Effectiveness of faith-based interventions on the rate of discharged against medical advice in the tertiary newborn units in Nigeria: A protocol for an open label randomized control trial, the FBI-DAMA Study

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Research Article

Keywords: Discharged against medical advice, DAMA, religion, faith-based, intervention(s), spirituality, religiosity, social support, neonate, newborn, randomized control trial

Posted Date: March 9th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-306109/v1

Abstract

Background:

Discharged against medical advice (DAMA) is a risk factor that often leads to adverse outcomes and hospital re-admissions in neonatal units. Few studies have shown that spiritual/faith-based institutions (FBI) tend to have lower incidence of DAMA compared with public hospitals. Perhaps the holistic approach to patient care that addresses the spiritual needs, the soul and the body component of a being in this setting may account for the observed lower incidence of DAMA. Limited randomized control trials (RCT) exist on faith-based interventions with regards to DAMA in published literature. This study seeks to compare the effectiveness of FBI, social support, religiosity and types of FBI on neonatal DAMA against standard of care in tertiary hospitals in Nigeria.

Methods: This RCT will be carried out in 2 public tertiary teaching hospitals in 2 of 6 geopolitical zones in Nigeria. The socio-demographic and clinical details of all patients admitted to the neonatal wards during the study period will be documented. Study participants will be selected through a multistage sampling technique. Subjects will be randomized and allocated to treatment and control arms having established baseline measure of social support and religiosity. Ethical approval was obtained from the State Research Ethics Review Committee. Written informed consent will be obtained from the parents/caregivers prior to patient enrolment. The study will be conducted in line with Declaration of Hesinki 2013. Appropriate statistical tools will be used for data collection and analysis.

Discussion:

The outcome of this analysis will give insight into the effectiveness of FBI on DAMA. It will also predict the effect of the mediators of parents/caregivers' religiosity, spirituality, forms of FBI, parents/caregivers' religious sect and social support on rate of DAMA on neonatal admission in tertiary hospitals in Nigeria. This may help inform Public Health Institutions and Governments' decisions on the determinants of neonatal DAMA and how to mitigate such outcomes. It is hoped that the evidence from this study may guide policy formulation and guidelines to enhance hospital retention of sick neonates until they are fit for discharge.

Trial registration: This study was registered in the Pan Africa Clinical Trial Registry (PACTR202102670906630).

Background And Rationale

Approximately 130 million babies are born annually, about 4 million of these newborns in LMICs do not survive beyond the neonatal period.(2) More worrisome, is the increasing contribution of childhood mortality from the neonatal death. This narrative is not different in Nigeria where neonatal mortality represents one of the highest in the world, only behind India.(3)

The reasons for this trend are multi-factorial. They vary from ignorance, harsh health care workers altitude to caregivers/parents, poverty, lack of access to good health care, the need for spiritual support at a very trying time and discharged against medical advice (DAMA).(4-8) It is therefore important that those who get to a health service be treated holistically, providing physical, psychological and spiritual support to enable them complete treatment until when discharge is recommended by the treating clinicians.(4–6)

Discharge against medical advice (DAMA) occurs when an in-patient decides to leave the hospital before discharge is recommended by the treating clinicians or physicians. DAMA poses serious clinical, ethical, and legal challenges to the individual physician as well as the hospital.(2,7–10) The DAMA prevalence has been shown to vary depending on geographical areas and study population. The rate of DAMA compares inversely with the socioeconomic status: a relatively lower rate was observed at a hospital serving primarily middle and upper-class populations, whereas a higher rate was observed at a hospital serving disadvantaged urban areas.(10–14) The paediatric age group, and especially the newborns are at a greatest risk for DAMA in Nigeria from published literature (10–12).

DAMA has been shown to increase the risk of adverse outcomes ranging from medical complications requiring re-admission to death.(7,9) Associated outcomes also includes higher morbidity, increased mortality, longer hospital stays, and higher costs of treatment when re-admitted .(11, 12)

More challenging with DAMA is the ethical issues in neonates, as they have the least autonomy to participate in their health decision. The parents/caregivers entrusted with the right of decision-making often fail this vulnerable population. The very sick babies with a risk for residual long-term outcomes, higher risk for mortality and foreseeable future of being a burden are often thought of dispensing with by the parents/caregiver, and hence the request for DAMA. This poses a great challenge to the managing physician on maintaining a balance between the parents/caregivers autonomy against the fiduciary role of the physician. (5,7,9)

Few observational studies have shown lower incidences of DAMA in faith-based hospitals where spiritual leaders actively participate in patient care. (15-21) The holistic approach to patients' care that addresses the spiritual needs, the soul and the body component of a being in this setting may account for the observed lower incidence of DAMA. However, it may not be sufficient to explain the lower incidence of DAMA with just the involvement of the spiritual leader in care. The literature has suggested that a number of variables can interact to influence decision making. In this instance, perceived social support to parents/caregivers of newborns as well as their levels of religiosity may significantly influence decision to engage in DAMA.[21-23] Limited randomized control trials (RCT) studies on the effectiveness of FBI are available in the published literature.

This protocol provides a workflow for an open label randomized clinical trial to evaluate the effectiveness of spiritual/FBI intervention on hospital retention of neonates compared with standard of care. It also includes secondary outcomes such as patients' clinical outcome, parents/caregivers' satisfaction with intervention and their desire to see the intervention established as routine care for newborn in public tertiary hospital.

Objectives

General objective:

The general objective is to determine the effectiveness of religious intervention on rates of DAMA in neonates compared to the standard of care.

Specific objectives:

To determine:

1. To compare the effectiveness of religious intervention with standard of care on newborn rates of DAMA.
2. To determine the association if any between clinical and socio-demographic characteristics of patients on rates of DAMA.
3. To delineate the reasons for DAMA among neonates in Nigeria.
4. To model a prediction for rates of DAMA in neonates using explanatory variables (reasons) for DAMA.
5. To determine the effect of parents'/caregivers' religiosity, spirituality, types of FBI, the religiuos sect of parents/caregivers and social support on the outcomes of DAMA or hospital retention till discharge.

Trial Design

Intervention assignment

This will be an open label, parallel randomized control trial.

Simple randomization using a randomization table created by a computer software program (GraphPad Prism version 9) would be used to randomize subjects.

Allocation sequence would be concealed in sealed opaque envelopes.

Methods: Participants, Interventions And Outcomes

Study setting {9}

This study is a multicenter study involving 2 public tertiary hospitals located in two of the six geopolitical zones in Nigeria.[24-25] The selected tertiary hospital includes University College Hospital Ibadan and The Federal Medical Centre Kastina, Kastina state as shown in the map below.

Eligibility criteria {10}

Inclusion Criteria

1.All newborns admitted into the selected study sites whose parents /caregivers gave their informed consent to participate in the study.

Exclusion criteria:

1.Babies taken custody by institution such as motherless home or by government agencies for legal reasons.

2. Babies whose parents/ caregivers fail to give consent for the study

Who will take informed consent? {26a}

Prior to enrolment into the study, the research would be explained to parents/caregivers by the investigator who will obtain written informed consent. Parents/caregivers will be informed of their freedom to refuse to take part in the study without any negative consequences to them or their wards in the course of treatment.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Additional consent would be obtained for data availability for secondary analysis and for ancillary studies in the future.

Interventions

Explanation for the choice of comparators {6b}

The comparator is the standard of care for all babies admitted to the newborn units in the study sites. The standard of care is discharge by the attending Physician according to the Hospital Unit Protocol.

Interventiondescription {11a}

The treatment arm in this trial is a faith-based intervention (FBI). The FBI will involve religious counselling encouraging the caregivers/parents to stay in the hospital until their baby is medically discharged. This will also involve offering of prayers and reading of holy books for the babies' recovery based on their faith. Each participant will have 2-3 sessions of the FBI with each session lasting 20-30 minutes.

Criteria for discontinuing or modifying allocated interventions {11b}

Participants who wish to exit study after due counselling will be allowed.

