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Project PHIA: perinatal health intelligent agent

Submission date
24/11/2025

Recruitment status
Not yet recruiting

Registration date
25/11/2025

Overall study status
Ongoing

Last Edited
25/11/2025

Condition category
Mental and Behavioural Disorders

[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
Perinatal depression is common, consequential, and largely invisible in routine care in Nigeria. Prevalence reaches about 25% in low and middle-income countries (LMICs) and about 17–19% globally postpartum. Despite the high prevalence of perinatal mental health disorders in Nigeria, there is a persistent gap in the detection of these treatable mental health conditions with only 20% of sufferers being able to access the scarce, poorly coordinated and expensive care. This study aims to make perinatal depression visible, actionable, and equitably treated in Nigeria by embedding a multilingual, culturally grounded agent into routine care. The study is designed primarily to assess whether PHIA, as a psychometric tool, digital decision-support and monitoring system (not a psychotherapeutic intervention), improves detection, monitoring, referral, and care-seeking for perinatal depression symptoms.

Who can participate?
Perinatal women receiving antenatal or postnatal care at participating facilities in Rivers State, Nigeria; aged 18 years and over; currently pregnant or 12 months or less postpartum; primary fluency in at least one target language (Yoruba, Hausa, Igbo, or Nigerian Pidgin); own or have reliable access to a smartphone capable of running the PHIA app or WhatsApp interface.

What does the study involve?
Primary health care centers and hospital sites will be randomly allocated to:
Group 1: Enhanced Usual Care (EUC): Standard perinatal care with strengthened depression screening and referral protocols.
Group 2: EUC + PHIA: EUC plus deployment of PHIA for AI-supported screening, monitoring, and clinical decision support.
Group 3: EUC + PHIA + Proactive HEW Support: EUC plus PHIA, with structured HEW outreach and follow-up workflows.
The primary outcome will be mental-health screening completion and care-seeking.

What are the possible benefits and risks of participating?
Benefits: improved cultural fit, better accuracy and fairness, empowerment, higher uptake, stronger health system response, early detection, community-level gains.
Risks: privacy and surveillance concerns, emotional distress, stigma, participant burden, digital divide, potential algorithmic errors, inequitable compensation, and risks of technology overdependency.

When designing PHIA, these concerns can be mitigated through strong ethical governance, community advisory boards, transparent data practices, IPV-sensitive protocols, flexible opt-in /opt-out features, and ensuring human oversight in all clinical pathways.

Where is the study run from?
The study will be undertaken in Nigeria across primary, secondary and tertiary clinical sites - University of Port Harcourt Teaching Hospital (Departments of Obstetrics & Gynaecology, Mental Health as well as the Comprehensive Primary Health Centre in Aluu), Primary Health Centres in Rivers State (Rumuigbo MPHC, Ozuboko MPHC, Elekahia MPHC, Ozuogba MPHC, Secondary Health Facility under the State (Kelsey Harrison Hospital), Facility driven via a public-private partnership with robust community health insurance scheme (Obio Cottage Hospital)

When is the study starting and how long is it expected to run for?
March 2026 to February 2028

Who is funding the study?
This study proposal has been submitted for the Neuromatch Acceleration stage (on behalf of Wellcome Trust Limited) in the MEXA Programme on Generative AI for Anxiety, Depression and Psychosis Research Accelerator.

Who is the main contact?
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Additional identifiers

Grant Code
MEXA2025-035a

Study information

Scientific Title
PHIA: a multimodal GenAI system for culturally responsive perinatal mental health support in Nigeria

Acronym
PHIA

Study objectives
The project aims to make perinatal depression visible, actionable, and equitably treated in Nigeria by embedding a multilingual, culturally grounded agent into routine care. PHIA unifies smartphone rPPG vitals and multimodal signals (text, voice, video, behavior, clinical variable, SDoH) into a maternal health EHR module, patient portal, mobile app, WhatsApp conversational agent, and a clinician dashboard. Through rigorous validation and policy co-creation with the Ministry of Health (MoH), we will accelerate referrals, reduce documentation burden, and establish national guidance for safe, AI-enabled perinatal mental-health care
Objective 1 (co-design and internal validating and localization): internally validate and locally adapt existing consortium models and co-design culturally grounded language, workflows, and UX for AI-enabled perinatal mental-health monitoring, achieving stakeholder-approved specifications, CAB-approved governance artifacts, and target usability/intent thresholds.
Objective 2 (external validation in routine care): conduct a six-site, single-arm feasibility study of the full PHIA stack.
Objective 3 (confirmatory evaluation and policy translation): run a clustered randomized controlled trial across Southern Nigeria (urban, multi-ethnic) clinical sites, each with one referral hospital and two PHCs, to test acceptability, cultural fit, equity, safety, and effectiveness; deliver improved identification, referral timeliness, and symptom trajectories without added burden; and finalize a scale-up toolkit (SOPs, training, ETL, parity-audit scripts, rPPG QC tools). Through this iterate process, PHIA will engage at least ~3,500 unique Nigerian data citizens across development, testing, and governance—about 1,600+ in co-design and oversight (perinatal women, HEWs, clinicians, community leaders, CAB, MoH) and ~1,900 patients and clinicians in real-world pilots. Additional HEWs and cluster-RCT participants will expand this total in Year 3.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/11/2025, University of Port Harcourt Ethics Committee (Ethics Review Committee University of Port Harcourt Choba, Port Harcourt, 500102, Nigeria; +234 (0)8033360401; research.ethics@uniport.edu.ng), ref: UPH/CEREMAD/REC/MM105/032

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Single

Purpose
Device feasibility, Prevention, Screening, Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Perinatal depression

Interventions
This is a multicenter, three-arm, cluster randomized controlled trial. Randomization will be stratified by facility level (primary vs secondary/tertiary) and dominant language (Yoruba, Hausa, Igbo, Nigerian Pidgin) to balance service context across arms. Primary health care centers and hospital sites (clusters) will be randomized 1:1:1 to:
Arm 1: Enhanced Usual Care (EUC): Standard perinatal care with strengthened depression screening and referral protocols.
Arm 2: EUC + PHIA: EUC plus deployment of PHIA for AI-supported screening, monitoring, and clinical decision support.
Arm 3: EUC + PHIA + Proactive HEW Support: EUC plus PHIA, with structured HEW outreach and follow-up workflows.
Randomization will be stratified by facility level (primary vs secondary/tertiary) and dominant language (Yoruba, Hausa, Igbo, Nigerian Pidgin) to balance service context across arms.

The cRCT is designed primarily to assess whether PHIA, as a psychometric tool, digital decision-support and monitoring system (not a psychotherapeutic intervention), improves detection, monitoring, referral, and care-seeking for perinatal depression symptoms. While depressive symptoms will be measured, the unit of inference is the system and care processes rather than PHIA as a direct clinical treatment.

Intervention Type
Behavioural

Primary outcome(s)
1. Mental-health screening completion and care-seeking (cluster-level process outcome) measured using Patient Health Questionnaire-9 (PHQ-9) at T0, T1 (~weeks 16–20), T2 (~weeks 26–28)

Key secondary outcome(s))
1. Referral completion (process outcome) measured using EHR and PHIA escalation logs including HEW documentation at T0–T2

2. Depressive symptoms measured using PHQ-9 at T0, T1 (~weeks 16–20), T2 (~weeks 26–28)

3. Disability/functional impairment measured using WHODAS 2.0 at T0 to T2

4. Service utilization and care pathways measured using EHR and PHIA-linked logs at during the trial period

5. Implementation measured using reach, fidelity, burden, usability, acceptability, alert fatigue at throughout trial (T0–T2)

6. Mediation of PHQ-9 change by referral completion measured using multilevel mediation models (SEM or causal mediation) at throughout trial (T0–T2)

7. Relationship between PHIA self-monitoring and depressive symptoms measured using frequency of AI-supported self-monitoring (e.g., mood check-ins, rPPG captures, voice/video diaries) and change in PHQ-9 scores at T0–T2

8. Experience of care and perceived collaboration with PHIA measured using structured experience-of-care modules and qualitative interviews (IDIs/FGDs) with mothers, HEWs /midwives, supervisors, and community leaders at at or after T2

Completion date
29/02/2028

Eligibility

Key inclusion criteria
Target population (primary participants):
The cRCT will enroll perinatal women receiving antenatal or postnatal care at participating facilities in Rivers State, Nigeria (UPTH Departments of Obstetrics & Gynaecology and Mental Health; UPTH Comprehensive PHC in Aluu; Rumuigbo MPHC; Ozuboko MPHC; Elekahia MPHC; Ozuogba MPHC; Kelsey Harrison Hospital; Obio Cottage Hospital).
Inclusion criteria (perinatal women).

Perinatal women will be eligible if they:
1. Are ≥18 years of age
2. Are currently pregnant or ≤12 months postpartum
3. Have primary fluency in at least one target language (Yoruba, Hausa, Igbo, or Nigerian Pidgin)
4. Own or have reliable access to a smartphone capable of running the PHIA app or WhatsApp interface
5. Are receiving care at a participating clinical site
6. Have the capacity and willingness to provide written informed consent

These criteria ensure that participants can engage with PHIA's digital functions, are within the perinatal risk window, and can be followed within the cluster's routine care pathways

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Total final enrolment
3500

Key exclusion criteria
Perinatal women will be excluded if they:
1. Exhibit active suicidal ideation (endorsement of PHQ-9 item 9) or severe depression (PHQ-9 ≥20) at screening; such individuals will receive immediate referral to a mental-health professional outside the trial pathway.
2. Have a previous diagnosis of common or severe mental-health conditions (for example, bipolar disorder, schizophrenia, or recurrent major depressive disorder currently under specialist care);
3. Have high-risk pregnancies or significant pregnancy complications requiring intensive or tertiary-level management where PHIA-supported pathways would not be appropriate.
4. Are judged by the clinical team to have cognitive impairment or other conditions that preclude informed consent or reliable participation.
These exclusions are justified to protect participants at highest clinical risk, avoid interference with intensive specialist care, and ensure that the cRCT evaluates PHIA in the population for whom task-sharing and digital decision support are most appropriate.
Clinicians and HEWs are not primary trial participants for outcome analysis but will be involved as implementers within clusters; their inclusion follows active clinical practice at participating sites and willingness to participate in workflow and usability activities.

Date of first enrolment
02/03/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Nigeria

Sponsor information

Organisation
Wellcome Trust

ROR
https://ror.org/029chgv08

Funder(s)

Funder type

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available