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Patient-centred and economic effectiveness of a decision aid for patients with age-related cataract in China: study protocol of a randomised controlled trial

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ABSTRACT

Introduction The need for cataract surgery is on the rise due to our ageing population and high demands for greater visual functioning. Although the majority of patients want to participate in a shared decision-making process, no decision aid has been available to improve the quality of decision. The present study aims to determine whether a decision aid increases informed decision about cataract surgery.

Methods and analysis A parallel randomised controlled trial (772 participants) will be conducted. The decision aid will be implemented among patients with any age-related cataract in Yuexiu District, which is socioeconomically representative of a major metropolitan region in Southern China. Participants will be randomly assigned to receive either a patient decision aid or a traditional booklet, and they will complete three surveys: (1) baseline assessment before the intervention (time point (T)1), 2 weeks (T2) and 1 year (T3) after the intervention. The control group receives a traditional booklet with standard general information developed by the National Eye Institute to help patients understand cataract, whereas the intervention group receives a patient decision aid that includes not only the standard general information, but also the quantitative risk information on the possible outcomes of cataract surgery as well as value clarification exercise. The primary study outcome is the informed decision, the percentage of patients who have adequate knowledge and demonstrate consistency between attitudes and intentions. Secondary outcomes include perceived importance of cataract surgery benefits/harms, decision conflict and confidence, anticipated regret and booklet utilisation and acceptability at 2 weeks, and surgical rates and a cost–utility estimate of the decision aid at 1 year.

Ethics and dissemination Ethics approval was obtained from the Ethics Committee of Zhongshan Ophthalmic Center (reference number: 2019KYPJ090). Results will be published in peer-reviewed journals and presented at scientific meetings for academic audiences.

Trial registration number NCT03992807.

Strengths and limitations of this study

- The feasibility of implementing shared decision making in China has not been formally evaluated. The current study will be the first attempt to conduct a randomised controlled trial to evaluate the effectiveness of a patient decision aid in China.
- The community-based trial will provide evidence on the generalisability of the findings within the context of the community environment.
- Vision function, health-related quality of life and economic evaluation will be assessed 1 year after the intervention.
- The data will be collected by an independent non-profit company.
- The use of printed patient decision aid booklet precludes the possibility of directly conveying information to persons with reading difficulties.

INTRODUCTION

Cataracts remain the primary cause of blindness, with a prevalence estimate from 20% among those aged 50 years to 97% in individuals aged 70 years and above.[1 2] The current standard of care in cataract surgery is phacoemulsification with intraocular lens implantation. This procedure is the most commonly performed surgical intervention worldwide. It has led to a significant improvement in patient-reported outcomes, including satisfaction with vision and quality of life.[3] The broader adoption of cataract surgical services has resulted in a 30% reduction in the global prevalence of cataract-related blindness and associated visual impairment.[4]

Although modern cataract surgery is highly cost-effective, there is also a concern on its improper use or overutilisation, as there are no patient-related measures that are currently suitable for use as the surgical indication in clinical practice.[5] Many countries have witnessed a lowering of the traditional visual threshold for cataract surgery (6/12

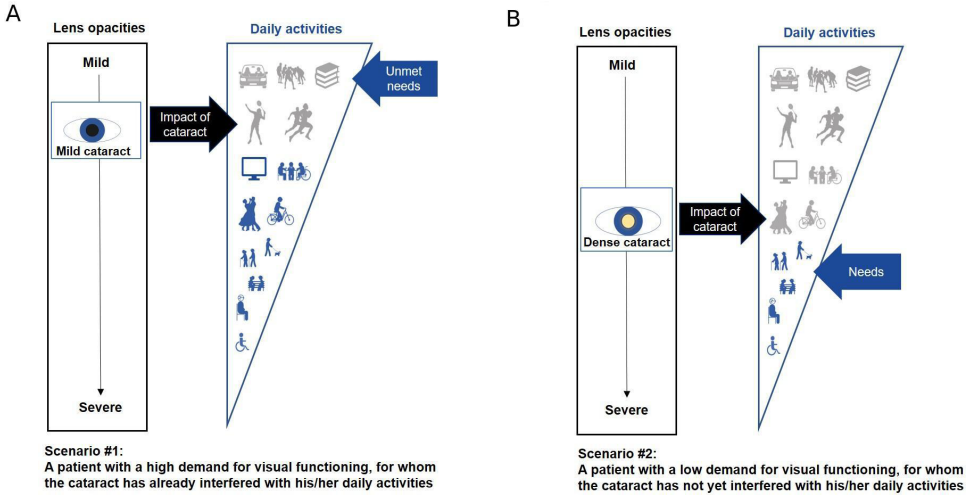

Figure 1 The rationale of promoting shared decision making for cataract surgery.

