

INFORMED CONSENT FORM

Title: Assessing the Effect of Informative Photo Referral Cards on Access to Eye Care Services Within a Community-Based Program in Kwale County: A Randomized Controlled Trial

INVESTIGATORS

Name	Title	Institution
Prof. Andrew Bastawrous	Chief Investigator	London School of Hygiene and Tropical Medicine (LSHTM)
Dr. Luke Allen	Co-Principal Investigator	LSHTM
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Dr. David Macleod	Co-Investigator	LSHTM
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Dr Jacqui Ramke	Co-investigator	LSHTM
Prof. Matthew J. Burton	Co-Investigator	LSHTM

Study location: Kwale County, Kenya

You have been invited to participate in this research study because you were referred to a local treatment outreach centre after you received eye health screening. This informed consent form explains the important things you should think about before deciding to join the study. Please ask questions about any of the information before you decide whether to participate.

Voluntary Consent: You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. You will not have to provide consent to participate in and benefit from the screening programme. You may decline to answer as many questions as you wish. There are no penalties, and you will not lose anything if you decide not to join or if after you join, you decide to quit or not answer some questions.

Purpose of the research: Blindness is preventable through access to quality eye care services. There exist cheap solutions to this problem, however, many people do not have adequate access to eye care services. The aim of this research is to see if an informative photo referral card improves attendance for eye health services. This card will include information about the available eye health services, their costs, the benefits of clinic attendance, and the clinic's location. In addition, we will take your photo with a phone, print it, and attach it to the referral card. The photo will be immediately deleted from the phone. We will compare this new method of referring patients with the current method, as described below.

Assignment to a group: If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping



a coin). There is no way of knowing which group you will be assigned to. You will have an equal chance of being placed in either group. Neither you nor the person screening you can choose what group you will be in. You will be told which group you are to get.

For Group 1 (Intervention arm): If you are picked by chance to be in Group 1, you will receive an informative photo referral card, verbal counseling at the point of referral, and SMS reminders today, the day before the appointment, and on the appointment day.

Group 2 (control arm): If you are randomized to Group 2, you will receive verbal counselling and SMS reminders today, the day before the appointment, and on the appointment day.

No matter which group you are assigned to, you will receive all necessary services provided by the Vision Impact Project at the outreach clinic.

Other procedures. We will collect your attendance data from the outreach clinic. This data is collected by staff when people check in. We will use this data to assess whether attendance rates are higher among those in the group that receive the informative photo referral card (Group 1) compared to those who do not receive this card (Group 2).

Duration of participation: Your participation in the study today will last 30 Minutes.

Risks. You will not be exposed to any risks whilst participating in this study. Should you face any discomfort you are free to withdraw from the study any time. This will not affect the services you receive from the Vision Impact project.

Benefits. If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will help benefit the ministry of health and relevant partners in planning for better delivery of eye care services.

Confidentiality: You will be given a unique number. We will publish our findings in a research paper and an online place where we keep and share research information, but your personal information such as your name, date of birth, address, phone number or any other identifying information will not be included. We will only include the unique number we will have given you.

Reimbursement: There will be no form of payment given for participating in this interview.

Contact: If you have any questions, you can ask anyone from our team now or later. If you have questions later, you may contact Sarah Karanja from Kenya Medical Research Centre, Phone number 0754 232 232. This research has been reviewed and approved by the Scientific Ethical Review Unit (SERU). If you have any questions about your rights as a research participant, you may contact: The Head, KEMRI Scientific and Ethics Review Unit, Post Office Box Address 54840-00200, City Square, Nairobi. Telephone: 0717719477; Email: seru@kemri.go.ke

CERTIFICATE OF CONSENT

Please read the statement below and indicate whether you consent.

"I confirm that I have understood the information provided about the research study that looks at ways to help more people go to eye health treatment clinics.". I have had the opportunity to consider the information, ask questions and have these questions answered satisfactorily. I understand that my information, without my name, might be shared with other researchers or put online where anyone can see it, but no one will know it is about me. . I understand that my participation is voluntary and that I am free to withdraw at any time without any given reason. I understand that my decision will not affect the care that I receive. I agree to take part in the study"

Name of Participant (*printed*)

Signature/Thumbprint

Date

Name of Person taking consent

Signature

Date

Consent by impartial witness (Witness only if required if participant is unable to read or write)

"I confirm that I have explained the information provided about the research study accurately, to the participant in Swahili or English. I confirm that this information was understood to the best of my knowledge by the participant and that he/she has freely given their consent to participate in the presence of the above-named impartial witness".

Name of Impartial Witness
(if required)

Signature

Date

One copy of this informed consent document must be provided to the participant, and one copy must be kept for study records.