University Hospitals Bristol NHS Foundation Trust

Gloucestershire Hospitals NHS Foundation Trust

Torbay and South Devon NHS Foundation Trust

Brighton and Sussex University Hospitals NHS Trust

Involve-CAT

A Feasibility Randomised Controlled Trial of a Cataract Decision Aid

Part of a

NIHR-Funded Programme Grant for Applied Research

Cataract Surgery: Measuring and Predicting Patient Level Vision Related Health Benefits and Harms

Study Information (Title):	Involve-CAT: A Feasibility Randomised Controlled Trial of a Cataract Decision Support Tool
Details of Sponsor	University Hospitals Bristol NHS Foundation Trust, Research and Innovation, Level 3, UH Bristol Education and Research Centre, Upper Maudlin Street, Bristol BS2 8AE. Tel: 0117 342 0233
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Safety Reporting	As this study does not involve any medicinal product/medical device/intervention, adverse events will not be collected. However any adverse incident occurring as a result of the research visit will be reported and documented in line with UH Bristol's "Policy for the Management of Incidents".
Monitoring and Audit	The study will be monitored and audited in accordance with University Hospitals Bristol's policies and procedures. All trial related documents will be made available on request for monitoring and audit by UH Bristol and the relevant Research Ethics Committee.
Data Protection	Data will be collected and retained in accordance with the applicable Data Protection Regulations.
Storage of records	Study documents (paper and electronic) will be retained in a secure location during and after the trial has finished. All source documents will be retained for a period of five years* following the end of the study. Where trial related information is documented in the medical records – those records will be identified by a 'Do not destroy before dd/mm/yyyy' label where date is five years after the last patient last visit.
Indemnity	This is an NHS-sponsored research study. For NHS sponsored research HSG(96)48 reference no. 2 refers. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.
Ethics & R&D approvals	The study will be performed subject to a favourable opinion from the Health Research Authority (HRA) and an independent NHS Research Ethics Committee (REC), and only after capacity and capability reviews have been completed for each of the participating NHS sites.
Research Governance Statement	This study will be conducted in accordance with the UK Policy Framework for Health and Social Care Research

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Glossary of Terms and Abbreviations

AE	Adverse Event
AR	Adverse Reaction
Cat-PROM5	Cataract-specific Patient Reported Outcome Measure
CDA	Cataract Decision Aid
CDQM	Cataract Decision Quality Measure
CI	Chief Investigator
CRF	Case Report Form
ICF	Informed Consent Form
HP	Healthcare Professional
HPIS	Health Professional (clinician) Information Sheet
HQIP	Health Quality Improvement Partnership
Observer OPTION[5]	An instrument to assess shared decision making processes
NHS REC	National Health Service Research Ethics Committee
R&I Office	Research & Innovation Office
NIHR	National Institute for Health Research
PAG	Patient Advisory Group
Participant	An individual who takes part in a research study
PI	Principal Investigator
PIS	Participant Information Sheet
PCR	Posterior Capsule Rupture
QA	Quality Assurance
QC	Quality Control
QoL	Quality of Life
REC	Research Ethics Committee
RNIB	Royal National Institute for the Blind
SAE	Serious Adverse Event
SDM	Shared Decision Making
SDV	Source Document Verification
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
PMG	Programme Management Group
PSC	Programme Steering Committee
VA	Visual acuity
WP	Work package

SIGNATURE PAGE

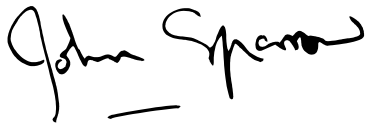
Chief Investigator Agreement

The clinical study as detailed within this research protocol (Version 1.0, dated 01June2018), or any subsequent amendments will be conducted in accordance with the UK Policy Framework for Health and Social Care Research, the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

Chief Investigator Name: Professor John Sparrow

Chief Investigator Site: Bristol Eye Hospital

Signature and Date:



01June2018

SUMMARY/SYNOPSIS

Short Title	*Involve-CAT*
Methodology	*A Feasibility Randomised Controlled Trial of a Cataract Decision Aid (component of a 5-year NIHR Programme Grant for Applied Research).*
Research Sites	*University Hospitals Bristol NHS Foundation Trust (Bristol Eye Hospital), Gloucestershire Hospitals NHS Foundation Trust (Cheltenham General Hospital and Gloucester Royal Hospital), South Devon Healthcare NHS Foundation Trust (Torbay Hospital) and Brighton and Sussex University Hospitals NHS Trust (Sussex Eye Hospital).*
Objectives/Aims	*The overarching aim of the Programme is to improve preoperative decision making in cataract surgery through provision of evidence-based, quantitative decision-support information on likely patient-reported benefits and risks of harm for individual patients and to estimate cost issues.* *This element of the programme 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.* *In summary these studies will consider:* • *How feasible would a full scale patient decision aid RCT be in terms of;* o *Ability to recruit participants in a timely fashion across 4 representative sites;* o *Assessment of suitability of candidate outcome metrics.* ▪ *A Cataract Decision Quality Measure (CDQM developed in WP3) will form the primary feasibility study outcome;* ▪ *Secondary / alternative outcomes assessing Shared Decision Making will also be evaluated in terms of group differences between trial arms and data distributions;* o *Sample size required to determine desired effect sizes for a possible future fully powered RCT;* • *Qualitative elements;* o *How does the decision aid influence preoperative shared decision making;* o *How do patients and clinicians perceive the*

	Cataract Decision Aid (CDA) in the context of routine care; • *Would it be feasible to estimate the decision aid implementation costs and potential savings in a fully powered trial;* • *An initial validation of the self-reported benefits prediction model;*
Number of Participants/Patients	*40 overall across four NHS sites.* *10 Participants from each of the four sites would provide sufficient data:* • *To gauge ease or difficulty of recruitment;* • *To identify point estimates and data distributions for candidate RCT outcomes;* • *To inform outcome selection and associated sample size;* • *To investigate qualitative elements;* o *The influence on preoperative shared decision making;* • *To provide initial quantitative information on;* o *Implementation costs / savings;* o *Initial validation of the self-reported benefits prediction model;*
Main Inclusion Criteria	*Patients undergoing cataract surgery are eligible to be recruited to the RCT and supporting studies if they meet the following criteria:* • *Aged 50 years or over at time of recruitment* • *Referred for **and** subsequently deemed clinically eligible for either first or second eye cataract surgery (although clinically eligible patients may or may not choose to proceed)* • *Ability to provide informed consent* • *Ability to understand and complete the Cat-PROM5 and CDQM questionnaire instruments as required* • *Willingness to participate*
Statistical Methodology and Analysis (if applicable)	*Full detail not applicable for a feasibility study*
Proposed Start Date	*25 June 2018*
Proposed End Date	*24 June 2019*
Study Duration	*12 months*

1.0 Introduction – An overview of the Research Programme

1.1 Summary

Cataract is an extremely common potentially blinding age-related condition, with cataract surgery the most frequently undertaken surgical procedure on the NHS[1], in the 2016-2017

NHS year there were an estimated 450,000 NHS cataract operations at a cost approaching £0.5Bn. Currently pre- and postoperative vision assessments are based on monocular (one eye at a time) letter recognition tasks of limited relevance to a person's everyday vision with both eyes open. UK relevant patient reported outcome measures of visual disability from cataract and its relief from surgery are lacking although as a result of the earlier stages in this NIHR funded research programme a brief NHS suitable cataract PROM (Cat-PROM5) is now available for implementation[2,3] and has already been adopted for use in all of Wales (including having been translated into Welsh), and is currently being piloted for possible future implementation as a patient focused outcome in the HQIP commissioned National Cataract Audit. As our primary sense, good vision is exceptionally important to human beings and a detailed knowledge of patient-reported benefits of cataract surgery is highly relevant to the priorities and needs of the NHS[4] and the public, many of whom will have cataract surgery within their lifetimes. Rates of surgery vary considerably[5] and there are concerns of an ongoing 'postcode-lottery' resulting from tightening NHS budgets. In the 2017 NICE Cataract guideline (NG77), the second highest priority research recommendation poses the research question: *"What vision-specific, quality-of-life measures best capture visual changes in a population with cataracts?"* and goes on to state *"The development and validation of suitable vision-specific, quality-of-life measures would aid the decision-making process for cataract surgery, and help to accurately quantify the quality-of-life gains that may be expected from surgery."*[6]. The current study is part of a 5-year research Programme which will address a series of issues of direct relevance to the perceptions of people with cataract undergoing surgery.

The overarching aim of the Programme is to improve preoperative decision making in cataract surgery through provision of evidence-based, quantitative decision-support information on likely patient-reported benefits and risks of harm for individual patients and to investigate cost issues through the following aims and objectives:

Q1. Visual Disability: how to measure cataract visual disability and benefit from surgery?
A1. A patient relevant measure for overall cataract visual disability and its surgical relief.
✓ *This element of the work has been completed.*

Q2. Predicting Harm: are published risk models for surgical complications and visual harm valid?
A2. Evaluation of 180,000 cataract operations to confirm or revise models
✓ *This element of the work has been extended and completed with analysis of >500,000 cataract operations*

Q3. Predicting Benefit: what are the magnitudes of different indicators of patient-reported benefit?
A3. Quantification of indicators of self-reported benefit in a cohort study of 1500 people undergoing cataract surgery
✓ *Data collection for this element of the work has been completed, analysis underway and expected to be complete for RCT*

Q4. Decision-Support: what information is helpful to assist shared decision making and how to present this?
A4. Development of a Cataract Decision Aid (CDA) containing personalised probability based information.
✓ *This element of the work has been completed.*

Q5. Health Utilities: how should cataract disability be calibrated against existing and emerging health economic indices?

A5. Investigation of relationships between the latent interval scale estimate derived from the Cat-PROM5 and utility values derived from health utility scales including exploration of co-calibration techniques.

✓ *Data collection for this element of the work has been completed, analysis underway*

Q6. Implementation: how do patient decision support tools influence preoperative shared decision making; what are implementation costs and potential savings; how feasible is a full scale decision-support RCT; how accurate is the benefits prediction model; why unexplained poor outcomes?

A6. A feasibility trial of a Cataract Decision Aid (CDA) with embedded qualitative assessments for a possible future fully powered RCT; evaluation of prediction model validity; qualitative investigations to include outcome mismatches (a continuation of qualitative aim commenced in WP3).

⇒ ***The current study takes the form of a feasibility randomised controlled trial (RCT) of a Cataract Decision Aid (CDA) to support patient-clinician shared decision making. Embedded in this feasibility RCT are qualitative and cost elements and an exercise to validate the benefits prediction model (developed earlier in the programme) for self-reported benefits from cataract surgery.***

2.0 Feasibility study of patient decision-support for cataract surgery (WP4)

2.1 Background

Patients and clinicians face significant uncertainties when approaching decisions about whether or not to proceed with cataract surgery. Benefits are usually presented in vague terms such as 'likely to see better after the operation', and risks are presented as either a list of possible adverse outcomes with or without overall averages for complications or visual harm. Surgeons may sometimes offer 'gut feeling' estimates for personalised probabilities of benefits and harms based on clinical experience. In a 'post-Montgomery'[7] environment these approaches are likely to be perceived by many as lacking precision, and it is unlikely that patients will be adequately involved in the decision-making process if such approaches are used.

Patient decision aids are evidence-based tools that are designed to support patients to make shared treatment management decisions, when more than one reasonable option exists[8]. They state the options, describe the options, and help people to think about the options from a personal view. As part of this programme we have developed a patient reported outcome measure, Cat-PROM5, which is able to measure the underlying latent scale of visual difficulty due to cataract. This measure forms the basis of a prediction model for self–reported benefit from surgery. Complementary to this are prediction models for the predicted probability of two adverse outcomes, an intraoperative surgical complication and monocular VA Loss related to surgery. Based on these models, personalised risk information can be calculated for individual operations and provided to patients and clinicians to assist with decision making. These risk prediction tools will be incorporated into a Cataract Decision Aid (CDA) for patients, which will provide bespoke information to the patient and the clinician advising them about likely risks and benefits of surgery. Most patient decision aids that have been produced to date include generalised population-level risk information only, and so the CDA will be a novel tool, which provides general information about the likely outcomes,

together with bespoke outcome information that is specific to the individual patient, and decision support exercises to help the patient think about what matters to them when making the decision.

Data from over 115 systematic reviews has highlighted the benefits of using patient decision aids to support patients to become more involved in the decision-making process. A recent Cochrane Review[8] has found that patient decision aids lead to improved patient knowledge about the options and likely outcomes, patients feeling better informed and more clear about what matters most to them, more accurate expectations of benefits and harms of the options, greater participation in decision making, and patients tend to reach decisions that are more aligned with their own personal preferences.

We hypothesise that decision making by patients and clinicians will be enhanced through use of the CDA, which is underpinned by patients' key concerns (or frequently asked questions) and incorporates generalised and personalised estimates of the likely risks and benefits associated with cataract surgery and non-operative management. We would expect that patients' knowledge of the treatment options would improve, that they would be able to consider their own personal values through a deliberation process, and they would be more ready to make a decision.

2.2 Overview

The preferred Cataract BDA FAQ formats and acceptability have been determined in WP3 and these refer to calculators delivering estimates of predicted benefit and risk of harm for individuals considering cataract surgery. Going forward the calculators will provide empirically based information to guide shared patient-clinician decision making with reference to likely benefits or harms in terms of predicted patient self-reported Cat-PROM5 outcomes, surgical complications and monocular VA loss.

A number of key issues will be addressed in WP4 (Involve-CAT), including

- What would be the feasibility of a full scale patient decision-support RCT using the Cataract Decision Aid (CDA) developed in this programme in terms of;
    - Ability to recruit and ease of recruitment of 40 participants in a timely fashion across 4 representative sites
    - Assessment of candidate outcome metrics in terms of group differences between trial arms and data distributions
    - Sample size required to determine desired effect sizes for a possible future fully powered RCT
- Impact of the CDA on patients knowledge, deliberation processes, and perceived readiness to make a treatment decision (using the Cataract Decision Quality Measure)
- An initial estimate of the decision aid implementation costs and potential savings
- An initial validation of the self-reported benefits prediction model for Cat-PROM5 benefit from surgery
- In addition, qualitative work will explore:
    - How the CDA (with incorporated risk-benefit prediction calculators) is perceived by patients and clinicians (acceptability, utility)
    - The feasibility of implementing the CDA in routine clinical settings for a possible future trial (and beyond)
    - How the CDA influences preoperative shared decision making about cataract surgery from the perspectives of patients and clinicians
    - Satisfaction with decision to undergo surgery and outcome of surgery

2.3 Aim

To undertake a feasibility RCT assessing the feasibility of a future full scale decision making RCT.

