be calculated and recorded.

Secondary outcome measures
Neurodynamic test 1 will be measured by a blind assessor to estimate the mechanosensitivity of the upper limb peripheral nervous system. The elbow angle will be measured by goniometer.

The objective tests will be repeated after each intervention set . The mean of three measurements will be calculated and recorded.

Overall study start date
15/03/2015

Completion date
25/03/2016

Eligibility

Key inclusion criteria
1. Aged at least 18
2. No history of neck or upper limb pain within last 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Red flags to manual therapy
2. Dizziness, drop attacks, nausea, dysphagia, dysarthria, diplopia, facial numbness, nystagmus
3. Inability to lie prone

Date of first enrolment
01/02/2015

Date of final enrolment
01/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College Birmingham
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Sponsor information

Organisation
University College Birmingham (UK)

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Sponsor type
University/education

ROR
https://ror.org/042ver755

Funder(s)

Funder type
University/education

Funder Name
This project is funded by the lead researcher and University College Birmingham

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request