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Improving traumatic brain injury care in Lagos State, Nigeria through adaptation and implementation of evidence-based guidelines

Submission date
19/03/2026

Recruitment status
Recruiting

Registration date
20/03/2026

Overall study status
Ongoing

Last Edited
20/03/2026

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Traumatic brain injury (TBI) is often called a silent epidemic. It is a major cause of death and long-term disability in Nigeria, particularly in Lagos State, where the burden from road traffic injuries and other forms of trauma is high. Although evidence-based clinical guidelines exist for the management of TBI, these guidelines are often difficult to apply directly in low- and middle-income health systems because of differences in hospital infrastructure, availability of diagnostic equipment, workforce capacity, and referral pathways. As a result, patients with TBI may experience delays in diagnosis, inconsistent early management, and unequal access to specialist care. This study aims to improve early in-hospital care for people with TBI in Lagos State by adapting international evidence-based guidelines to the local context and supporting hospitals and healthcare workers to implement them in a sustainable way.

Who can participate?
Healthcare professionals involved in emergency and early in-hospital TBI care and patients of all ages who present with traumatic brain injury to 14 public hospitals at primary, secondary, and tertiary levels of care, as well as two major private tertiary hospitals in Lagos State.

What does the study involve?
The study will begin with an assessment of current TBI care practices, patient outcomes, referral pathways, and health system readiness. International head injury guidelines will then be systematically adapted through structured engagement with clinicians, patients, carers, and policymakers. The adapted guidelines will be introduced alongside training programmes, clinical decision-support tools, and ongoing implementation support. Patient outcomes, healthcare processes, and costs of care will be monitored over time to evaluate the impact of the intervention.

What are the possible benefits and risks of participating?
There may be no direct benefit to individual participants but the study is expected to improve the quality, safety, and consistency of TBI care in participating hospitals and to strengthen health system capacity more broadly. The risks associated with participation are minimal and

relate mainly to the collection of clinical information and involvement in interviews or surveys. All data will be handled confidentially, and appropriate ethical safeguards will be in place.

Where is the study run from?
The study is led by the Lagos State University Teaching Hospital in collaboration with the Lagos State University College of Medicine and will be conducted in Lagos State, Nigeria.

When is the study starting and how long is it expected to run for?
March 2026 to December 2030

Who is funding the study?
1. Medical Research Council (UK)
2. Foreign, Commonwealth and Development Office (UK)

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
TRAIN: A multiphase mixed-methods implementation study to adapt and implement NICE traumatic brain injury guidelines in Lagos State, Nigeria

Acronym
TRAIN

Study objectives

1. Formative assessment: To assess baseline TBI care quality, referral pathways, system readiness, and implementation determinants across Lagos State health facilities.
2. Guideline adaptation: To adapt NICE TBI guidelines for the Lagos context using participatory consensus and co-design methods.
3. Implementation and evaluation: To implement the adapted guidelines using a stepped-wedge design and evaluate clinical, implementation, and health system outcomes.
4. Sustainability and scale-up: To assess cost, sustainability, and scalability to inform policy and national uptake.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/02/2026, Health Research and Ethics Committee of Lagos State University College of Medicine (LASUCOM) (Lagos State University College of Medicine No 1–5 Oba Akinjobi Street, Ikeja, -, Nigeria; +234 (0)803 316 4472; lasucomhrec@lasucom.edu.ng), ref: CM/HREC.183/066B

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Sequential

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Traumatic brain injury

Interventions
The TRAIN study is a stepped-wedge cluster randomised trial (SW-CRT) conducted across public hospitals in Lagos State, following a formative assessment phase.

Clusters (health facilities) are randomised to the timing of transition from control (usual care) to intervention using a computer-generated random sequence. The sequence is generated by an independent statistician not involved in implementation, ensuring allocation concealment at the cluster level.

Control Phase (Pre-Intervention):
Facilities provide standard care for TBI management, reflecting existing practice without structured protocol implementation.

Intervention Phase:
Facilities implement a contextually adapted TBI care package, which includes:
1. Adapted evidence-based clinical guidelines (based on National Institute for Health and Care Excellence recommendations)
2. Structured provider training (emergency, neurosurgical, and nursing teams)
3. Context-appropriate decision-support tools
4. Standardised neuroprotective care protocols
5. Optimised referral and care coordination processes
6. Continuous quality improvement processes

All clusters will transition sequentially from control to intervention until full coverage is achieved.

