ISRCTN11309852 https://doi.org/10.1186/ISRCTN11309852

A feasibility study of the use of a cataract surgery decision aid which includes personalised estimates of risks and benefits

Submission date
01/12/2018

Recruitment status
No longer recruiting

Registration date
16/05/2019

Overall study status
Completed

Last Edited
21/08/2019

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cataract surgery is the most frequently undertaken NHS surgical procedure with around 450,000 operations taking place in the UK each year. At the moment, potential levels of benefit and risk of cataract surgery are routinely explained to patients in general terms only (i.e. a potential level of risk based on what is known about the average population). The research team have developed a leaflet, called a Cataract Decision Aid, which presents information that is specific to you as an individual. The Cataract Decision Aid explains personalised levels of benefit and risk of cataract surgery, based on certain features related to your health, medical history and age, and how much your vision is affected by your cataract. It also includes some frequently asked questions about cataract and cataract surgery.

Who can participate?
Anyone who has a cataract and has been referred for an assessment and discussion about whether to go ahead with cataract surgery

What does the study involve?
Participants enrolled into the study are invited for a research appointment alongside their Cataract Assessment appointment. A member of the research team accompanies participants throughout all the stages of their appointment and (with permission) audio-records the conversations participants have with the doctor and nurses on the day. This allows the researchers to go back and accurately record and analyse the content after the appointment. During the appointment, participants are asked to complete a questionnaire about their knowledge and understanding of cataracts and cataract surgery, which results after surgery matter most to participants, and how ready participants feel to make a decision about cataract surgery. Participants are also asked to complete another questionnaire (the 'Cat-PROM5') which assesses how much they are affected by their cataract. Participants have a routine assessment with a nurse, and then see the doctor who discusses the potential for having cataract surgery. After an initial assessment of participant's eyes and vision, they are randomly allocated to either continue with a routine assessment, or to have a few additional eye health checks alongside using the Cataract Decision Aid as part of their discussion with the doctor. About half of the

participants have a routine assessment, the other half use the Cataract Decision Aid. Both sets of participants discuss the risks and benefits of cataract surgery, but only one set uses the Cataract Decision Aid as part of this discussion. Participants and the doctor then decide whether or not to add their name to the waiting list to have cataract surgery. After participants have finished their assessment with the doctor and nurses, they are asked to complete a second questionnaire about their knowledge and understanding of cataracts and cataract surgery, after which the appointment is complete. At a later date, a member of the research team contacts participants by post or phone to ask them to complete another 'Cat-PROM5' questionnaire and a 'postal follow-up cover sheet'. This captures changes in participants vision and additional information about their recent spectacle use and spectacle prescription. For participants who did have cataract surgery, these questionnaires are sent 6-8 weeks after surgery has taken place. If, however, they did not have surgery, these questionnaires are sent 8-12 weeks after their Cataract Assessment with the doctor. The researchers are also working with researchers from Cardiff University and the University of Bristol who would also like to get in touch with participants to have a short informal interview about their experience of deciding whether or not to have surgery. This interview can take place over the telephone or in a place convenient to them. The interview should take between 30 minutes and one hour, but participants can stop the discussion at any point.

What are the possible benefits and risks of participating?
Participants receive the same high level of care as they would if they were not taking part in the study. Participants allocated to receive the Cataract Decision Aid during the consultation will be able to discuss individual levels of potential risk and benefit of cataract surgery, rather than receiving information in general terms only. The results from the study will show whether using a Cataract Decision Aid will help future patients and doctors make a better-informed decision about if and when to opt for surgery, with the ultimate goal to improve patient care. The study assessments may take a little longer than normal clinic appointments as more detailed information is gathered about participants and their health. Because of this, if participants have already been sent an appointment, this may need to be rescheduled to a new date. Participants are contacted to offer an alternative appointment – this will not affect their position on the surgery waiting list and will be as close to their original appointment date as possible. Any additional assessments and questionnaires which are completed as part of the research appointment carry no additional risk.

Where is the study run from?
This study is being led by University Hospitals Bristol NHS Foundation Trust. The study is recruiting participants from across three sites:
1. University Hospitals Bristol NHS Foundation Trust
2. Brighton & Sussex University Hospitals NHS Trust
3. Torbay and South Devon NHS Foundation Trust

When is the study starting and how long is it expected to run for?
June 2018 to June 2019

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. John Sparrow

Contact information

Type(s)
Scientific

Contact name
Prof John Sparrow

Contact details
NIHR Cataract Research Programme
Queen Anne Building
Bristol Eye Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LX

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
246649

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS Project ID: 246649

Study information

Scientific Title
Involve-CAT: a feasibility randomised controlled trial of a cataract decision aid

Acronym
Involve-CAT

Study objectives
Involve-CAT will explore the feasibility of establishing a future Randomised Controlled Trial (RCT) using the Cataract Decision Aid as an intervention. Embedded within the trial will be qualitative and cost elements and an exercise to validate the benefits prediction model developed earlier in the research programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)

North West – Liverpool East Research Ethics Committee, Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, Tel: +44 (0)207 104 8001, Email: nrescommittee.northwest-liverpooleast@nhs.net, 06/09/2018, IRAS project ID: 246649, REC ref: 18/NW/0476

Study design
Feasibility randomised 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
Shared decision-making about cataract surgery

Interventions
Participants enrolled into the study will be invited for a research appointment alongside their Cataract Assessment appointment.

A member of the research team will accompany participants throughout all the stages of their appointment and (with permission) will audio-record the conversations participants have with the Doctor and nurses on the day. This allows the researchers to go back and accurately record and analyse the content after the appointment.

