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

**Submission date**
17/06/2011

**Recruitment status**
No longer recruiting

**Registration date**
28/07/2011

**Overall study status**
Completed

**Last Edited**
12/08/2016

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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# Contact information

### Type(s)
Scientific

### Contact name
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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 |