or worse),[6–9] which have led to an increased demand for surgery among those at the early stages of the disease.[10] For example, the percentage of patients with preoperative visual acuity (VA) better than 20/40 and 20/20 in the eye to be operated on was 62.5% and 2.6%, respectively, in the Netherlands; 44.5% and 1.7%, respectively, in Sweden.[11] The problem associated with shifting the surgical indication to those with reasonably good or almost no preoperative deterioration in VA, suggests the risk of overtreatment. This is supported by the finding from the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) database that worse postoperative VA after cataract surgery was seen in >10% of patients with excellent preoperative VA.[12] Unnecessary cataract surgery is also associated with a risk of surgical complications and surgery-related anxiety. Furthermore, because of the financial constraints in reimbursement systems,[13] it is important to prioritise those with vision-threatening cataract, while providing decision support for people with mild cataract or even no inconvenience.[14]

The choice of when to undergo cataract surgery is, therefore, a complex one, and it is increasingly recognised that such preference-sensitive care should involve trade-offs of benefits and risks based on the patient's values (figure 1). According to the Preferred Practice Patterns developed by the American Academy of Ophthalmology, the primary indication for cataract surgery is the visual functioning that no longer meets the patient's needs.[15] This statement reflects the need for patient-centred participation model. Indeed, patient involvement in shared decision making has been shown to improve therapeutic alliance and medical satisfaction.[16] We have also demonstrated that 88% of patients waiting for cataract surgery expressed a desire to participate in a shared decision-making process.[1] One approach to facilitate shared decision-making is through the use of decision aids.[16] Unlike a traditional brochure, a decision aid is a tool that provides evidence-based information about the benefits and harms of treatment options with easily understood images and simple statistics. The balanced information in decision aids is designed to help people make informed choices based on their own needs.[17]

We have therefore developed a decision aid for cataract patients facing the decision about cataract surgery. The present community-based trial will investigate the influence of written information about cataract surgical outcomes among people with age-related cataract. The primary purpose is to assess the impact of a decision aid on the patient's informed decision in the short-term. We will follow the participants for 1 year to assess their uptake of cataract surgery and patient-reported visual functioning. The ultimate goal is to develop and validate a tool of patient decision making on timely cataract surgery, as a strategy for a better assessment of patients' needs and eye care research allocation. This strategy has an important implication in China's population, which has increased longevity and lower fertility rate than before. The rapid ageing poses a challenge to the healthcare system in part due to surging medical expenditure.

METHODS AND ANALYSIS

Our trial protocol follows the Recommendations for Interventional Trials guidelines. The trial was registered on Clinicaltrials.gov. It is estimated that the study dates would be from 1 July 2019 to 1 July 2021.

Objectives

The primary goal is to evaluate whether a patient decision aid would help patients with age-related cataract to make an informed operational decision.

Specific aim 1 (primary outcome): to assess if a patient decision aid is superior to standard information on the informed decision about cataract surgery. An informed decision is measured by knowledge, attitudes and intentions, among patients with age-related cataract.

Specific aim 2: to evaluate if a patient decision aid would improve participants' performance on psychosocial measures (eg, decision conflict, decision confidence, level of anxiety and worry) 2 weeks after the intervention.

