

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

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

a.b.rushton@bham.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Alison Rushton

**Contact details**

University of Birmingham

School of Health & Population Sciences

College of Medical and Dental Sciences

52 Pritchatts Road

Edgbaston

Birmingham

United Kingdom

B15 2TT

+44 (0)121 415 8597

a.b.rushton@bham.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1

## Study information

**Scientific Title**

QQueen Elizabeth Physiotherapy post lumbar discectomy SStudy: 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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**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 measure**

Roland Morris Disability Questionnaire (0 to 24)

## **Secondary outcome measures**

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

## **Overall study start date**

26/10/2012

## **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

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

70

## **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**

England

United Kingdom

**Study participating centre**

**University of Birmingham**

Birmingham

United Kingdom

B15 2TT

## **Sponsor information**

**Organisation**

University of Birmingham (UK)

**Sponsor details**

Research Governance Team

Aston Webb Building

Edgbaston

Birmingham

England

United Kingdom

B15 2TT

+44 (0)121 414 4418

researchgovernance@contacts.bham.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.birmingham.ac.uk/researchsupportgroup>

**ROR**

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

# Funder(s)

## Funder type

Charity

## Funder Name

Queen Elizabeth Hospital Birmingham Charity (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?
<a href="#">Results article</a>	results	12/11/2015		Yes	No
<a href="#">Results article</a>	results	09/11/2016		Yes	No