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Can the Roland and Morris disability questionnaire be used to predict the response to physiotherapy treatment in chronic low back pain patients?

Submission date
28/09/2007

Recruitment status
Stopped

Registration date
28/09/2007

Overall study status
Stopped

Last Edited
05/10/2011

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N0283184549

Study information

Scientific Title

Study objectives
The aim of the pilot study is to see if it is possible to predict which patients with low back pain respond best to certain types of physiotherapy treatment. These treatments will be manipulation plus exercise, a spinal stability class and a general back class.

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
Musculoskeletal Diseases: Low back pain

Interventions
1. Manual therapy and exercise
2. Stability class
3. General back class

Added 21 August 2008: the trial was stopped before it started, firstly due to a staffing issue locally, then due to a change in clinical practice/evidence base.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Roland and Morris Disability Questionnaire.

Secondary outcome measures
1. Visual Analogue Scale (for pain)
2. Patient Specific Functional Scale
3. Self-Efficacy Questionnaire

Overall study start date
01/09/2006

Completion date
01/06/2007

Reason abandoned (if study stopped)
Lack of staff and change in clinical practice/evidence base

Eligibility

Key inclusion criteria
1. Aged 18-65
2. Non-specific LBP>3 month duration
3. Non-specific LBP or leg symptoms of spinal origin>3 months
4. Acute exacerbation of chronic LBP
5. Patients with longstanding, stable neurological deficit from LBP eg sensory loss, minor motor weakness at one level, loss of reflex at one level
6. Medically fit to exercise
7. Ability to understand spoken and written English
8. Suitable for working in group environment
9. Consented to participate

These are recognised inclusion criteria for similar trials with similar cohorts of patients, making the study and its findings potentially reflective of other work in this field.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex

Not Specified

Target number of participants
80

Key exclusion criteria
1. Pregnancy
2. Acute nerve root signs and symptoms
3. Spinal red flags as defined by RCGP and ARMA guidelines
4. Not meeting inclusion criteria

Date of first enrolment
01/09/2006

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Worthing & Southlands Hospitals NHS Trust
Worthing
United Kingdom
BN11 2DH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Sussex NHS Research Consortium (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