The effect of mobilisation of the fifth bone in the neck on head position sense

Submission date	Recruitment status	Prospectively registered
30/09/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
14/07/2008	Musculoskeletal Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0544147422

Study information

Scientific Title

Study objectives

This study aims to determine whether a manual therapy technique can alter head position sense. The manual therapy technique being utilised is a mobilisation (a gentle oscillatory movement) of the fifth bone in the neck. Head position sense refers to the ability to accurately relocate the head to a defined position following a movement. This concept, the mobilisation can influence head position sense, originated from the author observations during a practical session with fellow postgraduate students.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Granted by Addenbrooke's ethics committee.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal Diseases

Interventions

The purpose of this project is to determine whether mobilisation of the fifth bone in the neck alters head position sense. The hypothesis to be considered is: Mobilisation applied to a joint in the neck alters head position sense in healthy subjects. The Null hypothesis is that mobilisation applied to a joint in the neck does not have any effect on head position sense.

The proposed design involves one group of subjects and repeated random measures will be taken on these subjects. The subjects will undergo two conditions in a random order, to minimise the potential for an order effect. Randomisation will occur by utilising opaque envelopes containing a number indicating the condition to be performed first. The envelopes will contain an equal number of the conditions and will be well shuffled. Subjects will select an

envelope on commencing the study and this will determine the order in which they undergo the conditions. Thus testing of head position sense will be performed before and after both conditions. The two conditions involved are mobilisation (condition one), which will be compared with a control condition of lying still for 5 minutes (condition two). A control condition is included to determine whether any change in head position sense relates to the mobilisation or merely repeating the test. The subjects will essentially act as their own 'controls' since they will complete both conditions. Measurements will be taken during two separate testing sessions. Previous studies assessing the effect of manual therapy using a repeated random measures design have performed the conditions on separate days, presumably to be able to assess the true effect of each condition. It is recognised that these studies also included a placebo condition, however they demonstrated that this produced minimal or non-significant changes when assessing heart rate, respiratory rate and skin conductance in normal subjects. Although assessing the placebo effect of manual treatment on proprioception could be beneficial, the lack of significant changes in previous studies and the time and economical restraints on the researcher mean that a placebo condition will not be included in the present study.

Head position sense will be measured using the helmet method that has been used in several other studies. This method involves subjects wearing a helmet tied firmly to their heads, with a light beam attached to the top of the helmet and pointing to a target 90cm in front of the subjects. The target is mobile to facilitate the zeroing of the target in relation to the light beam on top of the subjects head. The target used will be similar to that used by a previous study, this involves a large sheet of graph paper divided into four by two axes, with the intersecting point being the centre of the target. It is thought that this target will facilitate accurate measurement, be practical and measurements can be checked after the testing session since one sheet of graph paper can be used and marked for each subject. Subjects will be seated facing the target with their vision occluded by goggles. They will be asked to concentrate for several seconds on the straight - ahead position, which corresponds to the centre of the target. They are then asked to perform a movement of the head and to try to return to the original position as closely as possible, without speed instruction. The point that the light beam stops is marked (a laser beam is usually used to facilitate accuracy). The global error relating to the centre of the target and the error in relation to the horizontal and vertical axes is measured. This provides a measurement of head repositioning accuracy.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Head position sense, utilising the helmet method which has been previously described and has been utilised in several other studies.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2004

Completion date

30/08/2004

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

20 participants

Key exclusion criteria

- 1. People with neck pain, whiplash injuries, upper back, shoulder or arm pain or previous history of these
- 2. People who have had previous manual therapy to their neck (ie seen an osteopath, chiropractor or physiotherapist or are a member of these professions)
- 3. People who have dizziness, vertigo, inner ear problems or suffer with consistent/ regular headaches

Date of first enrolment

01/04/2004

Date of final enrolment

30/08/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

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Sponsor information

Organisation

Department of Health

Sponsor details

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Sponsor type

Government

Website

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Funder(s)

Funder type

Government

Funder Name

Cambridge Consortium - Addenbrooke's (UK)

Funder Name

Own Account

Funder Name

NHS R&D Support Funding

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration