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

Submission date
26/01/2024

Recruitment status
No longer recruiting

Registration date
31/01/2024

Overall study status
Ongoing

Last Edited
11/02/2025

Condition category
Haematological Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

Study website
https://www.lstmed.ac.uk/patient-centred-sickle-cell-disease-management-in-sub-saharan-africa-pacts

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Imelda Bates

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Epidemiological study

Study setting(s)
Community, GP practice, Hospital, Telephone

Study type(s)
Prevention, Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/08/2022

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

Age group
Mixed

Lower age limit
15 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
1,754

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
Manhyia 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
Gwagalada 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

Sponsor details
Pembroke Place
Liverpool
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United Kingdom
L3 5QA
+44(0)151 705 3100
lstmgov@lstmed.ac.uk

Sponsor type
Research organisation

Website
http://www.lstmed.ac.uk/

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

Publication and dissemination plan

PACTS have identified primary (e.g. sickle cell disease patients) and secondary (e.g. heath providers and facility/blood service managers, families and communities of sickle cell disease patients, journalists) beneficiaries and have developed a research uptake, dissemination and engagement plan. The primary and secondary beneficiaries will be engaged throughout the project to ensure that research aligns with sickle cell disease patients' needs, and is sensitive to the context and resources available. Involvement of health/blood service providers, and facility managers will ensure the research also meets their needs, aligns with national policies and priorities, and that the results are locally owned sustainably embedded within existing structures.

PACTS stakeholder groups will be assessed for influence, power and interest and the engagement plan tailored accordingly. Representatives of these groups from across Africa (i.e. beyond the three partner countries) will be invited to participate alongside team members in open sessions at the three PACTS biennial workshops. These sessions will be dedicated to garnering inputs to the research plans, ensuring alignment with sub-Saharan African priorities, sharing and validating findings, and promoting uptake beyond partner countries. The project will work with communications officers in Abuja (with a focus on sickle cell disease patients and health providers/blood services) and Liverpool (with a focus on implementation researchers) who will work closely with existing communications units/channels in all partners' institutions to implement our engagement plan. The officers will be responsible for non-academic communications including social media (e.g. Twitter, Facebook, WhatsApp), quarterly project bulletins (1-2 pages to keep stakeholders abreast of developments), and website updates. PACTS will produce policy briefs for key policymakers including health ministries, medical associations and pharmaceutical societies. PACTS will work with journalists to create media briefs about the sickle cell disease research outputs including for the annual sickle cell disease days and Sickle Cell Awareness weeks.

Academic outputs (e.g. publications, conference presentations) will be developed as the research progresses and results are analysed.

Intention to publish date

31/07/2027

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?
Protocol file	version 2.0	30/01/2023	30/01/2024	No	No