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Do visual models improve patient satisfaction in orthopedic consenting? A single-blinded randomized controlled trial

Submission date
18/09/2016

Recruitment status
No longer recruiting

Registration date
22/06/2018

Overall study status
Completed

Last Edited
22/06/2018

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
During consultations surgeons tend to communicate with their patients using verbal explanations for about 10 minutes on average. The consultation experience could be improved with the use of visual models of the joint to explain the disease process and treatment options. Although visual aids are recommended to be used in the consultation and consenting process, there has been little research on how well they work. The aim of this study is to observe the effect of using visual three-dimensional (3D) models of the knee and shoulder joints on patient satisfaction during informed consent.

Who can participate?
Patients aged over 18 who are being consented for either knee or shoulder surgery by a senior attending orthopedic surgeon

What does the study involve?
Participants are randomly allocated to one of two groups. During informed consent patients in the first group are given a verbal explanation and are shown a 3D model of the joint, whilst the second group are given only a verbal explanation with no model. Afterwards, both groups are asked to fill in a questionnaire on their satisfaction with the consultation and are asked a set of questions as to why they were satisfied (or not). The results from the questionnaire and the interview are compared to see whether there was a difference between the groups as a result of the use of the visual model in the clinic.

What are the possible benefits and risks of participating?
Patients who are shown visual models may be more satisfied with the consultations. There are no risks involved in this study.

Where is the study run from?
St Mary's Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2014 to November 2014

Who is funding the study?
Imperial College London (UK)

Who is the main contact?
Dr Kapil Sugand

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effect of 3-dimensional visual aids on patient satisfaction in orthopedic consent: a single-blinded randomized controlled trial

Acronym
Simulating Trauma & Orthopaedic procedures with Models for Patients (STOMP)

Study objectives
There is a difference in patient satisfaction with the use of visual aids during orthopedic consenting as determined by MISS-26 scores.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Imperial College London Joint Research Compliance Office (JRCO) under NRES Committee East of England committee, 25/07/2013, ref: 13/EE/0191

Study design
Single-blinded single-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Degenerative orthopaedic joint disease

Interventions
52 patients undergoing elective knee or shoulder orthopedic operations were randomized into two groups when undergoing preliminary explanation and consent for their procedures. The intervention group (n=26) was given a verbal explanation and shown a 3D model of the joint whilst the control group (n=26) were given only a verbal explanation with no model.

Allocation was done by prior computerized random number generator using unique hospital numbers of patients. All other identifying data was anonymized and not featured within the study. Both surgeons and patients were masked as to which cohort they were assigned to until the consultation where the consultant was given or not given a visual model to use during the consultation.

After the consultation, patients rated their satisfaction on the validated Medical Interview Satisfaction Scale (MISS-26). Semi-structured interviews were analyzed for thematic analysis to determine key factors influencing patient satisfaction. No follow-up was conducted.

Intervention Type
Behavioural

Primary outcome(s)
Patient satisfaction, determined by the MISS-26 scores. The responses were collated into behavioral, cognitive, affective and overall scores, measured at the single study visit without follow up.

Key secondary outcome(s))
Key factors that contributed to patient and surgeon satisfaction, determined through thematic analysis from semi-structured interviews, measured at the single study visit without follow up

Completion date
30/11/2014

Eligibility

Key inclusion criteria

1. Adult patients (over 18 years of age), being consented for either knee or shoulder surgery by a senior attending orthopedic surgeon
2. Three attending orthopedic surgeons from clinic

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pediatric patients
2. Patients undergoing surgery on other joints
3. Attended previous consultations using visual models
4. Those undergoing non-operative management

Date of first enrolment
01/07/2014

Date of final enrolment
15/11/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St Mary's Hospital
Praed Street
Paddington
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

Funder Name
Imperial College London

Results and Publications

Individual participant data (IPD) sharing plan
Dataset will not be made available due to the addition of hospital identification numbers, date of births and possible patient identifying features that have been anonymized to the best of our abilities and in line with the ethics committee guidelines. The data will be held on a departmental computer (where the study was conducted) with access restricted only to research team. The data will be destroyed after publication of paper in a peer-reviewed journal or 5 years from end of study (whichever comes first).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/09/2016	22/06/2018	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes