

# The Kilimanjaro Diabetic Programme: the development of a sustainable regional eye health screening program to prevent blindness among diabetic patients due to diabetic retinopathy

<b>Submission date</b> 23/01/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/05/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

N/A

# Study information

## Scientific Title

A randomised controlled trial of screening strategies for diabetic retinopathy in Kilimanjaro region: a randomised controlled trial of the effect of a screening camera on uptake of screening for diabetic retinopathy (phase I) and a randomised controlled trial of the effect of mobile telephone text reminders of screening appointments on uptake of screening for diabetic retinopathy (phase II)

## Study objectives

Diabetes is a growing problem in Sub Saharan Africa. The number of diabetics in Eastern Africa is expected to reach 1.4 million by 2025. A high proportion of these patients develop sight threatening diabetic retinopathy. Uptake of screening for retinopathy is very poor throughout the region. We hypothesise that taking screening to the patients in diabetic clinics rather than asking them to go to an eye clinic and telephoning them prior to the screening appointment will lead to improvements in the uptake of screening.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Tumaini University (Tanzania) Ethics Committee approved in January 2009 (ref: 241)

## Study design

Single centre randomised interventional screening trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Diabetes mellitus, diabetic retinopathy

## Interventions

Phase I:

1. Intervention group: A digital diabetic retinopathy screening camera will be placed in the diabetic clinic at KCMC
2. Control group: patients will be advised to go to the eye clinic at KCMC for a dilated screening examination by an ophthalmologist
3. All patients will receive 3 information leaflets on diabetic retinopathy and be counselled by the health workers in the diabetic clinic that they should have screening for diabetic retinopathy
4. Visual acuity measurement will be performed and dilating drops installed by the screening team

Phase II:

1. The retinopathy screening camera will go to all district diabetic clinics twice in the 6 month intervention period
2. Patients registered at these clinics will all be advised by clinic staff to attend for retinopathy

screening

3. The intervention group will receive a text message by mobile phone advising them of the date of the screening and inviting them to come

### **Intervention Type**

Other

### **Phase**

Phase I/II

### **Primary outcome(s)**

Uptake of screening for diabetic retinopathy, measured in August 2011

### **Key secondary outcome(s)**

Measured in January 2012:

1. Prevalence of diabetic retinopathy in urban and rural diabetic patients in Kilimanjaro region
2. Prevalence of cataract in urban and rural diabetic patients in Kilimanjaro region

### **Completion date**

31/07/2011

## **Eligibility**

### **Key inclusion criteria**

All known adult diabetic patients resident in Kilimanjaro region and attending a diabetic clinic at Kilimanjaro Christain Medical Centre (KCMC) or at one of the district diabetic clinics in the 6 rural districts of Kilimanjaro region

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. Diabetic patients from outside Kilimanjaro region attending the above clinics
2. Refusal or withdrawal of consent
3. Psychiatric illness preventing screening examination
4. Patients too ill on the day of screening to have an eye examination

### **Date of first enrolment**

10/12/2010

### **Date of final enrolment**

31/07/2011

## Locations

### Countries of recruitment

Tanzania

### Study participating centre

#### Eye Department

Moshi

Tanzania

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## Sponsor information

### Organisation

Christoffel Blinden Mission (CBM) e.V. (Germany)

### ROR

<https://ror.org/04bc8dn02>

## Funder(s)

### Funder type

Charity

### Funder Name

Christoffel Blinden Mission (CBM) e.V. (Germany)

### Funder Name

AusAid (Australia)

### Alternative Name(s)

AusAID

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

Location  
Australia

## Results and Publications

Individual participant data (IPD) sharing plan  
Not provided at time of registration

IPD sharing plan summary  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	comic strip development	19/05/2022	23/05/2022	Yes	No
<a href="#">Other publications</a>	screening programme development	19/05/2022	23/05/2022	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes