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Function After Spinal Treatment, Exercise and Rehabilitation: Improving the functional outcome of spinal surgery

Submission date 26/08/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/01/2005	**Overall study status** Completed	
Last Edited 04/02/2016	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims.
Spinal stenosis is a degenerative disease that leads to pain in the back and leg, while disc prolapse is a more acute (severe and sudden) condition that causes leg pain. The diagnoses of these diseases are increasing, and consequently there is a steady rise in surgery for these conditions. There are large differences between surgeons in terms of the type and intensity of rehabilitation provided after spinal surgery, and in the restrictions suggested and advice given to patients. The success of spinal surgery varies widely, which may in part result from differences in management and rehabilitation after the operation. The aim of this study is to evaluate the benefits of a rehabilitation programme and an education booklet for the management of patients undergoing discectomy (for a disc prolapse) or lateral nerve root decompression (for spinal stenosis).

Who can participate?
Patients with low back and leg pain on the waiting list for spinal surgery.

What does the study involve?
Participants are randomly allocated into four groups, to receive rehabilitation, the booklet, both rehabilitation and the booklet, or usual care only. The rehabilitation consists of a 6-week programme involving aerobic fitness work, stretching, stability, strengthening and endurance, together with advice about daily activities and the development of skills in self-motivation and self-management. The booklet is designed to encourage a positive shift in beliefs and behaviours concerning pain, rehabilitation and self-management.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
April 2005 to March 2010

Who is funding the study?
Arthritis Research UK

Who is the main contact?
Prof. Alison McGregor

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
M0671

Study information

Scientific Title
Function After Spinal Treatment, Exercise and Rehabilitation: Improving the functional outcome of spinal surgery

Acronym
FASTER

Study objectives
Added as of 26/06/2008:
The primary aim of this study is to determine if the long-term functional outcome of spinal surgery and patient satisfaction can be improved via either a systematic programme of post-operative rehabilitation or an educational booklet, and whether a combination of both is even

more effective. The chief secondary objective is to assess whether such approaches are cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hammersmith & Queen Charlottes & Chelsea Research Ethics Committee, ref: 04/Q0406/49

Study design
Randomised controlled 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
Spinal lateral root stenosis and discectomy

Interventions
Current interventions as of 26/06/2008:
Rehabilitation Programme:
Patients randomised to the rehabilitation arms of the study will commence the programme 6 to 8 weeks following surgery. The programme will run for 6 weeks with subjects attending for 1 hour twice a week. Classes will be held first thing in the morning or at the end of the working day to accommodate, where possible, those who have returned to work. The classes will be run by an experienced physiotherapist, who will encourage patients individually to progress at their own pace. This structure allows new patients to join the programme at any time rather than in batches. There will be a maximum of ten patients per class. As previously stated, attempts will be made to keep the patients randomised to the rehabilitation-only group in separate classes from those randomised to the rehabilitation-plus-booklet group.

Educational Booklet:
Therefore a post-operative back book that has been developed, will be provided to those patients allocated to either the booklet-only group or the rehabilitation-plus-booklet group at discharge from hospital following their surgery. This resource was constructed with the aim of developing a patient centred, evidence-based booklet that spinal surgeons may give to their patients to reduce uncertainty and facilitate post-surgical management and recovery. The booklet thus aims to provide carefully selected messages that will lead to a positive shift in

beliefs and behaviours concerning pain, rehabilitation and self-management during the post-surgical period.

Usual care:
Patients randomised to the usual care control group will be managed routinely in the post-operative period, according to the relevant surgeons usual practice. This is likely to consist of a follow-up outpatient appointment some weeks after surgery plus general advice about progressively increasing the range and demands of physical activity, but no systematic programme of assessment and rehabilitation. The post-operative regimes of each surgeon will be quantified to define the usual post-operative care strategy and patients will be questioned via a self-completed questionnaire regarding any interventions or advice sought.

Previous interventions:
Post-operative rehabilitation programme versus usual post-operative review by the operating surgeon at 6 weeks.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Added as of 26/06/2008:
Oswestry Disability Index

Secondary outcome measures
Added as of 26/06/2008:
1. An economic analysis based on costs and EQ-5D (a validated, global measure of quality of life)
2. Visual analogue scales of back and leg pain
3. Measures of patient expectations and satisfaction
4. Return to work
5. Frequency of re-operation
6. Hospital Anxiety and Depression Scale (HADS)
7. Physical activity scale of the Fear Avoidance Beliefs Questionnaire

Overall study start date
01/04/2005

Completion date
01/03/2010

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/06/2008:
Eligible patients at participating hospitals are those currently on the waiting list for spinal surgery with either:
1. Signs, symptoms and radiological evidence of lateral nerve root compression, that is, patients presenting with radicular pain with an associated neurological deficit or with neurogenic claudication (pain in the buttock, thigh or leg that improves with rest), or

2. Lumbar disc prolapse, that is, patients with root symptoms and signs and magnetic resonance imaging (MRI) confirmation of lumbar disc herniation

Previous inclusion criteria:
People with low back and leg pain

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
344

Key exclusion criteria
Added as of 26/06/2008:
1. Any condition where either the intervention or the rehabilitation may have an adverse effect on the individual
2. Previous spinal surgery
3. Spinal surgery where a fusion procedure is planned due to the unknown hazards of the activity programme for this type of surgery
4. Pregnant women
5. Inadequate ability to complete the trial assessment forms
6. Any patient who is unable to attend the rehabilitation or the reviews or who is unsuitable for rehabilitation classes
7. Unable to complete outcome measures

Date of first enrolment
01/04/2005

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College London
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

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Sponsor type
Charity

Website
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ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (ARC) (UK) (ref: M0671)

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?
Protocol article	protocol	26/01/2010		Yes	No
Results article	results	01/10/2011		Yes	No