EARN TRIAL

Randomised controlled trial of the Economic Advantages of Readers for Near vision in Kenya

Clinical Trial Protocol

V1.3 – January 2025

SPONSOR: London School of Hygiene & Tropical Medicine is the main research sponsor for this study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:

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This trial will adhere to the principles outlined in the International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines, protocol and all applicable local regulations.

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Glossary of Abbreviations

EARN	Randomised controlled trials of the **E**conomic **A**dvantages of **R**eaders for **N**ear vision
RCT	Randomised controlled trial
VLEG	Vision Loss Expert Group
GBD	Global Burden of Disease
LMICs	Low- and middle- income countries
VRQoL	Vision related quality of life
VF20	20-item Visual Functioning Questionnaire
EQ5D	EuroQol 5 Dimension
VA	Visual acuity
SDG	Sustainable Development Goals
ICEH	International Centre for Eye Health
ODK	Open Data Kit
LSHTM	London School of Hygiene and Tropical Medicine
CI	Chief investigator
PI	Principal investigator
SRO	Senior Research Officer
KEMRI	Kenya Medical Research Institute
DSMB	Data Safety Monitoring Board
SAE	Serious Adverse Event
CHW	Community Health Worker
ILO	International Labour Organisation
CSSRI-EU	Client Sociodemographic and Service Receipt Inventory
WPAI-SHP	Work Productivity and Activity Impairment
ICLS	International Conference of Labour Statisticians

Keywords

Presbyopia
Refractive error
Eyeglasses
Household consumption
Quality of life
Income
Productivity
Health economics

Summary

TITLE	**EARN:** randomised controlled trials of the **E**conomic **A**dvantages of **R**eaders for **N**ear vision
DESIGN	Prospective, single-masked, parallel group, two-arm individually randomised controlled trial (RCT)
OBJECTIVES	**Primary objectives:** To determine if the provision of near vision glasses to people of working age with presbyopia leads to increased household consumption and/or vision related quality of life. **Secondary objectives:** To determine if the provision of near vision glasses to people of working age with presbyopia leads to: (i) increased individual income; (ii) increased household consumption, individual income, and/or workplace productivity in those who work in near vision intense/dependent occupations (occupational sub-group analysis).
OUTCOME MEASURES	**Co-primary outcomes:** • Household consumption at 12 months and vision related quality of life at 12 months **Secondary outcomes:** • Employment status and characteristics • Self-reported productivity (presenteeism and absenteeism) • Self-reported income sufficiency • Self-reported individual income • Health Related Quality of Life: EQ5D with vision bolt-on question.
STUDY AREA	The study will be conducted in Kisii County, Kenya (with additional recruitment from the neighbouring Bomet County if required).
PARTICIPANTS	Individuals with presbyopia (<N8) identified through established screening programmes, who meet the trial inclusion criteria (below).
ELIGIBILITY	**Inclusion criteria (must meet all):** 1. Bilateral presbyopia 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. **Exclusion criteria (any of the following):** 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.
INTERVENTION	Trial participants will be randomised to one of the following arms: • 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. • 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 it is possible that some may choose to independently purchase glasses themselves.

DURATION	The anticipated overall project duration is 5 years. • Initial study set up: 3 months • Pilot phase: 6-9 months • Baseline assessment: 1 year • Follow-up (year 1): 1 year • Follow-up (year 2): 1 year • Analysis, write up, dissemination: 1 year

Abstract

Background

In 2020, it was estimated that there were over 500 million people worldwide living with unaddressed near vision impairment due to presbyopia. Presbyopia usually starts during the 4th decade of life, and without glasses to correct presbyopia, people may struggle or are prevented from carrying out many daily tasks at home or in the workplace. It is hypothesised that a lack of access to near vision glasses has a negative impact on individual and household incomes. This could be through reducing workplace productivity, causing people to prematurely leave near-vision dependent occupations, or by preventing the uptake of near vision dependent occupations. Uncorrected presbyopia may also have a negative impact on quality of life. In view of: (1) the enormous unmet need for glasses for presbyopia worldwide, especially in low- and middle-income countries, and (2) the likely impact this has on an individual's quality of life and their potential to earn a higher income, there is a strong case for concerted action to address presbyopia. However, to further strengthen the case for action, this study aims to determine if the provision of near vision glasses to people of working age with presbyopia leads to increased household consumption and/or vision related quality of life.

Methods

This is a prospective, single-masked, parallel group, two-arm individually randomised controlled trial (RCT), which will be embedded within the community-based screening programme which is currently underway in Kisii County, Kenya (with additional recruitment from the neighbouring Bomet County, if required). We aim to recruit adults between the ages 35 and 65 years, who have been identified as having presbyopia during screening, and do not own near vision glasses. Trial participants will be randomised to either the intervention arm - whereby individuals will be given free near vision glasses at the start of the study, or the control arm – whereby individuals will be given free near vision glasses at the end of the trial follow-up period (2 years). The co-primary outcomes are household consumption at 12 months and vision related quality of life at 12 months. Our secondary analysis will examine if the provision of near vision glasses to people of working age with presbyopia leads to: (i) increased individual income; (ii) increased household consumption, individual income, and/or workplace productivity in those who work in near vision intense/dependent occupations (occupational sub-group analysis). The findings will be written up for peer-reviewed publication and actively shared with key stakeholders. If the intervention proves effective it will inform policy and may catalyse funding to improve access to this relatively cheap and potentially cost-effective intervention.

Lay Summary

Background

Many people worldwide are living with blurry near vision, making it harder to do close up tasks like reading or certain jobs. It is 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 from the age of 35 onwards. Presbyopia can be improved with simple glasses. However, without them, people with presbyopia may struggle or are prevented from carrying out some daily tasks at home or at work. 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 spending (a way to measure their financial situation) and/or their quality of life connected to vision.

Methods

We are carrying out a trial involving people with presbyopia (aged between 35 and 65 years), who have been identified through a vision screening programme which is currently underway in Kisii County, Kenya (with additional recruitment from the neighbouring Bomet County, ifneeded). 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) quality of life connected to vision. 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 Kenya and in other LMICs. .

Background / Problem Statement

For the year 2020 (the most recent VLEG/GBD analysis) it was estimated that there were 510 million people worldwide living with unaddressed near vision impairment due to presbyopia (hereafter "presbyopia") who needed glasses to enable them to perform near vision dependent activities.[1]

In a sample of participants aged ≥50 from Kenya in The Nakuru Eye Disease Study, the overall prevalence of functional presbyopia was 85.4%.[2] This study found that increasing severity of presbyopia was associated with near vision functional impairment, such as increased difficulty with reading, sewing, harvesting grains, and recognising small objects. The Rapid Assessment of Avoidable Blindness surveys (RAAB) include a crude assessment of reading glasses uptake in the over 50s.[3] RAAB surveys have recently been conducted in 8 counties in Kenya. Findings from the RAAB survey indicated that in most counties in Kenya, there is a notable gender disparity in the uptake of reading glasses. [3] On average, 9.6% of women reported owning near vision glasses, compared to 11.8% of men. The disparity was most pronounced in Bomet county where 7.2% of females reported ownership of near-vision glasses, compared to 14.5% of males. In addition, the proportion of those who owned reading glasses ranged between 1% to 19% across the counties.

Presbyopia typically begins to develop during the 4th decade of life. Without near vision glasses, people can struggle or are prevented from carrying out many different tasks at home or in the workplace. The lack of access to near vision glasses is hypothesised to have a negative impact on individual and household incomes - through reducing workplace productivity, causing people to prematurely leave near-vision dependent occupations at a relatively young age, or by preventing the uptake of near vision dependent occupations, which may have higher earning potential.

Through our work to map interventions to address vision impairment to specific targets within the United Nation's Sustainable Development Goals (SDG) framework, it is clear that action to address conditions causing vision impairment, such as presbyopia, can have a substantial positive effect on multiple SDGs through improved earning potential, such as SDG1 (No Poverty), SDG2 (Zero Hunger) and SDG8 (decent work and economic growth).[4]

Near vision glasses provide tangible benefit to the individual using them and they are relatively low-cost – typically just a few US$ per pair. However, there are very few studies exploring the cost-utility of near vision correction and the cost-effectiveness of alternative implementation strategies.[5,6] The very limited data that are available (a single conference abstract) suggest that the cost-utility ratios are very favourable for the provision of near vision glasses.[6]

Our work on the economic impact of vision impairment (all causes) found that, for the year 2020, unaddressed distance vision impairment in the working age population (15-64 years) resulted in an estimated annual global productivity loss of US$ 411 billion.[1,7] An earlier analysis of the global economic productivity loss due to uncorrected presbyopia alone for the year 2011 estimated this to be US$ 25 billion for people under 65 years of age, using the disability weight for uncorrected presbyopia to estimate the loss in productivity.[8] This methodological approach is potentially problematic, as the disability weights are designed to capture loss of well-being (not productivity). Surprisingly, there are no studies that directly measure the income of people with unaddressed presbyopia compared to people without near vision impairment (no presbyopia or have near vision glasses).

There is currently very limited data on the impact of providing near vision glasses on the productivity, income and quality of life of individuals with presbyopia, and the wider impact that this might have on household level consumption. One published trial in this field investigated the short-term change in productivity of tea-pickers in India who were given near vision glasses to use while harvesting the crop.[9] The intervention arm had an approximately 20% relative increase in weight of tea picked per day. This study is limited in its generalisability – one occupation, in one location, for one season – and did not assess effect on income. A second, recently published trial from Bangladesh focused on people in near vision intensive occupations. This found some evidence for increased self-reported monthly income with use of near vision glasses.[10]

There are a few small-scale studies that have investigated the impact of presbyopia on vision related quality of life (VRQoL). These indicate that uncorrected presbyopia is associated with significantly lower VRQoL compared to people without presbyopia.[11-15] When comparing uncorrected presbyopia with corrected presbyopia, utility scores were reported to be higher for those with correction (indicating better quality of life).[13]

Currently, there are no published data on the direct effect of providing near vision glasses on household level consumption or income earnt for a wide range of occupations in the working age population.

Justification/ Rationale

Globally, there is an enormous (>500 million people) unmet need for glasses for presbyopia, particularly in low- and middle-income countries. Evidence shows that presbyopia is associated with increased difficulty in activities of daily living, such as: reading, sewing, recognising small objects and harvesting grains.[2,16] Therefore, it is likely that uncorrected presbyopia has an adverse impact on an individual's vision related quality of life, and their ability to perform income-generating activities - especially those working in occupations which rely on precise near-vision work.[10,14,17] As such, there is a strong case for concerted action to address presbyopia.

However, to further strengthen the case for action and advocate for the large-scale funding needed to enable this – from both domestic and international sources – there is a need for more robust economic evidence, from well designed and carefully conducted studies, measuring the benefit of addressing presbyopia in terms of increased household consumption, income, productivity, and vision related quality of life.

Study Objectives

Primary Objectives

Test, in a two-arm, individually randomised controlled trial, the hypothesis that 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.

Secondary Objectives

1. Determine the impact of the provision of near vision glasses on the income of people with presbyopia.
2. Determine the impact of the provision of near vision glasses on the household consumption of a population sub-group who are in near vision intense / dependent occupations.
3. Determine the impact of the provision of near vision glasses on the income of a population sub-group who are in near vision intense / dependent occupations.
4. Quantify the impact of providing near vision glasses on measures of workplace productivity, in a population sub-group who are in near vision intense / dependent occupations.

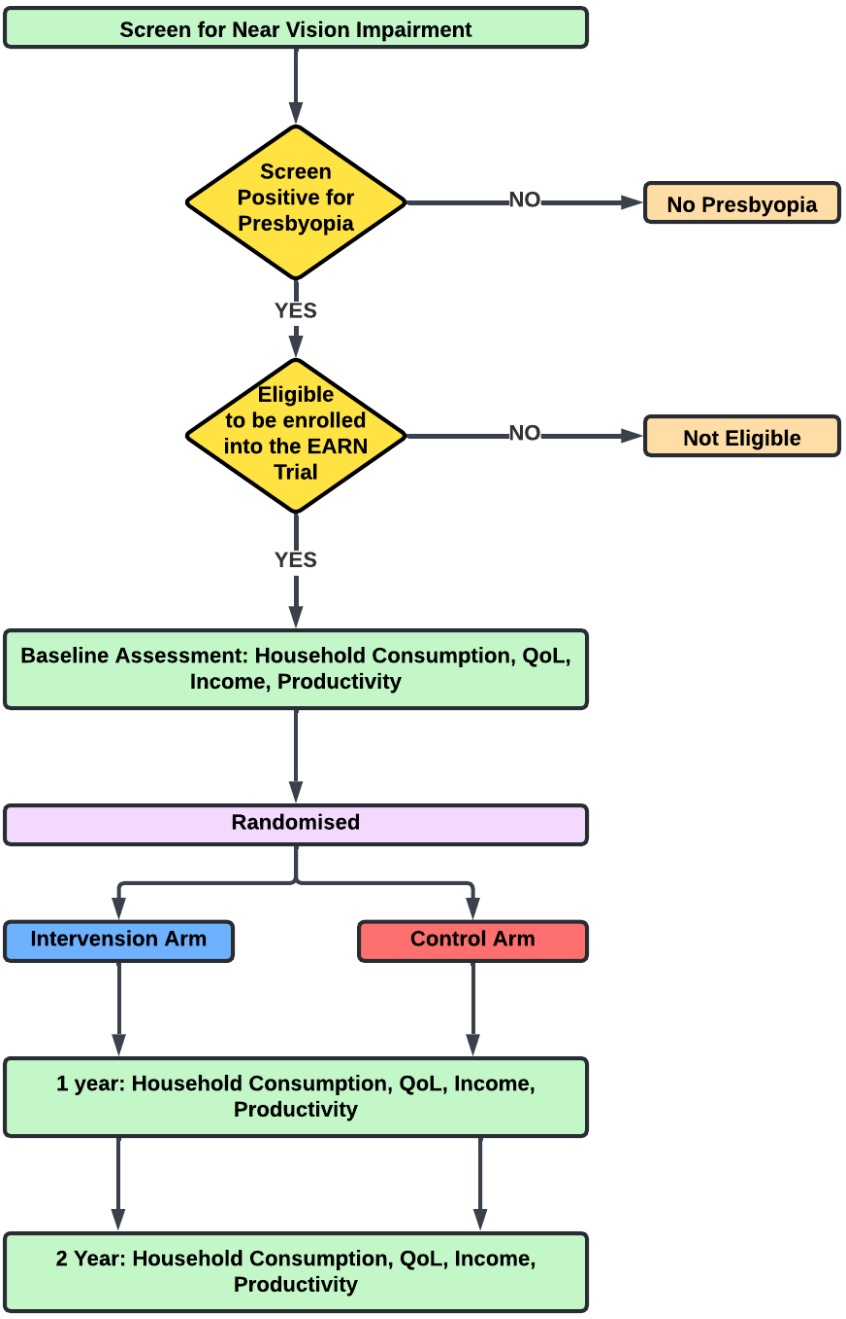
Methodology

Trial Design

Prospective, single-masked, parallel group, two-arm individually randomised controlled trial.

The rationale for an individually randomised (as opposed to a cluster-randomised controlled) trial design is that it is highly likely that income will be very clustered, and therefore a cluster-RCT would require a large number of clusters to ensure good balance between arms, and a sufficient sample size. An individually randomised trial will provide greater power for the same resources. A potential downside is the risk of intervention contamination – through people sharing glasses with control participants.

Figure 1: EARN Trial Flow Chart.



Research Partnership

The EARN research programme will involve two separate RCTs with the same core trial design, conducted in Kenya and India. The study will be conducted through a collaborative research partnership between: (1) Kenya Medical Research Institute (KEMRI), Kenya; and (2) International Centre for Eye Health, London School of Hygiene & Tropical Medicine (LSHTM), UK.

The trial sites were chosen based on (1) ICEH's current strong collaborative partnerships, and (2) current implementation locations for Peek powered screening programmes.

Kenya

- Research Partner Organisations: Kenya Medical Research Institute (KEMRI) and University of Nairobi.
- Key Contact: Dr Stephen Gichuhi – Associate Professor at the University of Nairobi and Chair of the Department of Ophthalmology / Hon. Associate Professor at ICEH/LSHTM.
- Key Contact: Sarah Karanja – Research Scientist at KEMRI, working on a joint LSHTM/Peek/KEMRI clinical trial called IM SEEN.
- Programme: Based in Kisii, funded by LIF, through Operation Eyesight Universal, using Peek system (or alternative site). If required, we will also recruit participants from the neighbouring Bomet County.

Study Population

Kenya:

The proposed trial recruitment region is Kisii County which has a population of 1,266,860 according to the 2019 National Population and Housing Census.[18] If required, we will also recruit participants from the neighbouring Bomet County.

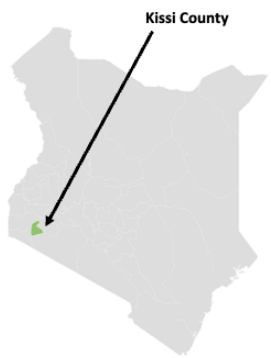
Kisii County has been selected for the following reasons:

(1) According to the 2019 National Population and Housing Census, Kisii County has a population of 1,266,860. We believe this population size will be sufficient to recruit 10,000 individuals with unaddressed presbyopia.

(2) The trial will include visual acuity screening and referrals to local eye care providers for conditions other than presbyopia. To ensure successful implementation, it is crucial that the local eye care system can accommodate the increased number of referrals resulting from expanded community screening efforts. In Kisii County, these services are provided by Innovation Eye Centre – Kisii Eye Hospital, a social enterprise offering high-quality, affordable, and accessible comprehensive eye care.

(3) Kisii Eye Hospital, Operation Eyesight and Peek Vision have a pre-existing partnership through which a door-to-door screening programme has been conducted, from which people with untreated presbyopia were recruited for a prior study. This sets a precedent for the EARN trial to run effectively. In the prior project, based around Ogembo Vision Centre (VC), in Bomachoge Sub-Location in Kisii County, over 20,000 people have been screened and in September 2023 over 5,000 were screened. Data from this has been used to determine the recruitment strategy for the EARN trial.

Figure 2: Map demonstrating the location of the trial site in Kenya



Recruitment Strategy

The aim is to recruit a representative core sample of people from the working age population, aged ≥35 years, within the communities where the trials are located. We will screen in a mixture of both urban and rural communities (recruitment units).

Vision testing will be done as part of a large community-based screening programme being run by the organization 'Operation Eyesight Universal'. The screening programme will be conducted throughout the entire county and facilitated through Kisii eye hospital. We will base the trials in communities where the Peek Community programme is being implemented, to provide the framework for community and workplace-based screening for near and distance vision impairment.[19] These programmes are systematically offering vision screening to the whole available adult population for vision impairment in a specific locality. The trial will recruit participants from the active screening programme, which includes as standard a near and distance visual acuity assessment through the use of smartphone-based apps that were jointly developed and validated by Peek and the ICEH teams and further validated by multiple institutions globally including at a WHO Collaborating Centre. Operation Eyesight Universal will have responsibility for the screening, and referrals to Kisii eye hospital for those that require further care for conditions other than presbyopia. Referrals will be made to Innovation Eye Centre – Kisii Eye Hospital, for conditions other than presbyopia. The CEO and COO at Kisii eye hospital are aware of this and Prof Kiage (CEO and Ophthalmologist) is on the advisory team for the trial. They have served as key stakeholders in the planning and preparation stages.

Before screening takes place, a carefully co-designed patient pathway is developed with a range of stakeholders including service providers (facilitated by Peek) to ensure people are referred to the appropriate location and that services are available. This design is then configured into the Peek platform which creates a profile for each user on the patient journey, including screeners, healthcare workers, optometrists, hospitals etc. The users then undergo software training to ensure competence in data collection and screening quality assurance.

When the programme starts data from each user is collated on a secure cloud-based server. Individuals referred for treatment or further assessment receive automated, personalised SMS messages (directly or to an appointed carer/guardian). The programme manager (and any designated stakeholder) has access to a Peek web-portal (Peek Admin) to track real-time programme progress and a suite of powerful analytics tools to identify dropouts and opportunities for programme optimisation. Currently there are 69 active programmes running in 12 countries which collectively screen approximately 100,000 people per week. High volume programmes provide an ideal recruitment base for trials such as EARN.

While recruiting the core sample of people of working age population we may need to supplement the sample for several specific occupation groups to provide sufficient power to examine changes in household consumption, income and work-place productivity by arm for these subgroups. These additional recruits would be excluded from the primary analysis of the population-based sample. Depending on the size of this supplementary recruitment, it is possible that the sub-group analysis would be underpowered to identify subtle changes in household consumption and income, but would be indicative of an effect, and will have greater power to pick up effects on quality of life. This additional recruitment will be through workplace-based screening.

Community Engagement

We will work with local Community Health Promoter (CHPs) to sensitise the local community. Prior to the community eye screening, participants will be mobilized by community health promoters (CHPs) and community health assistants (CHAs) through public gatherings and announcements on local radio stations where available. The community will be informed about the study by the CHAs and CHPs. Upon identifying eligible individuals, the screeners will acquaint them with the EARN trial and notify them that someone will visit them for recruitment. Information regarding potential participants will be shared with both the CHPs and study field supervisors. Throughout the recruitment process, the CHPs will accompany the data collectors, guiding them to the participants' households and introducing them to the household members. To ensure voluntary participation, confidentiality, and privacy, the CHPs will not be present during the consenting and interviewing of participants

Screening Participants

All people present in the screening locality will be offered vision screening if they meet all the following inclusion criteria and have no exclusion criteria.

Inclusion criteria for screening:

- Adults 35 years and older
- Provide verbal informed consent to be screened.

Exclusion criteria for screening:

- Age less than 35 years
- Inability to communicate / provide consent.

Screening Assessment

Individuals meeting the inclusion criteria for screening will have the following visual acuity (VA) screening tests:

Distance Visual Acuity - measured using the distance Peek Acuity app, on a smartphone.[20]

- Both eyes tested separately, at the 6/12 threshold level (rapid screening)
- Presenting VA (with distance glasses if they have them).
- Pinhole VA (if presenting VA <6/6).

Near Visual Acuity - measured using the near vision Peek Acuity app, on a smartphone.[21]

- For those with distance presenting or pinhole VA ≥6/12 in the better eye, near vision assessment will then be a pass / fail screening at the N8 threshold at 40cm.
- The test will be done binocularly, i.e., both eyes at the same time.
- Participants must correctly identify at least 4/5 tumbling E optotypes to pass.

The smartphone-based distance and near VA testing apps were jointly developed and validated by Peek and the ICEH teams and further validated at a WHO Collaborating Centre.

Trial Participants

People who screen positive for presbyopia (<N8) will then be considered for potential inclusion in the trial and assessed using the following criteria. To be included in the trial participants must fulfil all inclusion criteria and have no exclusion criteria. Some people who are excluded may have other ophthalmic conditions that require a referral by the study team.

Inclusion criteria:

- Bilateral presbyopia and do not currently own/use glasses for near vision. Adults aged between 35 and 65 years.
- 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.
- Provide informed consent and agreement to be randomly allocated to one of the two study arms.

Exclusion criteria:

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

Within the Peek software is a validated algorithm which takes participants through the following steps:

- A distance vision test that was developed and validated against Snellen acuity (clinical normal) charts and the Early Treatment Diabetic Retinopathy Study (ETDRS) logMAR chart (reference standard). Findings from this

validation exercise have been published in a peer reviewed journal and are available to view here. (If passed and 35 years or older)
- A near Vision Test. Journal publication with full results on the development and validation of this test is available here. (if failed)
- Reading glasses test to determine optimal power of correction

Once participants have been identified as having presbyopia from the ongoing screening programme, and fulfilling other trial inclusion criteria, the staff from the screening programme will refer them to the trial data collectors for further eligibility screening and consenting processes. It is planned that a screening team and trial team will be coupled and so will work in close proximity.

Occupational Sample Enrichment

To maximise the generalisability of the trial we will recruit the core sample from people without occupation restriction.

In addition, there is considerable interest in how this intervention might especially benefit people from certain occupation groups that particularly involve near vision dependent tasks. We aim to supplement the sample to look at occupation subgroups, in addition to the general population core sample, by adding to the main trial sample additional participants from these occupation groups, to enable sufficient sample size for subgroup analysis.

The proposed occupational sub-groups align with the International Standard Classification of Occupations (from the International Labour Organization).[22] Part of the pilot work will include refining these subgroups to the local context where the studies will be taking place.

- *Group 1: Agriculture, forestry and fisheries.*
- *Group 2: Crafts, repairs and operation of machinery*
- *Group 3: Clerical, sales and service occupations*
- *Group 4: Managerial, professional and technical occupations.*

Trial Interventions, Randomisation and Masking

Intervention Arm

Trial participants who are randomly allocated to the intervention arm will be given free near vision glasses (spherical, non-astigmatic correction), appropriate for their degree of presbyopia. When the glasses are dispensed participants will be counselled on the use and care of the glasses. The specific counselling provided will be context specific and fine-tuned during the pilot phase. In the period between (1) baseline assessment/glasses dispensing and (2) follow-up, we will not intervene further to encourage the use of glasses.

Near vision glasses will be provided by the Livelihood Impact Fund. These will be dispensed at the household level (where screening occurs) from the study supervisors, who will be either an ophthalmic clinical officer or an optometrist."

Control Arm

Trial participants who are randomly allocated to the control arm 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 it is possible that some may choose to independently purchase glasses themselves.

Baseline Data Collection

Baseline data will be collected from the trial participants in both arms shortly after the screening visit, once eligibility has been confirmed and the participant consented. The intervention arm participants will receive near vision glasses after the baseline questionnaire has been completed.

The baseline data collection will cover the following elements:

- Household Consumption
- Quality of Life
- Employment status and characteristics (e.g. hours worked)
- Nature of employment
- Presenteeism and absenteeism – self assessment of productivity
- Income from employment
- Income from own production
- Self-reported income sufficiency

We currently anticipate that this baseline and the subsequent follow-up data collection will take about two hours per participant / household to complete. This will be pilot tested in each study site and refined further as needed.

For a subset of participants involved in manufacturing work, we may conduct a workplace-based assessment of occupational productivity, with quantification of specific tasks completed, appropriate to occupation, e.g. number of units of production in a given time period.

Randomisation

Participants will be randomly assigned (1:1) to either the intervention arm or the control arm. A computer-generated randomisation list will be prepared by an independent statistician, with random block sizes of 2, 4 or 6. The allocation will be automated through the Peek systems. The randomisation will be stratified by screening location so that within each location a similar number are allocated to intervention and control arms. The random allocation and dispensing of the near vision glasses will be conducted by a fieldworker who is independent of all other aspects of the trial.

If more than one member of a household is eligible for recruitment into the trial, the individual will be randomly selected from among those eligible to be the study participant. The names of the eligible individuals will be written on separate papers, folded and selected at random from an opaque container.

Masking

In this trial, masking of participants to which group they are allocated will not be possible.

The people who are responsible for dispensing the near vision glasses to participants randomised to the intervention arm will have no role in the collection of baseline or outcome data. The data collection team will not be involved in the process of randomisation or dispensing the near vision glasses.

The statistician performing the analysis will be masked to the randomisation allocation. In practice, the statistician will receive the final locked dataset in which codes will be assigned (e.g., Group A and Group B) to the intervention and control groups. Once the analysis is complete, the groups will be unmasked.

The fieldworkers will be adequately trained to ensure that interviewer bias is minimised as much as possible. We do however acknowledge that this may be a study limitation and will be recorded and evaluate both during the pilot study, and the trial.

The existing Peek screening process and the EARN trial process

The screening and distribution process will be adapted slightly to facilitate the trial. We have summarised the existing screening process and how this will be adapted for the EARN trial process below:

Existing screening process through the Peek program (which is the entry point for the trial)

- Community Health Workers (CHWs) are trained to use Peek software for vision testing, recording eye health observations, demographic data capture and referral to the local vision centre for those who need it.
- CHWs then go house to house to screen anyone 40 years or older following logic embedded in the software. The logic determines if someone is eligible for reading glasses. If they have other conditions needing eye care services they are referred appropriately.
- Individuals who require glasses will receive them at the household level from the study supervisors, who will be either an ophthalmic clinical officer or an optometrist.

- The Vision Centre staff also have a configured version of the Peek app running and it includes a live list of patients referred from screening. New patients ("walk-ins") can also be captured in the system if they have not come from screening.
- As patients arrive at the Vision Centre their arrival is captured in the app and any further assessment, diagnosis, treatment or onward referral (e.g., to the hospital) is recorded.

EARN trial process

- The community-based house-to-house screening to identify working age individuals with presbyopia who may be eligible for the trial will be facilitated by Operation Eyesight Universal.
- Screeners will be trained to use Peek software for vision testing, recording eye health observations, demographic data capture and referral to the local vision centre/Kisii Eye Hospital for those who need it. This training is the same as the current standard Peek based programme more widely used in Kenya.
- Screeners will go house-to-house to screen anyone 35 years or older following logic embedded in the software. The logic determines if someone is eligible for reading glasses. If they have other conditions needing eye care services and are not eligible for the trial they are excluded and referred appropriately.
- Those eligible for the trial will then be referred to the trial study team (separate from the group doing the screening within the programme) consented and randomly allocated to the control or intervention arm.
- Participants who are recruited into the trial would not be referred to the Vision Centre. Those who are randomised to receive reading glasses would receive the glasses in their home context.

Outcome Measures

Primary Outcomes

This trial will have two, co-primary outcomes at 12 months: Household Consumption and Vision Related Quality of Life. The same outcome data will also be collected at 24 months.

1. Household consumption at 12-months (and 24-months).
For each country we will develop (and pilot test) a specific household consumption data collection tool for the trial, based on previously used questionnaires in each country. The questionnaire is reproduced in Appendix 2.

The measurement of a households' consumption over a certain period of time, is often broken into broad consumption categories and adjusted based on the number of people living in the household.[23] To measure household consumption, respondents will be asked a series of questions about the number of people living in their household and about how much (if anything) they have spent on certain goods and services, including: food items, non-food/non-durable items, durable goods and housing.[24,25] We aim to measure the total consumption of the household in the past year (reference period), to be able to dismiss temporary drops in consumption and to capture changes in living standards of a single individual or household over time. The recall period associated with the categories of goods and services mentioned above will be adjusted according to the consumption and purchasing frequency.

2. Vision Related Quality of Life at 12 months (and 24-months).
We will use the well-established and widely used WHOPBD/VF20 questionnaire.[26] This questionnaire is reproduced in Appendix 1. It has 20 vison related questions, six of which are relevant to near vision functioning.

Rationale: The choice of the primary outcomes was not simple for this trial, as there are several pros and cons to the various alternatives that could be considered which need to be balanced.[23] The co-primary outcomes we are proposing examine two very important and complementary aspects of the impact of near vision glasses on peoples livelihood and wellbeing. Consumption measures how income is actually used and has the advantage of usually being more consistent from month to month and can include home production which is a key component in rural settings.

In this process we also considered individual level income as an alternative for the primary outcome. In low- and middle-income country settings household consumption is generally preferred to individual income.[23] In the two countries where the trials would be conducted, using individual income as the primary outcome would be very challenging for several reasons:

- The sample size would be substantially larger (about 3x) if we used individual income, instead of household consumption. This larger sample is driven by the variability in income (Standard Deviation), compared to household consumption.
- Measuring income in societies where many people (possibly the large majority) are not in formal employment arrangements is more difficult to do and may be less reliable than household consumption. Recall and reporting bias is bigger if people don't receive a regular payslip.[27] People may also be reluctant to fully disclose their individual earnings.
- Income measurement in countries with a large informal work sector is particularly challenging since income may vary significantly from month to month if individuals' employment is intermittent, casual or seasonal.[23,27] Agriculture income is subject to a higher degree of underreporting and lack of precision.

While recognising these limitations, we have included individual income as a secondary outcome (rather than the primary outcome).

Secondary Outcomes

We will collect data at baseline, 1 year and 2 years on a panel of secondary outcome measures to provide multiple perspectives on the impact that providing near vision glasses can have on people's lives.

Secondary outcomes will include:
1. Employment Status and characteristics - Appendix 3.
2. Self-reported productivity (presenteeism) - Appendix 3.
3. Self-reported income sufficiency - Appendix 3.[28]
4. Self-reported individual income (from employment and production) - Appendix 3.

5. Health related Quality of Life: EQ5D with vision bolt-on question - Appendix 4.[29]

Individual Income will be assessed using an income questionnaire (Appendix 3). We will use the conceptual definition on the sources of income developed by International Conference of Labour Statisticians (ICLS / ILO, 2004) – see Appendix 5.[30] The baseline assessment will estimate total individual income for the preceding 12-month period. Where people are unable to provide an annual income amount, we will project monthly or weekly estimates to produce an annual income estimate.

Workplace Productivity. For certain sub-groupings of the working population, we will apply occupation specific measures to quantify workplace productivity, limited mainly to people in jobs with easily quantifiable units of production (e.g. garments made).

Recently, an increasing number of randomized controlled trials (RCTs) have measured the impact of healthcare interventions on work productivity.[31] Work productivity can be defined as the economic productivity of a workplace and, as such, might be described in terms of throughputs, costs, profits, or output targets and it can be measured from different perspectives. Worker productivity is a critical part of that broader measure of workplace productivity.[32] From an organizational/industry perspective worker productivity is one of the factors that contributes to the success of the organization/workplace. From a health economics perspective, the worker productivity loss is included as productivity costs in health economic evaluation studies.[32] At the individual level work productivity is related to the ability to work and work performance. It has typically been assumed that what constitutes individual work performance differs from job to job. Therefore, multiple different measures have been used. Objective measures include the number of days absent, counts of specified acts or output measures maintained in organizational records. Subjective measures are based in subjective judgments of quantity and quality of work from the employee himself, peers, or supervisors. Complete components of work productivity commonly include: 1) absenteeism; 2) presenteeism; 3) employment status changes.[33] Before transformed into monetary values, work productivity loss due to poor health is expressed as work time loss (e.g days missed from work, hours lost due to reduced productivity or stopped workdays).

We would like to measure objective and occupation specific measures of workplace productivity within this trial. However, this is only logistically feasible in a study recruiting from specific occupation groups. Given our study is recruiting a general sample of the population, we will utilise self-reported tools to facilitate a measure of productivity in a sample which includes a potentially wide range of occupational groups, for which it would not be otherwise possible to have a single objective measure of occupational productivity.

In the pilot phase we will learn much about the types and distribution of occupations in this area. This will enable us to refine further our occupational sub-groups. With this additional information we anticipate being able to define additional occupation specific questions about productivity for at least some of these sub-groups. For example, how specific areas of agricultural production are measured will enable us to define the most relevant production question for an occupation or group of occupations.

12-Month and 24-Month Data Collection

The primary end point data collection will be done 12-months after the baseline (+/- 2 weeks).

We will also collect the same outcome data set at 24-months after baseline, to assess the sustainability of any change or later gains / losses.

The 12 and 24- Month data will be collected from the trial participants in both arms using the same data collection tool as baseline.

It is highly likely that there will be seasonal variation in income amongst farming communities. To mitigate this, we plan to collect baseline and follow-up data from the same individuals / households at the broadly similar time each year (+/- 1 month). We will collect data from the control and intervention arms at the same time. We will document when the data is collected with respect to the agricultural cycle (e.g. a few weeks before harvest, during harvest, a few weeks after harvest).

Loss to Follow-up

From our recent experience of conducting studies in these localities, we anticipate loss to follow-up rates to be low.

Participants who are not present on follow-up visit will be contacted by telephone. A further follow-up attempt will be made by the study team. Reasons for the loss to follow-up will be recorded and reported.

We will monitor the proportion lost to follow-up after the first 200, 500 and 1000 participants are due to have been seen. If loss to follow up is high, or different between arms, action will be taken to strengthen our follow up completion rate.

Statistical Considerations

Sample Size

Summary:
1. Household Consumption: A sample of 10,000 participants (5,000 per arm), in each trial, would have 90% power to detect a 3% increase in household consumption between baseline and 1 year, if we exclude the households that are in the top 30% by consumption (based on data from the Kenya Life Panel Survey) and assume a correlation in household consumption between one year and the next of 0.6. This sample size would also have 80% power to detect a 3% increase in household consumption between baseline and 2 years, if we exclude the households that are in the top 30% by consumption (based on data from the Kenya Life Panel Survey).

2. Quality of Life: Based on the proposed sample size of 10,000 people we would have >99% power to identify a small improvement in vision related quality of life (VRQoL), given that VRQoL is a much less variable measure between individuals than household consumption. This would also allow us to explore occupation specific changes in QoL.

Detailed Explanation:
Since detailed context specific data is not yet available, these power calculations are based on some assumptions which may be overly cautious (or not cautious enough). For this reason, we propose to use data from the pilot phase to refine these estimates, and either adjust the participant recruitment criteria, and/or potentially the overall sample size.

Given the low cost of the intervention, and the large population that could benefit from it, even a small increase in household consumption could mean the intervention is cost effective. However, the large variation between individual household consumption makes the identification of a small effect size challenging, requiring the study to be large.

In developing the sample size estimates, we decided that a study of 10,000 people (5,000 per trial arm) per site was the largest feasible / affordable study to conduct (10,000 x 2 hours = 20,000 hours of interviews/data collection once recruited, per site), and therefore worked within this upper limit to develop the sample size options.

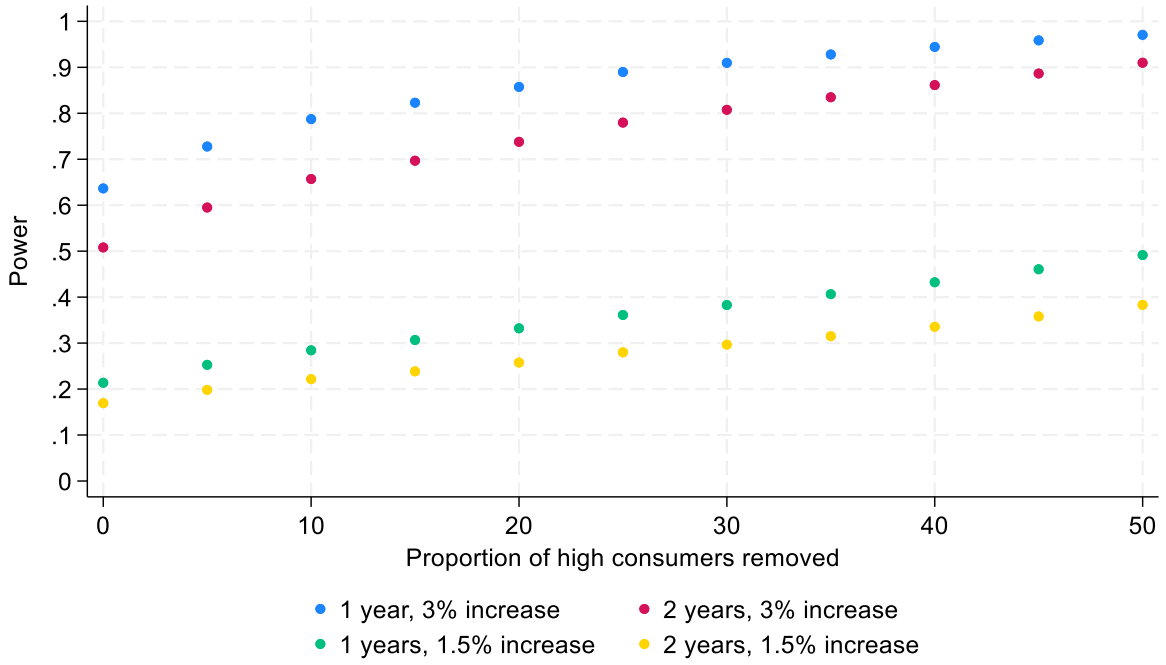
We used data from the Kenya Life Panel Survey, to provide an example of the distribution of household consumption.[34] The equivalent distribution data from India are comparable. We have assumed the shape of this distribution will be similar to the distribution in our target population (as it is the shape of the distribution, rather than the absolute values, that determine its effect on power). Also based on this data we assumed that household consumption between one year and the next was correlated, with a correlation coefficient of 0.6.

It is plausible that within a defined set of communities within each country that the variation in household consumption will be lower and the variation between years will be less (compared to the country as a whole), which would both increase the power of the study.

To increase the power within our maximum feasible sample of 10,000 participants, we examined the effect of limiting the eligibility criteria to exclude people from the wealthiest households in the distribution. In order to estimate the effect this would have on the power of the study we performed a range of simulations, based on removing the wealthiest households from our study.

Figure 3: EARN Trial power calculation scenarios for household consumption as the primary outcome. This figure illustrates the power of a range of trial design options: using a fixed sample size of 10,000 participants (5,000 per arm), for different trial periods to the primary outcome analysis (1 year or 2 years), for different increases in household

consumption (3% or 1.5%), and a between year correlation coefficient in household consumption of 0.6. To increase the power of the trial to detect these very small changes in household consumption the simulations progressively remove (in 5% steps) an increasing proportion of the upper end of the distribution (starting by removing the 5% with the highest household consumption).



We simulated several scenarios based on removing between the top 5% and top 50% of households by consumption, which increases power by reducing the variance in consumption among the group of people actually recruited into the trial. This results in substantial increases in power. To detect a 3% difference in household consumption at one year, if we exclude the top 15% of the household consumption distribution from the trial the power increases to 80%, and if we were to exclude the top 30% the power increases to 90%. However, based on these simulations power was still low to detect a small improvement of 1.5%.

We think that it is plausible that people who are in the top 15-30% of the household consumption range – the wealthiest households – may already own near vision glasses. Therefore, many may already be excluded from the trial. During the pilot phase we will learn about the household consumption distributions in the study locations in the two countries, which will allow us to refine the exclusion criteria if needed.

In each proposed trial location, we think that this sample size can be recruited in 12 months, based on current screening activities in these areas.

For the near-vision intense occupational sub-groups that we are proposing to do an additional secondary analysis for, if we assume (1) there is moderate correlation in income between years of 0.6, (2) much less variability in income, with a standard deviation of +/- 0.5 of the mean within the occupation groups, (3) a 20% loss to follow-up rate. A sample of 2010 individuals (1005 per arm) would have 80% power to detect a 5% or more increase in income. Again, these assumptions about income distributions by occupation would be assessed and updated in pilot phase.

It is possible that our initial core sample would have sufficient (or nearly sufficient) participants recruited within each of the occupation sub-group categories, therefore, the additional occupational sub-group sample enrichment needed may be quite modest. We would actively monitor the recruitment by sub-groups to determine how much additional sample enrichment is needed during the recruitment phase of the trials.

Analysis

Data will be analysed in STATA and R.

CONSORT guidelines for analysing and reporting randomised controlled trials will be followed. A flowchart will show all potentially eligible and ineligible participants for the trial, and reasons for exclusion. The number of participants enrolled per arm will be shown, along with number with outcome data. The baseline characteristics of trial participants will be summarised by arm.

The primary analyses will be by intention-to-treat (ITT), with participants analysed according to the arm to which they were randomised. It is possible that people who are randomised to the control arm may acquire near vision glasses during the year. Therefore, we will also perform a secondary analysis of the primary outcome by Complier Average Causal Effect, which estimates the effect of actually getting glasses.

Household Consumption: the primary analysis of the primary outcome will be household consumption at 12 months compared between the intervention arm and the control arm adjusting for baseline household consumption (ANCOVA). We will perform a secondary analysis of household consumption at 24 months, adjusted for baseline.

Vision Related Quality of Life: the primary analysis of the primary outcome will be VRQoL – WHO/VF20 at 12 months compared between the intervention arm and the control arm adjusting for baseline VF20 scores (ANCOVA). We will perform a secondary analysis of VF20 data at 24 months, adjusted for baseline.

Most of the secondary outcome measures are continuous variables. These will largely be analysed using the same method as the primary outcome.

In view of the low-risk nature of this trial, we do not plan to conduct an interim analysis.

Pilot Phase

We intend to conduct a short pilot phase (approximately 6 months) prior to initiating the trial. The purpose of this is to help us test and refine the trial data collection tools and to collect information on the distribution of household consumption to confirm the sample inclusion criteria.

Objectives

- Test and refine the survey questionnaires (Appendices1 to 4).
- Test and refine the electronic data capture tool (ODK or RedCap).
- Determine the distribution of household consumption and individual income within a similar population to the main trial population (facilitating sample size and study inclusion criteria refinement).
- Refine the counselling (on the use and care of eyeglasses) provided to the intervention group at baseline.
- Refine the occupational subgroups and test productivity measurement tools.

Recruitment Strategy

The recruitment strategy will match that used in the main trial (described in the relevant sections above).

Screening Assessment

The screening assessment will match that of the main trial (described in the relevant sections above).

Pilot Phase Participants

The inclusion and exclusion criteria for the pilot phase will match that of the main trial: people who screen positive for presbyopia (<N8) will then be considered for potential inclusion and assessed using the following criteria. To be included in the pilot participants must fulfil all inclusion criteria and have no exclusion criteria. Some people who are excluded may have other ophthalmic conditions that require a referral by the study team.

Inclusion criteria:

- Bilateral presbyopia and do not currently own/use glasses for near vision.
- Adults aged between 35 and 65 years.
- 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.
- Provide informed consent and agreement to be randomly allocated to one of the two study arms.

Exclusion criteria:

- Presbyopia and owns near vision glasses (met need or partially met need).
- Pinhole distance VA of worse than 6/12 in the better eye.
- Current illness or incapacity preventing the individual from working.
- Inability to communicate.
- Any occupation with formal guidance requiring safety glasses for near work.
- Another member of the household has already been enrolled into the pilot study.

Data Collection

Following the informed consent process, a survey will cover the following:

- Household Consumption- Appendix 2.
- Vision Related Quality of Life - Appendix 1.
- Employment Status and characteristics - Appendix 3.
- Self-reported productivity (presenteeism) - Appendix 3.
- Self-reported income sufficiency - Appendix 3.[28]
- Self-reported individual income (from employment and production) - Appendix 3.
- Health related Quality of Life: EQ5D with vision bolt-on question - Appendix 4.[29]

The pilot phase survey matches what will be used in the main trial (for baseline, year 1 and year 2) data collection. The pilot phase survey includes a wider range of questions within the domains of Household Consumption (Appendix 2). The survey questions relating to Household Consumption will be refined and confirmed prior to initiation of the main trial.

Eyeglasses

Following the survey assessment, all participants will be provided with free near vision glasses (spherical, non-astigmatic correction), appropriate for their degree of presbyopia. Participants will not be randomised.

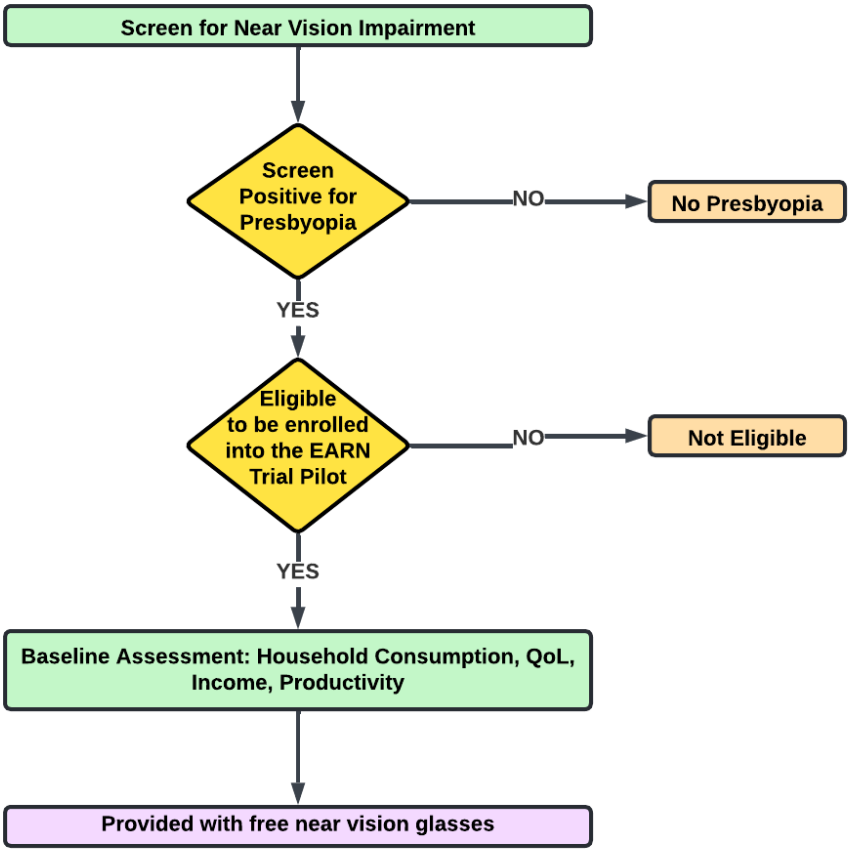
Pilot Phase Sample Size

One of the key objectives of the pilot phase is to gather information on household consumption to enable us to refine/confirm the sample size assumptions, and if needed, to slightly adjust the inclusion criteria to ensure sufficient power to estimate the effect on household consumption in the main trial. Given this in an information gathering process to facilitate more precise sample size calculations, it is not possible to determine a precise sample size needed for the pilot phase. However, we estimate that the sample size required for the pilot phase would be approx. 500-1000 participants at each trial site. Data collected from the pilot phase will be analysed at fortnightly intervals, and when sufficient data is collected on the distribution of household consumption data (to inform the sample size calculation and potential inclusion criteria adjustment for the main trial) – the pilot phase will end.

Follow-up

We do not intend to follow-up participants from the pilot phase.

Figure 4: Pilot phase flow chart.



Data Management and Archiving

Data from this trial will be managed jointly by the teams at LSHTM (UK) and KEMRI (Kenya). The day-to-day management will be by the local senior research officer and local PI. Any paper records, such as consent forms, will be stored in locked cabinets inside locked project offices at each site.

Data Collection Tools

Please see Appendices 1, 2, 3 and 4 for the data collection tools, listing the variables to be collected.

Data Storage

Data (including identifiable data) will be collected by KEMRI researchers onto the KEMRI REDCap system.

Authorised access: REDCap users have access only to data and information they are supposed to have access to within the application. Each user has their own account, and user privileges will be set up so that only the study team responsible for following up the participants at 1- and 2-years have access to participants' identifiable data (for the purposes of locating the participant for longitudinal follow up).

Data collection: data will be collected by field workers directly onto the REDCap mobile/tablet application. Data will be uploaded from mobile/tablet devices to the REDCap server daily.

Storage: data will be stored on KEMRI REDcap. The web server and database server are provisioned as virtual private servers by the KEMRI Internet Service Provider located securely behind a firewall. A Secure Socket Layer (SSL) certificate is deployed on the web server to maintain secure communication with the end user. REDCap database backups are performed daily (incremental backups) and weekly (full backups). The server in which the data is stored is located within Kenya.

De-identification and Data Sharing: researchers at LSHTM and KEMRI will have access to de-identified data within REDCap. This is to facilitate monitoring of data quality and completeness throughout the trial.

Statistical analysis: the final de-identified and masked dataset will be exported and sent to the study statistician and health economist (based at LSHTM) for analysis.

Logging and Audit Trial: REDCap has a built-in audit trail that automatically logs all user activity.

Paper records: any paper records, such as consent forms, will be stored in locked cabinets inside locked project offices. The KEMRI senior research officer and the local PI will be responsible for ensuring a secure and appropriate location for storage of study related documentation at the study site, as well as for ensuring that only members of site staff who are authorised have access to the files. The site Study Master File will be held at the project office. The Study Master File will at all times remain available for internal audits and/or inspections of regulatory authorities, including after completion of the project.

After study completion, all the relevant study documentation will be retained in accordance with the local legislation, for a minimum period of 10 years after completion of the study.

The final dataset will be archived and maintained at KEMRI and a de-identified data set will be also stored at LSHTM.

Anonymised data sets will be made publicly available (on appropriate request to the CI) after publication of the results, to ensure the data are available for other investigators to explore. Specific permission for this is requested in the consent form.

Data Analysis

Data will be analysed in STATA and R. Please see the analysis section above on page 23.

Regulatory Considerations

Ethics and Regulatory Approval

Ethics committee and regulatory review and approval will be required from:

UK:
London School of Hygiene and Tropical Medicine Ethics Committee, UK
Kenya:
The Scientific and Ethics Review Unit (SERU), Kenya Medical Research Institute (KEMRI)
National Commission for Science Technology and Innovation (NACOSTI)

The study will only begin after approval certificates have been received from each of the review bodies.

Any substantial amendments will not be implemented until a favourable opinion has been granted from the above ethics committees and regulatory bodies. .

Regular progress reports will be produced throughout the course of the study and shared with the ethics and other review bodies. The ethics and other review bodies will be notified of the end of the study and provided with an end of study report.

Informed Consent

There are two stages of the informed consent process in this trial. The initial stage is the routine informed consent obtained as part of the existing vision screening programme. The initial stage will be sought by screeners prior to vision screening (as per the existing programme). People who "screen positive" for presbyopia, and who meet the inclusion criteria for the trial will be provided with a full explanation of the trial, an information sheet, and time allowed for consideration. Signed participant informed consent will be obtained. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time from the protocol treatment without giving reasons. The PI is responsible for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence. A separate participant information sheet and consent sheet will be used for the pilot phase.

Confidentiality

Any participants' identifiable data collected by the Study Coordination Centre will be stored securely and their confidentiality protected in accordance with the Data Protection Act. The data collection tools (paper forms and electronic forms) include personal identifiers (name, address and unique study number), which are used by project staff to identify participants for the purpose of follow-up. To safeguard identifiable information all paper records will be kept in locked cupboards in secure (locked) project offices. These will only be accessible by designated staff. Electronic data will be kept on a secure LSHTM server (ODK or REDCap) in an encrypted form.

Compensation for Participants

Due to the extended duration of data collection, which may take up to two hours, participants will be compensated for their time (irrespective of their study group assignment). The proposed participant reimbursement in Kenya will be in the form of 500KES for each interaction (baseline assessment, 1-year follow up, 2-year follow up). Where possible, transfer of funds will be via M-PESA.

Indemnity

London School of Hygiene & Tropical Medicine holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies which apply to this trial.

Sponsor

London School of Hygiene & Tropical Medicine will act as the main sponsor for this study. Delegated responsibilities will be assigned locally.

Funding

GiveWell and the Livelihood Impact Fund are funding this study.

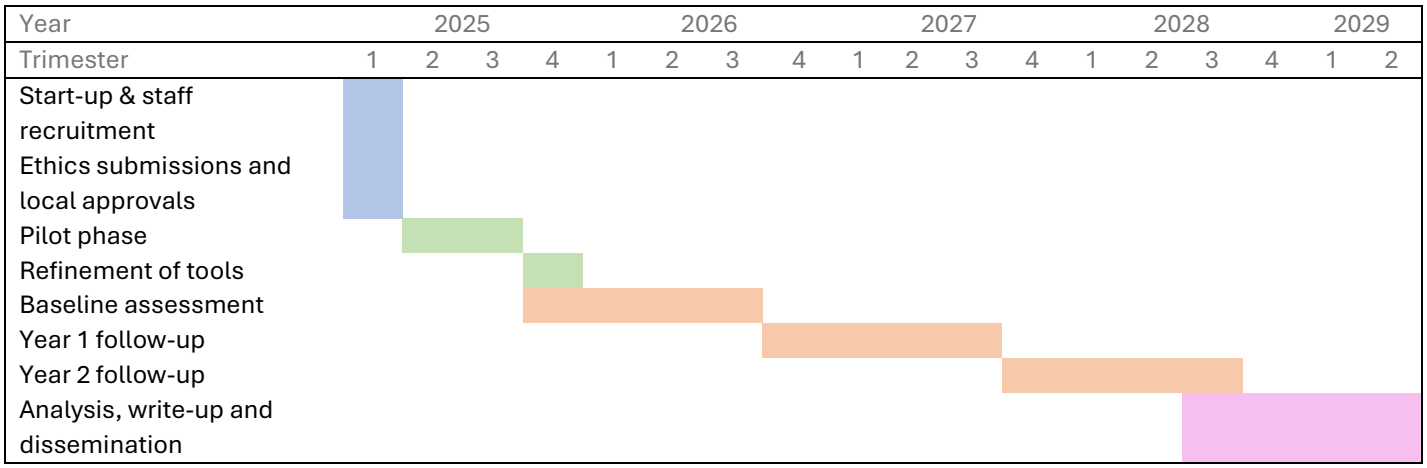
Trial Registration

This trial will be registered with the ISRCTN Registry after it has received approval from the relevant ethics committees and regulatory bodies.

Study Timeline

The target time for completing the study is 5 years:

- Initial study set up: 3 months
- Pilot phase: 6-9 months
- Baseline assessment: 1 year
- Follow-up (year 1): 1 year
- Follow-up (year 2): 1 year
- Analysis, write up, dissemination: 1 year



Trial Management

The day-to-day management of the trial will be co-ordinated by the local PIs and SROs with close supervision by the CIs, Prof. Matthew Burton and Prof Andrew Bastawrous.

Trial Steering Committee

The trial steering committee will have oversight of the study. The Trial Steering Committee includes staff from both recruitment sites:

Investigators

- Prof Matthew Burton (LSHTM, CI)[1]

- Prof Andrew Bastawrous (LSHTM, CI) [1]
- Dr Stephen Gichuhi (Kenya, PI) [1,2]
- Ms Sarah Karanja (Kenya, SRO) [3]
- Dr Shalinder Sabherwal (India, PI)
- Prof John Cairns (LSHTM, Health Economist) [1]
- Dr Patricia Marques (LSHTM, Health Economist) [1]
- Dr David Macleod (LSHTM, Statistician) [1]
- Dr Elliott Taylor (LSHTM, Research Fellow) [1]

Independent Members

- Prof Catey Bunce (Royal Marsden Hospital, Statistician and clinical trialist)
- Prof Michael Kremer (University of Chicago, Development Economist)

Observers:

- Erin Crossett (GiveWell)
- Kate Sabot (Livelihood Impact Fund)
- Abigail Steinberg (Livelihood Impact Fund)
- Keir Bradwell (GiveWell)

Advisors:

- Prof Daniel Kiage (Innovation Eye Centre – Kisii Eye Hospital)

Trial Monitoring

Risk Assessment

The study is considered low-risk.

Data Safety Monitoring Board (DSMB)

Due to the low-risk nature of the trial, we do not intent to appoint an independent Data and Safety Monitoring Board (DSMB). The field team will have approx. one supervisor for every five field workers. Supervisors will perform daily quality assurance monitoring checks on study processes (e.g. eligibility, informed consent) and data collection.

Monitoring at the Recruitment Sites

We will appoint a safety officer independent of the study team to report any SAEs.

Auditing trial conduct

The study may be subject audit by the London School of Hygiene & Tropical Medicine under their remit as sponsor, the Study Coordination Centre and other regulatory bodies to ensure adherence to Good Clinical Practice.

Adverse Event Reporting and Harms

An adverse event (AE) is defined as any untoward medical occurrence in a patient or study participant. A serious adverse event (SAE) is defined as any untoward medical occurrence that:

- Results in death
- Is life-threatening
- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Consists of a congenital anomaly or birth defect

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

All adverse events will be reported. Depending on the nature of the event the reporting procedures below will be followed. Any questions concerning adverse event reporting will be directed to the study coordination centre in the first instance.

Non-serious AEs

All non-serious AEs will be reported to the study coordination centre and recorded in a dedicated AE log within 72 hours. The entry must state the patient ID, date and time of AE, nature, and relation to the intervention, if any. The AE should also be reported to the PI within 72 hours. AE logs will be stored on a secure, password-protected file on a LSHTM computer.

Serious AEs

Serious Adverse Events (SAEs) will be reported to the PI and study coordination centre within 24 hours of the local site being made aware of the event. The PI will report the event to the CI within 48 hours and include it in the study safety report.

An SAE form will be completed and submitted to the PI and study coordination centre with details of the nature of event, date of onset, severity, corrective therapies given, outcome and causality. All SAEs whether expected, suspected or unexpected will be reported to regulatory bodies within 48 hours of occurrence. The responsible investigator will assign the causality of the event. All investigators will be informed of all SAEs occurring throughout the study. If awaiting further details, a follow-up SAE report should be submitted promptly upon receipt of any outstanding information.

Any events relating to a pre-existing condition or any planned hospitalisations for elective treatment of a pre-existing condition will not need to be reported as SAEs.

Contact details for reporting SAEs

SAE forms will be sent to the LSHTM trial manager *(to be appointed)* and the local PI using the title 'Urgent - SAE'

Kenya: sgichuhi@uonbi.ac.ke

Limitations

1. Potential under-reporting of household consumption and/or income – reluctance to disclose full income.
2. Potential problems with recall of information on household consumption and/or income.
3. Unable to double mask.
4. Risk of reporting and observer bias.
5. Risk of contamination of the intervention between participants.

Dissemination

Results will be presented at international conferences and submitted for open access publication. All presentations and publications relating to the study will be authorised by the Trial Steering Committee. Additionally, the Committee members will conduct meetings and workshops with key local stakeholders to disseminate the findings and collaborate on translating the evidence into policy and practice.

References

1. Burton MJ, Ramke J, Marques AP, et al. The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. *Lancet Glob Health* 2021; **9**(4): e489-e551.

2. Sherwin JC, Keeffe JE, Kuper H, Islam FMA, Muller A, Mathenge W. Functional presbyopia in a rural Kenyan population: the unmet presbyopic need. *Clinical & Experimental Ophthalmology* 2008; **36**(3): 245-51.

3. About RAAB; Rapid Assessment of Avoidable Blindness (RAAB). https://www.raab.world/about-raab.

4. Zhang JH, Ramke J, Jan C, et al. Advancing the Sustainable Development Goals through improving eye health: a scoping review. *Lancet Planet Health* 2022; **6**(3): e270-e80.

5. Angell B, Ali F, Gandhi M, et al. Ready-made and custom-made eyeglasses in India: a cost-effectiveness analysis of a randomised controlled trial. *BMJ Open Ophthalmol* 2018; **3**(1): e000123.

6. Papas E, Tahhan N, Fricke TR, et al. Global Cost-Effectiveness of Correcting Near Vision Impairment Due to Uncorrected Presbyopia. *Invest Ophthalmol Vis Sci* 2015; **56**(7): 2132.

7. Marques AP, Ramke J, Cairns J, et al. Global economic productivity losses from vision impairment and blindness. *EClinicalMedicine* 2021; **35**: 100852.

8. Frick KD, Joy SM, Wilson DA, Naidoo KS, Holden BA. The Global Burden of Potential Productivity Loss from Uncorrected Presbyopia. *Ophthalmology* 2015; **122**(8): 1706-10.

9. Reddy PA, Congdon N, MacKenzie G, et al. Effect of providing near glasses on productivity among rural Indian tea workers with presbyopia (PROSPER): a randomised trial. *Lancet Glob Health* 2018; **6**(9): e1019-e27.

10. Sehrin F, Jin L, Naher K, et al. The effect on income of providing near vision correction to workers in Bangladesh: The THRIVE (Tradespeople and Hand-workers Rural Initiative for a Vision-enhanced Economy) randomized controlled trial. *PLoS One* 2024; **19**(4): e0296115.

11. Patel I, Munoz B, Burke AG, et al. Impact of presbyopia on quality of life in a rural African setting. *Ophthalmology* 2006; **113**(5): 728-34.

12. Berdahl J, Bala C, Dhariwal M, Lemp-Hull J, Thakker D, Jawla S. Patient and Economic Burden of Presbyopia: A Systematic Literature Review. *Clin Ophthalmol* 2020; **14**: 3439-50.

13. Tahhan N, Papas E, Fricke TR, Frick KD, Holden BA. Utility and uncorrected refractive error. *Ophthalmology* 2013; **120**(9): 1736-44.

14. Muhammad N, Alhassan MB, Umar MM. Visual function and vision-related quality of life in presbyopic adult population of Northwestern Nigeria. *Niger Med J* 2015; **56**(5): 317-22.

15. Lu Q, Congdon N, He X, Murthy GVS, Yang A, He W. Quality of Life and Near Vision Impairment Due to Functional Presbyopia among Rural Chinese Adults. *Investigative Ophthalmology & Visual Science* 2011; **52**(7): 4118-23.

16. Fafiolu VO, Ajibod HA, Onabolu OO, Jagun OO, Bodunde OT, Otulana TO. The impact of presbyopia on the quality of life in a semi-urban community in Southwest Nigeria. *African Vision and Eye Health* 2020; **79**(1).

17. Patel I, Munoz B, Burke AG, et al. Impact of Presbyopia on Quality of Life in a Rural African Setting. *Ophthalmology* 2006; **113**(5): 728-34.

18. The Kenya National Bureau of Statistics. https://www.knbs.or.ke/?wpdmpro=2019-kenya-population-and-housing-census-volume-i-population-by-county-and-sub-county.

19. Rono H, Bastawrous A, Macleod D, et al. Effectiveness of an mHealth system on access to eye health services in Kenya: a cluster-randomised controlled trial. *Lancet Digit Health* 2021; **3**(7): e414-e24.

20. Bastawrous A, Rono HK, Livingstone IA, et al. Development and Validation of a Smartphone-Based Visual Acuity Test (Peek Acuity) for Clinical Practice and Community-Based Fieldwork. *JAMA Ophthalmol* 2015; **133**(8): 930-7.

21. Katibeh M, Sanyam SD, Watts E, et al. Development and Validation of a Digital (Peek) Near Visual Acuity Test for Clinical Practice, Community-Based Survey, and Research. *Transl Vis Sci Technol* 2022; **11**(12): 18.

22. ILO. International Standard Classification of Occupations ISCO-08. 2012. https://webapps.ilo.org/wcmsp5/groups/public/---dgreports/---dcomm/---publ/documents/publication/wcms_172572.pdf.

23. Howe LD, Galobardes B, Matijasevich A, et al. Measuring socio-economic position for epidemiological studies in low- and middle-income countries: a methods of measurement in epidemiology paper. *Int J Epidemiol* 2012; **41**(3): 871-86.

24. O'Donnell O, Doorslaer E, Wagstaff A, Lindelow M. Analyzing Health Equity Using Household Survey Data. A Guide to Techniques and their Implementation: World Bank Institute Development Studies; 2007.

25. Carletto G, Tiberti M, Zezza A. Measure for Measure: Comparing Survey Based Estimates of Income and Consumption for Rural Households. *The World Bank Research Observer,* 2022; **37**(1): 1-38.

26. World Health Organization. Consultation on development of standards for characterization of vision loss and visual functioning (WHO/PBL/03.91). Geneva: World Health Organization, 2003.

27. Galobardes B, Shaw M, Lawlor DA, Lynch JW, Davey Smith G. Indicators of socioeconomic position (part 1). *J Epidemiol Community Health* 2006; **60**(1): 7-12.

28. McCormick I, Kim MJ, Hydara A, et al. Socioeconomic position and eye health outcomes: identifying inequality in rapid population-based surveys. *BMJ open* 2023; **13**(3): e069325.

29. Gandhi M, Ang M, Teo K, et al. A vision 'bolt-on' increases the responsiveness of EQ-5D: preliminary evidence from a study of cataract surgery. *Eur J Health Econ* 2020; **21**(4): 501-11.

30. United Nations. Canberra Group Handbook on Household Income Statistics, Second Edition. Geneva, 2011.

31. Zhang W, Tocher P, L'Heureux J, Sou J, Sun H. Measuring, Analyzing, and Presenting Work Productivity Loss in Randomized Controlled Trials: A Scoping Review. *Value Health* 2023; **26**(1): 123-37.

32. Escorpizo R, Bombardier C, Boonen A, et al. Worker productivity outcome measures in arthritis. *J Rheumatol* 2007; **34**(6): 1372-80.

33. Zhang W, Bansback N, Anis AH. Measuring and valuing productivity loss due to poor health: A critical review. *Soc Sci Med* 2011; **72**(2): 185-92.