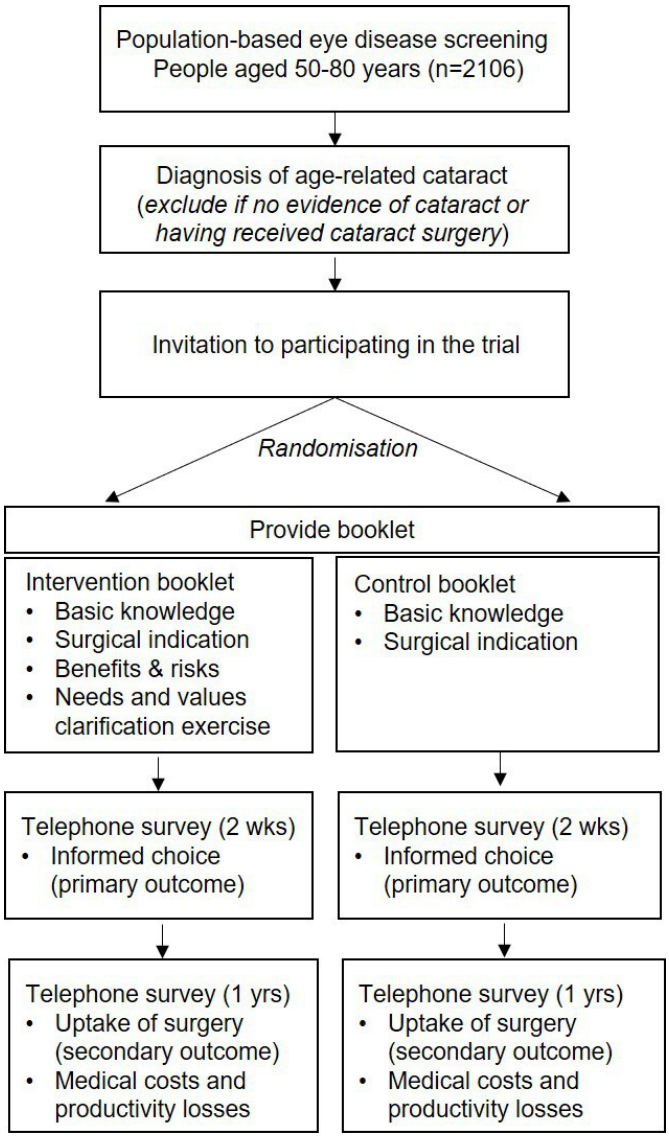

Figure 2 Flowchart of the trial.

Specific aim 3: to evaluate the acceptability of a patient decision aid among patients with age-related cataract at 2 weeks.

Specific aim 4: to determine the impact of a patient decision aid on surgical uptake, the incidence of fall and visual functioning at 12 months.

Specific aim 5: to evaluate the cost–utility of a patient decision aid for patients with age-related cataract compared with those receiving standard information at 12 months.

Trial design

We will conduct a community-based, longitudinal, parallel-group, randomised controlled trial. Patient enrolment started in 2019 and is estimated to end in 2021. Figure 2 summarises the design of the trial.

Setting

We will apply a random cluster sampling method, previously described in our population-based eye study.[18] In brief, the study subjects will be enrolled from a population-based eye disease study in Yuexiu District, Guangzhou, Southern China. Yuexiu District is 1 of 12 administrative regions in Guangzhou, and has a population of 1.17 million (National Census 2017). The decision to select this district is based on a stable, older population and socioeconomic profile representative of Guangzhou. Population data will be obtained from the Statistics Bureau of Guangzhou. In Yuexiu District, Huanghua Gang Street is a community with a population of 89 400, among which approximately 20% (n=17 880) are aged 50–80 years. Fifteen clusters within this street block are identified. These are defined geographically by Residence Administrative Committees subdivisions, and they each have an approximately equal number of residents aged 50–80 years (n=1190). With the assumption that the prevalence of bilateral cataract is 59% among the metropolitan elderly Chinese population,[19] we expect that the number of persons with bilateral cataract would be 702 in each cluster.

Pilot study

A pilot study including 30 subjects aged from 50 to 80 years was conducted in June 2019. After the pilot study, study interviewers and investigators shared their recruitment approaches and identified challenge in communicating the needed information during the study enrolment. We have found it necessary to use more than one recruiting approach (eg, distributing pamphlets, displaying posters or placing phone calls or sending messages) to enrol potential participants. The pilot study also highlighted the importance of identifying a 'person of trust' (eg, Resident Committee Manager who can build a connection between our study team and potential participants) to introduce the clinical trial to potential participants. Finally, issues identified by the pilot study was discussed at study investigator meetings. It was decided to use structured checklists by the interviewers to assure correct participant identification and to ensure completeness of questionnaire. The telephone interview scripts have been further revised to improve overall clarity.

Participants and recruitment

Population-based eye study

We will identify households with eligible subjects from the selected clusters, using the information of addresses; the name of household head and subjects; date of birth from the Household Resident Register Record. This information will be further confirmed by community health service centres. A database including name and telephone numbers will be encrypted and sent to the Guangzhou Hengfu Social Work Service Organization (HSWSO), a non-profit organisation with a track record of performing population surveys and questionnaire interviews. The trained HSWSO interviewers will telephone potential residents to verify their residential addresses, and subsequently arrange appointments for the eye disease study at the primary eye care clinic. Written informed consent

will be obtained, and study coordinators will explain the purpose of the eye disease study as well as the benefits and risks of the examination.

Immediately after the eye examination at the primary eye care clinic, the trial investigators will briefly introduce the study and determine the eligibility based on a series of simple questions. Potential participants who meet all the inclusion criteria and none of the exclusion criteria will receive information about the trial (that they would read one of the two booklets to make sure the written information about cataract and cataract surgery is clear and help to people with cataract). For subjects enrolled in this trial, written informed consent (online supplementary file 1) will be obtained. For each household, if one resident has already been successfully recruited in the trial, any other persons from the same household will not be invited to participate.

ELIGIBILITY CRITERIA

Inclusion criteria

1. Individuals aged 50–80 years who have been resident in the selected study district for more than 6 months.
2. A definite diagnosis of age-related cataract.
3. Having not received cataract surgery.
4. Willing to participate in the study and provide informed content.

Exclusion criteria

1. Bilateral blindness (presenting distance VA worse than 3/60).
2. Having ocular, hearing or mental disorder precluding reading or telephone interview.
3. Ocular disorders other than cataract leading to permanent vision loss that could not be corrected through cataract surgery.
4. Having cataract surgery contraindication.

INTERVENTION AND CONTROL ARMS

1. Intervention: participants will receive a printed decision aid booklet with information about cataract surgery choice.
2. Control: participants will receive a usual booklet about cataract and cataract surgery.

After enrolment, eligible participants who provide written informed consent for this trial will complete an interviewer-administered questionnaire. This face to face survey is to obtain baseline information (T1) including demographic characteristics, education, literacy, patient-reported visual function, conceptual knowledge about cataract surgery and decision-making factors (stage of decision making, intentions and attitudes towards cataract surgery). After the baseline assessment, the participants will be consecutively randomly assigned to one of the two trial arms in a ratio of 1:1 with permuted block sizes of four and eight. They will either receive the intervention using a decision aid booklet or the one using traditional cataract booklet, and they will be asked to carefully read the brochure at home before the 2-week telephone interview. The interviewers' performance will be regularly monitored throughout the survey to ensure the interviewer read off a list of questions from a structured script.

At 2 weeks, the HSWSO interviewers masked to the study allocation will initiate a structured telephone interview to obtain information on outcome measures (T2). The participants will be asked if they have already read the study materials. If not, an arrangement will be made to call back at another time within 1 week. If they have already read the booklet, a 45-min telephone survey will be conducted using standard wording. The interviewers' performance will be regularly monitored throughout the study to ensure the interviewer read off a list of questions from a structured script.

Long-term follow-up

A follow-up assessment will be collected at 12 months after the intervention. The HSWSO interviewers will call patients to remind them about the study assessment and confirm their operational status, fall event, self-assessed visual function, health status and ophthalmology related and other healthcare use in the past 12 months and work during the last 4 weeks.

Decision aid booklet

The patient decision aid booklet was developed for this study and is designed to inform but not to influence cataract patients either towards or away from choosing surgery. The content and presentation were developed based on the understanding of cataract-related information, areas of concern or confusion and views on communication among aged patients. Independent epidemiological, clinical and communication experts reviewed the decision aid booklet, and thoroughly piloted for its acceptability and comprehension.

Table 1 summarises the topics covered in the two booklets. The usual booklet includes standard general information developed by the National Eye Institute (NEI) for patients with age-related cataract, and it has been implemented in clinical practice. The content of the usual booklet consists of the following:

1. Description and visual impact of age-related cataract.
2. A statement that age-related cataract is treatable only with surgery, and there is a high rate of success.
3. Description of the cataract surgical procedure.
4. A statement that the cataract surgery is indicated only when visual function no longer meets the patient's needs.

PRE-ENROLMENT EYE EXAMINATION

We followed a population-based study protocol used in our previous study[20] for the current eye examination and questionnaire data collection in our population-based eye study programme.