Strategies to improve adherence to interventions {11c}

Prior to recruitment, parents/caregivers of study participant will be educated on the study in order to gain their cooperation.

Relevant concomitant care permitted or prohibited during the trial {11d}

Both the experimental and control group will have access to medical treatment based on their conditions except for the intervention in the experimental arm.

Provisions for post-trial care {30}

The outcome measure is a one time off measure and would not require follow up.

Outcomes {12}

The primary outcome

1. The primary outcome of this study is the retention rate of sick newborns with the faith-based intervention in public tertiary hospitals in Nigeria compared with the standard of care.

Secondary outcomes

1. The secondary outcomes are reasons and determinants of DAMA among the neonates in the tertiary hospitals in Nigeria.
2. Effect of parents/caregivers' religiosity, spirituality, types of FBI, the sect of parents/caregivers and social support on the outcomes of DAMA or hospital retention in neonatal admission.
3. Patients' clinical outcome
4. Parents/caregivers' satisfaction with intervention and their desire to see the intervention established as routine care for newborn in public tertiary hospital.

Participant timeline {13}

Table 2 Participant timeline[1]

STUDY PERIOD						
Enrolment	**Allocation**	**Post-allocation**				**Close-out**
TIMEPOINT**	$-t_1$	0	*12hs*	*72hrs*	t_x	
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Administration of Research screening tools	X					
Clinical History and examination	X	X				
Allocation	X					
INTERVENTIONS:						
[Intervention A]	X	X				
[Intervention B]						
ASSESSMENTS:						
[List outcome variables]	X					

Sample size {14}

The sample size required for this study was determined using the Raosoft sample size calculator (http://www.raosoft.com/samplesize.html) for single proportion with estimated 50% prevalence of DAMA. A sample size of 359 has 80 % power to detect the rate of DAMA at the alpha level of significance 0.05.

Recruitment {15}

Invitation: The caregivers/parents of the eligible patients will be verbally invited during their hospital admission.

Eligibility: Subjects will be assessed based on the eligibility criteria enumerated above.

Enrolment: Eligible subjects will be enrolled into the study after giving written informed consent.

Informed Consent: Parents and caregivers will give a written informed consent during enrolment. This will be signed by Principal Investigator, the parent/caregiver, and a witness. A copy of informed consent will be retained by the parent, while a copy will be kept in the patient's file.

Sampling technique

In stage I: The list of the tertiary hospitals in Nigeria formed the sample frame for the study. A random number was allocated to each centre. Two institutions were randomly selected from this list.

In Stage II, an allocation sequence for the 2 arms will be generated using simple randomization from GraphPad Prism version 9. In the selected hospitals, consecutive neonates whose parents/caregivers give informed consented would be allocated to one of the 2 arms based on the allocation sequence.

Allocation:

Allocation will be by simple randomization using random numbers generated from GraphPad Prism (version 9) for the study.

1. Arm A: The intervention for FBI
2. Arm B: The standard of care for neonates admitted into the unit born units of selected hospital

Subjects will be allocated to two arms of the study in parallel (concurrent): faith-based intervention (Arm A) and standard of care (Arm B) based on the randomization process. The allocation ratio is 1:1.

Assignment of interventions: allocation

Sequence generation {16a}

A random number will be generated using simple randomization from GraphPad Prism version 9 for consecutive patient being enrolled for the study.

Concealment mechanism {16b}

This study will be open label (Masking Not Used)

Implementation {16c}

A record officer will be responsible for generating a random number and its allocation using GraphPad Prism version 9.

Assignment of interventions: Blinding

Who will be blinded {17a}

This is open label trial. The intervention and comparator will not be concealed. Both the investigator and the subject will be aware of what intervention they would receive.

Procedure for unblinding if needed {17b}

This study will be open label (Masking Not Used)

Data collection and management

Plans for assessment and collection of outcomes {18a}

Training will be held for the researchers prior to commencement of the trial via zoom meeting. The validated questionnaire, the trial protocol, religiosity, spirituality and social scales would be tested. The experience with understanding the tools and the ease of administration of the tools would be assessed. Observation from the training will be incorporated into the study instruments to improve the data entry and address other observed limitations.

Plans to promote participant retention and complete follow-up {18b}

The outcome of the study is one time point: until DAMA occurs or medical discharge, follow-up does not apply.

Data management {19}

Data obtained from the study will be entered into a password protected and encrypted institutional REDCap database. Only specific individuals from the collaborating centres will be given access to the database. All data from all the centres will be de-identified and managed through secure code.

Confidentiality {27}

All information collected in this study will be given code numbers, and no name will be recorded. This cannot be linked to the patients, parents or care provider in any way. Identifier will not be used in any publication or reports from the study.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

This trial has no intention to collect biologic sample for genetic study.

Statistical methods for primary and secondary outcomes {20a}

Data from this study will be analysed in GraphPad Prism 9 (GraphPad Software 2365 Northside Dr. Suite 560 San Diego, CA 92108). The appropriate descriptive statistics will be used to present the socio demographic characteristics of study participants. The comparison of ccategorical outcomes between the arms will be analysed using the Chi-squared or Fisher’s exact tests, as appropriate, and presented as

risk differences, risk ratios, or odds ratios and 95% confidence intervals. P-values < 0.05 will be considered statistically significant for all analyses.

Interim analyses {21b}

Data will be analysed at the end of the study

Methods for additional analyses (e.g., subgroup analyses) {20b}

Subgroup analysis will be performed using variables such as geopolitical region, gender, socioeconomic status of parents and care provider, level of education and occupation.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

The result of the study will be analysed per protocol. Missing data will be accounted for and the proportion with desirable outcome will be analyzed.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

The protocol shall be published in a peered review journal and made publicly accessible to interested individuals or body.

Individual Patient data will be de-identified and stored encrypted in a password protected computer. De-identified data will also be stored in highly secured cloud computing. The participant level dataset and statistical code shall be made available after following due process adhering to good ethical standard.

Sharing Time Frame

The de-identified data will be publicly available for 2 years on the trial website.

Key Access Criteria

Open access to de-identified data set which can be used for any analysis related to discharged against medical advice (DAMA)

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

A trial steering committee will consist of the principal investigator, two scientific enquirers, the public enquirer and a biostatistician. They will meet frequently to provide an oversight function for the trial conduct over the two centres in the country.

Each centre will have a hospital trial group headed by a consultant paediatrician who will be responsible for running daily events in the hospital, providing organizational support and reporting on a weekly basis

to the steering committee.

Composition of the data monitoring committee, its role and reporting structure {21a}

The Data monitoring committee will consist of the Head of the Information Technology at the University College Hospital Ibadan. He will centrally manage the database. He will be support by two assistants in event he is unable to perform his duties. They will be responsible for entering data from the UCH centre to the database. The Head will give access to focal persons (information technologist) at the collaborating centres in Nigeria. These individuals will be responsible for entering data into the central database in UCH. Regular Zoom meeting will be head among the group members to address pressing issues. The data monitoring committee shall be independent of the core trial committee.

Adverse event reporting and harms {22}

The trial is a social intervention. If any incident of abuse is reported by any participant, it will be handled on case-by-case bases by the steering committee.

Frequency and plans for auditing trial conduct {23}

The local ethics board will monitor the progress of this trial and the intervention, and update will be relayed to the body as events unfold.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

Any modification to the protocol or trial update will be communicated to the Ethical Approval bodies, Trial Registry and any other relevant parties.

Dissemination plans {31a}

The outcome of this study will be communicated to participants, ethics board, healthcare professionals. It will be published in peer-reviewed scientific journals for public access. Data will be made available to the public maintaining ethic guidance.

Discussion

The outcome of this analysis will give insight into the effectiveness of faith-based intervention on DAMA compared to the standard of care. It will also predict the effect of the mediators of parents'/caregivers' religiosity, spirituality, forms of FBI, parents'/caregivers' religious sect and social support on rate of DAMA on neonatal admission in tertiary hospitals in Nigeria. This may help inform Public Health Institutions and Governments decision on the determinant of neonatal DAMA and how to mitigate such outcomes. It is hoped that the evidence from this study may inform policy formulation and guidelines toward enhancing hospital retention of sick neonates until they are fit for discharge.

Declarations

Trial status

The trial is active but has not started recruiting

Declarations

Acknowledgements

We acknowledged the the children, parents and care providers who would voluntarily give consent to participate in this study. We are grateful to the Nursing staff and the senior colleagues who would contribute to make the trial a great success.

Authors' contributions {31b}

A.M.A: The Principal Investigator; he conceived the study, led the proposal and protocol development. Critically revised the protocol for important intellectual content; gave final approval; agree to be accountable for all aspects of the work in ensuring that questions relating to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

1. **I**. Contributed to the design and development of the proposal and protocol; critically revised protocol; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy

1. **B** Contributed to the design and development of the proposal and protocol; critically revised protocol; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

N.O.E Contributed to the design and development of the proposal and protocol; critically revised protocol; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

A.O.A Contributed to the design and development of the proposal and protocol; critically revised protocol; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy.

O.O.P Contributed to the design and development of the proposal and protocol; critically revised protocol; gave final approval; agrees to be accountable for all aspects of work ensuring integrity and accuracy

All authors read and approved the final manuscript.

Funding {4}

This study is currently funded by the authors.

Availability of data and materials {29}

Data and material from this study will be made available to the public unhindered. Individual Patient data will be de-identified and stored encrypted in a password protected computer. The de-identified data will be

publicly available at the trial website. De-identified data will also be stored in highly secured cloud computing.

Ethics approval and consent to participate {24}

Ethical approval was obtained from the State Research Ethics Review Committee (**Ref:AD13/479/3047**[A]) and the trial was also registered (**PACTR202102670906630**).

Consent for publication {32}

The Informed Consent Form will be redacted before sharing publicly. Patient identifiers will be removed from all documents for public access. The template for the informed consent form would be available on request through the corresponding author.

Competing interests {28}

The author(s) declared no potential conflicts of interest with respect to finance, conduct of the research, authorship, and/or publication of this protocol.

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4. Department of Psychology, University of Ibadan

Abbreviations

RCT: Randomized Clinical Trial

PACTR: Pan Africa Clinical Trial Registry

FBI: faith-based intervention

LMIC: Low and Middle-Income Countries

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Table 1

Table.1 Administrative information. (1)

Title {1}	Effectiveness of faith-based interventions on the rate of discharged against medical advice in the tertiary newborn units in Nigeria: A protocol for open label randomized control trial, the FBI-DAMA Study
Trial registration {2a and 2b}.	This study was registered in the Pan Africa Clinical Trial Registry, with registration number: PACTR202102670906630
Protocol version {3}	Issue date: 29.12.2020, Protocol Number 01
Funding {4}	This study will be funded by the authors.
Author details {5a}	1. Alao Michael Abel: Department of Paediatrics University College Hospital Ibadan Oyo State, Nigeria. 1. Ibrahim Olayinka Rasheed: Department of Paediatrics, Federal Medical Centre, Kastina, Kastina State, Nigeria 2. Ogunbosi Oluwatosin Babatunde: Department of Paediatrics University College Hospital Ibadan, Oyo State, Nigeria. 3. Emmanuel Okechukwu Nna: The Molecular Pathology Institute, 44 Rangers Avenue, Independence Layout, Enugu, Enugu State. 4. Adanze Onyenonachi Asinobi: Department of Paediatrics University College Hospital Ibadan, Oyo State, Nigeria. 1. Olapegba Olamakinde Peter: Department of Psychology, University of Ibadan, Oyo State, Nigeria
Name and contact information for the trial sponsor {5b}	Michael Abel Alao, Department of Paediatrics, Universality College Hospital, Layi Ayanniyi Street, Ibadan Oyo State, Nigeria.Email: mikevikefountains@gmail.com Tel: +2348053967839 ORCID ID Michael Abel Alao https://orcid.org/0000-0003-0109-4435
Role of sponsor {5c}	The sponsor would serve as funder except if grant is obtained for the study. He is involved as a member of the steering committee. He designed the study, will be involved with interpretation of result; writing of the report; and the decision to submit the report for publication,and data availability

