ISRCTN60371376 https://doi.org/10.1186/ISRCTN60371376

The economic effects of free reading glasses for near vision in Kenya

Submission date 20/05/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/05/2025	**Overall study status** Ongoing	
Last Edited 23/05/2025	**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 clearly up close, and this process usually starts during the 4th decade of life. Presbyopia can be corrected with glasses. However, without glasses, people with presbyopia may struggle or are prevented from carrying out some daily tasks at home or in the workplace. Therefore, it is possible that a lack of access to glasses which correct someone's presbyopia may have a negative impact on their income. Uncorrected presbyopia may also negatively impact an individual's quality of life. We would like to test if 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 resident in the locality where the study is being conducted and should provide informed consent and agreement to participate.

What does the study involve?

We are carrying out a trial involving people with presbyopia (aged between 35 and 65 years), who have been identified through vision screening programme which will be running in Kisii County Kenya. 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 we are interested in 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 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?

Participation in this study is not expected to pose undue risks and this specific intervention has

been reviewed by various ethics committees. Near vision glasses provide tangible benefit to the individual using them by correcting their vision impairment.

Where is the study run from?
Kisii County, Kenya

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?
Ms Sarah Karanja, sashkaranja@gmail.com

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Prof Matthew Burton

ORCID ID
https://orcid.org/0000-0003-1872-9169

Contact details
International Centre for Eye Health
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0) 20 7958 8315
matthew.burton@lshtm.ac.uk

Type(s)
Scientific, Principal Investigator

Contact name
Prof Andrew Bastawrous

ORCID ID
https://orcid.org/0000-0001-8179-556X

Contact details
International Centre for Eye Health
London School of Hygiene and Tropical Medicine
Keppel Street

London
United Kingdom
WC1E 7HT
+44 (0) 20 7958 8315
andrew.bastawrous@lshtm.ac.uk

Type(s)
Scientific, Principal Investigator

Contact name
Prof Stephen Gichuhi

ORCID ID
https://orcid.org/0000-0002-7062-4869

Contact details
University of Nairobi,
Department of Ophthamology,
University Way
Nairobi
Kenya
-
(+254) 020-4910000
sgichuhi@uonbi.ac.ke

Type(s)
Public, Scientific

Contact name
Ms Sarah Karanja

ORCID ID
https://orcid.org/0000-0001-5275-5534

Contact details
Kenya Medical Research Institute,
Mbagathi Rd
Nairobi
Kenya
-
+254202722541
skaranja@kemri.org

Type(s)
Public, Scientific

Contact name
Dr Malebogo Tlhajoane

ORCID ID
https://orcid.org/0000-0002-0601-5516

Contact details
International Centre for Eye Health
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0) 20 7958 8315
malebogo.tlhajoane@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
31099

Study information

Scientific Title
Randomised controlled trial of the economic advantages of free near-vision glasses in working-age people with bilateral presbyopia in Kenya

Acronym
EARN - Kenya

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: 31099

2. Approved 26/03/2025, Kenya Medical research Institute (KEMRI) Scientific and Ethics Review Unit (Mbagathi Rd, Nairobi, -, Kenya; +254 20 2722541; ddrt@kemri.go.ke), ref: 5116

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home

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

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

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 using a smartphone-based near-vision acuity test embedded within a validated mobile phone application. The near vision test includes an algorithm that allows an individual 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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/10/2024

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 >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

Age group
Adult

Lower age limit
35 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
10,000

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 into the trial.

Date of first enrolment
01/10/2025

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
Kenya

Study participating centre
Kenya Medical Research Institute
Mbaghathi Road
Nairobi
Kenya
-

Study participating centre
Kisii Eye Hospital
Nyanchwa
Kisii
Kenya
-

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

Sponsor details

Keppel Street
London
England
United Kingdom
WC1E 7HT
+44 (0)20 7636 8636
rgio@lshtm.ac.uk

Sponsor type
University/education

Website
http://www.lshtm.ac.uk/

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

Publication and dissemination plan
The researchers will present all findings to local eye care programme managers and local government teams as they emerge. They will publish their findings in the scientific literature in open-access journals and present findings at international conferences and meetings.

Intention to publish date
01/12/2028

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be stored in a non-publicly available repository to protect anonymity. Summary data will be published in a journal article. Further anonymous data will be available upon request from Ms Sarah Karanja (sashkaranja@gmail.com). 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?
Protocol file	version 1.3	01/01/2025	23/05/2025	No	No