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Enhanced patient counselling and enhanced SMS reminder messages to improve access to community-based eye care services in Meru, Kenya

Submission date
14/01/2024

Recruitment status
No longer recruiting

Registration date
02/02/2024

Overall study status
Ongoing

Last Edited
02/02/2024

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
The Vision Impact Project (VIP) is a major community-based eye screening programme running in Kenya with the aim of promoting eye health for all. Previous studies embedded within the programme in Meru County have found that a third of people who are screened require care for an eye problem, however only half of these people manage to access outreach treatment clinics. Access varies between sociodemographic groups, and only 30% of young adults (18-44 years old) were able to access care. In previous mixed-methods work researchers conducted interviews and surveys with non-attenders from this 'left-behind' group to explore what could be done to improve access. The aim of this study is to test whether the provision of enhanced counselling and reminder SMS messages is associated with a higher probability of accessing care.

Who can participate?
Adults aged over 18 years screened by the Vision Impact Project in Meru County, Kenya and referred to a local treatment outreach clinic to receive further eye care.

What does the study involve?
This study will be embedded within the Vision Impact Project (VIP) that is operating in Meru County, Kenya. As the study is pragmatic, the responsibility for recruiting screening participants lies exclusively with local programme managers. Programme implementers will enrol participants by seeking consent from all those who require referral for further assessment and care.
Participants will be randomly allocated to either the intervention group (enhanced counselling and reminder SMS) or the control group (usual care). The intervention is a script and reminder SMS message that has been developed in line with suggestions from intended service beneficiaries from the group least likely to attend and includes the provision of information around clinic opening times, services, costs, and the importance of attending, via in-person

counselling at the point of referral and three reminder SMS messages. This will be compared against usual care: standard in-person counselling at the point of referral and three standard SMS reminder messages.

What are the possible benefits and risks of participating?
The primary aim is to improve eye clinic attendance rates in the group found to have the lowest attendance overall. The researchers also aim to investigate if the intervention improves overall attendance. This is to hedge against adopting an intervention that improves access for specific subgroups but leads to a large overall fall in attendance across the entire programme. Participation is not expected to pose undue risks and this specific intervention has been reviewed by various ethics committees.

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)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
29549

Study information

Scientific Title
Enhanced patient counselling and enhanced SMS reminder messages to improve access to community-based eye care services in Meru, Kenya: an individual-level, two-arm, superiority randomized controlled trial within an adaptive platform trial

Study objectives
The provision of additional information around clinic opening times, services, costs, and the importance of attending eye clinic appointments via in-person counselling at the point of referral and via reminder SMS messages increases the probability of accessing treatment outreach clinics compared to standard care.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 10/01/2024, London School of Hygiene & Tropical Medicine Ethics Committee (Room LG36, Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7927 2221; ethics@lshtm.ac.uk), ref: 29549

2. Not yet submitted 18/12/2023, Kenya Medical Research Institute: Scientific and Ethics Review Unit (K N H, Mbagathi Rd, Nairobi, N/A, Kenya; +254 (0)722205901; seru@kemri.org), ref: Reference number not provided

Study design
Bayesian pragmatic superiority two-arm individual-level randomized controlled trial embedded within the Vision Impact Project screening programme in Meru, Kenya

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Undifferentiated eye problems identified by community-based screeners using the Peek Vision screening app

Interventions

This trial is part of an adaptive platform that 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 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 (ISRCTN53970958).

The researchers will use computer-generated random numbers to generate the allocation sequence and assign all consented, referred participants to intervention arms, with equal numbers of participants in each arm. The allocation sequence will be generated within the Peek system in real-time, as participants are referred. As human trial managers are not involved in allocation there is no need for concealment.

The intervention for this RCT is a script and reminder SMS message that have been developed in line with suggestions from intended service beneficiaries from the groups least likely to attend. More specifically, this includes the provision of information about clinic opening times, services, costs, and the importance of attending, via in-person counselling at the point of referral and three reminder SMS messages. Participants randomised to the control group will receive standard in-person counselling at the point of referral and three standard SMS reminder messages.

Adults aged 18-44 years old have been identified at baseline as part of the 'identify' stage of the IM-SEEN process. A focus on left-behind groups is important to programme managers who are trying to close gaps, extend health service coverage, and ensure that their services do not exacerbate existing inequalities. When referred participants check in at ophthalmic clinics, attendance status is recorded by administrative staff using the Peek app, which automatically updates a central database that holds records of each participant's eye care need, sociodemographic characteristics, arm allocation, and attendance status at the ophthalmic clinic on the appointed date. A Bayesian algorithm will review the attendance data for every referred participant every 72 hours and calculate the probability of attendance within each arm. The researchers' modelling has estimated that 100 people will be referred every 72 hours.

If this intervention is found to increase attendance among the left-behind group, the researchers also want to check whether there has been an impact on the overall mean attendance rate. 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. The researchers will use absolute percentage differences in attendance for comparisons between the left-behind and general populations exposed to the intervention.

This trial is embedded within routine screening programmes and uses stopping rules to determine trial end:
1. There is a >95% probability that one arm is best, i.e. the difference between the two arms is >0%
2. There is a >95% probability that the difference between the best arm and the arms remaining in the trial is <1%
The researchers will check if any of the stopping rules have been met every 7 days, starting from the date of the first referred person's clinic appointment.

Intervention Type
Behavioural

Primary outcome measure
The proportion of people attending the triage clinic on their appointed date among adults aged 18-44 years old, measured using attendance data collected by staff when people check in for the duration of the study

Secondary outcome measures
The proportion of people attending the triage clinic on their appointed date across the entire population, measured using attendance data collected by staff when people check in for the duration of the study

Overall study start date
01/01/2023

Completion date
01/12/2025

Eligibility

Key inclusion criteria
Adults (>18 years) screened by the Vision Impact Project in Meru, Kenya and referred to a local treatment outreach clinic to receive further eye care

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
As they are using stopping rules, the researchers will not pre-specify a minimum sample size or estimate effect sizes for the intervention arms. Instead, participants will be continually recruited until sufficient data accrue to trigger one or more of the other stopping rules. Based on extensive scenario modelling, the researchers have decided to use the following stopping rules for this trial: 1. There is a >95% probability that one arm is best, i.e. the difference between the two arms is >0%. 2. There is a >95% probability that the difference between the best arm and the arms remaining in the trial is <1%.

Key exclusion criteria
Not eligible for local screening programme and outside of target population characteristics

Date of first enrolment
18/02/2024

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Kenya

Study participating centre
Kenya Medical Research Institute, KEMRI
K N H, Mbagathi Rd
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Kenya
Not Applicable

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

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Sponsor type

University/education

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ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research organisation

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 Research, NIHR

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

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

Intention to publish date
01/12/2025

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 (luke.allen@lshtm.ac.uk). The date when data will be available is currently not known. The researchers will share anonymised data showing the attendance odds for each of the sociodemographic groups. Consent is required to share anonymised data. Informed consent is being sought. Names will not be used in the analysis or publication of data. Data will be aggregated so that individuals cannot be identified.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			31/01/2024	No	No