34. Miguel E, Kremer M, Hamory J, Walker M. Kenya Life Panel Survey, Round 4 (KLPS-4). V1 ed: Harvard Dataverse; 2023.

35. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics* 1993; **4**(5): 353-65.

Appendix 1: WHO/VFQ20 Questionaire.[26] The six (out of twenty) questions highlighted in green relate to near vision.

General Vision	Overall, how would you rate your eyesight using both eyes – with glasses or contact lenses if you wear them?	Very Good Good Moderate Bad Very Bad
Ocular pain/discomfort	How much pain or discomfort do you have in your eyes (e.g. burning, itching, aching)?	None Mild Moderate Severe Extreme
Distance vision difficulty	Because of your eyesight, how much difficulty do you have in going down steps or stairs?	None Mild Moderate Severe Extreme
Distance vision difficulty	How much difficulty do you have in noticing obstacles while you are walking alone (e.g. animals or vehicles)?	None Mild Moderate Severe Extreme
Glare	How much difficulty do you have in seeing because of glare from bright lights?	None Mild Moderate Severe Extreme
Near vision difficulty	Because of your eyesight, how much difficulty do you have in searching for something on a crowed shelf?	None Mild Moderate Severe Extreme
Colour vision difficulty	How much difficulty do you have in seeing differences in colours?	None Mild Moderate Severe Extreme
Near vision difficulty	Because of your eyesight, how much difficulty do you have in recognizing the face of a person standing near you?	None Mild Moderate Severe Extreme

Near vision difficulty	How much difficulty do you have in seeing the level in a container when pouring?	None Mild Moderate Severe Extreme
Distance vision difficulty	Because of your eyesight, how much difficulty do you have in going to activities outside of the house (e.g. sporting events, shopping, religious events)?	None Mild Moderate Severe Extreme
Distance vision difficulty	Because of your eyesight, how much difficulty do you have in recognizing people you know from a distance of 20 metres?	None Mild Moderate Severe Extreme
Near vision difficulty	How much difficulty do you have in seeing close objects (e.g. making out differences in coins or notes, reading newsprint)?	None Mild Moderate Severe Extreme
Distance vision difficulty	How much difficulty do you have in seeing irregularities in the path when walking (e.g. potholes)?	None Mild Moderate Severe Extreme
Light/dark adaptation	How much difficulty do you have in seeing when coming inside after being in bright sunlight?	None Mild Moderate Severe Extreme
Near vision difficulty	How much difficulty do you have in doing activities that require you to see well close up (e.g. sewing, using hand tools)?	None Mild Moderate Severe Extreme
Role limitations	Because of your eyesight, how much difficulty do you have in carrying out your usual work?	None Mild Moderate Severe Extreme
Social functioning limitations	Because of your eyesight, how often have you been hesitant to participate in social functions?	None Rarely Sometimes Often Very often

Mental well-being	Because of your eyesight, how often have you found that you are ashamed or embarrassed?	None Rarely Sometimes Often Very often
Dependency	Because of your eyesight, how often have you felt that you are a burden on others?	None Rarely Sometimes Often Very often
Mental well-being	Because of your eyesight, how often do you worry that you may lose your remaining eyesight?	None Rarely Sometimes Often Very often

Appendix 2: Household Consumption Questionnaire

Dimension	Sample questions/areas to probe	Response options	Source
A. Household composition			
A.1.Household size	**A.1.1 How many adults (other than yourself) are in your household, "eat from the same pot" and spend X nights or more in an average week/month sleeping in your home?** **A.1.2 How many children (other than yourself) are in your household, "eat from the same pot" and spend X nights or more in an average week/month sleeping in your home?**	Number of adults Number of children	India – Household Consumption Expenditure Survey: 2022-23 Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1 Kenya Integrated Household Budget Survey 2015-2016
A.2 Household characteristics	**A.2 What is the relationship of Adult X/Children X to the household head?**	1. Self 2. Spouse of head 3. Married child 4. Spouse of married child 5. Unmarried child 6. Grandchild 7. Father/mother/father-in-law/mother-in-law 8. Servants/employees/other non-relatives	India – Household Consumption Expenditure Survey: 2022-23 Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1 Kenya Integrated Household Budget Survey 2015-2016
Collect information from A.3 to A.6 for each adult or child living in the household.			
A.3 Household composition - Gender	**A.3 What is the gender of Adult x/Children X?**	1. Male 2. Female 3. Transgender	
A.4 Household composition - Age	**A.4 What is the age of Adult x/Children X?**	Age in years	
A.5 Household composition - Education level	**A.5 What is the education level of Adult x/Children X?**	1. Not literate 2. Below primary 3. Primary 4. Upper primary/middle 5. Secondary 6. Higher secondary 7. Diploma/ certificate course 8. Graduate	
A.5 Household composition - Occupation	**A.6 What is the occupation of Adult x/Children X?**		
B. Dwelling characteristics			
B.1 Housing type	**B.1 What type of the MAIN dwelling does the household live in?**	1. Flat 2. Maisonnette 3. Swahili	India – Household Consumption Expenditure Survey: 2022-23

		4. Shanty 5. Traditional house 6. Other (specify)	Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1 Kenya Integrated Household Budget Survey 2015-2016
B.2 Ownership	**B.2 Does your household own this dwelling (house,flat, shack) do you rent it, or do you live here without pay?**	1. Owns 2. Pays Rent/Lease 3. No rent, with consent of owner 4. Other (specify)	
B.3 Rent/Loan	**B.3 How much per month does household health pay to rent/ pay for the loan this dwelling?**	Amount in local currency	
B.4 Number of rooms	**B.4 How many separate rooms do you have in your house?**	Number of rooms	
B.5 Floor	**B.5 Of what material are the floors made?**	1. Grass/straw/leaves/bamboo etc 2. Cement/RBC/RCC 3. Mud/unburnt brick 4. Tiles/slate 5. Other katcha 6. Other (specify)	
B.6 Roof	**B.6 Of what material are the roof made?**	1. Iron/tin/zinc 2. Grass/straw/leaves/bamboo etc 3. Canvas/cloth 4. Mud/unburnt brick 5. Other katcha 6. Tiles/slate	
B.7 Walls	**B.7 Of what material are the walls made?**	1. Grass/straw/leaves/bamboo etc 2. Mud/unburnt brick 3. Canvas/cloth 4. Timber 5. Burnt brick/stone/lime stone 6. Iron or other metal sheet 7. Cement/RBC/RCC	
B.8 Cooking	**B.8 What is the primary source of energy of the household for cooking?**	1. Firewood and chips 2. Natural gas 3. Kerosene 4. Biogas 5. Electricity 6. No cooking arrangement 7. Others	
B.9 Lighting	**B.9 What is the primary source of energy of the household for lighting?**	1. Electricity 2. Kerosene 3. Other oil 4. Gas 5. Candle 6. No lighting arrangement 7. Others	
B.10 Drinking Water	**B.10 What is the source of drinking water from which most of the drinking water is obtained by the household during last 365 days?**	1. Bottled water 2. Piped water into dwelling	

		3. Piped water to yard/plot 4. Public tap/standpipe 5. Tube well 6. Hand pump 7. Others	
B.11 Toilet	**B.11 What kind of toilet facility does your household use most often?**	1. None 2. Latrine 3. Toilet 4. Portable toilet 5. Other (specify)	
B.12 Ration Card	**B.12 What is the type of ration card possessed by the household as on the date of survey?**	1. Antyodaya Anna Yojana (AAY) 2. Below Poverty Line (BPL) 3. Above Poverty Line (APL) 4. Priority House Holds (PHH) 5. State Food Security Scheme (SFSS) 6. Others 7. No ration card	India – Household Consumption Expenditure Survey: 2022-23
C. Food Items			
C.1. Staples	**C.1 Consumption of cereals and pulses,** **[ITEM] e.g Maize, Millet, Sorghum, Rice, edible oil etc**	Please select the check if procured any [ITEM] given below ration card during the past 30 days? If yes During the last 12 months, how many months did your household purchase [ITEM] using ration card? During these months that you purchased with ration card how much did your household consume in a typical week? (quantity (kgs) and value (local currency)) Has your household consumed [ITEM] during the past 12 months? Yes/No Has your household grown or produced [ITEM] during the past 12 months? Yes/No If No -proceed to items for purchase goods If yes During the last 12 months, how many months was your household consuming [ITEM] that your household grew or produced? (months) During these months that your household grew produced how much of this production did your household	India – Household Consumption Expenditure Survey: 2022-23 Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1 Kenya Integrated Household Budget Survey 2015-2016

		consume in a typical week? (quantity (kgs) and value (local currency))	
		Has your household <u>purchase</u> [ITEM] during the last 7 days? Yes/No If No -proceed to items for gift goods If yes During the last 12 months, how many months did your household purchase [ITEM]? During these months that you purchased How much did your household consume in a typical week? (quantity (kgs) and value (local currency))	
		What is the total amount of the [ITEM] consumed that your household received as a gift in the past 12 months? quantity (kgs) and value (local currency))	
C.2 Vegetables, Fruits, Meat and Dairy, Other Food	**C.2 Consumption of milk & milk products, vegetables, fruits, egg, fish & meat, edible oil, spices, beverages** **[ITEM] e.g egg, tomatoes, apples,salt, sugar, pepper etc**	Please select the check if procured any [ITEM] given below ration card during the past 30 days? If yes During the last 12 months, how many months did your household purchase [ITEM] using ration card? During these months that you purchased with ration card How much did your household consume in a typical week? (quantity (kgs) and value (local currency))	India – Household Consumption Expenditure Survey: 2022-23 Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1 Kenya Integrated Household Budget Survey 2015-2016
		Has your household consumed [ITEM] during the past 12 months? Yes/No	
		Has your household <u>grown or produced</u> [ITEM] during the past 12 months? Yes/No If No -proceed to items for purchase goods If yes	

		During the last 12 months, how many months was your household consuming [ITEM] that your household grew or produced? (months) During these months that your household grew produced how much of this production did your household consume in a typical week? (quantity (kgs) and value (local currency))	
		Has your household <u>purchase</u> [ITEM] during the last 7 days? Yes/No If No -proceed to items for gift goods If yes During the last 12 months, how many months did your household purchase [ITEM]? During these months that you purchased How much did your household consume in a typical week? (quantity (kgs) and value (local currency))	
		What is the total amount of the [ITEM] consumed that your household received as a gift in the past 12 months? quantity (kgs) and value (local currency))	
D. Frequent non-food items			
D.1 Fuel	**Consumption of energy (fuel, light) during the last 30 days**	Has your household consumed/ or produced FUEL during the past 12 months? If Yes Has your household <u>purchase</u> [ITEM] during the last 7 days? Yes/No If No -proceed to items for gift goods If yes During the last 12 months, how many months did your household purchase [ITEM]? During these months that you purchased How much did your household consume in a typical week? (quantity (kgs) and value (local currency)) What is the total amount of the [ITEM] consumed that your household received as a gift in the past 12 months? quantity (kgs) and value (local currency))	India – Household Consumption Expenditure Survey: 2022-23 Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1 Kenya Integrated Household Budget Survey 2015-2016

