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Protocol for a platform trial of interventions to equitably improve access to community eye services in Botswana, India, Kenya and Nepal

Submission date	**Recruitment status**	[X] Prospectively registered
31/08/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/02/2025	Eye Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

School and community-based eye screening programmes are running in Botswana, India, Kenya and Nepal. Preliminary data suggests that only 30-50% of people referred for onward care actually attend their appointments. They may not be able to access their local centre, afford transport, or face any number of other barriers to accessing the care they need. In a previous study we spoke to non-attenders - or in the case of school-based programmes, their parents /guardians - to explore the barriers that prevent them from attending their referral appointments. This was done in order to elicit their ideas for ways that programmes could be modified to make it easier for people to attend. These suggestions will be presented to stakeholders and programme managers within the eye health sector in each country to turn them into interventions and programme modifications that can be tested. In this current study, we plan to set up a platform trial in each country to run a series of randomised trials to test each of these interventions and service modifications in turn. The overall aim is to identify service modifications that produce the largest improvements in attendance. The process of engaging with non-attenders and coming up with new interventions/service modifications is ongoing, so we don't yet know exactly what we will be testing. However, each intervention will be tested in the same group of people (those referred for eye care) and we will use the same outcome (did they attend?) and perform the same analysis, looking at whether people from groups with the lowest attendance rates benefit disproportionately.

Who can participate?

Community members aged 5 years old and over who are referred to the local eye service for further assessment/treatment

What does the study involve?

This platform trial protocol sets the population, outcome, and statistical approach that will be used to run a series of individual studies that each test different interventions – as yet undefined – that will be developed based on the suggestions of intended service users in a series of related qualitative studies. In each setting, the population will be people found to have an eye health need at screening and referred to the local triage clinic. The primary outcome will

be the proportion of people from the population group with the worst attendance at baseline who attend the triage clinic. The secondary analysis will examine overall mean attendance across all groups. Then serial study will run in each country, each testing different interventions against a control. Each study will be registered, and undergo ethical approval locally.

What are the possible benefits and risks of participating?
The primary aim of this platform trial is to improve equity. The study focuses on improving attendance rates in the left-behind group. If an intervention is found to increase attendance among the left-behind group, whether there has been an impact on the overall group's mean attendance rate will also be investigated. This is to hedge against adopting an intervention that improves access for the left-behind group but leads to a large overall fall in attendance across the entire programme.

Participation is not expected to pose undue risks. As and when new interventions are selected for testing, they will be externally reviewed by an independent national ethics committee.

Where is the study run from?
London School of Hygiene & Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
January 2023 to December 2025

Who is funding the study?
1. Wellcome Trust (UK)
2. National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Luke Allen, luke.allen@lshtm.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Protocol for a platform trial of interventions to equitably improve access to community eye services Botswana, India, Kenya & Nepal

Study objectives
The study team have engaged with people who have been referred to community eye services but have not been able to attend their appointments to garner their ideas for ways to improve access. This platform trial will iteratively test a series of interventions selected with the intended service beneficiaries to increase attendance rates in community-based eye screening programmes in Botswana, India, Kenya and Nepal. Programme managers in each country are interested in identifying incremental gains from multiple, small service modifications to deliver iterative improvements in attendance. The hypothesis is that the intended service user-derived interventions will increase access to services.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/01/2024, LSHTM ethics committee (LSHTM, Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; rgio@lshtm.ac.uk), ref: 29549

Study design
Pragmatic platform randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Undifferentiated eye problems identified by community-based screeners using the Peek Vision screening app.

Interventions
This is a platform architecture for RCTs, embedded within local screening programmes so further eligibility criteria will be set locally. Interventions will be suggested by intended service

users from groups that face the highest barriers to accessing care (as identified in previous sister studies in each setting). The intention is to continuously improve attendance rates with the most significant gains focused on left-behind groups. All interventions will be low-risk public health /service modifications.

This platform trial forms the testing element of a broader continuous improvement model called 'IM-SEEN' (IMprovement Studies for Equitable and Evidence-based iNnovation). The model has already been integrated into Peek programmes. The Peek app is the mature and validated app-based screening system developed by Peek Vision – an LSHTM not-for-profit spin-out. In this continuous improvement approach, data collectors gather contact details and sociodemographic data from those found to have an eye problem prior to referring them. This means that programme managers using Peek have a complete record of who has not attended the clinic on the appointed day, and they are able to identify the population group with the lowest attendance. Next, the programme leadership team can engage with representatives of left-behind groups to elicit barriers and identify potential service improvements that would reduce non-attendance – such as changing the clinic location or amending the wording of the SMS reminder messaging. The final step is to use embedded RCTs to test these proposed improvements with new referrals. Effective interventions will be adopted across the programme. Further information on the broader IM-SEEN approach has been published elsewhere.

Intervention Type
Other

Primary outcome(s)
The proportion of people from the population group attending the triage clinic with the lowest attendance, measured using attendance data collected by staff in the Peek app when people check in at baseline

Key secondary outcome(s))
The proportion of people attending the triage clinic on their appointed date across the entire population, measured using attendance data collected by staff in the Peek app when people check in at baseline

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Community members screened using the Peek Vision app and referred to the local eye service for further assessment/treatment
2. Aged 5 years old and over

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
5 years

Sex
All

Key exclusion criteria
Not eligible for local screening programme

Date of first enrolment
01/02/2024

Date of final enrolment
01/05/2025

Locations

Countries of recruitment
Botswana

India

Kenya

Nepal

Study participating centre
Nepal Netra Jyoti Sangh
Bagmati Marg
Kghatmandu
Nepal
44600

Study participating centre
Dr. Shroff`s Charity Eye Hospital
5027, Kedarnath Ln
Opposite DAV School
Daryaganj
Delhi
India
110002

Study participating centre

University of Botswana
4775 Notwane Rd
Gabarone
Botswana
None available

Study participating centre
KEMRI
K N H, Mbagathi Rd
Nairobi
Kenya
None available

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a non-publicly available repository to protect anonymity. Summary data will be published in a journal article. Further anonymous data will be available upon request from Dr Luke Allen at luke.allen@lshtm.ac.uk.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/02/2025	03/02/2025	Yes	No
Protocol file	version 2		21/09/2023	No	No