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

Submission date
23/08/2017

Recruitment status
No longer recruiting

Registration date
25/08/2017

Overall study status
Completed

Last Edited
25/08/2017

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
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

01/01/2012

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