

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

Submission date 12/07/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/07/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/04/2010	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Other

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(s)

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>

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

United Kingdom

Scotland

Study participating centre

West of Scotland Heart and Lung Centre

Glasgow

United Kingdom

G81 4HX

Sponsor information

Organisation

Glasgow Royal Infirmary (UK)

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**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