D.2 Personal and household articles	**Expenditure on toilet articles and other household consumables** **[ITEM] e.g soap, hair shampoo, toothbrush, washing powder, toilet paper etc**	Has your household bought or spent money on any [ITEM] or received it as a gift during the past 12 months? Yes/NO If Yes How much did your household spent for [ITEM] in the past 7 days? How much did your household spend for [ITEM] in a typical month in the past 12 months? What is the value of all [ITEM]that your household received as a gift during the past 12 months?	
D.3 Services	**Expenditure on conveyance, consumer services (excluding conveyance), entertainment, rent and taxes during the last 30 days** **[ITEM] e.g telephone calling card, internet usage, TV decoder charges, transport expenses (bus, train, boat) etc**	Has your household bought or spent money on any [ITEM] or received it as a gift during the past 12 months? Yes/NO If Yes How much did your household spent for [ITEM] in the past 7 days? How much did your household spend for [ITEM] in a typical month in the past 12 months? What is the value of all [ITEM]that your household received as a gift during the past 12 months?	
E. Durables			
E.1 Transportation	**Expenditure for purchase of transport durable goods for domestic use** **[ITEM] e.g bicycles, scooters, cars, motor boats etc**	Has your household bought or spent money on any [ITEM] or received it as a gift during the past 12 months? Yes/NO If Yes How many [ITEM] did your household acquire in the past 12 months, through gift and purchase? Did your household purchase it, or receive it as a gift or by barter? If Purchase - How much did your household pay in total for all the [ITEM] that you purchased in the past 12 months? If gift/barter – What was the total value of all [ITEM] that you received as a gift or by barter in the past 12 months?	Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1

E.2 Household durable goods for domestic use	**Expenditure for purchase of furniture, cooking and other household appliances** **[ITEM] e.g tables, beds, chairs, mosquito nets, refrigerator etc**	Has your household bought or spent money on any [ITEM] or received it as a gift during the past 12 months? Yes/NO If Yes How many [ITEM] did your household acquire in the past 12 months, through gift and purchase? Did your household purchase it, or receive it as a gift or by barter? If Purchase - How much did your household pay in total for all the [ITEM] that you purchased in the past 12 months? If gift/barter – What was the total value of all [ITEM] that you received as a gift or by barter in the past 12 months?	Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1
F. Non -frequent non-food items			
F.1 Clothing, footwear and bedding	**Expenditure for clothing, footwear and bedding during the last 365 days** **[ITEM] e.g women´s clothing, cloth, tailoring expenses, linens (sheets, blankets, towels) etc**	Has your household bought or spent money on any [ITEM] or received it as a gift during the past 12 months? Yes/NO If Yes How much did your household spend on [ITEM] in the past 7 days? How much did your household spend on [ITEM] in a typical month in the past 12 months? If Gift What is the value of all the [ITEM] that your household received as a gift during the past 12 months?	India – Household Consumption Expenditure Survey: 2022-23 Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1 Kenya Integrated Household Budget Survey 2015-2016
F.2 Medical expenses	**Expenditure in doctor, hospital and clinic fees**	Has your household bought or spent money on any [ITEM] or received it as a gift during the past 12 months? Yes/NO If Yes How much did your household spend on [ITEM] in the past 7 days? How much did your household spend on [ITEM] in a typical month in the past 12 months? If Gift What is the value of all the [ITEM] that your household received as a gift during the past 12 months?	India – Household Consumption Expenditure Survey: 2022-23 Kenya – Kenya Life Panel Survey Round 4 (KLPS-4) E-Plus Module Wave 1 Kenya Integrated Household Budget Survey 2015-2016

Appendix 3: Data collection tools for employment status, income, presenteeism, absenteeism:

Dimension	Sample questions/areas to probe	Response options	Source
A. Employment status			
A.1. Main Activity at present	**A.1.1. During the past year, did you work for someone else for pay, for one or more hours?** *If No* -	**Yes/No** If yes, go to B.1	
	A.1.2. Did you run or do any kind of business, farming or other activity to generate income? *If No* -	**Yes/No** If yes, go to F.1	
	A.1.3. Did you help in a family business or farm? *If No* -	**Yes/No** If yes, go to F.1	
	A.1.4. Did you do anything to find a paid job? *If No* -	**Yes/No** If yes, go to E.1	ILO LFS
	A.1.5. Which of the following options best describes what you are mainly doing at present? Note: The first question in general, excludes persons who worked as self-employed, for example in a business or market- oriented activity with the intention of earning a profit, whether as employer or own-account worker, or helping in a family business.	1. Studying or training 2. Engaged in household or family responsibilities. 3. Farming or fishing to produce food for the family. 4. Retired or pensioner. 5. With a long-term illness, injury or disability (excluded) 6. Doing volunteering, community, or charity work 7. Engaged in cultural or leisure activities. Please proceed to G.1. (except for option 3 – which should go to C.1)	
B. For those in paid employment			
B.1. Characteristics of Main Job	**In your job, what kind of work you do?**	Occupational title, if any *ISCO CODE* *(International Standard Classification Occupation)* Please proceed to B.2	ILO LFS
B.2. Characteristics of Main Job	**Do you work?**	1. As an [employee] 2. In (your/his/her) own business activity 3. Helping in a family or household business 4. As an apprentice, intern 5. Helping a family member who works for someone else. Please proceed to B.3	ILO LFS

B.3. Characteristics of Main Job	**Which of the following types of pay do you receive for this work?**	1. A wage or salary 2. Payment by piece of work completed. 3. Commissions 4. Tips 5. Fee for services provided 6. Payment with meals or accommodation 7. Payment in products 8. Other cash payment (specify) Please proceed to C.1	ILO LFS
C. Income (from employment and self-production)			
C.1. Income	**What is your main income source?**	1. Salary/Wage 2. Other forms of profit related pay (tips, bonuses, commission) 3. Self-employed - Income from own agricultural production 4. Self-employed – trading in non-agricultural products for sale. 5. Free or subsidised goods and services from an employer 6. Family support Please proceed to C.2	CSSRI-EU
C.2. Income	**What is your total personal gross/net income from employment and/or self-employment?** *(Note: if gross income not known, please give net income, i.e. after tax and other deductions. For self-employment production the amount to record is the income earnt, minus the costs for making or growing the product)*	Specify amount and whether Weekly / Monthly / Yearly Please proceed to D1	CSSRI-EU
D. Presenteeism			
D.1. Presenteeism	**During the past 4 weeks, how much did your PROBLEM with VISION affect your productivity while you were working?** [*Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual]*	Scale 0 to 10 [*If PROBLEM affected your work only a little, choose a low number. Choose a high number if PROBLEM affected your work a great deal.]* Please proceed to G.1	WPAI - SHP
D.2 Absenteeism	**D.2.1 During the past seven days, how many hours did you miss from work because of problems associated with your PROBLEM?** [Include hours you missed on sick days, times you went in late, left early, etc., because of your PROBLEM. Do not include time you missed to participate in this study.]	____ hours	
	D.2.2 During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?	____ hours	
	D.2.3 During the past seven days, how many hours did you actually work?	____ hours	

E. For those who said they were trying to find a job			
E.1. Search Job	For how long have you been without work and trying to find a paid job or start a business?	Less than 1 month / 1 month to < 3 months / 3 months to < 6 months / 6 months to < 12 months / 1 year to < 2years / 2 years or more Please proceed to E.2	ILO LFS
E.2. Search Job	During the last four weeks, that is from [DATE] up to [last DAY/yesterday] did you do anything to find a paid job/ start a business?	Yes/No Please proceed to WHO/VFQ20	
F. For those who said they run or help in a family business or farm			
F.1. Agricultural Work	Last week did you do any work in…	1. Farming / Rearing farm animals – if yes, go to F.2 2. Fishing or fish farming – if yes, go to F.2 3. Another type of business – if yes, go to B.1 4. None of the above – if yes, go to A.1.4.	ILO LFS
F.2. Agricultural Work	Thinking about the work you do in [farming, rearing animals, and/or fishing], are the products from this work intended…	1. Only for sale - if yes go to B.1 2. Mainly for sale - if yes go to B.1 3. Mainly for family use - if yes go to F.3. 4. Only for family use - if yes go to F.3.	ILO LFS
F.3. Agricultural Work	Were you hired by someone else to do this work?	Yes/No If yes, please proceed to B.1. If no, please proceed to A.1.4.	
G. Self-reported income insufficiency			
G.1. Food adequacy	When you think about the food in your household, would you say you have	1. Less than adequate food for the needs of your household 2. Just adequate food for the needs of your household 3. More than adequate food for the needs of your household Please proceed to G.2	28
G.2. Income sufficiency	When you think about the income in your household, would you say it is	1. Not enough to cover our needs, we must borrow 2. Not enough to cover our needs, we use savings 3. Just enough to cover our needs 4. Enough to cover our needs, we are able to save a little 5. Enough to cover our needs, we are building savings' Please proceed to G.3	28
G.3. Economic ladder question	Please look at this ladder (5 step ladder pictured). If the bottom step (1) of the ladder represents the people who are poorest in your community, and the top step (5) represents the people who are richest, on which step of the ladder do you feel your household stands on?	Record a number between 1 and 5 Please proceed to WHO/VFQ20	28

References:
ILO LFS: International Labour Organisation Labour Force Surveys - https://ilostat.ilo.org/resources/lfs-resources/
CSSRI-EU: Client Sociodemographic and Service Receipt Inventory - CLIENT SERVICE RECEIPT INVENTORY (dirum.org)
WPAI – SHP: work productivity and activity impairment[35]

Appendix 4: Health related Quality of life generic questionnaire: EuroQol 5 Dimension (EQ5D-5L) with vision bolt on (self-complete version).[29]

Domains	Response options	Source
Please select the One Box (option) that best describes your health today		
Mobility	1. I have no problems in walking about 2. I have slight problems in walking about 3. I have moderate problems in walking about 4. I have severe problems in walking about 5. I am unable to walk about	EuroQol
Self-Care	1. I have no problems washing or dressing myself 2. I have slight problems washing or dressing myself 3. I have moderate problems washing or dressing myself 4. I have severe problems washing or dressing myself 5. I am unable to wash or dress myself	EuroQol
Usual Activities (e.g work, study, housework, family, leisure activities)	1. I have no problems with performing my usual activities 2. I have slight problems with performing my usual activities 3. I have moderate problems with performing my usual activities 4. I have severe problems with performing my usual activities 5. I am unable to do my usual activities	EuroQol
Pain/ Discomfort	1. I have no pain or discomfort 2. I have slight pain or discomfort 3. I have moderate pain or discomfort 4. I have severe pain or discomfort 5. I have extreme pain or discomfort	EuroQol
Anxiety/Depression	1. I am not anxious or depressed 2. I am slightly anxious or depressed 3. I am moderately anxious or depressed 4. I am severely anxious or depressed 5. I am extremely anxious or depressed	EuroQol
Vision – Bolt on	1. I have no problems seeing 2. I have slight problems seeing 3. I have some problems seeing 4. I have severe problems seeing	29

	5. I have extreme problems seeing	

Reference: Digital demo versions – EQ-5D (euroqol.org)

Appendix 5: The conceptual definition of household income *(established by the ICLS (ILO 2004), and adopted in the UN Canberra Group Report 2011.[30])*

"Household income consists of all receipts whether monetary or in kind (goods and services) that are received by the household or by individual members of the household at annual or more frequent intervals, but excludes windfall gains and other such irregular and typically one-time receipts.

Household income receipts are available for current consumption and do not reduce the net worth of the household through a reduction of its cash, the disposal of its other financial or non-financial assets or an increase in its liabilities.

Household income may be defined to cover: (i) income from employment (both paid and self- employment); (ii) property income; (iii) income from the production of household services for own consumption; and (iv) current transfers received."

References:

http://www.ilo.org/global/statistics-and-databases/standards-and-guidelines/resolutions- adopted-by-international-conferences-of-labour-statisticians/ WCMS _087503/lang-- en/index.htm

https://pubdocs.worldbank.org/en/102301605019744632/Canberra-Handbook.zip