# Randomized controlled trial evaluating an incentive-based community eye-care programme

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
23/08/2017	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/08/2017	Completed	Results
Last Edited	Condition category	Individual participant data
25/08/2017	Eye Diseases	Record updated in last year

## Plain English summary of protocol

Background and study aims

People with visual impairment who undergo community eye screening often do not attend tertiary follow-up even if significant eye diseases are detected. The aim of this study is to assess an incentive-care scheme (ICS) to improve the attendance rates of tertiary eye-care visits following community eye screening.

Who can participate?

Patients aged over 21 with visual impairment

## What does the study involve?

Participants are randomly allocated into two groups. One group receives the usual care after community eye screening - a GP referral letter and advice to attend the tertiary eye care facility most accessible to them. The other group receives the usual care and also the ICS, which involves patient education, social support and financial assistance. ICS participants are assisted with scheduling their tertiary care appointments, given telephone reminders, and provided with a one-off transportation allowance and subsidy for their first tertiary eye-care consultation, and participants with mobility issues are assisted by volunteers. A medical social worker is also involved for continuing financial support for further follow-up under various government schemes. Participants' uptake of tertiary referral is measured using attendance to tertiary hospital after 3 months.

What are the possible benefits and risks of participating? Participants receive tertiary eyecare with financial assistance. There are no risks involved.

Where is the study run from? Singapore National Eye Centre

When is the study starting and how long is it expected to run for? January 2012 to January 2017

Who is funding the study? Singapore National Eye Centre

Who is the main contact? Dr Anna Tan

# Contact information

## Type(s)

Public

#### Contact name

Dr Anna Tan

## Contact details

11 Third Hospital Ave Singapore Singapore 168751

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

## Secondary identifying numbers

R1102/4/2014

# Study information

#### Scientific Title

Randomized controlled trial evaluating an incentive-based community eye-care programme for elderly with visual impairment

## **Study objectives**

To evaluate the efficacy of an incentive-care scheme (ICS) to improve the attendance rates of tertiary eye-care visits following community eye screening using a randomized controlled trial design.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Singhealth IRB, 17/04/2014, ref: R1102/4/2014

## Study design

Randomised controlled study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Community

## Study type(s)

Quality of life

## Participant information sheet

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

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

Visual impairment

#### Interventions

Eligible participants were approached for informed consent and after they agreed to participate, they were randomised into 2 arms with a 1:1 ratio, either in the intervention arm where they received the ICS or the UC arm. Randomisation was performed by a random allocation sequence that was generated by a computer with no blocks or restrictions, and implemented by concealing the number-coded treatment within sealed envelopes until just before the procedure. After a potential participant was enrolled by the investigators and had given informed consent, a research coordinator performed assigned the participants to their groups after opening the sealed envelope. Due to the nature of the intervention, participants and researchers were unable to be masked to group assignment.

The usual stand of care (UC) after community eye screening was to provide a GP referral letter and advice to attend a tertiary eye care facility most accessible to them. In addition to the UC, those assigned to the ICS also received social and financial support to incentivise and improve compliance. All ICS participants were assisted with scheduling their tertiary care appointments, given telephone reminders, provided once-off transportation allowance and subsidy for their first tertiary eye-care consultation - while participants with mobility issues were assisted by volunteers. A medical social worker was also involved for the suitability of continuing financial support for further follow-up under various government schemes.

## Intervention Type

## Primary outcome measure

Uptake of tertiary referral, measured using attendance to tertiary hospital at 3 months

## Secondary outcome measures

- 1. Visual acuity, measured on Snellen chart at 3 months
- 2. Vision-related quality of life (VRQoL), assessed using the 28-item Impact of Vision Impairment (IVI) questionnaire at baseline and at 3 months

## Overall study start date

## Completion date

01/01/2017

# **Eligibility**

## Key inclusion criteria

- 1. Over 21 years of age
- 2. The ability to speak English and/or Mandarin
- 3. Adequate hearing with/without hearing aids to respond to normal conversation
- 4. Not currently undergoing regular assessment/care with an ophthalmologist (at least yearly)
- 5. The ability to undergo visual acuity testing and provide reliable results
- 6. Visual acuity of 6/12 or worse in either eye after best correction

## Participant type(s)

**Patient** 

## Age group

Adult

#### Sex

Both

## Target number of participants

140

## Key exclusion criteria

Absence of the inclusion criteria and any other contraindication(s) as indicated by the general practitioner responsible for the participant

#### Date of first enrolment

01/06/2014

## Date of final enrolment

01/06/2016

# Locations

## Countries of recruitment

Singapore

Study participating centre Singapore National Eye Centre

168751

# Sponsor information

## Organisation

Singapore National Eye Centre

## Sponsor details

11 Third Hospital Ave Singapore Singapore 168751

## Sponsor type

Hospital/treatment centre

## **ROR**

https://ror.org/029nvrb94

# Funder(s)

## Funder type

Hospital/treatment centre

## **Funder Name**

Singapore National Eye Centre

## **Results and Publications**

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

## Intention to publish date

01/01/2018

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Marcus Ang (marcus.ang@snec.com.sg). Data is available for 1 year and is masked with no identifiers. Informed consent was taken from all participants.

## IPD sharing plan summary

Available on request