2.4 Specific Objectives

- Trial feasibility:
    - To undertake a feasibility RCT of implementation of a CDA (which incorporates probability based estimates of potential benefits and harms) in 4 NHS cataract surgical services in terms of:
        - Ability to recruit participants in a timely fashion across 4 representative sites
        - Use of the Cataract Decision Quality Measure (CDQM, developed as part of WP3) as the Primary Outcome Measure
        - Integration of the CDA into routine service settings
        - Assessment of candidate secondary / alternative trial outcome metrics in terms of differences between trial arms and data distributions
        - Sample size required to determine desired effect sizes for a possible future fully powered RCT
    - To use the Cataract Decision Quality Measure to assess the effects of using the CDA on:
        - patients' knowledge about the options and potential outcomes,
        - use of deliberation (patient's preferences),
        - readiness to make a decision
    - Assess the quality and level of SDM that takes place during consultations (using Observer OPTION[5] – refer to page 23)
    - To make an initial evaluation of the additional data collection burden and associated extra costs of acquiring information necessary to implement tools, and to plan for setting this against potential cost savings from avoidance of high risk / low benefit surgery, and the potential cost savings of avoiding costly complications and complication induced visual disability in a possible future full scale RCT

- Qualitative assessments
    - To assess perceived acceptability, utility, and influence of the CDA (which incorporates personalised predictions for benefits and harms) on preoperative patient-clinician SDM (from the perspective of patients and clinicians)
    - To investigate the feasibility of implementing the CDA in a routine service environment (from the perspective of patients and clinicians)

- Benefits model validation
    - To make an initial validation of the benefits prediction model for Cat-PROM5 based self-reported benefit from cataract surgery

3.0 Methodology

3.1 Trial design

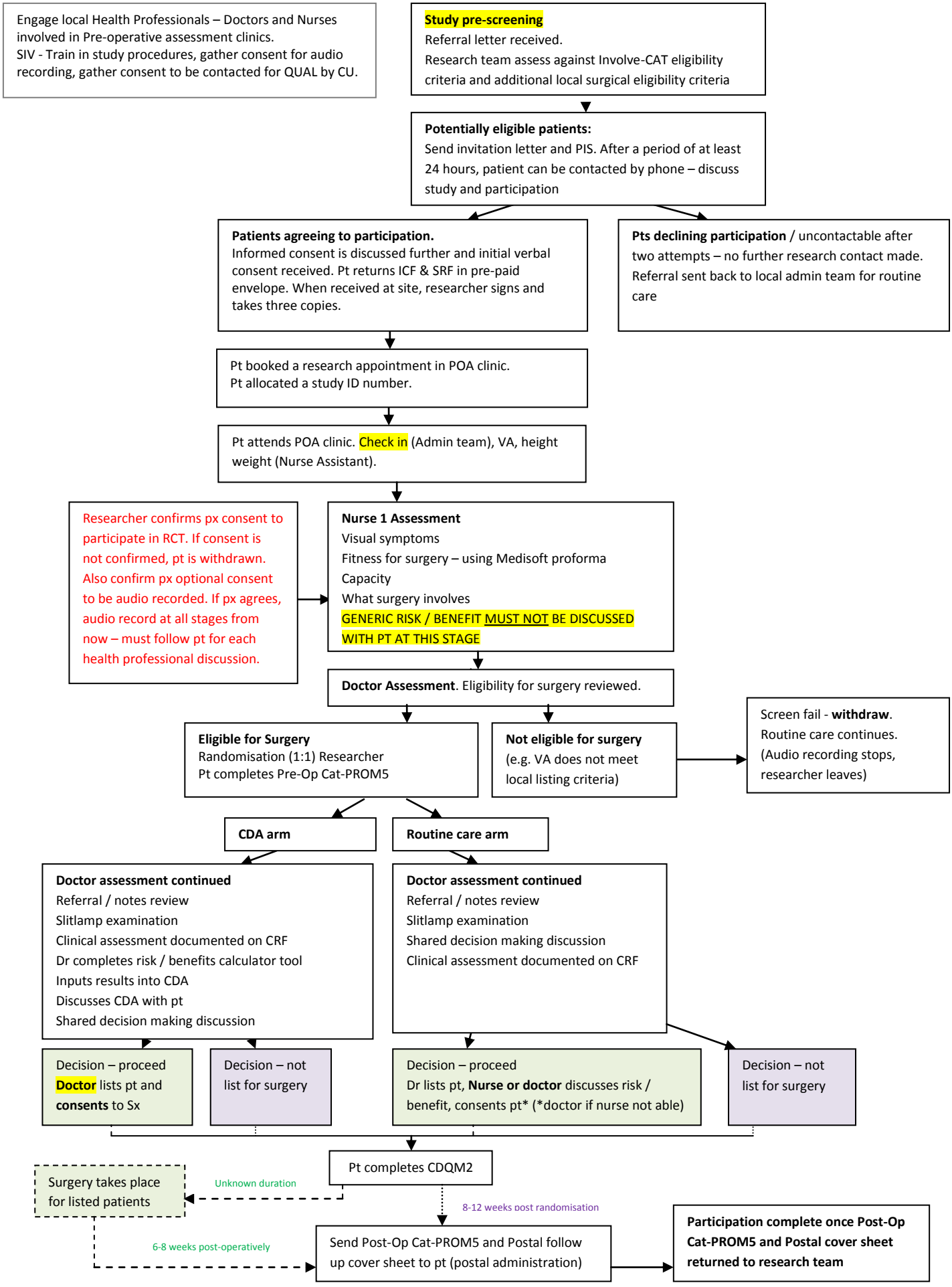
A two-arm feasibility trial of the CDA versus usual care in four UK NHS cataract surgical centres

3.2 Study setting

The feasibility RCT will be conducted at the four NHS cataract surgical centres involved in the Cataract Research Programme. The recruiting centres will be University Hospitals Bristol NHS Foundation Trust (Bristol Eye Hospital), Gloucestershire Hospitals NHS Foundation Trust (Cheltenham General Hospital and Gloucester Royal Hospital), South Devon Healthcare NHS Foundation Trust (Torbay Hospital) and Brighton and Sussex University Hospitals NHS Trust (Sussex Eye Hospital). Cardiff University researchers will play an active collaborative role in the CDA and CDQM aspects of the work.

3.3 Clinic flowchart to show example of a patient pathway

Patient flow and referral pathways will vary between sites, the diagram on page 16 provides an indication of one of the many types of pathway a patient may follow prior to cataract surgery.


