# The effectiveness of patient-reported outcome measures (PROMs) in improving the quality of care for patients undergoing hip replacement surgery

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
17/06/2011		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/07/2011	Completed	[X] Results		
<b>Last Edited</b> 12/08/2016	Condition category  Musculoskeletal Diseases	Individual participant data		

#### Plain English summary of protocol

Background and study aims

All patients in England who are having hip replacement surgery are invited to complete a Patient Reported Outcome Measures (PROMs) questionnaire before and six months after their operation. The NHS in England developed this initiative in order to improve the quality of the care that it provides. In Ireland, surgeons' performance data lacks both the patients' view and outcome measures. The aim of this study is to find out whether collecting patient-reported outcomes from hip replacement patients and feeding the results back to surgeons is effective at improving patient outcomes.

#### Who can participate?

Orthopaedic surgeons and patients aged over 18 undergoing hip replacement surgery

#### What does the study involve?

Patients are asked to complete a questionnaire before and six months after their hip replacement surgery. Surgeons are randomly allocated to one of three groups. The first group receives no feedback on outcome scores. The second group receives feedback and an educational session covering interpretation of the data. The third group receives the same as the second group but with additional information to improve their interpretation of the data.

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

#### Where is the study run from?

- 1. AMNCH, Tallaght
- 2. Cappagh National Orthopaedic Hospital, Dublin
- 3. St. Mary's Orthopaedic Hospital, Cork
- 4. Croom Regional Orthopaedic Hospital, Limerick
- 5. Lourdes Orthopaedic Hospital, Kilkenny

- 6. Our Lady's Hospital, Navan
- 7. Tullamore Regional Hospital, Offaly
- 8. Merlin Park Regional Hospital, Galway
- 9. Bon Secours Hospital, Cork
- 10. Bon Secours Hospital, Dublin
- 11. Bon Secours Hospital, Galway
- 12. Blackrock Clinic, Dublin
- 13. Hermitage Medical Clinic, Dublin
- 14. Sports Surgery Clinic, Dublin
- 15. The Beacon Medical Clinic, Dublin

When is the study starting and how long is it expected to run for? April 2011 to May 2013

Who is funding the study?
The Health Research Board (Ireland)

Who is the main contact? Prof. John Browne J.Browne@ucc.ie

# Contact information

#### Type(s)

Scientific

#### Contact name

Prof John Browne

#### Contact details

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### Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

#### Scientific Title

Does providing patient-reported outcome feedback to orthopaedic surgeons improve outcomes for patients undergoing hip replacement surgery compared to providing no feedback? A cluster randomised controlled trial

#### Acronym

**PROFILE** 

#### **Study objectives**

PROFILE (Patient Reported Outcomes: Feedback, Interpretation and Learning Experiment)

- 1. Providing feedback with benchmarking of PROMs data to surgeons will improve outcomes for patients undergoing hip replacement surgery.
- 2. Using methods to improve the interpretability of PROMs will further improve outcomes for patients undergoing hip replacement surgery.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Clinical Research Ethics Committee, University College Cork, 07/12/2010

#### Study design

Multi-centre cluster randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Cluster randomised trial

#### Study setting(s)

Hospital

#### 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

Osteoarthritis/primary hip replacement surgery

#### **Interventions**

Participating surgeons will be randomly assigned by an independent person who has no patient or physician contact to one of three groups using a computer generated list of random permuted blocks of numbers. The three arms of the trial are:

- 1. No feedback on outcome scores (control group).
- 2. Feedback plus educational session covering benchmarking and interpretation of data (intervention group 1)
- 3. As intervention group 1 but with additional use of Rasch analysis to improve interpretability of the data (Intervention group 2)

Blinding of surgeons will not be possible, however blinding of patients and those carrying out statistical analyses will be used.

This study will involve a quality improvement package based upon PROMs including a feedback report and an educational session. The type of feedback report will depend on the intervention group and will contain personalised PROMs data for each surgeon. The feedback will be benchmarked against UK PROM data and anonymous Irish peer data to eliminate contamination and confidentiality issues. The educational session will be provided to the intervention groups and will describe the content, scoring and interpretation of the PROMs data. Intervention group 2 will be provided with additional information regarding Rasch analysis.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

The Oxford hip score. It is widely used specific instrument to estimate outcomes after hip replacement. It has shown to be responsive to change and is the disease-specific instrument used in the UK PROMs programme. This data will be captured before the operation and at six months after the operation.

#### Secondary outcome measures

- 1. The EQ-5D score
- 2. The Hip Osteoarthritis Outcome Score
- 3. Surgical complication rate

Measured before the operation and at six months after the operation

#### Overall study start date

01/04/2011

#### Completion date

31/05/2013

# **Eligibility**

#### Key inclusion criteria

Surgeon:

High volume hip replacement surgeons (defined as at least two primary, unilateral, elective hip replacement operations per week)

#### Patient:

- 1. Aged over 18
- 2. Undergoing primary, unilateral, elective hip replacement surgery
- 3. Public and private patients

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

27 surgeons and 1,350 patients

#### Key exclusion criteria

Surgeon:

- 1. Low volume hip replacement surgeons
- 2. Near retirement (in next 2 years)

#### Patient:

- 1. Aged under 18
- 2. Undergoing a bilateral or revision hip replacement
- 3. Surgery due to trauma
- 4. Unable to complete a written questionnaire in English be it due to: cognitive impairment, literacy or language comprehension

#### Date of first enrolment

01/04/2011

#### Date of final enrolment

31/05/2013

## Locations

#### Countries of recruitment

Ireland

# Study participating centre University College Cork

Cork Ireland N/A

# Sponsor information

#### Organisation

The Health Research Board (Ireland)

#### Sponsor details

73 Lower Baggot St Dublin Ireland N/A

#### Sponsor type

Government

#### ROR

https://ror.org/003hb2249

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Health Research Board

#### Alternative Name(s)

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

Local government

#### Location

Ireland

# **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?
Results article	results	31/07/2015		Yes	No