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Assessing the clinical prediction rule for spinal manipulation in a chronic lower back pain (LBP) population

Submission date
24/07/2013

Recruitment status
No longer recruiting

Registration date
06/09/2013

Overall study status
Completed

Last Edited
17/12/2014

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Chronic lower back pain (CLBP) is a significant public health problem with significant associated costs. There are currently over 200 different treatments available for CLBP. Spinal manipulation (SMT) is commonly used for CLBP. However, there is a need to identify those patients who are most likely to respond to SMT. The clinical prediction rule for SMT (CPRSMT) is to predict responsiveness to SMT in patients with acute (severe) lower back pain; however, there is a need to validate this rule in a chronic (long-term) lower back pain population. The aim of this study was to find out how well the CPRSMT predicted responsiveness to SMT compared to active exercise therapy (AET).

Who can participate?
Men and women over the age of 18 with a history of back pain for more than three months can participate in the study.

What does the study involve?
Patients came to a screening visit to find out their status on the CPRSMT and based on their status, they were then randomly allocated to either SMT or AET. Patients underwent two treatments per week for four weeks of SMT or AET.

What are the possible benefits and risks of participating?
Patients undergoing care may experience improvement in their CLBP. Patients undergoing either therapy may experience soreness or worsening of their CLBP.

Where is the study run from?
The study took place in Rochester (NY, USA) in Veteran Affairs clinics or outpatient chiropractic and physical therapy clinics.

When is study starting and how long is it expected to run for?
The study began recruiting participants in 2006 and was closed to enrolment in 2009.

Who is funding the study?
Department of Health and Human Services Health Resources and Services Administration (USA).

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
HRSA Grant #: 4 R18HP07641-03-03

Study information

Scientific Title
Evaluation of the clinical prediction rule for spinal manipulation in chronic lower back pain: a prospective randomized clinical trial

Study objectives
Objective 1. To test the impact of a patient individual difference, i.e., treatment responsiveness, as defined by the Childs et al, validated Clinical Prediction Rule as a moderator of the effectiveness of Spinal Manipulative Therapy (SMT) and Active Exercise Therapy (AET) program, utilizing Visual analogue scale, Oswestry disability index and bodily pain and physical functioning subscales of the SF-36 as outcomes.
Hypothesis 1. Outcomes, immediately post, 3 months post and 6 months post intervention, will be significantly more positive in the SMT conditions compared to the AET conditions (i.e., a significant main effect of treatment).

Hypothesis 2. Outcomes, immediately post, 3 months post and 6 months post intervention, will be significantly more positive in patients in the Positive Clinical Prediction Rule group compared to patients in the Negative Clinical Prediction Rule group (i.e., a significant main effect of patient group).
Hypothesis 3. Outcomes, immediately post, 3 months post and 6 months post intervention, will be most positive when patients in the Positive Clinical Prediction Rule group are treated by SMT compared to patients who are in the Negative Clinical Prediction Rule group and Positive Clinical Prediction Rule group patients treated by AET (i.e., a significant treatment by patient group interaction).

Objective 2. To collect prospective data on potential negative outcomes associated with SMT and AET by convening a data and safety board that will monitor negative treatment outcomes. This will be done in a single blinded prospective fashion to enable direct statistical comparison between the chiropractic treatment and active physical therapy groups.
Hypothesis 1: The incidence of adverse events between the SMT and APT group will show no statistical difference.
Hypothesis 2: Side effect data in the SMT and APT groups will be similar to reported side effects, based on historical review of the literature.

Objective 3. To compare satisfaction with routine chiropractic management versus active exercise therapy in a population with chronic lower back pain using a validated patient satisfaction questionnaire.
Hypothesis: Patients receiving routine SMT will be more satisfied with their care compared to those patients AET.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Syracuse VA Institutional Review Board (IRB): MIRB 00367
2. New York Chiropractic College IRB: 07-01

Study design
Randomized Trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Chronic Lower Back pain

Interventions
Interventions were performed two times per week for four weeks (total of eight treatments).
Spinal Manipulative Therapy: SMT included high velocity low amplitude spinal manipulation, flexion distraction therapy, mobilization, and advise on heat/ice all of which are commonly performed by chiropractors. The practitioner was allowed to give the patient one of two stretches to do at home, either cat/camel stretch or knee to chest stretch.
Active Exercise Therapy: AET included directional preference exercises, lumbar stabilization, general flexibility, and specific training exercises. The exercises were divided into different categories, dynamic lumbar stabilization, directional preference, flexibility and specific training exercises.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pain: Visual Analogue Scale
2. Disability: modified Oswestry Disability Index
Outcome measures were administered at: baseline, immediately post intervention (4 weeks post baseline), 12 weeks post baseline and 24 weeks post baseline.

Secondary outcome measures
1. Bodily Pain and Physical Functional subscales of the SF-36
2. Patient Satisfaction
3. Patient Expectation
Outcome measures were administered at: baseline, immediately post intervention (4 weeks post baseline), 12 weeks post baseline and 24 weeks post baseline.

Overall study start date
01/06/2006

Completion date
18/12/2009

Eligibility

Key inclusion criteria
1. LBP for 12 weeks prior to enrollment
2. Pain upon deep palpation of the lumbar erector spinae
3. LBP from L1 to sacroiliac joint inclusive
4. Live within 50 miles of Rochester, NY
5. Have a baseline > 30mm on the Visual Analogue Scale (VAS) and > 20% on the Oswestry Disability Index (ODI)
6. Subjects had to be willing to undergo no new or different treatment during the study intervention and follow up period, although they were allowed to continue any medications.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
192

Key exclusion criteria
1. Radiographic or clinical evidence of cauda equina syndrome, spinal neoplasia or metastatic disease
2. Destructive joint pathology such as rheumatoid arthritis
3. Bowel/bladder dysfunction associated with the LBP
4. Peripheral neuropathy or progressive lumbosacral radiculopathy
5. Progressive myelopathy or neurogenic claudication
6. Spinal surgery within the past six months.
7. Subjects were excluded if they had undergone a course of SMT or supervised AET within the six months prior to enrollment into the study
8. If they could not perform an exercise program based on a New York Heart Association Classification of grade III or IV

Date of first enrolment
01/06/2006

Date of final enrolment
18/12/2009

Locations

Countries of recruitment
United States of America

Study participating centre
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Sponsor information

Organisation

U.S. Department of Health and Human Services (USA)

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Sponsor type
Government

Website
http://bhpr.hrsa.gov/grants/geriatricsalliedhealth/cdp.html

ROR
https://ror.org/033jnv181

Funder(s)

Funder type
Government

Funder Name
This project was funded by Health Resources and Services Administration (HRSA), USA. The grant was administered through the New York Chiropractic College (USA).

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	18/11/2014	Yes	No