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Assessing the effectiveness of a lateral glide cervical spine mobilisation on cervicobrachial (neck and arm) pain

Submission date	Recruitment status	[ ] Prospectively registered
16/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2017	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

09/H1203/45

Study information

Scientific Title
A randomised controlled trial to assess the effectiveness of a lateral glide cervical spine mobilisation on cervicobrachial (neck and arm) pain

Acronym
CBS Trial

Study objectives
The primary objective of this study is to investigate whether a self-management protocol with lateral glide mobilisation is more beneficial than a self-management protocol in isolation for participants with cervicobrachial syndrome (CBS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Staffordshire Local Research Ethics Committee approval pending as of 17/06/2010

Study design
Randomised controlled trial

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 contact details below to request a patient information sheet

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

Interventions
Patients will be randomised to
1. Lateral glide with self-management
2. Self-management

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Pain, assessed by Visual Analogue Score (VAS)

Secondary outcome measures
1. Short Form 36-item Health Survey (SF36) (RAND)
2. Neck and Upper Limb Index (NULI)
3. Tampra scale of Kinesiophobia
4. Global Rating of Change (GROC)
5. Self-Administered Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS)
6. Upper limb nerve extensability test
7. Cervical Active Range Of Motion (AROM)

Overall study start date
24/06/2009

Completion date
24/06/2012

Eligibility

Key inclusion criteria
1. Aged 18 - 65 years experiencing CBS (described as pain originating in the neck with associated pain radiating below the level of the shoulder joint into the arm) with or without parasthesia and or weakness in a dermatomal distribution
2. Had symptoms for greater than 6 weeks
3. Adequate knowledge of English to participate in a neuro-musculoskeletal examination and to answer the study questionnaire
4. Able to attend assessment and treatment appointments
5. Will have verbally agreed to attend the review appointment at 6, 26 and 52 weeks following initiation of the treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
96

Key exclusion criteria
1. Presenting with any red flags: severe unremitting night pain, unexplained weight loss, history of cancer, general malaise, and constant unvarying pain
2. Bilateral arm symptoms
3. Signs and symptoms strongly suggestive of thoracic outlet syndrome or a specificperipheral pathology e.g. adhesive capsulitis, sub acromial impingement etc.
4. Specific pathology affecting nerve function e.g. multiple sclerosis, known peripheral vascular disease, diabetes
5. Known specific pathology affecting systemic joint function e.g. rheumatoid arthritis, ankylosing spondylitis
6. Cervical spine surgery, botulinum toxin injections or epidural injections to cervical spine or planned imminent treatment
7. Having other forms of manual therapy for their CBS symptoms e.g. osteopathy or chiropractics
8. Involved in compensation and or litigation associated with neck and or upper limb pain
9. Already involved in a research trial

Date of first enrolment
24/06/2009

Date of final enrolment
24/06/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen's Hospital
Burton on Trent
United Kingdom
DE13 0RB

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
c/o Brendan Laverty
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Other

Funder Name
Manipulation Association of Chartered Physiotherapists (UK)

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 summary
Not provided at time of registration