Participant Information Sheet: Main trial

Artificial Intelligence Supported Diabetic Retinopathy Screening in Tanzania

We'd like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about 10 minutes. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.

Then we give you more detailed information about the conduct of the study.

Please ask if anything is unclear.

Summary of Research Project

We want to investigate whether using a new automated system to screen for diabetic retinopathy provides a better service than the current system. We hope that this will help improve diabetic eye screening services for patients such as yourself.

The project will be run within the Kilimanjaro Diabetic Programme, which you are already registered with. This programme screens people with diabetes for diabetic retinopathy, a potentially blinding complication of diabetes. We want to test whether a new system that automates the interpretation of the photographs of the back of your eye (the retina), which are taken during screening improves the service.

This new system would enable us to give you your result immediately after the photograph is taken. We can then answer any questions you may have about your eyes and follow-up recommendations at the same time.

You do not have to do anything different to what normally happens when your eyes are screened. We will collect the same information as usual. Some participants in the project will get their result straight away and some as usual, 2-3 weeks after screening.

The study will take place across the whole of Kilimanjaro and Arusha regions and will last for about 2 years. There are no risks to your health in taking part as eye photography is safe and non-invasive.

Background to the Research Project

The purpose of this research project is to try and improve diabetic eye screening in Tanzania. Diabetic retinopathy is a potentially blinding complication of diabetes. However, if it is detected and treated at an early stage, vision loss can often be avoided.

A screening service for diabetic retinopathy has been running in the Kilimanjaro region for over 10 years, but there are problems with the system and it does not work as well as we would like it to.

We want to test whether using an automated artificial intelligence system to screen for diabetic retinopathy will improve the service and help people such as yourself access eye care services and treatment.

What would taking part involve?

If you agree to participate in the study, we will collect exactly the same information from you as would be collected during routine diabetic eye screening. This includes your name, contact details and the village where you live. We will also measure your vision, blood sugar levels and BP and take a photograph of the back of your eye (the retina). The back of your eye, what is called the retina, is the bit of the eye that can

become damaged from diabetes. All the information we would collect in the research project are all collected during routine diabetic eye screening.

The intervention that we are testing automates the analysis of the photograph of the back of your eye and gives a result quickly, within about 1 minute. This will enable us to give you your result at the time of screening and give you advice there and then.

This is what might be different for you if you take part in the study.

However, not all people enrolled in the study will get their result immediately. We understand this might be frustrating if others know their result right away and you do not, but this is the best way for us to test if this new system really is better.

Who will have access to my data?

The study team and the diabetic eye screening team will have access to your personal information.

We plan to keep the photographs of the back of your eyes at the end of the study and may use them in other research studies to further improve health services. It is not possible to identify individuals from the photographs of the back of the eye and any data that is used in the future will be completely anonymised.

What are the possible benefits of taking part?

The benefits of taking part are that you are helping to improve diabetic eye care services in Tanzania. We hope that this project will contribute to the improvement of diabetic eye screening in Tanzania and help prevent people losing vision from diabetic retinopathy.

You may also benefit from taking part in the study by receiving your result on the day of screening.

What are the possible risks of taking part?

There are no risks to your health or eye health from taking part in this research project. Retinal photography is safe and non-invasive and poses no risk to your eyes.

As is the case in all diabetic eye screening programmes, your pupils will need to be dilated before the pictures can be taken. Pupil dilation can last for several hours and can cause blurred vision; we therefore advise you not to drive after having your pupils dilated. In addition, pupil dilation can cause some mild discomfort and stinging for 5 seconds are so when the drops are put into your eyes..

Will my information be kept confidential?

Yes.

All personal information we will collect during the study is routinely collected during diabetic eye screening events. This information will be kept on a secure computer in a locked office at Kilimanjaro Christian Medical Centre. No one other than the study team and the diabetic eye screening team will have access to your personal data.

When the information collected during screening is analysed by the research team all personal identifiable information will be removed.

We plan to keep the retinal photographs and other anonymized data at the end of the study. These anonymized data may be used in future research studies to further improve health services. It will not be possible to identify you from these data.

What if something goes wrong?

We do not anticipate any participant harm in the study. Eye screening is safe and non-invasive and in the 11 years that the screening programme has been running in the Kilimanjaro region no patient safety issues have been recorded.

However, if you are unhappy with any aspect of the study you are able to complain to the following persons. In the first instance, you should ask to speak to the researchers who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting any of the persons listed at the bottom of this information sheet.

Can I withdraw from the study and what will happen to my personal information if I do withdraw?

You are free and able to withdraw from the study at any time. If you chose to withdraw, we will erase all information we have collected from you in relation to the study. The diabetic screening team will continue to hold your information so they are able to monitor your diabetic retinopathy.

What will happen to the results of this study?

We plan to publish the results of this research in medical journals. This will enable other doctors and eye care professionals to learn from the study to improve diabetic eye screening services in other regions of Tanzania and other countries. No personal information at all will be included in any publications of the research.

Who has reviewed the study?

Prospective research such as this is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by (1) the London School of Hygiene and Tropical Medicine Research Ethics Committee, (2) KCMC Ethics Committee and (3) National Institute of Medical Research in Tanzania.

Who is organising and funding this study?

The London School of Hygiene and Tropical Medicine in partnership with the Kilimanjaro Christian Medical Centre are organising and running this study.

The study is funded by the British Council for the Prevention of Blindness, Christian Blind Mission and the Sir Halley Stewart Trust. The individuals leading the project have no conflicts of interest and are not being paid anything above their normal salaries to take part in the research.

Consent Process

If, having read and discussed this participant information sheet, you are happy to be involved in our research study a nurse will ask you to sign the consent form. The nurse will then also sign the consent form and provide you with a copy of it and this participant information sheet.

Further information and contact details

General information about research, diabetes and diabetic retinopathy: The medical team at your diabetic clinic team will be able to answer any questions you have about diabetes and diabetic retinopathy. There are also posters displayed in the diabetic clinic providing more information.

Specific information about this research study: Members of the study team will be very happy to answer any questions you may have about this research. You can also contact the following persons:

Mr William Makupa, at +255 27 275 4890
Dr Charles Cleland, at +44 20-7636-8636 or charles.cleland@lshtm.ac.uk

Advice as to whether I should participate: The diabetic clinic doctor and nurse can provide with you independent advice as to whether you should participate in this research. They are not involved in the research project.

Who can I approach if I am are unhappy with the study: If you are unhappy with any aspect of the study please speak to a study team member in the first instance. If they do not satisfactorily address your concerns then please contact:

Kilimanjaro Christian Medical Centre Ethics Committee, at +255 272754377. Their physical address is: KCM College, Opposite Tumaini Restaurant.