Table 1 Summary of topics covered in the decision aid and control booklets

Decision aid booklet	Control booklet
Front cover: title+image	Front cover: title+image
Introduction to purpose of decision aid	Introduction to purpose
Basic knowledge	Basic knowledge
Benefits associated with surgery	
Risks associated with surgery	
Benefits associated with delaying surgery	
Risks associated with delaying surgery	
Suggested indication for cataract surgery	Suggested indication for cataract surgery
Needs and values clarification exercise	
Additional information	Additional information
References	References
Glossary	Glossary
Back cover: further information sources	Back cover: further information sources

Visual acuity

Distance presenting visual acuity (PVA) and best-corrected visual acuity will be measured using an Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Precision Vision, 213 Villa Park, Illinois, USA) with standard illumination.

Intraocular pressure measurement

Intraocular pressure (IOP) will be measured by automated non-contact tonometer (TX-F; Canon, Tokyo, Japan) accordingly, and individuals whose IOP ≥21 mm Hg will be advised to have a further examination to exclude glaucoma or other ocular diseases.

Lens Opacities Classification System III

Slit-lamp images will be collected using a slit-lamp microscope (model BQ-900; Haag-Streit, Köniz, Switzerland) under pupil dilation with 0.5% tropicamide and 0.5% phenylephrine hydrochloride eye drops, and the severity of cataract will be graded using Lens Opacities Classification System III (LOCS III) system. A well-trained ophthalmologist will make the grading of cataract by using standard photographic slides for nuclear opalescence (NO), nuclear colour (NC), cortical (C) and posterior subcapsular (P) cataract. Individuals who meet the following criteria will be diagnosed as age-related cataract: NC/NO ≥2, C≥C2 or P≥1. Different studies have employed different arbitrary LOCS III cut-off points,[21] and the ones used in this study may enable us to include patients with a very mild stage of cataract. We have chosen the P score of 1 as the cut-off, given that previous studies found that posterior subcapsular cataract has a more significant visual impact than the other cataract types.[22]

Fundus examination

Fundus photo will be taken by fundus photography (Zeiss FF450, Zeiss, Oberkochen, Germany). Each photo will be reviewed to exclude any sight-threatening retinal diseases.

RANDOMISATION AND MASKING

Computer-generated randomisation sequences will be made by a statistician who has no contact with participants before beginning enrolment. Participants will be allocated to either the intervention or control arm in a 1:1 ratio with permuted block sizes of four and eight. Both the patient decision aid booklets and standard education booklets are printed in the same size and have the same cover with the same title 'Cataract: what is the best time to have surgery?'. An independent coworker not involving in this study put each booklet into a sequentially numbered and opaque folder and seal it, using an allocation sequence provided by the statistician. Due to the nature of the intervention, blinding of participants is not possible, but they will be instructed to take home a sealed folder containing a booklet and they will not be given any specific information on the type of booklet they receive. Investigators responsible for recruiting participants and interviewers who supervise the preintervention questionnaire (T1) will not be aware of the allocation, in order to ensure allocation concealment. HSWSO interviewers who oversee the telephone interviews (T2, T3), will also not be aware of the assignment to interventions, and they will ask questions using standardised wording with precoded responses within a supervised environment.

PREINTERVENTION QUESTIONNAIRE SURVEY (T1)

An interviewer-administered questionnaire will be used to obtain information on health literacy and demographic and socioeconomic data. The shortened version of the Chinese Health Literacy Questionnaire (19 items)[23] will be used to assess the level of health literacy. Other sociodemographic information includes age, gender, education, occupation, stage of decision making about surgery,[24 25] basic conceptual knowledge, attitudes[26 27] and intentions.[28 29]

DATA COLLECTION

Eye examination data will be collected by local research staff, including grading of cataract and PVA. Trained HSWSO interviewers will conduct a telephone survey to collect postintervention outcome data 2 weeks after randomisation, and will carry out further brief telephone surveys for long-term follow-up at 1-year postintervention.

The HSWSO interviewers do not belong to the research team. The interviews will be conducted within a supervised environment in which interviewer performance is

monitored to ensure scripts are read as written. All survey questions use standardised wording, and the questions are designed such that the study group allocation is unknown to the interviewer.

