

# Evaluating the socioeconomic impact of cataract surgery for elderly patients in China

<b>Submission date</b> 19/12/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/01/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/12/2016	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cataracts are cloudy areas on the lens of the eye. They can appear for a number of reasons however they are most common in older people, developing over a long period of time (senile cataract). The lens sits near the front of the eye, and plays an important role in vision. When cataracts cause the lens to become clouded, it can prevent light from reaching the back of the eye (retina) to form an image that can be interpreted by the brain. When this happens, vision becomes blurred and distorted, and can eventually lead to blindness. In many cases, the only effective treatment is to undergo cataract surgery, which involves removing the affected lens and replacing it with a clear artificial one (intraocular lens). Un-operated cataract remains the leading cause of blindness in China, and China's cataract surgical rate (CSR) of 1000/million/year is lower than that of neighboring countries such as Vietnam (2000) and India (5500). This problem is particularly bad in rural (countryside) areas. The aim of this study is to investigate the socioeconomic (social and financial) impact of receiving free cataract surgery.

### Who can participate?

Adults aged 40 years and over living in Handan County, China with poor vision in one eye due to cataracts that have not been operated on.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive cataract surgery immediately. Those in the second group are placed on a waiting list to receive cataract surgery a year later. At the start of the study and then after one year, participants in both groups complete a number of questionnaires designed to measure their household income, whether they are working and their wellbeing.

### What are the possible benefits and risks of participating?

Participants who receive the surgery immediately will benefit from an improved ability to see clearly. There are no notable risks involved with participating other than the general risks of undergoing eye surgery.

### Where is the study run from?

Shaanxi Normal University (China)

When is the study starting and how long is it expected to run for?  
September 2016 to January 2018

Who is funding the study?  
Stanford University (USA)

Who is the main contact?  
Mr Matthew Boswell

## Contact information

**Type(s)**  
Public

**Contact name**  
Mr Matthew Boswell

**Contact details**  
Stanford University  
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616 Serra Street  
Stanford  
United States of America  
94305

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
39156

## Study information

**Scientific Title**  
Socioeconomic Impact of Cataract Surgery for Elderly Patients in China: Results from a Randomized Trial

**Acronym**  
Handan Cataracts Study

**Study objectives**  
The aim of this study is to measure the impact of cataract surgery on key household socioeconomic outcomes such as income and labor market participation.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Home

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Cataracts

**Interventions**

Participants are randomised to one of two groups based on baseline characteristics.

Intervention group: Participants undergo cataract surgery in February 2017. This involves small incision manual cataract surgery performed by an experienced surgeon with insertion of an appropriate intra-ocular lens, power to be determined in standard fashion by measurement of corneal curvature, axial length and refractive power in the operative and non-operative eyes.

Control group: Participants are placed on a wait-list and receive their cataract surgery in February 2018 after the collection of the final outcome measures.

Participants in both groups are followed up in standard fashion by an ophthalmologist from Tongren Hospital and complete follow up surveys after one year.

**Intervention Type**

**Primary outcome measure**

1. Household income is measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months
2. Household member time allocation is measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months
3. Household member labor market participation is measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months

## Secondary outcome measures

1. Household member educational outcomes are measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months
2. Household member subjective wellbeing is measured using the Handan Cataract Study Household Socioeconomic Survey at baseline and 12 months

## Overall study start date

30/09/2016

## Completion date

30/01/2018

# Eligibility

## Key inclusion criteria

1. LogMAR vision  $\geq 0.5$  in the better-seeing eye due to un-operated cataract identified in the original Handan Eye Study (2012)
2. Resident of Handan County, China
3. Aged 40 years and over

## Participant type(s)

Other

## Age group

Adult

## Sex

Both

## Target number of participants

400

## Key exclusion criteria

1. Unwilling to give consent or unable to be contacted
2. Other ocular or health conditions that contraindicate or prevent the patient from undergoing cataract surgery

## Date of first enrolment

30/01/2017

## Date of final enrolment

02/07/2017

# Locations

## Countries of recruitment

China

**Study participating centre**  
**Shaanxi Normal University**  
Shaanxi  
Xi'an  
China  
710119

## **Sponsor information**

**Organisation**  
Stanford University

**Sponsor details**  
450 Serra Mall  
Stanford  
United States of America  
94305

**Sponsor type**  
University/education

**ROR**  
<https://ror.org/00f54p054>

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
Stanford University

## **Results and Publications**

**Publication and dissemination plan**  
Planned publication in one or more high-impact peer reviewed journals prior to one year following the conclusion of the trial.

**Intention to publish date**  
30/01/2019

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Matthew Boswell (boswell@stanford.edu)

**IPD sharing plan summary**

Available on request