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The economic effects of free near-vision glasses in working-age people with bilateral presbyopia in India

Submission date 28/04/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/05/2025	**Overall study status** Ongoing	
Last Edited 06/10/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

Many people worldwide are living with uncorrected impairment of their near vision, caused by a condition called presbyopia. Presbyopia occurs when eyes gradually lose the ability to see things up close, and this process usually starts during the fourth decade of life. Presbyopia can be corrected with glasses. However, without glasses, people with presbyopia may struggle or be prevented from carrying out some daily tasks at home or in the workplace. Therefore, a lack of access to glasses which correct someone's presbyopia may harm their income. Uncorrected presbyopia may also negatively impact an individual's quality of life. This study will test whether providing free glasses to people with presbyopia improves their household consumption (a measure of economic position) and/or their quality of life related to vision.

Who can participate?

Adults between the ages of 35 and 65 years with presbyopia (<N8) identified through established screening programmes. Participants should not own a pair of near vision glasses, should be residents in the locality where the study is being conducted and should provide informed consent and agreement to participate.

What does the study involve?

The vision screening programme is underway in Shahjahanpur and Lakhimpur Kheri districts, Uttar Pradesh, India. In this trial, half of the participants will receive glasses immediately, while the other half will receive glasses at the end of the trial (in two years). Participants will be allocated to one of the two groups at random. The main outcomes are (1) the amount the household consumes (on average) over one year; and (2) vision-related quality of life. These outcomes will be measured at the beginning of the study, and after 1 and 2 years of follow-up, to assess for changes over time. If glasses are found to improve household consumption and quality of life, this information could encourage funding to improve access to eyeglasses within India and in other LMICs.

What are the possible benefits and risks of participating?

Near vision glasses provide a tangible benefit to the individual using them by correcting their

vision impairment. Participation in this study is not expected to pose undue risks, and this specific intervention has been reviewed by various ethics committees.

Where is the study run from?
Mohammadi, Utter Pradesh, India

When is the study starting and how long is it expected to run for?
October 2024 to March 2029

Who is funding the study?
1. Givewell (US)
2. Founders Pledge (UK)
3. Livelihood Impact Fund (US)

Who is the main contact?
Dr Shalinder Sabherwal, shalinder.sabherwal@sceh.net

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
31138, CTRI/2025/04/084351

Study information

Scientific Title
Randomised controlled trial of the Economic Advantages of Readers for Near vision in India

Acronym
EARN - India

Study objectives
The provision of near vision glasses to people of working age with presbyopia leads to increased household level consumption and/or vision related quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 30/10/2024, London School of Hygiene & Tropical Medicine Interventions Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 31138

2. approved 12/03/2025, Dr. Shroff's Charity Eye Hospital Ethics Committee (5027, Kedarnath Road, Daryaganj, New Deldi, 110002, India; +91 (0)1143524444; manisha@sceh.net), ref: SCEHEH /2025/04

Study design
Prospective single-masked parallel-group two-arm individually randomized controlled trial

Primary study design
Interventional

Study type(s)
Other, Quality of life, Treatment

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

Interventions
Trial participants will be randomised to one of the following arms:
1. Intervention arm: individuals will be given free near-vision glasses (spherical, non-astigmatic correction), appropriate for their degree of presbyopia. As they are given glasses, they will be counselled about the use and care of the glasses.
2. Control arm: Individuals will not be given free near-vision glasses at baseline. They will be given free near-vision glasses (spherical, non-astigmatic correction), appropriate for their degree

of presbyopia, at the end of the trial follow-up period (2 years). However, they will be informed that they have presbyopia at baseline, so some may choose to independently purchase glasses themselves.

Near vision glasses for the trial will be prescribed by data collectors who have received training to be able to do so. Prescribing will be done using a smartphone-based near-vision acuity test embedded within a validated mobile phone application. The near vision test includes an algorithm that allows the data collector to prescribe near-vision (reading) glasses. This includes the following steps: (i) a rapid distance vision test to determine if a participant is eligible for potential presbyopia screening (ii) near-vision test to determine if someone may benefit from near-vision glasses (iii) use data on the participants age and uncorrected near-vision score to determine the start point for the near-vision test and (iv) guiding the data collector in terms of processes that a clinician would follow to determine the correct power for reading glasses.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Near vision glasses

Primary outcome(s)
1. Household consumption measured using an adapted version of the Kenya Life Panel Survey-round 4 (KLPS-4) at baseline, 1 year and 2 years
2. Vision-related quality of life measured using the WHO/VFQ20 Questionnaire at baseline, 1 year and 2 years

Key secondary outcome(s))
1. Employment status and characteristics measured using an adapted version of the Kenya Life Panel Survey-round 4 (KLPS-4) at baseline, 1 year and 2 years
2. Self-reported productivity (presenteeism and absenteeism) measured using an adapted version of the Work Productivity and Activity Impairment Questionnaire (WPAI - SHP) at baseline, 1 year and 2 years
3. Self-reported income sufficiency measured using an adapted version of the 2019 Gambia National Eye Health Survey at baseline, 1 year and 2 years
4. Self-reported individual income measured using an adapted version of the Kenya Life Panel Survey-round 4 (KLPS-4) at baseline, 1 year and 2 years
5. Health-related quality of life measured using the EQ5D with vision bolt-on question at baseline, 1 year and 2 years

Completion date
31/03/2029

Eligibility

Key inclusion criteria
1. Bilateral presbyopia (<N8) and do not currently own/use glasses for near vision
2. Adults aged between 35 and 65 years
3. Normally resident in the locality where the study is being conducted, defined as: lived there

for >6 months and intend to continue living there for the next two years
4. Provide informed consent and agreement to be randomly allocated to one of the two study arms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Presbyopia and owns near vision glasses (met need or partially met need)
2. Pinhole distance VA of worse than 6/12 in the better eye
3. Current illness or incapacity preventing the individual from working
4. Inability to communicate
5. Any occupation with formal guidance requiring safety glasses for near work
6. Another member of the household has already been enrolled on the trial

Date of first enrolment
12/01/2026

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
India

Study participating centre
Dr Shroff's Charity Eye Hospital
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Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Livelihood Impact Fund

Funder Name
GiveWell

Funder Name
Founders Pledge

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the entire period of study will be stored in regional non-publicly available repositories in compliance with all prevailing applicable Data Protection Laws (including but not limited to the Data Protection Act 2018 (India) and the General Data Protection Regulation (EU) 2016/679 (GDPR) and any successor legislation together with all applicable laws, regulations, orders and codes of practice in force relating to data protection. Summary data without personal identifiers will be published in a journal article. Further anonymous data will be available only upon written request from Dr Shalinder Sabherwal (shalinder.sabherwal@sceh.net). The date when data will be available is currently not known.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet version 1.2	11/11/2025	11/11/2025	No	Yes
Protocol file		01/10/2024	20/05/2025	No	No