OUTCOME MEASURES

Primary outcome

The primary outcome is an informed choice about cataract surgery (adequate knowledge and consistency between attitudes and cataract surgery intentions).[30–32] An informed decision will be assessed as a dichotomous outcome combining measures of knowledge, attitudes and intentions 2 weeks after intervention. A participant is judged to have made an informed choice if he/she has adequate knowledge and his/her attitudes and intentions are consistent.[30–32]

We use a competency-based approach to evaluate knowledge of cataract surgery.[33 34] The knowledge questionnaire involves 12 items to measure both the conceptual and numerical information, following the methods used in previous decision aid trials.[32] A person will be determined to have adequate knowledge score based on a marking scheme developed a priori. Attitudes towards cataract surgery will be assessed with a theory-based generic screening attitude scale. Intentions about having cataract surgery will be measured by a single item, using a set of five response options. An intention will be classified as either a positive ('definitely will' or 'likely to') or a negative one ('unsure', 'not likely to' or 'definitely will not').

Secondary outcomes

Perceived importance of surgical benefit/harms (T2)

Purpose-developed items will be used to ask participants about their perceptions of the importance of specific outcomes[32] in their decision-making about cataract surgery. The following questions will be asked: 'In deciding whether to have timely surgery, how important is it for you to consider the chance of vision improvement after surgery so as to meet the need of your daily activities?' and 'In deciding whether to have timely surgery, how important is it for you to consider the chance of no improvement after surgery, or even deterioration in vision due to complications of surgery?'. The answers are four response categories ranging from 'very important' to 'not at all important'.

Perceived personal chances of surgical benefit/harms (T2)

Participants will be asked about their perceived personal likelihood of experiencing specific outcomes[32] if they have cataract surgeries, compared with an average patient who had undergone cataract surgery. The following questions will be asked: 'What is your perceived chance of vision improvement after surgery relative to the average person?' and 'What is your perceived chance of no vision improvement after surgery, or even deterioration in vision due to surgical complications, relative to the average person?'. The answers are five response categories ranging from 'much lower' to 'much higher'.

Decisional conflict (T2)

Decisional conflict will be assessed using a 16-item Decisional Conflict Scale.[35] Scores range from 0 (no decisional conflict) to 100 (extremely high decisional conflict).

Decisional confidence (T2)

Decisional confidence will be assessed using an 11-item Decision Self Efficacy Scale.[36] Score ranges from 0 (not at all confident) to 4 (very confident) for each item.

Time perspective (T2)

This outcome will be assessed using a 4-item short form of the Consideration of Future Consequences Scale, with five response categories ranging from strongly agree to strongly disagree.[37 38]

Anticipated regret (T2)

Two items from a validated scale will measure anticipated regret about having cataract surgery (action regret) and about not having cataract (inaction regret).[39 40]

Cataract worry and anxiety (T2)

A single item will measure participants' level of worry about having a cataract, using four verbal response categories ranging from not worried at all to very worried.[32] Anxiety will be measured with a 6-item short form.[41] The total score ranges from 20 to 80.

Booklet utilisation and acceptability (T2)

Acceptability and utilisation of materials will be assessed by questionnaire items measuring how participants used and evaluated the decision aid booklets.[32 42]

Undergoing cataract surgery (T3)

Self-reported undergoing cataract surgery will be assessed via a telephone survey at 1 year.

Decision regret (T3)

The Decision Regret Scale[32] will measure participants' level of regret regarding their initial decision whether to have cataract surgery or not.

Visual functioning (T1, T3)

The visual function will be assessed using the Catquest 9SF questionnaire.[43]

Fall questionnaire (T3)

At 12 months, the following question will be asked by the HSWSO interviewers to collect information related to falls: 'Did you have any fall in the past 12 months whereby you landed on the ground or floor?'. The participant will be classified as a 'faller' if a fall would happen in the past 12 months. Otherwise, he or she will be classified as a 'non-faller'.[44]

Heath-related quality of life (T1, T3)

We obtained the authorisation of the simplified Chinese version of the EQ-5D-5L telephone interview script from the EuroQol research foundation.[45] The questionnaire is a standardised measure of health status including five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each of the five dimensions is divided into five levels of perceived problems.[46]

Costs (T1, T3)