Figures

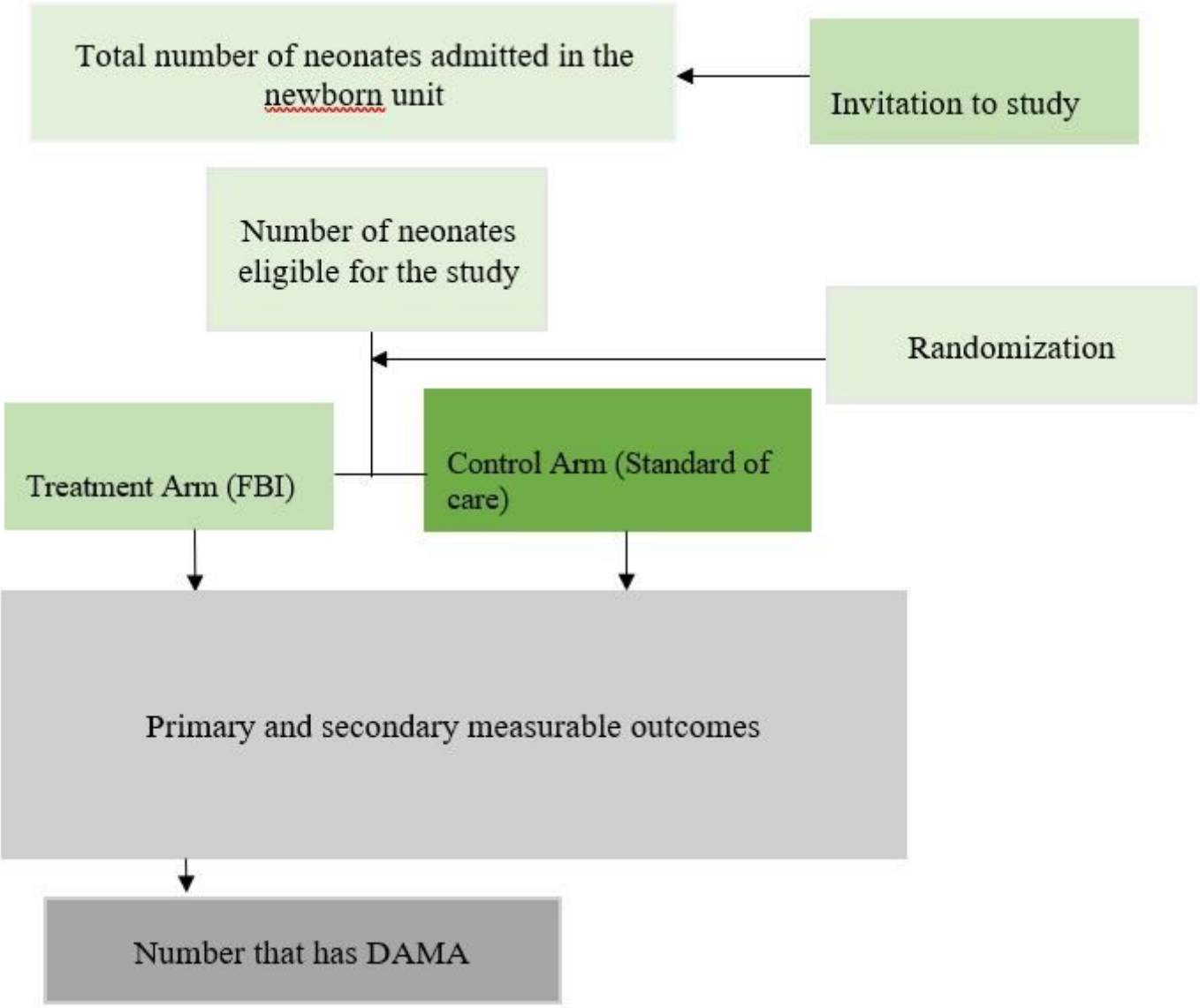

Figure 1

Study Participant Flow Chart

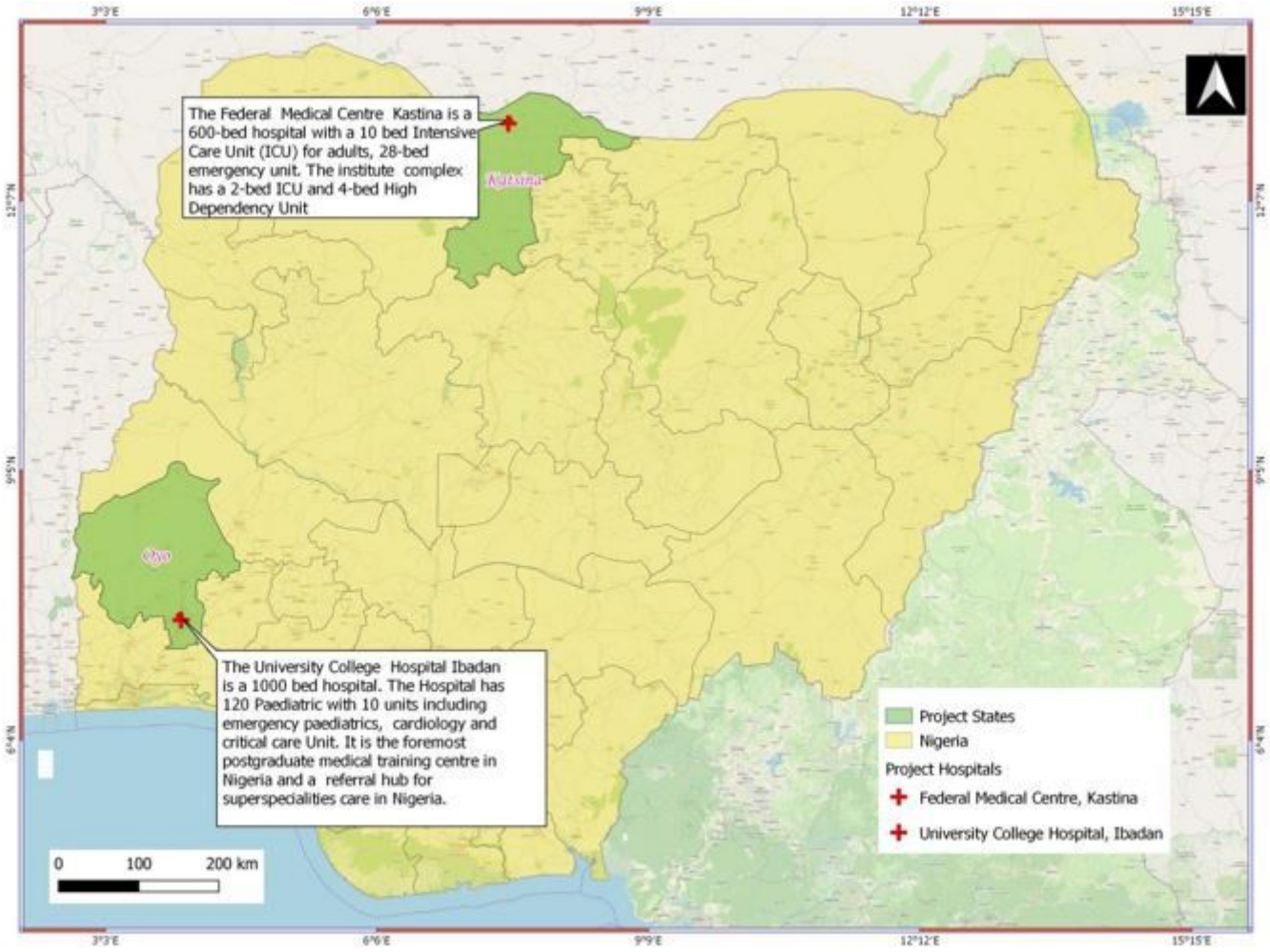

Figure 2

Map of the study centres in Nigeria

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- TheRCTonFBIregistered.pdf