

Randomised controlled trial (RCT) comparing long term effect of exercise to rehabilitate spinal stabilisation, manual therapy & an education booklet in the treatment of chronic back pain

Submission date

23/01/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

08/01/2010

Condition category

Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

REC00075

Study information

Scientific Title

Study objectives

The number of patients referred to Physiotherapy because of chronic low back pain continues to increase and it is well recognised that the management of these patients creates an increasing burden to the NHS. A growing body of evidence indicates that an active rehabilitation approach to these patients is effective at reducing pain and disability. More recently evidence has emerged that rehabilitating the deep lumbar stabilising muscles may reduce the recurrence rate of low back pain. In contrast, the effectiveness of standard NHS physiotherapy for low back pain has not been established, and whilst 50% of all patients referred to Physiotherapy outpatients have low back pain, to our knowledge there are no pragmatic studies concerned with investigating the effectiveness of this management strategy.

We propose to conduct a randomised control trial to compare the effects of exercises to rehabilitate spinal stabilisation, manual therapy and as a control and minimal treatment condition, an education booklet in the conservative treatment of low back pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Spinal conditions

Interventions

1. Exercises to rehabilitate spinal stabilisation
2. Manual therapy
3. (Control) minimal treatment condition, an education booklet in the conservative treatment of low back pain

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Pain (0-100 numerical rating scale for back pain intensity, 0-100 scale for leg pain intensity, The Pain Diagram)
2. Impairment (Shuttle walking test, modified Schober technique for range of lumbar flexion)
3. Disability (Revised Oswestry Pain Questionnaire, The Low Back Outcome Score)
4. Handicap (Low Back Outcome Score: Return to work/work status/sick leave)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1997

Completion date

01/09/2000

Eligibility

Key inclusion criteria

Subjects aged between 18-65 years with Chronic Low Back Pain of at least 7 weeks duration will be recruited from the physiotherapy departments in St George's Healthcare.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

346 (added 08/01/10, see publication)

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/09/1997

Date of final enrolment

01/09/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St George's Healthcare NHS Trust

London

United Kingdom

SW17 0QT

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2006		Yes	No