The English version of Treatment Inventory of Costs in Patients with psychiatric disorders (TIC-P) questionnaire (2018) authorised by the Institute for Medical Technology Assessment was translated into Chinese by a certified translation agency. The questionnaire is about participants' use of care in the past 12 months and about work during the last 4 weeks. Direct and indirect medical and non-medical costs are collected with the TIC-P questionnaire.[47 48]

ADHERENCE IMPROVEMENT PROVIDED TO BOTH ARMS

To improve the adherence of the participants enrolled in this particular trial, a face-to-face adherence reminder session will take place after the eye examination. This session will include the followings:

1. Highlighting the importance of following study guidelines for adherence to this study.
2. Detailed explanations about the trials, mentioning that there would be an about 45-minute telephone interview.
3. Emphasising the importance of calling the study staff if they have any questions about the information in the decision aid booklet.
4. Noting that participants will have an opportunity to ask questions and critical messages.

TIME SCHEDULE

Schedule of enrolment, interventions, assessments and visits for participants are shown in the schematic diagram in table 2.

SAMPLE SIZE

The primary analysis will be comparing two groups on the proportion of patients who make an informed choice. We aimed to recruit 386 participants in each group (772 in total) based on the following assumptions.

Provided that 10% of participants assigned to control group would make an informed choice 2 weeks after the intervention, and in order to detect a group difference of 10% in the primary outcome, we need 219 participants per study group to achieve 80% power (α of 5% two-sided test). Allowing for 10% loss to follow-up at 2 weeks, we need to recruit 244 participants in each group (488 in total).

Further, assuming that 30% of participants assigned to control group would receive cataract surgery 1 year after the intervention, and in order to detect a group difference of 10%, we need a total of 313 participants per group. Assuming an additional 10% loss to follow-up (in addition to the 10% loss to follow-up at 2 weeks) at 1 year after the intervention, we needed to recruit 386 participants in each group (772 in total). This sample size is larger than the one calculated based on the primary endpoint.

ADVERSE EVENTS

Adverse events (AEs) are identified during the face-to-face interview, and telephone interviews at the time of study follow-up visits. Severe AEs and specific procedure-associated AEs are reported to the clinical research centre of Zhongshan Ophthalmic Center (ZOC) within 24 hours. Only study-related AEs will be reported to the Ethics Committee. If AEs occur, the safety of the participants would be the first concern, and any treatment emergent symptom will be referred to a physician or a psychologist.

DATA MANAGEMENT

All telephone interviews will be administered through a computer-assisted telephone interview (CATI) programme. The CATI and quality control processes ensure that interviewers do not skip any statements while providing information to respondents.

The study investigators will ensure that the confidentiality of the patients' data is preserved. Individual participant data will not be disclosed outside and will not appear on any publications, and the data will be de-identified before it passed to the study statistician. Printed records with identifiable data will be stored in locked cabinets, whereas electronic records will be password protected on a secure server for 10 years and then securely destroyed.

Data entry and management will be conducted using an Electronic Data Capture System by data administrators. If there are any detections of omissions, errors or items requiring clarification or changes to Case report form (CRF), the item will be written down on the data query form and forwarded to the clinical monitor for processing. Data correction and validation will be made according to International Conference on Harmonization guidelines.

Compliance of regulatory documents and study data accuracy and completeness will be maintained through an internal study team quality assurance process. Data will be de-identified before is it passed to the statistician. Records containing identifiable data will be stored in locked cabinets at the ZOC with restricted access. Digital data will be password protected and stored on a secure server at the ZOC for 10 years and then securely destroyed. Only the investigators will have access to the data.

Table 2 Study schedule

Timing			−1 week	Baseline	2 weeks	1 year
Recruitment			×			
Baseline information	Basic characteristics			×		
	Health literary and education			×		
	Stage of decision making			×		
	Quality of visual functioning			×		×
	Quality of life			×		×
	Medical costs and productivity losses			×		×
Major outcomes	Knowledge	Knowledge about cataract		×	×	×
		Knowledge about timing for cataract surgery			×	×
		Knowledge related to undergoing surgery (conceptual)		×	×	×
		Knowledge related to undergoing surgery (numerical)			×	×
		Knowledge related to delaying surgery (conceptual)		×	×	×
		Knowledge related to delaying surgery (numerical)			×	×
	Intentions for surgery			×	×	×
	Attitudes for surgery			×	×	×
Secondary outcomes	Perceived importance of benefits/risks				×	
	Perceived changes of benefits/risks				×	
	Decision conflict				×	
	Decision self-efficacy				×	
	Time perspective				×	
	Anticipated regret				×	×
	Worry				×	×
	Anxiety				×	×
	Booklet utilisation/acceptability				×	
Long-term secondary outcomes	Decision regret					×
	Uptake of cataract surgery					×
	Fall question					×