Engage local Health Professionals – Doctors and Nurses involved in Pre-operative assessment clinics.
SIV - Train in study procedures, gather consent for audio recording, gather consent to be contacted for QUAL by CU.
Study pre-screening
Referral letter received.
Research team assess against Involve-CAT eligibility criteria and additional local surgical eligibility criteria
Potentially eligible patients:
Send invitation letter and PIS. After a period of at least 24 hours, patient can be contacted by phone – discuss study and participation
Patients agreeing to participation.
Informed consent is discussed further and initial verbal consent received. Pt returns ICF & SRF in pre-paid envelope. When received at site, researcher signs and takes three copies.
Pts declining participation / uncontactable after two attempts – no further research contact made. Referral sent back to local admin team for routine care
Pt booked a research appointment in POA clinic.
Pt allocated a study ID number.
Pt attends POA clinic. Check in (Admin team), VA, height weight (Nurse Assistant).
Researcher confirms px consent to participate in RCT. If consent is not confirmed, pt is withdrawn. Also confirm px optional consent to be audio recorded. If px agrees, audio record at all stages from now – must follow pt for each health professional discussion.
Nurse 1 Assessment
Visual symptoms
Fitness for surgery – using Medisoft proforma
Capacity
What surgery involves
GENERIC RISK / BENEFIT MUST NOT BE DISCUSSED WITH PT AT THIS STAGE
Doctor Assessment. Eligibility for surgery reviewed.
Eligible for Surgery
Randomisation (1:1) Researcher
Pt completes Pre-Op Cat-PROM5
Not eligible for surgery
(e.g. VA does not meet local listing criteria)
Screen fail - withdraw.
Routine care continues.
(Audio recording stops, researcher leaves)
CDA arm
Routine care arm
Doctor assessment continued
Referral / notes review
Slitlamp examination
Clinical assessment documented on CRF
Dr completes risk / benefits calculator tool
Inputs results into CDA
Discusses CDA with pt
Shared decision making discussion
Doctor assessment continued
Referral / notes review
Slitlamp examination
Shared decision making discussion
Clinical assessment documented on CRF
Decision – proceed
Doctor lists pt and consents to Sx
Decision – not list for surgery
Decision – proceed
Dr lists pt, Nurse or doctor discusses risk / benefit, consents pt* (*doctor if nurse not able)
Decision – not list for surgery
Pt completes CDQM2
Surgery takes place for listed patients
Unknown duration
8-12 weeks post randomisation
6-8 weeks post-operatively
Send Post-Op Cat-PROM5 and Postal follow up cover sheet to pt (postal administration)
Participation complete once Post-Op Cat-PROM5 and Postal cover sheet returned to research team

3.4 Intervention

Patient decision support in the form of a CDA incorporating personalised risk based estimates for patient reported benefit, surgical complications and visual loss as an additional element over and above 'usual practice' to support shared decision making.

3.5 Assignment of intervention

Allocation: 1:1 block randomisation by centre
Participants:

Arm 1: 5-6 patients per site who receive the CDA
Arm 2: 5-6 patients per site who do not receive the CDA

Sequence generation/ Randomisation method
Randomisation to study group will occur after a brief initial assessment of clinical eligibility for surgery by the clinician conducting the assessment. Once it is established that the participant is eligible for surgery, participants will be randomised by the Involve-CAT CTEU study database to either Arm 1 or Arm 2 on a 1:1 block allocation per-site. Participants deemed clinically ineligible for surgery will be withdrawn from study as a retrospective screen fail and will not count towards the recruitment target.

3.6 Blinding (masking)

Participants and researchers will not be masked.

3.7 Trial Feasibility

Ease of recruitment and uptake by potential participants across 4 typical cataract surgical sites will be assessed to inform feasibility of recruitment to a fully powered RCT. The primary feasibility trial outcome, the CDQM, will be assessed in terms of group differences between intervention and control arms and data distribution. Alternative candidate outcomes will be assessed as alternative primary and secondary outcomes. For each potential outcome sample size estimates for a possible future full trial will be estimated. Trial feasibility assessment will be supported by a range of quantitative assessments.

Initial Estimation of Costs

To make an initial evaluation of the additional data collection burden and associated extra costs of acquiring information necessary to implement decision support tools, and to plan for setting this against potential cost savings from avoidance of high risk / low benefit surgery, and the potential cost savings of avoiding costly complications and complication induced visual disability in a possible future full scale RCT.

Qualitative Assessments (led by Cardiff University)

The embedded qualitative research will focus on understanding the acceptability and usefulness of the CDA to patients and clinicians, and the feasibility of integrating the CDA into routine clinical settings, and using it in a full-trial setting. To do this, we will:

- Conduct follow-up interviews with patients who consent to take part in the study and will explore their views about the CDA, including acceptability, ease of use, whether it captures all aspects they think are important when making a decision

about cataract surgery, and any suggestions they have for improvements (design, content, delivery etc).

- Recruit study participants who did not receive the CDA to take part in a follow-up interview, to understand their experience of the decision making process
- Undertake follow-up interviews with the clinicians using the CDA to explore their views on the usefulness, practicability in a trial and clinical setting, and also whether the CDA (which includes Cat-PROM5) cover all the issues they feel are important when discussing cataract surgery with patients.
- Consultations/discussions with participants from both arms of the study will be audio-recorded, with consent. For consultations during which the CDA is used, its use will be assessed for evidence of acceptability, levels of information provision and practicability/suitability.
- Attempts will be made to complete in-depth qualitative analysis, such as discourse analysis, to explore turn-taking in the patient-clinician discussion, and whether the preference elicitation process is patient or clinician led.
- In relation to recruitment and retention, attempts will be made to interview those who opt out to discover whether there are practical difficulties with either the CDA (or Cat-PROM5).

Qualitative research data will be collected using the following approaches:

- Interview topic guides (one for patients and one for clinicians) will be used to ensure similar areas are covered in each interview, with flexibility to allow issues of importance to the informants to emerge.
- A range of patients and healthcare professionals will be selected. Patients will be selected to include men and women, and a range of ages and socio-demographic characteristics.
- Relevant health professionals will be selected.

3.8 Outcomes

Primary Feasibility Trial Outcomes

The Cataract Decision Quality Measure (CDQM) developed in WP3 will be used to assess patients' knowledge about options, patients' preferences, and readiness to make a decision. DQMs are bespoke measures that are developed in conjunction with a decision aid. The Cataract DQM is a measure of patients' cataract / cataract surgery specific knowledge, their personal preferences (which outcomes matter most to them), and readiness to make a decision about cataract surgery.

Feasibility Outcomes

We will undertake modelling of trial procedures, including the training of clinicians to use the CDA; the acceptability of the decision aid to patients and clinicians; detailed monitoring of recruitment, randomisation, and retention; and use the effect size to estimate sample size as well as decide on the most appropriate primary and secondary outcomes for the main trial.

Candidate Secondary and Qualitative Outcomes

Cat-PROM5 self-reported difficulty with vision; process measures of CDA usage to monitor fidelity; uptake of cataract surgical option following patient-clinician interaction; patient and clinician perceived usefulness and influence of support tools on shared patient-clinician decision making; patient and clinician experience of the use of decision support tools.

Health Economic Outcomes

Estimation of the decision support intervention costs (additional data collection burden for population of CDA risk estimates, additional time taken in clinic etc.), subsequent NHS costs of surgery undertaken or avoided, and costs of secondary care and community services. Patient outcomes assessed using the Cat-PROM5 and utilities data (e.g. EQ5D-5L) derived in WP3. We will investigate the likely effectiveness and cost-effectiveness of the decision support tool and the need for a subsequent full scale trial.

Benefits Model Validation

The feasibility trial data will be used for an initial validation of the benefits prediction model for self-reported Cat-PROM5 benefit from surgery.

3.9 Sample size

Feasibility RCT Participants: 40 Patients considering cataract surgery to be randomised, 10 from each of the four collaborating centres. If we cannot recruit the target number of patients from any one of the sites, we will recruit more patients from the remaining sites.

3.10 Eligibility Criteria

Inclusion Criteria:
Patients undergoing cataract surgery are eligible to be recruited to the study if they meet the following criteria:

- Aged 50 years or over at time of recruitment
- Referred for **and** subsequently deemed clinically eligible for either first or second eye cataract surgery
- Ability to provide informed consent
- Ability to read and understand study materials (PIS, Cat-PROM5, CDA, CDQM etc.)
- Willingness to participate

Exclusion Criteria:

- Previous participation in earlier elements of the cataract research programme

3.11 Recruitment

Patient participants

Patient recruitment and randomisation will use a combined consent and randomisation process for the RCT and qualitative elements of Involve-CAT (WP4). For the RCT, patients will be consenting to be audio-recorded during their appointment, to completing two versions of the CDQM (before and after consultation), to receive (or not) the CDA. Audio recording will be preferred, though optional, and patients may still take part in the RCT even if they do

not wish to be audio-recorded. For the qualitative aspects patients will be consenting to be contacted about taking part in a follow-up interview. For patients who do consent to be contacted about a follow-up interview, specific consent will be received by the qualitative researcher prior to the interview itself, using a separate consent form.

Eligible patients will receive a copy of the feasibility RCT Patient Information Sheet (PIS), informed consent form (ICF) and a study reply form (SRF) by a member of the study team or their clinical care team, in clinic or by post (depending on local arrangements) prior to attending their hospital cataract referral appointment. After an appropriate period (minimum 24 hours), the local research team will contact the patient by telephone to discuss the study with them, address any questions the patient may have and ask if they would like to be involved in the study. A patient may also choose to contact the study team by phone to discuss the study. If a patient wishes to take part, they will be asked to complete and return the SRF and the ICF in the pre-paid envelope to the local study team, including preferred contact details. If a patient does not wish to be involved in the study, no further contact from the study team will be made. Declining patients will not have to state a reason for declining but will be invited to provide a reason if they wish to.

Duplicate copies of these forms will also be provided in the patient's medical notes for the clinician to review prior to the patient's consultation, along with the case report form (CRF) and blank CDA (to be completed during the assessment IF the participation is randomised to the CDA arm – see randomisation and clinic flow diagram on page 16).

If a patient has consented to be contacted for a follow-up interview, the CU study team will make contact again at a later date with further information in the form of a specific PIS-ICF and to arrange a convenient time and location for the follow-up interview to take place (either in person or via telephone).

Clinician participants

Clinician recruitment will use a combined consent and randomisation process for the RCT and qualitative elements of Involve-CAT (WP4). For the RCT, clinicians will be consenting to be audio-recorded during the participant examination. For the qualitative aspects clinicians will be consenting to be contacted about taking part in a follow-up interview. Specific consent will be received by the qualitative researcher prior to the interview itself, using a separate consent form.

All clinicians (ophthalmologists, optometrists and nurses) that will be using the CDA during the feasibility RCT will take part in a Shared Decision Making (SDM) training session led by CU researchers prior to them using the tool in clinic with patients. This session will introduce the concept of shared decision making, outline the core skills used during shared decision making, and it will introduce the clinicians to the CDA (covering ideas for suggested use). It is likely that the training session will be incorporated into the site initiation visits that will take place prior to the Involve-CAT feasibility RCT commencing (WP4). Any additional clinical training required for participating clinicians to carry out the study assessments will be conducted by the CI (or a delegated member of the lead site clinical team) outside of the SIV.

Clinicians will be approached informally by the member of the study team and given a Health Professionals study information sheet (HPIS), informed consent form (ICF) and study reply

form (SRF). After an appropriate period, the research team will contact the clinician to arrange consent and training. If they wish to participate, they will be asked to complete the Health Professionals study reply form and Health Professionals consent form. It is anticipated clinician consent will be received will take place during the local site initiation visit, alongside the SDM training session. The CU study team will make contact again with clinicians at a later date with further information about the follow-up interview in the form of a specific HPIS-ICF and to arrange a convenient time and location for the follow-up interview to take place (either in person or via telephone).

3.12 Data collection

Demographic and clinical data

Following initial eligibility checking, randomisation will take place. Eligible patients will be asked to complete the baseline CDQM (CDQM1) and Cat-PROM5 measures. Those who are subsequently found clinically to be unsuitable for surgery will exit the study at this point and will be withdrawn from the study as a retrospective screen fail and audio-recording of these patients will cease.

Basic demographics and relevant routinely collected clinical data will be recorded on the Involve-CAT CRF for eligible participants by the clinician assessing the patient.

For those in the 'usual care' arm, the consultation will proceed with discussion and completion as per routine care.

For those in the intervention arm, information gaps in the routinely collected clinical data will be supplemented with any outstanding clinical details required to populate the benefits and risks prediction models with the outputs from the prediction models noted within the CDA (variables will be determined following results from the analysis of data from the cohort study conducted as part of WP3). Patients will be given appropriate time during their consultation (at least 20 minutes) to consider the FAQs and individualised benefits / risks information contained in the CDA, following which the consultation will be completed with the clinician discussing the options that are available to the patient (using a shared decision making consultation style for which clinicians will have received training during the SIV)[9]. Issues covered should include any as perceived by either the patient or the clinician in the context of general information and that contained in the CDA.

A research assistant will be present during the consultation for all participants to facilitate audio-recording, randomisation and completion of study documentation.

Ocular/Medical Examination

The following tests all form part of a routine clinical investigation and will form part of the data collection for Involve-CAT (WP4). In addition to the patients' hospital paper notes, information will be collected from the local site electronic (Medisoft) or paper based patient record and from a clinical patient examination and collated onto the Involve-CAT CRF.

- Confirmation of eligibility
- Height/weight

- Demographics/Ethnicity/socio-economic status
- Diabetic status
- Surgical / Medical/Ocular History
- Concomitant medications
- Unaided/Habitual/Best corrected visual acuity (LogMAR, or Snellen), monocular
- Unaided/Habitual/Best corrected near vision (LogMAR or 'N plates') monocular
- Focimetry
- Habitual / Corrected contrast sensitivity (Pelli-Robson), binocular
- Dilation (Tropicamide 1% and Phenylephrine 2.5%, following angle depth check)
- A full dilated Slit-lamp examination will be performed:
    - Anterior segment assessment
    - Cataract grading (using Oxford central / LOCSIII grading)
    - Fundus / optic disc examination
- Intraocular Pressure (IOP) check (Goldmann Applanation Tonometry)

Cataract Decision Quality Measure (CDQM)

All consented eligible patients will be asked to complete the Cataract DQM (developed as part of WP3), prior to their consultation (CDQM1). The Cataract DQM is a measure of patients' cataract / cataract surgery specific knowledge, their personal preferences (which outcomes matter most to them), and readiness to make a decision about cataract surgery. Immediately following the consultation, all patients will be asked to complete another Cataract DQM (CDQM2).

Consultation audio recordings

Consultations between the patient and clinician will be audio-recorded using an approved audio-recording device, and transcribed verbatim for analysis.

Postal Cat-PROM5 follow up

Participants will be contacted by post (or phone if more convenient for the participant) to complete another Cat-PROM5 questionnaire and a 'postal follow up cover sheet', in order to capture changes in their vision and additional information about their recent spectacle use and spectacle prescription. The date of follow-up contact is dependent on whether or not the participant proceeded to surgery, and will be determined as follows:

Participants who <u>proceed to surgery</u> will be contacted by post (or phone) at 6-8 weeks following the date of their surgery to complete another Cat-PROM5 questionnaire and a 'postal follow up cover sheet'.