Intervention Type
Mixed

Primary outcome(s)
1. Functional outcome measured using the Glasgow Outcome Scale – Extended (GOS-E), assessed via structured patient or caregiver interview at 6 months post-injury

Key secondary outcome(s))
1. In-hospital mortality measured using hospital medical records and discharge registers during admission (up to discharge or death)
2. Time to CT imaging measured in minutes from hospital arrival to CT scan using hospital radiology records and emergency department logs during admission
3. Adherence to neuroprotective care protocols measured using a structured clinical audit tool based on predefined protocol indicators, assessed during admission (within the first 72 hours of care)
4. Time to definitive referral measured in hours from presentation to referral decision using clinical case notes and referral documentation during admission
5. Length of hospital stay measured in days from admission to discharge using hospital administrative and clinical records
6. Complication rates (e.g., hypotension, hypoxia, chest infection) measured using patient monitoring charts and clinical records, assessed during admission (up to discharge or death)
7. Health-related quality of life measured using the EQ-5D questionnaire at baseline (or discharge where baseline is not feasible) and 6 months post-injury
8. Cost-effectiveness assessed using incremental cost-effectiveness ratios (ICERs) based on disability-adjusted life years (DALYs) at 6 months, using patient-level cost and outcome data collected during the study

Completion date
26/12/2030

Eligibility

Key inclusion criteria

1. Facilities providing emergency or inpatient traumatic brain injury (TBI) care
2. Healthcare professionals involved in TBI management
3. Patients presenting with TBI (for observational components)

Healthy volunteers allowed
No

Age group
All

Lower age limit
0 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Facilities not providing TBI-related services
2. Individuals unwilling or unable to provide consent where required

Date of first enrolment
01/05/2026

Date of final enrolment
31/08/2030

Locations

Countries of recruitment
Nigeria

Sponsor information

Organisation
Lagos State University Teaching Hospital

ROR
https://ror.org/02wa2wd05

Funder(s)

Funder type

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Foreign, Commonwealth and Development Office

Alternative Name(s)
Foreign, Commonwealth & Development Office, Foreign, Commonwealth & Development Office, UK Government, FCDO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
During the active phase of the research, access to identifiable participant data will be strictly limited to:
1. The principal investigator (PI) and authorised members of the immediate research team who require access to perform their duties.
2. Institutional ethics committees (or institutional review boards) of the participating hospitals, should they require access for regulatory oversight or audit purposes.

3. The study sponsor and/or funder, who will receive data only in a de-identified format for monitoring and reporting purposes.
4. Relevant regulatory bodies in Nigeria, upon their official request and in compliance with national laws.

Upon project completion, a comprehensive, de-identified final dataset will be generated. All direct and indirect identifiers will be removed to protect participant privacy. This de-identified dataset will be securely stored at the Lagos State University Teaching Hospital (LASUTH), which will serve as the central data repository.

Access to the de-identified data for secondary research will be governed by a formal Data Access Committee (DAC). The DAC will be comprised of representatives from LASUTH and participating partner hospitals. The DAC is responsible for:
1. Reviewing data access requests: evaluating all requests from bona fide researchers for data usage.
2. Ensuring compliance: verifying that any proposed secondary analysis aligns with:
2.1. The original informed consent provided by participants.
2.2. The approvals granted by all relevant institutional ethics committees.
2.3. All applicable national data protection regulations in Nigeria.

All data sharing will be executed under formal, binding Institutional Data Sharing Agreements between LASUTH and the requesting researcher's institution. These agreements will explicitly outline the terms of use, publication rights, and data security requirements.

No identifiable data will be transferred outside of Nigeria. Any transfer of the de-identified dataset to international collaborators will be subject to a rigorous review by the Data Access Committee and will only occur under the following strict conditions:
1. A formal data sharing agreement is in place.
2. Additional ethical approval is secured from the relevant Nigerian ethics committees for the proposed transfer and secondary analysis.
3. The receiving institution provides robust guarantees and safeguards for data protection, equivalent to Nigerian standards.

The de-identified dataset at LASUTH will be preserved for the long term to maximise its value. The governance framework is designed to align with the FAIR data principles, ensuring the data is:
1. Findable: through clear metadata and documentation (data dictionaries) associated with the stored dataset.
2. Accessible: via a transparent and equitable request process managed by the Data Access Committee.
3. Interoperable: by using standard, non-proprietary data formats where possible to facilitate integration with other datasets.
4. Reusable: by maintaining rich contextual metadata (provenance) and ensuring that any reuse adheres to ethical and consent-based restrictions.

IPD sharing plan summary

Available on request