ANALYSIS PLAN

Analysis will be carried out blinded to intervention status. The primary analysis is to compare the proportions of informed decision between two study groups. We will perform intention to treat analysis, in which all randomised participants will be included in the primary analysis, which will be undertaken when the last participant has completed the 2-week follow-up. The results of the primary analysis will be published in appropriate journals.

Dichotomous outcomes will be analysed using a χ^2 test, and continuous outcomes using a two-sample t-test or Wilcoxon rank-sum test. We will use generalised linear models with Poisson regression to estimate the relative risk associated with the intervention. All reported p values are two-sided, with a p value <0.05 considered as significant. We will use multiple imputation techniques, which creates 20 copies of the data by chained equations or sensitivity analysis to handle missing values. Analyses will be carried out using Stata V.13.1 software.

The economic evaluation will be carried out by cost–utility analysis to determine the cost in terms of utilities (quality of life). Direct and indirect medical and non-medical expenses will be considered according to a societal perspective and be calculated based on the consumer price index. The utility value is assessed with the EQ-5D-5L value set.[45] The incremental cost–utility ratio (ICUR) is a standard application in cost–utility analysis and defined as the ratio between the difference in total costs and the difference in quality-adjusted life years between the two trial arms. A 95% CI of the ICUR will be calculated using 5000 bootstrap replications. Sensitivity

analysis will be performed to study the effect of uncertain main cost.[49]

TRIAL MONITORING

The independent steering committee will oversee the study design, delivery, quality assurance and data analysis. The data monitoring committee will review reports including recruitment and drop-out rates, adherence to SOPs and adverse events.

PATIENT AND PUBLIC INVOLVEMENT

We have established a Patient Advisory Committee (PAC) to improve the design of the patient decision aid and the design of the current study. The PAC group includes three patients with age-related cataract who had interest in how different types of education booklets might have an impact on patients' decision. We had a meeting with the PAC, who provided feedback on the study design and suggestions on the interviewer-administered questionnaires. In addition, our study results will be disseminated to primary eye care clinics to share information with study participants and patients.

ETHICS AND DISSEMINATION

This protocol (version 1.0; 9 July 2019) and the template informed consent forms (version 1.0; 9 July 2019) were reviewed and approved by the Ethics Committee of Zhongshan Ophthalmic Center (approval number: 2019KYPJ090). Any protocol modifications will be sent for review by the ethics committee. Written informed consent will be provided from all participants during the visit for an eye examination at the study site, as well as from enrolled subjects before trial intervention. Explaining the study and obtaining consent will facilitate comprehension and reduce the unnecessary burden entailed in a written consent form. There will be plain-language written study information to inform the participants of the right to refuse participation or withdraw consent. The results of the trial will be published in peer-reviewed journals and presented at scientific meetings for academic audiences. The trial will be reported following the Consolidated Standards of Reporting Trials statement.

DISCUSSION

The findings from this trial may provide high-quality evidence to determine whether a patient decision aid is useful for patients with age-related cataract. It is important to note that providing the patients the opportunity to make informed choices, based on the balanced information of the benefits and risks of different treatment options, is the goal of facilitating decision making. Thus, the key performance indicators of our intervention should be informed choice, irrespective of whether the eventual long-term decision is to undergo surgery or not.

To the best of our knowledge, there has been no publication regarding the impact of a patient decision aid on medical decisions in China. Patient decision-making tool has not been previously delivered to the general public in the Chinese population, and it is plausible that these people may still be accustomed to the usual booklet with standard information. As such, we are interested in the comparison of the effects of decision aid booklet with the usual booklet. Another essential purpose of our study is to know if the patient decision aid is cost-effective compared with routine care, to permit generalisation of our finding to the clinical practice.

Contributors YZ, BQ, LJ, CW, MH and YL conceived and designed the study. LJ will lead the statistical analysis. YuxinZ oversaw data acquisition and implementation on site. All authors reviewed and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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