ISRCTN12458386 https://doi.org/10.1186/ISRCTN12458386

# The efficacy of exercises for the treatment of chronic low back pain.

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 30/09/2004 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 30/09/2004 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 16/07/2008 | Musculoskeletal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Jeremy Lewis

**Contact details**
Physiotherapy Dept
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH
+44 (0)181 746 8406
jeremy.lewis@chelwest.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0060055840

# Study information

## Scientific Title

## Study objectives
Experimental hypothesis: A specific exercise protocol will be clinically more beneficial as well as being more cost effective than other forms of treatment for chronic low back pain.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised single-blind placebo-controlled clinical trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## 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
Musculoskeletal Diseases: Chronic low back pain

## Interventions
Eighty patients with chronic low back pain (> 3 months) were randomized to one of the following treatments, involving 8 treatments over 8 weeks:
1. one to one treatment involving 30 minutes of manual therapy (mobilizations to the spine) and spinal stabilization exercises
2. a 10 station exercise class involving aerobic exercises, spinal stabilization exercises and manual therapy.

Three physiotherapists lead the hour long group with a maximum of 10 patients. Questionnaires were completed and physical measurements were taken by a blinded observer before randomization, at the completion of treatment, at 6 months and 12 months after the completion of treatment. The intention to treat principle was used in data analysis.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Prior to July 2008:
Visual analogue scale (pain intensity). Objective measures (lumbar range of movement, straight leg raise, Biering-Sorenson test). Functional test.

Modified July 2008 to:
Quebec back pain disability questionnaire

### Secondary outcome measures
Added July 2008:
1. Subjective rating of change
2. Visual analogue scale for pain
3. Perceived level of fitness
4. Analgesic use
5. Number of cigarettes / day
6. Level of confidence relating to back pain
7. Lumbar range of movement
8. Range of straight leg raise

### Overall study start date
01/01/2000

### Completion date
01/08/2003

## Eligibility

### Key inclusion criteria
Added July 2008:
1. Subjects between the ages of 18 to 75 years
2. Fluency in English
3. Mechanical low back pain for more than 3 months (of a non-radicular nature). Mechanical pain was defined as LBP which increased with movement.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex

Both

### Target number of participants
80 subjects

### Key exclusion criteria
1. Patients with cardiac, respiratory, kidney, blood pressure or blood circulatory problems, spinal surgery, fracture, inflammatory or infectious diseases of the spine, metabolic disease, neurological deficit, rheumatoid arthritis or diabetes
2. Health professionals and staff members at the institution where data was collected
3. Potential subjects who were pregnant or attempting to become pregnant
4. Patients who were not capable of participating in a graded exercise program were also excluded

### Date of first enrolment
01/01/2000

### Date of final enrolment
01/08/2003

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Physiotherapy Dept**
London
United Kingdom
SW10 9NH

## Sponsor information

### Organisation
Department of Health

### Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

### Sponsor type
Government

### Website
http://www.dh.gov.uk/Home/fs/en

## Funder(s)

### Funder type
Government

### Funder Name
Chelsea and Westminster Healthcare NHS Trust (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 | 01/04/2005 | | Yes | No |