Participants who <u>do not proceed</u> to surgery will be contacted by post (or phone) at 8-12 weeks following the date of their randomisation to complete another Cat-PROM5 questionnaire and 'postal follow up cover sheet'.

Follow-up interviews

Follow-up interviews will be led and conducted by the Cardiff University team, but they may be supported by University of Bristol researchers if required, depending on the number of interviews and locality of the interviewee.

Patients

We aim to recruit 10-12 patients across all participating sites (5-6 patients who received the CDA and 5-6 patients who did not receive the CDA) to take part in an audio-recorded follow-up interview. If the patient has consented to be contacted about taking part in a follow-up interview, the CU team will contact them with a specific PIS-ICF with further information and to arrange a convenient time and location for the interview to take place (this may be via telephone). The semi-structured interview will explore the patient's experience of the consultation and the CDA more specifically (if the patient was randomised to this arm). The interviews will also explore issues of acceptability, usability and feasibility of the CDA, and also perceived usefulness of the CDA in supporting the decision making process.

Clinicians

Clinicians who used the CDA during the feasibility RCT (from across the study sites) and have consented to be contacted about a follow-up interview, will be contacted by the CU team with a specific HPIS-ICF with further information and to arrange a convenient time and location for the interview to take place (this may be by telephone). We aim to recruit 1-3 clinicians per site to be interviewed about using the CDA during the feasibility RCT. If we cannot recruit the target number of health professionals from any one of the sites, we will recruit more clinicians from the remaining sites. Semi-structured interviews will be used to explore the clinicians' experiences of the shared decision making consultations with their patients, and to gather their feedback on the use of the CDA. We will explore issues of usability and feasibility of using the tool in every day clinical settings, including any barriers to use.

All interviews will be audio-recorded, with consent, and transcribed verbatim for analysis.

This will conclude the participant's involvement in Involve-CAT. Patient participants will be referred on from the research programme to their clinical care team/GP as appropriate and in line with local policy and guidelines.

No vulnerable groups will be recruited into the study.

4.0 Data Analysis and Statistical Methods

4.1 Feasibility RCT

4.1.1 Quantitative analysis - conducted by Cardiff Team

The primary trial outcome for the feasibility trial will be the Cataract Decision Quality Measure (CDQM). Data will be analysed using SPSS[10]. The full analysis plan will be determined once the CDQM has been developed, but analysis will involve

descriptive statistics, frequency statistics, use of paired sample t-tests to compare CDQM1 (before intervention) with CDQM2 (after intervention) scores, and independent t-tests to compare CDQM1 / CDQM2 scores of the intervention group with the usual care group.

Shared Decision-Making will be analysed quantitatively using the Observer OPTION[5] [11] instrument to analyse SDM during consultations as a secondary quantitative outcome. Audio recordings of the consultations during which the patient and clinician discuss the treatment options will be transcribed verbatim. The instrument assesses the SDM process against five key areas of SDM, scored on a 5-point Likert scale (0 = no effort – 4 = exemplary effort). The total score is calculated by adding up the score for each item (score range 0 – 20), rescaling from 0 – 100, and a mean of the two raters score is taken; higher scores indicate that a greater number of SDM elements were observed (deliberative process was assessed across two consultations for breast cancer patients; sum of highest item scores across either encounter used). Each consultation audio recording will be assessed independently by two trained raters.

4.1.2 Quantitative analysis - conducted by Bristol team

Sample size estimates will be derived from analysis of primary and secondary / alternative potential trial outcome measures based on observed effect sizes and distributions of candidate outcomes for a possible future fully powered trial.

Initial validation of the benefits prediction model will take the form of comparisons between predicted and actual self-reported Cat-PROM5 scores at the postoperative time point.

4.1.3 Qualitative analysis – conducted by Cardiff team

Quantitative work will be supported and enhanced by qualitative elements involving both patients and clinicians. Audio recordings of follow-up interviews (patient and clinician) will be transcribed verbatim for qualitative analysis using a recording device approved by CU. Transcripts will be imported into NVivo. A framework analysis approach[12] will be used to analyse the patient and clinician data separately (based on the key topic areas covered by the interview guide e.g. experience of SDM, usefulness of the CDA, additional FAQs, feasibility of using the CDA in routine clinical settings / trial setting). This will include the following stages: a) familiarisation of the data, b) coding of the data, c) charting the data by each code, d) reviewing and summarising each of the charted codes for the groups of participants. Feedback on the CDQM will be analysed separately.

Audio recordings of the consultations during which the patient and clinician discuss the treatment options will be transcribed verbatim. The framework analysis approach described above will also be used to analyse the consultations, based on models of SDM[13], to identify the elements of SDM that were observed. Attempts will be made to complete discourse analysis to explore turn-taking in the patient-clinician discussion, and whether the preference elicitation process is patient or clinician led.

5.0 Data Collection & Data Management

5.1 Case Report Forms (CRFs)

The following CRFs and forms will be completed at various stages as appropriate for study participants as detailed in study specific standard operating procedures:

- Participant Identification Form
- Patient information sheet
- Patient study reply form
- Patient consent form
- Health Professionals information sheet
- Health Professionals study reply form
- Health Professionals consent form
- Cat-PROM5
- CDQM1
- CDQM2
- CDA (if randomised to intervention arm)
- Involve-CAT CRF
- Postal follow up cover sheet CRF
- Patient information sheet – Follow-up interview
- Patient consent form – Follow-up interview
- Health Professionals information sheet – Follow-up interview
- Health Professionals consent form – Follow-up interview
- Follow-up interview topic guide (patient and Health Professionals)
- Correspondence CRF (if required)
- Study Completion CRF

5.2 Data management

RCT

All study data collection will be collated onto the Involve-CAT Case Report Forms/Questionnaires during the combined cataract assessment/research appointment.

All CRFs (apart from the Participant Identification Form, Informed Consent Form and Study Reply Form) will be pseudonymised and will not contain any patient identification data (PID). All pseudonymised CRFs will be stored securely at each site, in a locked cabinet/file accessible only to study team members.

Audio-recorded consultations/discussions will be transferred securely to the CU team via encrypted USB memory sticks for transcription and analysis.

Follow up interviews

Participant interviews will be audio-recorded by the research team and pseudonymised by study ID number. Permission will be obtained from all participants prior to recording, and informed consent procedures will be followed. Audio-recorded consultations and/or interviews will be recorded on encrypted equipment approved by the qualitative researchers and files will be backed up on encrypted USB memory sticks. Encrypted files will be

transferred securely to the CU team via encrypted USB memory sticks. Transcriptions services will be provided by a University-approved supplier with a confidentiality agreement in place. All recordings (and associated transcriptions) will be stored securely on Cardiff University secure electronic drives. All data will be stored securely as per the Involve-CAT data management standard operating procedures. Any analyses sent via email will be encrypted. Only personnel involved in the study will have access to the audio files / transcriptions. The recordings will only be retained for the duration of the Cataract Research Programme, and then erased.

5.3 Electronic Study Databases

Information regarding demography, concomitant medications and co-morbidities will be taken from the electronic (Medisoft) or paper based patient record, verified at the cataract assessment appointment with the participant, and entered into the paper CRF. All data from the CRF and questionnaires will then be transcribed to the Involve-CAT study database. The database is a validated, bespoke database designed in SQL server, with a web based front end for data entry constructed and maintained by the Clinical Trials and Evaluation Unit (CTEU), University of Bristol. Only staff with an NHS email account are able to use the database and access is strictly limited to Involve-CAT study staff. Where feasible and convenient, direct data entry into the database (avoiding the need for paper forms and transcription) will be deployed.

Study staff will be trained in completion of all study documentation and databases at study initiation and throughout the study as required, and study standard operating procedures will document all procedures.

Participants enrolled into Involve-CAT will be entered on to the CTEU Involve-CAT database Screening and Recruitment log after eligibility has been confirmed and written, informed consent has been received. This will sequentially allocate them a unique trial ID which should be entered onto all hard copy data collection tools. The database will randomise eligible participants to a study arm. Each record will be tagged on the database to record the recruiting site.

All paper based CRF and questionnaire data will be transcribed onto the CTEU Involve-CAT database. All paper based data will be subject to regular, source data verification (see Section 9.0) and at the end of the data collection period, the data will be cleaned and any queries finalised prior to database lock, data analysis then archiving.

5.4 Data Security

Data will be stored in line with the General Data Protection Regulations 2018 and local policies and guidelines. Access to the Involve-CAT study database will be granted only to members of the study team by the Programme Manager and Senior Trial Coordinator. The database is only accessible to PCs on the NHS N3 secure network. Case report forms will be stored at local sites in a lockable storage unit accessible only by members of the study team. As outlined in section 5.2, participants will be assigned a unique study ID for the purposes of data collection and analysis. Pseudonomised study data will be securely stored in line with the General Data Protection Regulations and local policies and procedures for the duration of the study. Local sites teams will receive training in the study Standard Operating Procedures for managing and storing study data.

5.5 Archiving

Archiving of hard copy and electronic data will be as per local site guidelines. Minimum archiving duration will be five years and arrangements for archiving will be made via the local Trusts' Research and Innovation office with all study documentation being archived in the Trust third party archive facility

5.6 Subject withdrawal

Participants are free to discontinue with the study at any point. Should they wish to withdraw or become no longer eligible to take part, they will be return-referred back to the standard NHS clinical cataract care pathway by the clinician. Any information gathered during the study pertinent to the ongoing care of the patient shall be documented in the patients' electronic record and/or clinical paper notes. Pseudonomised study data will continue to be securely stored in line with the General Data Protection Regulations and local policies and procedures for the duration of the study as for all other study participants but not used for analysis or included in the final study report unless the participant has given permission for collected data to be included.

5.7 Schedule of Assessment

Assessment	**Screening / Baseline (pre-op)**	**Follow-up(Post-op 6-8 weeks / Post-randomisation 8-12 weeks)***
Review of eligibility	X	X
Informed consent	X	
Randomisation	X	
Cat-PROM5 questionnaire	X	X
Postal follow-up cover sheet		X
CDQM(1) questionnaire	X	
CDA**	X	
Demographics/SE status	X	
Weight & Height	X	
Diabetic status	X	
Medical/Ocular/Surgical History	X	

Concomitant medications	X	
Focimetry	X	
Unaided/Habitual/Best corrected visual acuity	X	
Unaided/Habitual/Best corrected near vision	X	
Habitual Contrast Sensitivity (Pelli-Robson)	X	
IOP	X	
Dilated slit lamp examination***	X	
CDQM(2) questionnaire	X	
Follow-up interviews****	X	

* Depending on whether or not participant had surgery** Depending on 1:1: randomisation allocation
*** Including anterior segment assessment, Cataract grading and Fundus / optic disc examination
**** Depending on participant consent

5.8 End of Study Definition

The end of study is defined as completion of analysis and report writing.

6.0 Health Economics

6.1 Methodology and Analysis

We will record on the CRF the start and end time of the consultation for all patients, including the first and second parts of the consultation in patients randomised to the CDA. The CRF will also document any additional resources used to provide missing information for the benefits and risks prediction models. We will record the role and grade of clinicians present during the consultation in order to estimate the total cost of the consultation in each arm of the trial. We will extract data from the medical record at three months after randomisation to identify ophthalmology-related secondary care (e.g. OP appointments, cataract surgery). We will describe the total NHS costs of secondary care in both groups.

7.0 Outputs

- Feasibility assessment of a possible future full powered RCT of cataract surgery decision-support in terms of
  - Ability to recruit
  - Effect sizes for candidate outcomes for a possible future fully powered RCT
  - Sample size necessary for a possible future fully powered RCT
- Investigation of the acceptability to health professionals and patients of the use in a clinical environment of CDA for shared decision making

- Evaluation of implementation issues (usability, ease of uptake, perceived usefulness) for routine use of decision aid and risk calculator tools by doctors and patients
- If sufficient data, understanding of the impact of clinician use of CDA for avoidance of high risk low benefit surgery with avoidance of morbidity and costly complications
- Initial validation of Cat-PROM5 benefits prediction model performance in an independent group of patients
- Identification of the additional data collection burden and associated costs of routine decision-support implementation in NHS cataract services

8.0 Benefits to Patients, the Public and the NHS

- Feasibility assessment for possible future full powered RCT of decision support for cataract surgery, the most frequently undertaken surgical procedure on the NHS
- Empowerment of patients considering surgery through provision of FAQ formatted CDA incorporating personalised benefit / risk prediction information
- Opportunities for enhanced patient care through improved decision making by doctors, service users, commissioners

9.0 Quality Assurance & Quality Control

During the study, the research team will conduct regular, monitoring visits. Frequency of monitoring visits will be approximately every two months but may be adjusted according to recruitment rate. Source data verification (SDV) on at least 10% of study data will be conducted as part of the data monitoring process. Error rates of >2.0% will trigger additional SDV. 100% of participant eligibility and informed consent will be verified.

Internal audits may be conducted by a sponsor's or funder representative.

Definition: "A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s)."

A study may be identified for audit by any method listed below:

1. A project may be identified via the risk assessment process.
2. An individual investigator or department may request an audit.
3. A project may be identified via an allegation of research misconduct or fraud or a suspected breach of regulations.
4. Projects may be selected at random. The Department of Health states that Trusts should be auditing a minimum of 10% of all research projects.
5. Projects may be randomly selected for audit by an external organisation.

10.0 PRODUCTS, DEVICES, TECHNIQUES AND TOOLS

Devices

Standard clinical ophthalmic equipment will be used to conduct the clinical assessments such as the following (models may vary across sites and are subject to prior approval by the CI):

1. Haag-Streit BM900 Slit Lamp with Volk 90D lens
2. Goldmann AT900 tonometer
3. Takagi LM-10 lensmeter

VA and contrast sensitivity will be conducted using the following visual acuity charts:

1. Internally illuminated slim line LogMAR chart
2. 2 metre ETDRS Chart 1 Original
3. 2 metre ETDRS Chart 2 Original
4. Pelli Robson Contrast Sensitivity chart

Weight will be measured using standard Trust clinical equipment (Seca scales) as will height.

Tools

Various validated questionnaires will be used to collect data:

Cat-PROM5: A cataract specific patient reported outcome measure developed as part of the host research programme of which this study is a component to measure the underlying latent scale of visual difficulty due to cataract

CDQM: A cataract specific measure developed as part of the host research programme of which this study is a component to assess patients' knowledge about options, patients' preferences, and readiness to make a decision

CDA: A decision support tool developed as part of the host research programme of which this study is a component containing bespoke information to the patient and the clinician advising them about likely risks and benefits of surgery

11.0 Safety Reporting

Definitions

An Adverse Event (AE) is any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with study activities.

A Serious Adverse Event (SAE) is defined as an untoward occurrence that

1. results in death;
2. is life-threatening;
3. requires hospitalisation or prolongation of existing hospitalisation;
4. results in persistent or significant disability or incapacity;
5. consists of a congenital anomaly or birth defect; or

6. is otherwise considered medically significant by the investigator.

An SAE occurring to a research participant should be reported to the main REC where in the opinion of the Chief Investigator the event was:

1. Related – that is, it resulted from administration of any of the research procedures, and
2. Unexpected – that is, the type of event is not listed in the protocol as an expected occurrence.

Recording, Notification and Reporting of Serious Adverse Events for Involve-CAT

As this study does not involve any medicinal product/medical device/intervention, adverse events will not be collected. This is a low-risk study involving the use of a decision aid only; there are therefore minimal risks to participants. All clinical assessments would be conducted as part of routine clinical care pre-cataract surgery.

Expected events which may occur throughout the study are related to operative complications, such as posterior capsular rupture (PCR). These will not be reported as an adverse event. However, any adverse incident occurring as a result of the research visit or the participant's clinical care, will be reported and documented in line with UH Bristol's "Policy for the Management of Incidents" and the policy of local sites.

Annual Safety Reporting

The CI will send the Annual Progress Report to the main REC using the NRES template (the anniversary date is the date on the MREC "favourable opinion" letter from the MREC) and to the sponsor.

12.0 Ethics and dissemination

The Involve-CAT study will be carried out in accordance with the UK Policy Framework for Health & Social Care Research and its subsequent amendments and applicable legal and regulatory requirements.

Approval from the Health Research Authority (HRA) will be sought for the study to ensure governance and legal compliance, and an independent ethical opinion from a recognised Research Ethics Committee (REC). No study procedure will commence until approval is received from the HRA/REC and capacity and capability reviews have been completed for each of the participating NHS sites.

In this study participants will be undergoing standard clinical assessments and as such the study does not raise any significant ethical or legal issues. In addition to collecting clinical data which would normally be collected as part of routine, clinical care for cataract surgery patients pre-operatively, participants will be asked to complete questionnaires regarding the impact which their cataracts have on their ability to see and to function in their every-day environment and the CDQM1/CDQM2. Participants in the intervention arm may also

undergo additional ocular assessments which would not normally be undertaken as routine clinical care (e.g. contrast sensitivity). None of these assessments raise any ethical issues and all carry no risk. The burdens associated with participating in the study will be minimal: one study visit integrated into their planned NHS assessment clinic, post-assessment completion of CDQM2 and the option to participant in a qualitative follow up interview following the assessment (this may be face-to-face or over the telephone).

Patients who do not have the capacity to consent will not be involved in this study.

12.1 Informed Consent Procedure

Patient participants

Only a member of study staff trained in Good Clinical Practice, Informed Consent, the study protocol and SOPs will approach patients to take part in the study. Potential participants will be identified through assessment of referrals to cataract care (either internal or external referrals) and those deemed initially eligible will be sent a Patient Information Sheet (PIS), informed consent form (ICF) and study reply form (SRF) for consideration of the study.

The patient will be given a reasonable amount of time to consider taking part in the study (minimum 24 hours). After this time, the patient will then be contacted by the local research team and will be given the opportunity to ask any questions regarding the study and asked if they would like to be involved. If deemed eligible at this stage, the informed consent procedure will be discussed and verbally confirmed by the participant, after which they will be scheduled a combined NHS / research visit within a clinic provided by Health Professionals trained in Involve-CAT study procedures. Study staff receiving consent from the participant should check that they understand the study and what is required of them. Participants will be asked to complete the informed consent form (ICF) and study reply form (SRF) and return using the pre-paid envelope provided. Alternatively, if necessary, written consent may be received by a member of the study team on the day of the patients' combined NHS / research visit. The ICF will be countersigned by the researcher, and copies taken (**three copies)**. The **original** will be filed in the PID, one **copy** returned to patient, one **copy** sent to the Cardiff researchers and one **copy** filed in the paper notes (patients only).

For patients who agree to be contacted about a follow-up interview, the qualitative researchers will send the patient a specific PIS-ICF with further information. Participants will be asked to complete the follow-up interview ICF and return direct to the qualitative team using the pre-paid envelope provided. The ICF will be countersigned by the researcher, and filed locally by the qualitative team. If necessary, consent may be received verbally by a member of the qualitative team on the day of the patients' interview if the interview is being conducted by phone.

Clinicians

Study staff receiving consent from clinicians should check that they understand they are consenting to being audio-recorded during the patient's examination and to be approached by the Cardiff University researchers at a later date to take part in a follow-up interview.

They will be approached informally by the member of the study team and given a Health Professionals study information sheet (HPIS), informed consent form (ICF) and study reply form (SRF). If they wish to participate, they will be asked to complete the Health Professionals study reply form and Health Professionals consent form. The research team will contact the clinician to arrange consent and training – it is anticipated clinician consent will be received and training will take place during the local site initiation visit.

The clinician consent form will be countersigned by the researcher, and copies taken (**two copies).** The **original** will be filed in the PID, one **copy** returned to clinician and one **copy** sent to the Cardiff University researchers.

The qualitative researchers will send the clinician a specific HPIS-ICF with further information about a follow-up interview. Clinicians will be asked to complete the follow-up interview ICF and return direct to the qualitative team using the pre-paid envelope provided. The ICF will be countersigned by the researcher, and filed locally by the qualitative team. If necessary, consent may be received verbally by a member of the qualitative team on the day of the follow-up interview if the interview is being conducted by phone.

13.0 Programme Committees

Programme Management Group (PMG)
The PMG will meet regularly at the lead site and will consist of the core lead site study team. Day to day operational issues will be dealt with and managed by this group.

Programme Steering Committee (PSC)
The Programme Steering Committee meet annually during the programme, supported by the programme manager and chief investigator, with applicants and collaborators eligible to join as observers. A six-month interim report is circulated between annual meetings and periodic updates on key phases of the programme are provided by email as appropriate.

Independent Members (2 ophthalmologists, of whom one is chair; 1 lay member; 1 patient group representative (RNIB); 1 Statistician / Methodologist) are:

- Mr Larry Benjamin (Chair)
- Mrs Myra Higgins (patient and public representative)
- Mr Steve Hyde (RNIB)
- Mr Nicholas Strong (ophthalmologist)
- Dr Catey Bunce (Statistician / Methodologist)

Patient Advisory Group (PAG)
The PAG will consist of a group of up to eight patient representatives who have provided advisory input throughout the duration of the research programme and have fed directly into the development of the tools to be implemented in WP4 Involve-CAT. The group meet a minimum of twice annually and is chaired by Professor David Evans.

14.0 Finance and Funding

The Predict-CAT study is part of a 5-year Research Programme, Grant funded by the National Institute for Health Research (Programme Grant for Applied Research). The funder's reference number is RP-PG-0611-20013, and the total amount awarded for the Programme is £1,967,079.00 over 60 months (commencing December 2013).

15.0 Indemnity

The sponsor for the study is University Hospitals Bristol NHS Foundation Trust, who will provide insurance and indemnity.

16.0 Dissemination of Research Findings

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.

17.0 KEY REFERENCES

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