

Reducing delays in cancer care in sub-Saharan Africa

Submission date 14/04/2026	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/04/2026	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/04/2026	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In low- and middle-income countries (LMICs), including Kenya and Nigeria, many cancers are not diagnosed until the late stage, when compared to high-income countries. There are several stages in the diagnosis pathway where patients experience a delay. Patients may delay seeking care when symptoms first present. Even after patients have sought care, though, there may be delays in receiving a diagnosis, due to a lack of referral or delay in taking up a referral. A third delay may be experienced between receiving a diagnosis and treatment.

Who can participate?

1. Healthcare facilities

Facilities offering general outpatient primary care consultations for undifferentiated patients

2. Patients

Patients over the age of 18 who are referred to secondary/specialist care with symptoms consistent with cancer

3. Clinicians

All clinical staff in our selected health facilities who see patients for a primary care consultation will be eligible to participate in the study

What does the study involve?

The PRIMED (PRImary care Management to Enhance early cancer Diagnosis) study comprises a cluster randomized trial with embedded process evaluation of a training (provider education and clinic strengthening) and navigation support intervention to reduce treatment delay for cancer in two sites in Nigeria and one in Kenya. The study will test a multicomponent intervention designed to reduce delay by strengthening primary care referral and patient support. Clusters will be facilities providing general outpatient primary care consultations, including small clinics and large hospital polyclinics. In each site, the study will randomly allocate 75 clusters to one of three trial arms (intervention, crossover, or control). The primary outcome will be the delivery of correct and appropriate care to patients presenting with symptoms consistent with cancer. The study will also assess clinician knowledge and time to receive a diagnosis among referred patients.

What are the possible benefits and risks of participating?

The study presents minimal risk to patients and clinicians. The intervention will provide education to clinicians, strengthen clinics, and support patients to navigate the health care system. There is no obligation on patients to take up the navigation support, and the education component constitutes part of clinical continuing education and has been developed by local and international experts in the area. At worst, there will be no change in the standard of care, and at best, there will be fewer errors in patient care and an improvement in care quality. The evaluation itself also does not present a risk to patients.

Where is the study run from?

University of Birmingham, UK.

When is the study starting and how long is it expected to run for?

April 2026 to April 2028

Who is funding the study?

National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?

Jen Knight (project manager), j.knight.2@bham.ac.uk

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Study information

Scientific Title

Cluster randomised trial of an education and navigation support intervention in primary care facilities in low and middle-income countries to reduce delays in cancer diagnosis

Acronym

PRIMED Study

Study objectives

1. To estimate the average difference in the quality (including proportion correctly managed) of primary care consultations for patients presenting with potential symptoms of cancer in the intervention state versus under usual care.
2. To estimate the average difference in healthcare provider knowledge about cancer presentation in primary care settings after receiving the intervention versus under usual care. Our sample size was designed to be able to estimate this parameter with high precision.
3. To estimate the average difference in the proportion of patients referred to secondary care settings with potential symptoms of cancer who reach a resolution (either treatment or all-clear) within four months in the intervention versus under usual care.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 28/01/2026, Oyo State Ministry of Health Research Ethics Committee (HREC) (Ministry of Health, Department of Planning, Research and Statistics Division, Ibad, Private Mail Bag No, Nigeria; +234 08038210122; info@oyostate.gov.ng), ref: NHREC/OYOSHRIEC/10/11/22
2. approved 05/03/2026, University of Ibadan/University College Hospital Ethics Committee (UI/UCH EC) (Institute for Advanced Medical Research and Training (IAMRAT), Ibadan, 200285, Nigeria; +234 (0)8023268431; ikeajayi2003@yahoo.com), ref: UI/EC/25/01255
3. approved 09/02/2026, Bayero University, Kano - Health Research Ethics Committee (BUK-HREC) (Bayero University - Health Research Ethics Committee (BUK-HREC), Kano, P.M.B. 3011, Nigeria; +234 (0)8032349387; provost.chs@buk.edu.ng), ref: NHREC/BUK-HREC/773/10/2311
4. approved 17/02/2026, Health Research Ethics Committee of Kano State of Nigeria Ministry of Health (Kano State of Nigeria Ministry of Health, 2nds and 3rd Floor, Post Office Road, Kano, P. M.B 3066, Nigeria; +234 (0)8033238779; smoh.kano2019@gmail.com), ref: NHREC/17/03/2018
5. submitted 14/04/2026, African Population Health Research Center (APHRC Campus, 2nd Floor, Manga Close, Off Kirawa Road, Nairobi, PO Box 10787-00100, Kenya; +254 (0)720098388; info@aphrc.org), ref: N/A
6. submitted 14/04/2026, AMREF Ethics and Scientific Review Committee (Amref Health Africa in Kenya, Nairobi, PO Box 30125-00100, Kenya; +254 (02)206994000; info.kenya@amref.org), ref: N/A
7. submitted 14/04/2026, National Commission for Science, Technology and Innovation (Off Waiyaki Way, Upper Kabete, Nairobi, PO Box 30623 - 00100, Kenya; +254 (0)204007000; dg@nacosti.go.ke), ref: N/A

8. notYetSubmitted

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Hybrid (hybrid between a parallel and staggered cluster trial)

Purpose

Health services research, Prevention

Study type(s)

Health condition(s) or problem(s) studied

Reducing the time interval between presentation to the formal health sector with a symptom and receiving treatment for patients presenting with symptoms consistent with cancer

Interventions

Education

In-person education sessions will be delivered to different cadres of clinical staff face-to-face, followed by an online refresher/consolidation course. The syllabus is based on need and existing evidence and guidelines for referral. The syllabus also includes management and leadership training for clinic strengthening. The syllabus has been developed with support from local and international experts (in clinical work and in education).

Clinic strengthening

Patients who are referred do not often remember all that they are told and may be confused about where precisely they should attend and when. We will therefore implement a system to reinforce and extend the information that is provided verbally.

We will co-design and implement a leaflet to provide people with more information and links to other sources of relevant information. This leaflet will include the telephone number of a peer navigator they can contact for further support. Text messages on mobile phones will reinforce the importance of attending and provide patients with information on where they can get help and support to facilitate navigation to the appropriate specialist or diagnostic service. Patients will receive telephone support from the referring clinic. We shall mentor clinics so that they have a consistent process to guide the patient through the clinic and onward to the appropriate hospital for their needs. If necessary, further support will be provided from peer navigators recruited and trained for the purpose.

Peer navigation

Peer navigation services will be offered to referred patients in our selected health facilities to help patients, especially poor people with low health literacy, to take up their referrals. A peer navigator is someone who is drawn from civil society, who is trained and will support a patient navigate the healthcare system following their referral.

Each of the three trial arms will receive all three components of the intervention at different time points over the 55-week trial period. 25 health facilities will be randomised to each trial arm, resulting in 75 facilities per site and 225 facilities overall. Randomisation will be conducted using R software.

Intervention Type

Mixed

Primary outcome(s)

1. Delivery of correct and appropriate care to patients presenting with symptoms consistent with cancer measured using audit measurement at regular intervals during the trial period

Key secondary outcome(s)

1. Clinician knowledge measured using knowledge tests at the start of data collection period 1, the start of data collection period 3 and following the implementation of the intervention in the control arm in all trial arms (around week 47)

2. Time to diagnosis measured using follow up interviews at 4 months after referral

Completion date

30/04/2028

Eligibility

Key inclusion criteria

Healthcare facilities

1. Within each of the defined study areas facilities offering general outpatient primary care consultations for undifferentiated patients will be eligible for participation. These facilities include both small practices to large hospital polyclinics.

Clinicians

1. All clinical staff who see patients for a primary care consultation will be eligible to participate in the study. This includes all relevant cadres of clinical staff: doctors, nurses, clinical officers, community health workers, community health assistants, and community health extension workers.

Patients

2. Patients who are over the age of 18 and referred to secondary / specialist care with symptoms consistent with cancer.

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

Total final enrolment

0

Key exclusion criteria

Healthcare facilities

1. 'Single-handed' facilities providing fewer than ten clinical sessions per week, where a "session" is defined as a half-day by one clinical staff member.
2. Facilities that do not receive "walk-in" patients.
3. Facilities that do not receive all patients represented by the standardized patient cases, for example, male- or female-only facilities.
4. Specialist clinics not offering diagnosis and treatment of undifferentiated patients.

Clinicians

1. Does not see patients in a clinical setting.

Patients

1. Pregnant
2. Children (under age 18)
3. Emergency referrals
4. Previous diagnosis of cancer or presenting for routine follow up of existing cancer diagnosis.
5. Patients not fulfilling criteria of symptoms consistent with cancer.

Date of first enrolment

27/04/2026

Date of final enrolment

30/09/2027

Locations

Countries of recruitment

Kenya

Nigeria

Study participating centre

University of Ibadan

-

-

Nigeria

-

Study participating centre

Bayero University

-

-

Nigeria

-

Study participating centre

APHRC

-

-

Kenya

-

Sponsor information

Organisation

University of Birmingham

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

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

IPD sharing plan summary

Not expected to be made available