

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/06/2018	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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
Dr Kapil Sugand

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/07/2014

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

53

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

England

United Kingdom

Study participating centre

St Mary's Hospital

Praed Street

Paddington

London

United Kingdom

W2 1NY

Sponsor information**Organisation**

Imperial College London

Sponsor details

Sir Alexander Fleming building

South Kensington

London

England

United Kingdom

SW7 2AZ

Sponsor type

University/education

ROR

<https://ror.org/041kmwe10>

Funder(s)**Funder type**

University/education

Funder Name

Imperial College London

Results and Publications

Publication and dissemination plan

Aimed towards publication in a PubMed-indexed journal and international conference presentations.

Intention to publish date

28/09/2016

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