ISRCTN20081026 https://doi.org/10.1186/ISRCTN20081026

# A randomised controlled trial to assess the impact of audiotaped consultations on the quality of informed consent in cardiac surgery

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| **Submission date**<br>12/07/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>16/07/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>21/04/2010 | **Condition category**<br>Circulatory System | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

Version 2, 24/05/2004

# Study information

### Scientific Title

### Study objectives
Audiotaping outpatient consultations could improve informed consent in cardiac surgery

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
This trial was approved by the Institutional Ethics Committee of Glasgow Royal Infirmary in November 2004

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Other

### Participant information sheet

### Health condition(s) or problem(s) studied
Coronary artery disease

### Interventions
The participants were randomly allocated to three trial arms. The control group (Group A; n = 29) received no tape. The 'generic' group (Group B; n = 25) received a copy of a tape which contained general information about coronary artery surgery which we scripted to include information covering each of the domains described by the General Medical Council. The 'consultation' group (Group C; n = 30) received a tape of their consultation interview.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Impact of audiotape in improving the informed consent process, as measured by a knowledge questionnaire, in cardiac surgery. The assessment was carried out a day before surgery within 2 hours of signing the consent form.

Publication of the result of a pilot study to design and validate the knowledge questionnaire can be found at http://www.ncbi.nlm.nih.gov/pubmed/16932081

### Secondary outcome measures
Impact of audiotapes on the Health Locus of Control Scale and the Health Anxiety and Depression Scale. The assessment was carried out a day before surgery within 2 hours of signing the consent form.

### Overall study start date
10/02/2005

### Completion date
15/03/2006

## Eligibility

### Key inclusion criteria
1. Both males and females, no age limits
2. Patients undergoing first time coronary artery bypass graft (CABG) surgery with a single consultant surgeon

### Participant type(s)
Patient

### Age group
Other

### Sex
Both

### Target number of participants
84

### Key exclusion criteria
1. Patients undergoing CABG + valve surgery
2. Patients undergoing redo (second or third time) CABG

### Date of first enrolment
10/02/2005

### Date of final enrolment
15/03/2006

## Locations

### Countries of recruitment
Scotland

United Kingdom

### Study participating centre
**West of Scotland Heart and Lung Centre**
Glasgow
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## Sponsor information

### Organisation
Glasgow Royal Infirmary (UK)

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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/00bjck208

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Glasgow Royal Infirmary, Department of Cardiothoracic Surgery (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? |
|---|---|---|---|---|---|
| Results article | results | 01/04/2010 | | Yes | No |