During the appointment, participants will be asked to complete a questionnaire about their knowledge and understanding of cataracts and cataract surgery, also which results after surgery matter most to participants, and how ready participants feel to make a decision about cataract surgery. Participants will also be asked to complete another questionnaire (the 'Cat-PROM5') which assesses how much they are affected by their cataract.

Participants will have a routine assessment with a nurse, and then see the Doctor who will discuss the potential for having cataract surgery. After an initial assessment of participant's eyes and vision, they will be randomly allocated to either continue with a routine assessment, or to have a few additional eye health checks alongside using the Cataract Decision Aid as part of their discussion with the Doctor. About half of the participants will have a routine assessment, the other half will use the Cataract Decision Aid. Both sets of participants will discuss the risks and benefits of cataract surgery, but only one set will use the Cataract Decision Aid as part of this discussion. Participants and the Doctor will then decide whether or not to add their name to the waiting list to have cataract surgery.

After participants have finished their assessment with the Doctor and nurses, they will be asked to complete a second questionnaire about their knowledge and understanding of cataracts and cataract surgery, after which the appointment will be complete.

At a later date, a member of the research team will contact participants by post or phone to ask them to complete another 'Cat-PROM5' questionnaire and a 'postal follow up cover sheet'. This will be to capture changes in participants vision and additional information about their recent spectacle use and spectacle prescription. For participants who did have cataract surgery, these questionnaires will be sent to 6-8 weeks after surgery has taken place. If, however, they did not have surgery, these questionnaires will be sent to 8-12 weeks after their Cataract Assessment with the Doctor.

The trialists are also working with researchers from Cardiff University and the University of Bristol who would also like to get in touch with participants to have a short informal interview about their experience of deciding whether or not to have surgery. This interview can take place over the telephone or, in a place convenient to them. The interview should take between 30 minutes and one hour, but participants can stop the discussion at any point.

Intervention Type
Other

Primary outcome measure
Patients' knowledge about options, their preferences and readiness to make a decision, assessed using the Cataract Decision Quality Measure before and after pre-operative clinician consultation

Secondary outcome measures
The likely effectiveness and cost-effectiveness of the decision support tool and the need for a subsequent full-scale trial, assessed through analysis of the following themes:
1. Estimated sample size, and the most appropriate primary/secondary outcomes for a main trial assessed using the effect size
2. Recruitment and retention rates, comparing numbers of study completion, declines and screen failures against routine care volume over the recruitment period
3. Decision support costs estimated through analysis of the duration and staff costs of pre-operative assessment and data collection in the intervention arm compared to routine care arm
4. Potential cost savings from avoidance of high risk/low benefit surgery and avoiding costly complications and complication-induced visual disability
5. Quality and level of shared decision making assessed using the Observer OPTION5 instrument during pre-operative assessment
6. Patient and clinician experience of the use of decision support tools, assessed using qualitative interviews after the pre-operative assessment study visit
7. Acceptability of the decision aid to patients and clinicians, assessed using qualitative interviews after the pre-operative assessment study visit
8. Self-reported difficulty with vision, assessed using the Cat-PROM5 questionnaire pre- and post-operatively
9. Uptake of cataract surgical option following patient-clinician interaction when using CDA compared to routine care
10. Initial validation of the benefits prediction model developed earlier in the Programme for predicting self-reported Cat-PROM5 benefit from surgery, assessed pre and post-operatively

Overall study start date

24/06/2018

Completion date
10/06/2019

Eligibility

Key inclusion criteria
Patients:
Patients undergoing cataract surgery are eligible to be recruited to the study if they meet the following criteria:
1. Aged 50 years or over at time of recruitment
2. Referred for and subsequently deemed clinically eligible for either first or second eye cataract surgery
3. Ability to provide informed consent
4. Ability to read and understand study materials (PIS, Cat-PROM5, CDA, CDQM etc)
5. Willingness to participate

Health Professionals:
Health Professionals are eligible to be recruited to the study if they meet the following criteria:
1. Willingness to participate
2. Ability and willingness to use the Cataract Decision Aid to help patients make a decision about whether or not to have cataract surgery

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
40

Total final enrolment
49

Key exclusion criteria
Previous participation in earlier elements of the cataract research programme

Date of first enrolment
09/10/2018

Date of final enrolment
29/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Bristol NHS Foundation Trust
NIHR Cataract Research Programme
Room QA2-007 Queen Anne Building
Bristol Eye Hospital, Lower Maudlin Street
Bristol
United Kingdom
BS1 2LX

Study participating centre
Brighton & Sussex University Hospitals NHS Trust
Brighton & Sussex University Hospitals NHS Trust
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
Torbay and South Devon NHS Foundation Trust
Torbay and South Devon NHS Foundation Trust
Torbay Hospital
Lawes Bridge
Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

Sponsor details
Trust Headquarters
Marlborough Sheet
Bristol

England
United Kingdom
BS1 3NU

Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
NIHR

Alternative Name(s)
NIHR School for Social Care Research, SSCR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Outputs will be presented at academic meetings including the Annual Congress of the Royal College of Ophthalmologists but also at meetings relevant to research, clinical and social science disciplines appropriate to particular work. We will encourage members of our Patient Advisory Group to participate in co-presentation.

Reports will be submitted to research and scholarly journals for publications, strengthening the formal evidence base.

The CDA will in addition be published and freely available on the internet page of the Healthcare Communication and Quality research programme Decision Laboratory, Institute of Primary Care & Public Health, Cardiff University, and will be offered to the Royal College of Ophthalmologists for inclusion on their College and National Ophthalmology Database Audit websites.

Intention to publish date
24/09/2020

Individual participant data (IPD) sharing plan
Once the researchers have completed the study, including the analysis, the results will be published in accordance with academic due process. Participant level data will be archived in line with local policy.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No