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General versus specific spinal manipulation for back pain

Submission date
16/03/2017

Recruitment status
No longer recruiting

Registration date
12/04/2017

Overall study status
Completed

Last Edited
22/10/2019

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Pain in the lower back is very common and can get better over time. However, if it becomes worse it can require treatment. Spinal manipulation is often used to treat the low back pain. Spinal manipulation is therapeutic technique applied by a doctor, physiotherapist or other manual therapist to help patients with spinal pain. Spinal manipulation involves the rapid movement (thrust) of the spine to stimulate the nerves and joints in a certain way that reduces pain. This often makes a popping noise come from the joints. The application of spinal manipulation has traditionally involved targeting the technique to a particular level of the spine where the problem is occurs. This involves a time-consuming assessment process to figure out where this is, which has been deemed necessary as the effect of spinal manipulation was thought to be related to specific joint changes, found both before and after manipulation. Recent research has questioned both the accuracy of spinal manipulation and the necessity for specific targeting of the spine. This study evaluates the effects of a targeted manipulative thrust technique versus a thrust of equal magnitude (strength), applied to the spinal region, to assess any difference in muscular responses and pain.

Who can participate?
Adults aged 18 to 60 with lower back pain.

What does the study involve?
Participants are randomly allocated to one of two groups. All participants attend three one hour treatment sessions within seven to nine days apart. Those in the first group receive a targeted thrust at a certain part of the spine (as determined by their physiotherapist). Those in the second group receive a thrust in a more general area of the lower spine. The thrusts in both groups are done with the same amount of strength and force. Participants are measured for their pain levels and muscle responses at each of the sessions.

What are the possible benefits and risks of participating?
Participants may benefit from long-term reduction in back pain. There is a small risk of short-term (less than 24 hours) of soreness after a treatment session.

Where is the study run from?
Wellcome Clinical Research Facility (UK)

When is the study starting and how long is it expected to run for?
April 2005 to June 2007

Who is funding the study?
Investigator initiated and funded (UK)

Who is the main contact?
Dr Chris McCarthy
cmccarthy@mmu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Chris McCarthy

Contact details
Manchester School of Physiotherapy
Brooks Building
Manchester Metropolitan University
Manchester
United Kingdom
M15 6GX
+44 161 247 2517
cmccarthy@mmu.ac.uk

Additional identifiers

Protocol serial number
005/CMFT/005

Study information

Scientific Title
A randomised controlled trial comparing targeted thrust manipulation with a general manipulation thrust in low back pain: Is a general approach as effective as specific?

Study objectives
Targeted spinal manipulation is more effective at reducing low back pain than a general thrust technique.

Ethics approval required
Old ethics approval format

Ethics approval(s)

North Manchester Local Research Ethics Committees, 01/03/2005, ref: 02/NM/406

Study design
Single centre double blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lower back pain

Interventions
Participants are randomly allocated to one of two groups. Randomisation is done through minimisation using BMI and gender as variables. Participants receive three sessions that are spaced seven to nine days apart. At the initial visit, all participants go through an initial assessment for their history of back pain prior to their therapy.

Group 1: Participants receive a targeted manipulative thurst (TT) to the lumbar spine. This is done through a single high velocity low amplitude thrust delivered to the participant in a side lying position localised to a clinician-defined symptomatic spinal level.

Group 2: General manipulation thrust (GT) to the lumbar spine. This is done through a high velocity movement with the participants in the side lying position not directed towards a specific lumbar level.

Participants receive the treatment for three treatment sessions spaced seven to nine days apart. Pressure-pain thresholds (PPT) are assessed using algometry and muscle activity (magnitude of stretch reflex) via surface electromyography (EMG) before and after each session. Subjective assessments of pain and disability are also collected using Roland Morris Disability and VAS scores before and after each session. The subjects received the same intervention at each of the tree sessions to examine any changes in response with repeated intervention.

Intervention Type
Other

Primary outcome(s)
Pain is measured using the Visual Analogue Scale for pain experienced at baseline and after session one, two and three.

Key secondary outcome(s))
1. Self-reported disability is measured using Roland Morris Disability Questionnaire at baseline and after session one, two and three
2. Pressure pain threshold is measured using a manual algometry pressure on the spinal muscles at baseline and after session one, two and three
3. Muscular reflexogenic responses (peak EMG amplitude) are measured using surface electromyography at session one, two and three

Completion date

11/06/2007

Eligibility

Key inclusion criteria
1. Adults aged 18 to 60 with low back pain
2. Roland Morris Pain and Disability Questionnaire (RM) score of 4 or more at the initial examination
3. Symptoms for at least 3 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Frank spinal deformity
2. Lumbosacral anomalies
3. Neoplastic disease of skeletal or soft tissue of the spine
4. Bone disease e.g. Paget's disease, osteoporosis, osteomyelitis
5. Inflammatory arthritis, rheumatoid arthritis, ankylosing spondylitis
6. Gout
7. Cord signs: signs of a upper motor neuron lesion at the spinal cord level
8. Positive Lhermitte's sign: This is where on flexion of the neck tingling or shock like sensations run down the arms to the fingers or down the legs and is a sign of a lesion in the posterior columns of the cervical cord (Draper, 1985).
9. Cervical and thoracic joint conditions producing neurological symptoms in one or both lower limbs
10. Evidence of involvement of one or more spinal nerve root
11. Cauda equina syndrome- triad of low back and or leg pain, numbness in the sacral region and loss of bladder or bowel control (Draper, 1985).
12. Advanced diabetes when tissue vitality might be low
13. Vascular abnormalities, visceral arterial disease
14. Congenital generalised hypermobility Ehlers-Danlos syndrome
15. Advanced degenerative changes
16. Severe root pain
17. Undiagnosed pain
18. Painful joint conditions, psychologically reinforced where manipulation runs the risk of producing an obsessional neurosis of vertebral displacement.
19. Warfarin sodium anticoagulant medication.
20. Pregnancy

Date of first enrolment
01/06/2005

Date of final enrolment
01/03/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Wellcome Clinical Research Facility
Central Manchester Foundation NHS Trust
Grafton Street
Manchester
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Christopher McCarthy

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2019	22/10/2019	Yes	No
Basic results		31/03/2017	24/04/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes