

Queen Elizabeth physiotherapy post lumbar discectomy Study: a pilot and feasibility trial - QUEST

Submission date 09/11/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/12/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/02/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

At some time in their life, 60% to 80% of people will have low back problems and surgery for its treatment is the greatest cost to the NHS. Lumbar discectomy surgery is a common procedure for patients with pain in their legs. However, 30-70% of patients continuing to have problems even after the surgery. Recovery after surgery is, therefore, an important area to research. Currently, treatment following lumbar discectomy comprises a patient leaflet or physiotherapy or both. Practice varies across hospitals and it is unknown whether providing a patient leaflet and physiotherapy benefits patients' recovery compared with use of a patient leaflet alone. This is why we are conducting the study. This study is conducted to help us improve the design and prospects to do a future larger study.

Who can participate?

Men and women aged over 18 who have recently undergone the first lumbar discectomy surgery

What does the study involve?

All participants are asked to attend two assessment clinics at 4 and 16 weeks after surgery and half the participants at each hospital are asked to attend a third assessment clinic at 30 weeks after surgery. Assessments comprise of a short questionnaire and two simple physical tests that assess how well patients can move their back and legs. Patients are randomly allocated one of the following groups: patient leaflet and individual outpatient physiotherapy, or patient leaflet alone; and 30-week follow-up, or not. Participants allocated to receive individual outpatient physiotherapy and the patient leaflet receive up to 8 treatment sessions with a physiotherapist, starting as soon as possible after the 4-week assessment clinic. At their final assessment visit, participants are invited to attend a meeting with other participants who received the same treatment, to discuss their experience.

What are the possible benefits and risks of participating?

We cannot promise that taking part in the study will help the participants, but the information obtained could help them and patients like them in the future. All participants receive a copy of a Patient Leaflet that has been designed specifically for patients following lumbar discectomy

surgery. The leaflet contains information about the patient's back, surgery and recovery after surgery. There are no known risks of taking part in the study.

Where is the study run from?

Queen Elizabeth Hospital Birmingham (UK) and Salford Royal NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

Recruitment for the study started in January 2013. Participants will be enrolled on the study for 7 months.

Who is funding the study?

Queen Elizabeth Hospital Birmingham Charity (UK)

Who is the main contact?

Dr Alison Rushton

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

1

Study information

Scientific Title

QUEen Elizabeth Physiotherapy post lumbar discectomy STUDy: a feasibility and pilot phase II trial to inform the development of a future phase III randomised controlled trial (QUEST)

Acronym

QUEST

Study objectives

One to one physiotherapy plus the Patient Leaflet will be more beneficial than the Patient Leaflet (phase II trial)

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands - Solihull Research Ethics Committee, 25/09/2012, ref: 12/WM/0224

Study design

Pilot/feasibility study of a randomised controlled trial with two arms

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rehabilitation following lumbar spinal surgery

Interventions

1. Up to 8 sessions of individualised 1-1 physiotherapy over an 8-week period; treatment in-line with pre-defined framework for decision-making; starting approximately 4 weeks post surgery AND specifically designed patient leaflet
2. Specifically designed patient leaflet

Intervention Type

Behavioural

Primary outcome(s)

Roland Morris Disability Questionnaire (0 to 24)

Key secondary outcome(s)

1. Global Perceived Effect scale (0 to 7)
2. VAS back pain (0 to 10cm) & VAS leg pain (0 to 10cm)
3. Straight Leg Raise (cm)
4. Time to return to work / normal function / full duty (as relevant) from date of operation
5. EQ-5D 5L
6. Tampa Scale for Kinesiophobia (fear of movement)
7. Fear avoidance and beliefs questionnaire
8. Range of lumbar movement
9. Use of medication
10. Re-operation
11. Level of compliance with exercises

Completion date

26/05/2014

Eligibility

Key inclusion criteria

1. Male and female patients aged >18 years
2. Post primary, single level, lumbar discectomy (including microdiscectomy)
3. Ability to communicate in English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Previous surgery at the same spinal level
2. Co-morbidities that might impact on ability to participate in study interventions e.g. neurological disorders, cognitive dysfunction, uncontrolled cardiovascular disease, osteoporotic fracture, spondylolysis, MS, tumour
3. Complications from surgery e.g. excessive bleeding, severe intra-operative root damage, level error, or severe wound infection that would prevent participation in either intervention
4. Participation in a concurrent trial

Date of first enrolment

13/01/2013

Date of final enrolment

26/05/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Charity

Funder Name

Queen Elizabeth Hospital Birmingham Charity (UK)

Results and Publications

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	12/11/2015		Yes	No
Results article	results	09/11/2016		Yes	No