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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

Contact name
Mr Chris Mercer

Contact details
Worthing & Southlands Hospitals NHS Trust
Worthing Hospital
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH
+44 01273 455622 x 3489
christopher.mercer@wash.nhs.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Roland and Morris Disability Questionnaire.

Key secondary outcome(s)
1. Visual Analogue Scale (for pain)
2. Patient Specific Functional Scale
3. Self-Efficacy Questionnaire

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Not Specified

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
Sussex NHS Research Consortium (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration