

# Patient-centred sickle cell disease management in sub-Saharan Africa (PACTS)

<b>Submission date</b> 26/01/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/02/2025	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In sub-Saharan Africa (SSA) ~1:50 babies have sickle cell disease (SCD): 50–90% die before the age of 5 years. SCD is a genetic abnormality of red blood cells and a major public health priority in SSA. It causes anaemia, sudden severe pain, and eventually damages organs (lungs, brain, kidneys). In high-income countries, most SCD patients survive well into middle age because they are diagnosed early and given treatments to prevent infections, anaemia and organ damage. Though these treatments are available in SSA they are not taken up by most patients and are not systematically provided by clinicians. SCD patients, their carers and health workers will be our co-researchers, exploring why SCD patients do not get these treatments and testing out solutions. Our partners' governments recognise that skills to undertake this type of 'know-do' research (i.e. how to get take-up of treatments that are known to work) need strengthening in SSA.

### Who can participate?

Adolescents living with SCD, aged 15 and older. Carers of people living with SCD who are caring for at least one person with SCD. SCD healthcare providers who are supporting the clinical management of patients with sickle cell disease. SCD decision-makers/stakeholders involved in policymaking/guideline development for SCD, resource allocation for SCD, clinical training for SCD, and working with community-based or non-governmental organizations that support people living with SCD and their families. Journalists who can influence public education and reduce the stigma around SCD.

### What does the study involve?

To better understand the situation, the study team will collate relevant published information and conduct surveys in our partners' countries (Nigeria, Ghana, and Zambia) among SCD patients who do/do not access treatment. Then a range of health facilities (clinics/hospitals) will be selected that provide SCD care (6/country). For each facility, two research teams will be created and brief about the current situation – one comprising SCD patients, health workers and community members; and one comprising health workers from the facility. Each team will test out solutions to different problems in accessing SCD care identified by patients, in sequential cycles over two years. SCD patients are at the heart of everything done so the focus of the team's research will be to make sure the SCD services meet patients' needs and are patient-friendly.

By documenting what happens during all these research cycles, the team will learn what works, for whom and why. To explore if distance from health facilities is an important problem, they will map the facilities, communities and patients' travel costs in representative sites in all three countries. Sub-projects on media reporting of SCD and strengthening capacity for research to test solutions in practice are embedded.

What are the possible benefits and risks of participating?

This study will help to understand key factors to improve the quality of care for people with SCD, earlier diagnosis of SCD, and better uptake of care. Participants will reflect on their experiences, propose solutions and be involved in testing these out in practice. In addition to improvements in SCD care being involved in research is empowering for patients and essential to make sure the outputs are relevant for them. This is a low-risk study and participants will be fully informed and able to opt out at any stage without any negative consequences for themselves.

Where is the study run from?

Liverpool School of Tropical Medicine (UK)

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

August 2022 to July 2026

Who is funding the study?

National Institute for Health and Care Research (NIHR)

Who is the main contact?

Prof Imelda Bates, [imelda.bates@lstmed.ac.uk](mailto:imelda.bates@lstmed.ac.uk)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Prof Imelda Bates

### ORCID ID

<https://orcid.org/0000-0002-0862-8199>

### Contact details

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[imelda.bates@lstmed.ac.uk](mailto:imelda.bates@lstmed.ac.uk)

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

**Protocol serial number**

LSTM REC 22-070, NIHR134482

## Study information

**Scientific Title**

Participatory Approaches to Support Patient-centred Sickle Cell Disease Management in Africa (PACTS): Implementation Research

**Acronym**

PACTS

**Study objectives**

Patient-designed approaches to enhance the uptake of interventions recommended in guidelines can help to improve care for patients with sickle cell disease (SCD)

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

1. approved 12/01/2024, Liverpool School of Tropical Medicine (Pembroke Place, Liverpool, L3 5QA, United Kingdom; +44 (0)1517053100; lstmrec@lstmed.ac.uk), ref: 22-070
2. approved 28/12/2023, Komfo Anokye Teaching Hospital Institutional Review Board (PO Box 1934, Kumasi, PO Box 1934, Ghana; +2333200223014; info@kath.gov.gh), ref: KATHIRB/AP/128/23
3. approved 18/12/2023, Kwame Nkrumah University of Science and Technology Committee on human research, publication and ethics (Room 7, Block L, School of Medicine and Dentistry, KNUST, University Post Office, Kumasi, University Post Office, Ghana; +233322063248; chrpe@knust.edu.gh), ref: CHRPE/AP/1102/23
4. approved 12/06/2023, National Health Research Authority (Paediatric Centre of Excellence, University Teaching Hospital, PO Box 30075, Lusaka, PO Box 30075, Zambia; +260211250309; znhrasec@nhra.org.zm), ref: NHREB0004/12/06/2023
5. approved 21/06/2023, ERES CONVERGE (Plot no 272 Cnr Olive Tree Meanwood Road, Meanwood Ibex, Lusaka, Meanwood Ibex, Zambia; +260955155633; eresconverge@yahoo.co.uk), ref: 2023-May-018
6. approved 12/05/2023, National Health Research Ethics Committee of Nigeria (Federal Ministry of Health, Planning, Research & Statistics, 11th Floor, Federal Secretariat Complex Phase III, Ahmadu Bello Way, Abuja, Ahmadu Bello Way, Nigeria; +234095238367; secretary@nhrec.net), ref: NHREC/01/01/2007-12/05/2023

**Study design**

Participatory (with patients and health professionals) implementation research study

**Primary study design**

Observational

## **Study type(s)**

Prevention, Treatment

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

Patient-centred sickle cell disease management in sub-Saharan Africa

## **Interventions**

Within each country (Ghana, Zambia, Nigeria), PACTS will work with six health facilities with known sickle cell disease care provision, by identifying a team of healthcare providers with responsibility around sickle cell disease care and will work with a community group from the catchment area of each facility. This group will be comprised of individuals with sickle cell disease, carers of patients with sickle cell disease, and community influencers.

The facility group will carry out a standards-based audit (SBA) to embed the use of the clinical mainstays. The community group will use participatory action cycles (PACs) to drive community sensitisation to improve earlier detection and uptake of care and to overcome access barriers. The facility and community groups will come together to co-develop guidance for patient-centred sickle cell disease care in biannual learning collaboratives, which should be reflected in the care provided at each facility.

To study the use of PACs and SBA to drive earlier uptake of patient-centred sickle cell disease care, PACTS will conduct a realist evaluation with three phases. In phase one, PACTS will undertake a situational analysis to understand current knowledge on social factors affecting access to sickle cell disease care; patient/carer expectations of patient-centred care; and key barriers constraining implementation of evidence-based sickle cell disease clinical mainstays and adopting patient-centredness in care provision. Information from a scoping (literature, policy), and media review summarising what is known about sickle cell disease and the accuracy of public information and a patient survey about barriers to accessing care will be used to brief the PACs and SBA research teams. Additional information will be obtained from a qualitative study.

Insights from the situational analysis will also be collated and then discussed in a participatory workshop with key stakeholders to generate an initial programme theory for the realist evaluation, underscoring how PACs and SBA will drive improved sickle cell disease care and translate into practice.

Phase 2 will implement the PACs and SBA and implementation will be studied through three "rounds" of data collection in the realist evaluation. These will involve intensive collection of process data, qualitative data from PAC and SBA teams and other stakeholders, and contextual data. Throughout each round, data will be collated, and analysed, and the programme theory refined with stakeholders (as for the initial programme theory development), resulting in a "final" programme theory.

Phase 3 is a dissemination phase moving findings into policy and practice.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Facilities and access/care-seeking measured from data collected at baseline using qualitative and quantitative methods between years 1-2
2. Access to care/facilities measured using Geographic information science (GIS) in epidemiology

data between years 2-4

3. Changes in media awareness of SCD measured using media content analysis of SCD newspaper articles at year 1 (baseline) and years 3-4

4. Institutional research capacity strengthening measured using a needs analysis (year 1) and progress against action plans for year 1 and years 2-4

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

There are no secondary outcome measures

### **Completion date**

31/07/2026

## **Eligibility**

### **Key inclusion criteria**

Adolescents living with sickle cell disease

1. Aged 15 and older
2. Parent/caregiver has provided informed consent
3. Adolescent has given assent to participate

Carers of people living with sickle cell disease

1. Aged 18 and older
2. Caring for at least one person with sickle cell disease

Sickle cell disease healthcare providers

1. Aged 18 and older
2. Playing a role in supporting clinical management of patients with sickle cell disease

Sickle cell disease decision-makers/stakeholders

1. Aged 18 and older
2. Playing a role: in policymaking/guideline development for sickle cell disease; resource allocation for sickle cell disease; clinical training for sickle cell disease
3. Working with community-based or non-governmental organisations that support people living with sickle cell disease and their families

Standards-Based Audit and Participatory Action Cycle leads

1. Members of the study team facilitating PAC and SBA activities

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

Healthy volunteer, Carer, Employee, Resident, Service user, All, Other

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

15 years

### **Upper age limit**

100 years

**Sex**

All

**Key exclusion criteria**

1. Any participant not consenting to participate. If an adolescent does not give assent, this will be prioritised, even if the parent/guardian has given consent.
2. Adolescent carers of someone living with sickle cell disease

**Date of first enrolment**

12/05/2023

**Date of final enrolment**

31/01/2025

**Locations**

**Countries of recruitment**

Ghana

Nigeria

Zambia

**Study participating centre**

**Komfo Anokye Teaching Hospital**

Okomfo Anokye Road

Kumasi

Ghana

P.O.Box 1934 Adum-Kumasi

**Study participating centre**

**Kwame Nkrumah University of Science and Technology Hospital**

N6

Kumasi

Ghana

None available

**Study participating centre**

**Kumasi South Hospital**

Lake Road

Kumasi

Ghana

None available

**Study participating centre**

**Manhya Hospital**

4 Zongo Rd

Kumasi

Ghana

None available

**Study participating centre**

**Maternal and Child Hospital**

Okomfo Anokye Road

Kumasi

Ghana

None available

**Study participating centre**

**Aswoka Children's Hospital**

Okomfo Anokye Road

Kumasi

Ghana

None available

**Study participating centre**

**University of Abuja Teaching Hospital**

Gwagwalada-Zuba

Abuja

Nigeria

Gwagwalada 902101

**Study participating centre**

**National Hospital**

Plot 132 central business district (phase II), PMB 425, Garki

Abuja

Nigeria

900103

**Study participating centre**

**Nyanya General Hospital**

Area B, Nyanya

Abuja  
Nigeria  
Abuja 900101

**Study participating centre**  
**Gwagwalada Township Clinic**  
Gwagwalada  
Gwagwalada  
Nigeria  
Gwagwalada 902101

**Study participating centre**  
**Tunga Maje**  
355R+RHP  
Tunga Maje  
Nigeria  
Anagada 902101

**Study participating centre**  
**Dutse Makaranta**  
Tasha-Bwari Express Road  
Dutse Alhaji  
Nigeria  
Dutse Alhaji 901101

**Study participating centre**  
**University Teaching Hospital**  
Nationalist Road  
Lusaka  
Zambia  
None available

**Study participating centre**  
**Matero Primary Hospital**  
Commonwealth Road  
Lusaka  
Zambia  
10101

**Study participating centre****Kabwe General Hospital**

Mukobeko Road  
Kabwe  
Zambia  
80784

**Study participating centre****Arthur Davidson Children's Hospital**

Boundary Road  
Ndola  
Zambia  
None available

**Study participating centre****Kasama General Hospital**

Kasama  
Zambia  
P.O Box 410056

## Sponsor information

**Organisation**

Liverpool School of Tropical Medicine

**ROR**

<https://ror.org/03svjbs84>

## Funder(s)

**Funder type**

Government

**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

The data-sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 2.0	30/01/2023	30/01/2024	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes