



Research Article

Effect of a hospital-based maternal counseling guide on exclusive breastfeeding practices in Anambra State, Nigeria: A protocol for a cluster-randomized controlled trial (HOME Trial)

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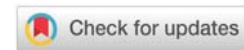
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Keywords: Hospital-based; Counseling guide; Exclusive breastfeeding; Nigeria; Cluster-randomized controlled trial

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Abstract

Background: Optimal breastfeeding is so critical that it could save the lives of over 820,000 children under the age of five years each year. For optimal growth, development, and health, the WHO recommends Exclusive Breastfeeding (EBF) in the first six months. To ensure nursing mothers breastfeed their children exclusively, they should also have access to skilled practical help to build mothers' confidence and prevent or resolve breastfeeding problems. Interventions promoting optimal Infant and Young Child Feeding practices could prevent 19% of under-five deaths, and such intervention could improve nursing mothers' understanding and practice of EBF.

Objective: This trial is designed to formulate a hospital-based counseling guide on EBF, implement it, and determine its effect on improving EBF practice in Anambra State, Nigeria.



Methods: The study is a cluster randomized controlled trial conducted in selected hospitals in Anambra State, Nigeria. Based on inclusion criteria, 12 hospitals that offer comprehensive ante-natal and post-natal clinic services and have a higher population of women assessing care in the ante- and post-natal clinics were selected for the study. Six hospitals each were randomized to either the intervention or the control arm. The intervention hospitals received the formulated hospital-based counseling guide and the hospital's usual care, while the control hospitals received only the hospital's usual care. Statistical analysis will be conducted using Statistical Package for Social Science (SPSS version 25). Descriptive statistics will be used to summarize and present demographic and clinical characteristics. Categorical variables will be expressed as frequencies or percentages and quantitative variables as means, standard deviations, median, and interquartile ranges. An intention-to-treat analysis will be conducted.

Abbreviations

EBF: Exclusive Breastfeeding; WHO: World Health Organization; SPSS: Statistical Package for Social Sciences; DSMB: Data Safety Management Board

Introduction

Background and rationale

Optimal breastfeeding is so critical that it could save the lives of over 820,000 children under the age of five years each year. For optimal growth, development, and health, the WHO recommends exclusive breastfeeding in the first six months, introducing appropriate complementary foods at six months, and continuing breastfeeding for up to two years or more. However, many infants and children do not receive optimal feeding [1,2]. Poor Infant and Young Child Feeding practices have been widely documented, with only 39% of infants exclusively breastfed for six months in developing countries and 25% in Africa [3]. In Nigeria, the Federal Ministry of Health (FMOH), in her document "Saving Newborn Lives Maternal and Child Health", reported that Nigeria has one of the lowest EBF rates in the African continent [4]. The recent data indicated that the percentage of infants exclusively breastfed to the age of six months is fluctuating, from 17% in 2003 to 13.1% in 2008 and returned to 17% in 2013, while the proportion of children less than six months who received complementary foods increased from 18% to 35% in 2008 and dropped to 23% in 2013 (Nigerian Demographic & Health Survey [NDHS]) [5]. This could be due to inadequate promotion of EBF.

Exclusive Breastfeeding (EBF) during the first six months of life provides sufficient nutrients for the infant to support good health, growth, and development. EBF and continued breastfeeding up to 11 months can singularly prevent 13% of all annual deaths occurring in infants worldwide [6,7]. Exclusive breastfeeding rates have remained stagnant globally since 1990, with only 36% of children aged less than six months exclusively breastfed in 2012 and with only a slight increment in 2016 (i.e. 40%) in the same age bracket [8]. Although breastfeeding is arguably the single most effective preventive intervention for reducing children's mortality by less than five years [9,10] and is associated with lower risks of diarrhea- and pneumonia-related infant morbidity and mortality than breastfeeding with the addition of other fluids and solids in both developed and developing world settings [11,12], its practice is still low.

Numerous factors influence the beginning and continuation of breastfeeding. Some of the leading predictors are maternal intention to breastfeed, knowledge deficiency about the improvement of lactation, and little confidence in possessing breastfeeding skills [13,14]. Even though it is a natural act,

breastfeeding is also a learned behavior. Virtually all mothers can breastfeed provided they have accurate information and support within their families and communities and the health care system [15]. To ensure nursing mothers breastfeed their children exclusively, they should also have access to skilled practical help from, for example, trained health workers, lay and peer counselors, and certified lactation consultants, who can help to build mothers' confidence, improve feeding techniques, and prevent or resolve breastfeeding problems [15]. Meanwhile, in several studies, maternal breastfeeding self-efficacy has been strongly associated with EBF duration [16,17]. In a systematic review by Ejie, et al. 2020, breastfeeding mothers demonstrated poor awareness and understanding of EBF, which affected their practice. It revealed that mothers did not understand what constitutes EBF (i.e. what it involves and for how long it is recommended) and could not differentiate EBF from partial and predominant breastfeeding [18]. The study by Ejie, et al. 2020, also revealed that mothers' opinions of EBF and knowledge of the benefits of EBF encouraged them to practice EBF despite pressures from their husbands, other family members, and the community at large [18]. For these reasons, practical education, counseling, and support programs are considered necessary to promote breastfeeding and prolong the duration of EBF to up to six months of age. Therefore, education and support are the cornerstones supporting the framework of lactation and breastfeeding [19]. Implementing health education programs significantly promotes maternal breastfeeding Knowledge, Attitude, and Practice (KAP) [20–22]. By conducting four 60-min sessions of an educational program, Kang, et al. reported remarkable improvement rates in breastfeeding empowerment and practice [23].

Several studies have reported the positive impact of breastfeeding education during pre- and post-natal periods [24] and, in some cases, placed more emphasis on prenatal education as an initial action [25,26]. Comprehensive and culturally appropriate breastfeeding education through counselors (be they doctors, nurses, midwives, lactation consultants, or peer counselors) during the prenatal period, in the hospital during the first week postpartum, and repeated, continual support in the mother's home may be critical for facilitating breastfeeding among mothers, especially those belonging to the low-income groups [27–29]. Both pre- and post-natal education is vital as the incidence of breastfeeding is affected primarily by prenatal education. In contrast, breastfeeding duration and exclusivity are affected by both prenatal and postpartum management [30,31]. Breastfeeding promotion is a global priority with benefits for maternal and child health, especially in low-/middle-income countries where its relevance for child survival is undisputed [6]. Therefore, EBF promotion is a vital public health strategy to

prevent morbidity and mortality in infants. The promotion of Exclusive Breastfeeding (EBF) has been a cornerstone of public health measures to promote child survival for several decades [6]. Thus, a hospital-based maternal counseling guide on EBF may improve EBF practice and ultimately enhance maternal-child health outcomes.

Few studies have been carried out on interventions to improve EBF practice. For instance, a study in Iran reported that a smartphone-based educational intervention improved EBF practice, but it was limited to only mothers who own and understand the use of smartphones [32]. Also, in Nigeria, a study conducted using community volunteers to promote exclusive breastfeeding reported that counseling is a useful strategy for promoting the duration of EBF for six months and recommended additional resources to enable nursing mothers to practice EBF [33]. Although there are several studies on interventions to improve EBF practice, however, to the best of our knowledge, no study has formulated and/or implemented a hospital-based maternal counseling guide intervention to improve EBF practice. Interventions promoting optimal Infant and Young Child Feeding practices could prevent 19% of under-five deaths in countries with high mortality rates [6]. Such intervention could improve nursing mothers' understanding, acceptance, and practice of EBF. Therefore, this study aims to formulate a hospital-based counseling guide on exclusive breastfeeding, implement it, and determine its effect in improving EBF practice in twelve hospitals in Anambra State, Nigeria. Ethical approval was obtained from Chukwuemeka Odumegwu Ojukwu University Teaching Hospital Amaku Awka Anambra State Ethics Committee (COOUTH/CMAC/ETH.C/VOL.1/FN:04/202).

Research hypotheses

1. Intervention will not produce any difference in knowledge, attitude, and practice of EBF among the study participants.
2. There will be no changes in child weight-for-length z-score (WHZ) and length-for-age z-score (HAZ) after the intervention.
3. There will be no experiences, facilitating, or limiting factors associated with the intervention.

Study objectives

Primary objective: To evaluate the effect of a hospital-based maternal counseling guide on EBF practices.

Secondary objectives:

1. To assess the knowledge, attitude, and practice of EBF of the study participants before and after the intervention.
2. To evaluate the changes in child weight-for-length z-score (WHZ) and length-for-age z-score (HAZ).
3. To assess the experiences, facilitating, and limiting factors associated with the intervention.

Materials and methods

Trial design

The HOME Trial is designed as a cluster-randomized, controlled, multicenter parallel trial with two parallel groups and a primary endpoint of six months of EBF practice. The study is in twelve secondary hospitals in Anambra State, southeast Nigeria. A cluster is defined as a senatorial zone, and for this study, we have three clusters representing the three senatorial zones in Anambra State. Twenty secondary hospitals that offer comprehensive ante-natal and post-natal clinic services and have a higher population of women accessing care in the ante- and post-natal clinics were selected. Two State governments and eighteen mission-owned hospitals in Anambra State met the selection criteria. After selection, the two State governments- and the eighteen mission-owned hospitals were categorized into urban and rural based on their location. After categorization, the two State government-owned yielded one rural and one urban, while the eighteen mission-owned hospitals yielded ten urban and eight rural. Of the ten urban hospitals, five were selected for randomization into the intervention and control arm, and of the eight rural hospitals, five were selected for randomization into the intervention and control arm. In selecting the twelve hospitals, the three clusters were still taken into consideration. Convenient sampling, simple random selection throw of a coin, and simple random selection (using serialized numbering and selecting every odd number) were employed depending on the number of hospitals in the cluster to select the hospital that will participate in the study. The selected rural and urban hospitals were randomly assigned to the intervention or the control arm. Further details of the trial are shown in Table 1 and Appendix 1 (CONSORT checklist) and Appendix 2 which shows the schedule of enrolment, interventions, and assessments for the trial design.

Eligibility criteria

Inclusion criteria:

1. Pregnant women between the ages of 18 to 50 years in their second trimester living in the catchment areas intending to stay for the next year at the time of the study.
2. Pregnant women willing to give informed consent, and able to comply with scheduled visits and other study procedures.

Exclusion criteria:

1. Pregnant women between the ages of 18 to 50 years in their second trimester living in the catchment areas intending to stay for the next year at the time of the study who have given their consent but will not be available during the study.
2. Pregnant women attending the ante-natal clinic at the time of the study who are mentally unstable, critically ill, or refused to give their informed consent to participate in the study.

**Table 1:** The World Health Organisation (WHO) trial registration dataset.

Data category	Information
Primary registry and trial identifying number	The Pan African Clinical Trials Registry: https://pactr.samrc.ac.za/ (PACTR202203618023651)
Date of registration in primary registry	14 March 2022
Source of monetary or material support	None
Primary sponsor	Nnamdi Azikiwe University, Awka, Nigeria
Contact for public queries	co.esimone@unizik.edu.ng
Public title	Effect of a hospital-based maternal counseling guide on exclusive breastfeeding practices in Anambra State, Nigeria: A cluster-randomized controlled trial
Scientific title	Effect of a hospital-based maternal counseling guide on exclusive breastfeeding practices in Anambra State, Nigeria: A cluster-randomized controlled trial
Country of recruitment	Nigeria
A health condition or problem studies	Exclusive breastfeeding
Interventions	Hospital-based maternal counseling guide on exclusive breastfeeding practices
Key inclusion criteria	Pregnant women between the ages of 18 to 50 years in their second trimester living in the catchment areas intending to stay for the next year at the time of the study
Study type	Interventional
Date of first enrolment	15 th March 2022
Target sample size	288
Recruitment status	Commenced
Primary outcome	Exclusive breastfeeding to six months
Key secondary outcome	Mothers' KAP pre- and post-intervention, intention to practice EBF, initiation of breastfeeding within one hour of delivery, use of only colostrum or breast milk in the first 3 days of life, children's mean birth weight, exclusive breastfeeding to one and three months, changes in child weight-for-length z-score (WHZ), changes in child length-for-age z-score (HAZ)

3. Nursing mothers with infants that have medical conditions such as cerebral palsy or physical disability and mothers and infants whose physician had recommended formula feeding due to breastfeeding contraindications because of the mothers' health condition (e.g., gynecological cancer such as CA breast or uterus, cancer chemotherapy, HIV-positive mothers who opted out of breastfeeding).

Study setting

Anambra State is one of the 36 states in Nigeria, located in the southeastern part of the country, with Awka as its capital. The creation of the present Anambra State resulted mainly from the desire to spread economic development gains and arrest the national problem of the north-south, geopolitical dichotomy evident in the former Anambra State. Two State government and ten mission-owned hospitals in Anambra State that offer comprehensive ante-natal and post-natal clinic services were used for the study. The twelve hospitals were categorized as either urban or rural based on location. Only two State government hospitals were selected out of about twenty general hospitals in Anambra State because they have a considerable number of women accessing care in the ante- and postal clinics and the majority of the mission hospitals were selected because they have a high number of women accessing care in the ante- and post-natal clinics. After randomization into intervention and control arm, the hospitals that received the intervention are Holy Rosary Specialist Hospital & Maternity Waterside Onitsha, St. Felix Catholic Specialist Hospital Nnewi, and Immaculate Heart Specialist Hospital Nkpor-Agu in the urban and Immaculate Heart Multi-Specialist Hospital Aguleri,

Joint Hospital Ozubulu, and General Hospital Enugwu-Ukwu in the rural. In the control arm, the urban hospitals are General Hospital Onitsha, Our Lady of Lourdes Specialist Hospital Ihiala, and Regina Caeli Specialist Hospital Awka and the rural hospitals are Immaculate Heart Hospital Umunze, Visitation Hospital Umuchu, and Our Lady of Fatima Specialist Hospital Awka-etiti. The trial has three periods – pre-intervention, intervention, and post-intervention periods.

Intervention: The hospital-based counseling guide on EBF was designed to provide the required knowledge for educating mothers during ante- and post-natal clinics. Information from the WHO Infant and Young Child feeding practices [34], the Federal Ministry of Health Ante-natal care orientation package for health care providers [35], and results from our formative study were used to formulate the hospital-based counseling guide. The formative study includes a systematic review and a qualitative study. The systematic review was qualitative research on barriers and facilitators to exclusive breastfeeding practice in sub-Saharan African countries. Afterward, a qualitative study on factors affecting exclusive breastfeeding practice among nursing mothers in Southeast Nigeria was carried out to determine the context-specific barriers and facilitators of EBF practice from the nursing mothers' perspective. Results from the formative study revealed that maternal factors were the most significant factor affecting EBF practice hence the need to produce a maternal-targeted intervention in the form of a hospital-based counseling guide on EBF [18,36]. The hospital-based counseling guide was based on the WHO/UNICEF breastfeeding counseling/ lactation management courses [9], the Federal Ministry of Health Antenatal Care Orientation Package [35], and results from the formative study

[18,36]. It also includes information on the production of breast milk, the definition of exclusive breastfeeding, the benefits of exclusive breastfeeding for the mother and the child, the recommendations for effective breastfeeding, breastfeeding techniques (positioning and attachment), the on-demand and frequent feedings, the problems created by pre-lacteal, the adequacy of breastfeeding for six months, breast milk substitutes, myths and truths about EBF, preparation for EBF, solutions to the barriers to EBF practice from the formative study. The hospital-based counseling guide on EBF was given to four healthcare workers (doctor, pharmacist, nurse, and midwife) for their expert opinion to ensure robustness and all-inclusive information. With the input of the four healthcare workers, the final version of the hospital-based counseling guide on EBF was produced and then validated by an education expert.

Each center's study personnel (nurse) was trained using the hospital-based counseling guide on EBF and study requirements by an experienced nurse/midwife. Training content covered basics of breastfeeding, EBF, benefits of EBF, myths vs. facts about breastfeeding, preparing for EBF, foods that can improve breast milk production in mothers, initiating breastfeeding after birth, colostrum and its benefits, frequency of breastfeeding, factors affecting EBF practice, breastfeeding positions, and breastmilk expression, and the survey instrument.

Assignment of interventions

Sequence generation: Hospitals will be randomly assigned to either a control or intervention group with a 1:1 allocation as per a computer-generated randomization schedule stratified by senatorial zone.

Allocation concealment mechanism: Allocation was not concealed as the randomization was at the cluster level.

Implementation: The hospitals that gave their approval to participate in the study and fulfill the inclusion criteria were categorized and randomized. An independent person who is not part of the research team did the categorization and randomization schedule.

Blinding: Not applicable

Comparison: The hospitals allocated to the control arm (usual/standard care hospital-based nutritional counseling guide) will continue with their usual care. Their study personnel did not receive any training/education on EBF.

Nutrition education process

The nutrition education process will employ the health belief model. The Health Belief Model (HBM) is the most commonly used theory to change health behaviors. According to the model, the messages will achieve optimal behavior change if they successfully target perceived barriers, benefits, self-efficacy, and threats [37]. It is based on the belief that the perception an individual has determines their success in taking on that behavior change. Individual perception of health

behavior is controlled by modifying variables, cues to action, and self-efficacy, and successful promotion of health behavior depends on the understanding of the factors that influence perception. Women will breastfeed as recommended if they are influenced to develop a positive perception of breastfeeding [38]. Positive perception and intention toward health behavior will result in self-efficacy and intention to promote health behavior [38,39]. Studies done using the health belief model brought a significant change regarding maternal breastfeeding knowledge and attitude, self-efficacy, and perceived barriers. According to a study done in Greece, women in the intervention group had a more positive attitude towards breast-feeding (73.5 % v. 66.1 %), greater knowledge (14.6 % v. 13.1 %) and more breast-feeding self-efficacy (51.4 % v. 45.6 %) compared to the control group. Furthermore, they had significantly fewer perceived barriers regarding breastfeeding (27.4 % v. 31.0 %) [40].

Outcomes: Our primary study outcome is exclusive breastfeeding for six months. Secondary outcomes are, mothers' KAP pre- and post-intervention, intention to practice EBF, initiation of breastfeeding within one hour of delivery, use of only colostrum or breast milk in the first 3 days of life, children's mean birth weight, exclusive breastfeeding to one and three months, changes in child weight-for-length z-score (WHZ), and changes in child length-for-age z-score (HAZ). EBF is defined as a child receiving only breast milk and no other type of milk, water, or other liquids and solids but allows for vitamins, drops of other medicines, and oral rehydration therapy. Data for both primary and secondary outcomes will be collected using an adapted questionnaire [41] and case report forms.

Participants' timeline: The participants in the intervention hospitals received EBF education/training using the formulated hospital-based counseling guide and the hospital's usual care while those in the control hospitals received EBF education/training only from the hospital's usual care. The hospital's usual care is standard care specific to the hospital which does not have any standard plan/approach/format as education/discussions are based on the mothers' questions during the clinics or what the nurse on duty deems fit for the day. The intervention was initiated in the third pregnancy trimester and will continue until six months after birth. During pregnancy, the counseling interval will be at the 30th week, 32nd week, 34th week, 36th week, 38th week, and 40th week which coincides with their routine ante-natal clinic appointments. The interval is consistent with the 2016 WHO ANC model recommendation [35]. After giving birth, participants in the intervention arm will, in addition, receive at least one counseling session per month, either in the hospital during post-natal clinic days at their homes, or through phone calls. The time was chosen to coincide with the dates of their immunization schedules. Participants in the control arm will only receive usual care as it pertains to the hospital.

For both arms during the post-natal clinics, when the mothers come for the infants' vaccination, the infants will be assessed on developmental aspects based on weight, and

length tests to determine their overall health. The study personnel (nurses/midwives) will follow up with the mothers as the directly responsible parents and encourage them to report any breastfeeding challenge and even call them (nurses/midwives) if need be. During the follow-ups, the mothers will be asked about their breastfeeding problems and counseled appropriately for the intervention arm.

To ensure participants adhere to the scheduled visits, we intentionally developed a relationship with them. We collected their phone numbers and home addresses and then we will facilitate their access to see the doctor each time they come for ante- and post-natal clinics. The mothers will be reminded of these visits through phone calls, text messages, and/or visits to their homes. Also, most mothers are usually eager to know how much weight their child has gained so we will weigh their child on every visit.

Sample size: Sample size calculation was calculated using a web-based sample size calculator of the UCSF Clinical & Translational Science Institute [42]. Sample size calculation is based on the proportion of participants that practiced EBF and those that did not practice EBF. Based on a power of 80% and an α of 0.05 (two-sided), 64 participants per group will be needed to observe a 12% (assumed standard deviation of 24%) increase in the number of participants that practiced EBF as previously reported [43]. This is shown in the formula below:

$$\text{The standard normal deviate for } \alpha = Z_{\alpha} = 1.960$$

$$\text{The standard normal deviate for } \beta = Z_{\beta} = 0.842$$

$$A = (1/q_1 + 1/q_0) = 4.000$$

$$B = (Z_{\alpha} + Z_{\beta})^2 = 7.849$$

$$\text{Standardized Effect Size} = (E/S) = 0.500$$

$$\text{Without correcting for clustering, total group size} = N_{\text{total}} = AB/(E/S)^2 = 125.58$$

$$\text{i.e., } N_1 = 63, N_0 = 63, N_{\text{total}} = 126$$

After adjustment for the cluster design, based on an assumed intracluster correlation coefficient of 0.047 and a fixed cluster per arm of 6 treatment hospitals, the effective sample size increased to 120 patients per arm (i.e., a total of 240 patients). This is shown in the formula below:

$$\text{Cluster size} = m = (1-p)/((C_1/N_1)-p) = 19.63, \text{ rounded to } 20$$

$$\text{Design Effect} = 1+(p(m-1)) = 1.88$$

Where p = Within-cluster correlation coefficient, C_1 = Number of Clusters in Group 1

A fixed number of 3 clusters or 6 hospitals per arm (i.e., 12 hospitals in total for the trial). Each of the hospitals will therefore recruit 20 participants as they have a similar patient load. Due to potential attrition that could arise, we added four participants per hospital i.e., 20% of the calculated sample size to increase the number of participants in each arm to 144 (i.e.,

a total of 288 participants). Each of the hospitals had a target to recruit 24 participants.

Recruitment: Participants' recruitment is in the second pregnancy trimester done through routine antenatal clinic visits, whereby pregnancy registration is done for pregnant women assessing care in the hospital and lasts for two months. This was complemented by a research assistant to ensure high coverage. The first 24 women who met the inclusion criteria were recruited. Each recruited participant in the intervention arm received hospital-based information materials starting from the third trimester. The trial team recruited eligible study personnel/nurses or research assistants at each trial site. Each study participant was assigned to a study nurse/personnel working in the hospital, and they will be tracked with their mobile phone numbers where necessary.

Data collection, management, and analysis

Data collection methods: The process of data collection is from March 2022 to November 2022. During each pre- and post-intervention appointment, the mothers will complete the questionnaire pack consisting of maternal demographic and KAP questions. The study focused on the following data: (1) sociodemographic information on the infants' age and sex, mothers' age, family income, education, and occupation; and (2) mothers' KAP. Infants' birth weight will be obtained from birth records and measured by nurses using infant weighing scales made available to all the twelve included hospitals. All the nurses in the control and intervention arm received training on anthropometric measurements, and the scales will be checked biweekly to ensure accuracy. Children's anthropometric measurements will be taken at each visit following standard procedures [43]. Recumbent length will be measured using length boards with 0.1 cm precision. Infants will be weighed in light clothing using electronic scales with a precision of 100 g. All measurement instruments will be calibrated before each measurement session. All measurements will be performed twice. Standardization exercises for anthropometric measurements will be conducted during the initial training and repeated bi-monthly during the study. After the intervention, data will be collected to assess satisfaction with the intervention, challenges, and enabling factors from mothers' and study personnel's perspectives. To validate infant feeding practices, two categories will be established using self-reports: exclusive and non-exclusive breastfeeding.

Summary of data collection methods: Quantitative data will be collected through interviewer-administered questionnaires from all mother-child pairs in both intervention and control arms. Data will include:

- Pre-intervention (third trimester) and post-intervention Knowledge, Attitudes, and Practices (KAP) - (Objective 1).
- Changes in child weight-for-length z-score (WHZ) and changes in child length-for-age z-score (HAZ) - (Objective 2).

- Mothers' and study personnel's experiences, facilitating and limiting factors associated with the intervention. - (Objective 3).

Data management: The participant's data will be treated with confidentiality. All personal data collection and processing will be carried out according to European Union (EU) and national legislation. Personal data collected are those necessary to establish primary and secondary study outcomes. Unique identifiers and a password-protected database will be used to protect the personal information of the study participants. We will keep a written document with detailed information on the origin of all used human samples. All the study partners in the different study sites will receive training on procedures for handling pseudonymized data during study briefing/training. The Principal Investigator (PI) (including the data analyst) will receive only key-coded data to ensure personal data protection.

The nurses in the study sites will be provided with file jackets, a small cupboard, and a padlock to ensure the safety of all collected data. The PI will have a fortified steel cupboard for the storage of collated data and these data will remain safe in the cupboard for a minimum of five years before they are destroyed.

Statistical methods: Statistical analysis will be conducted using Statistical Package for Social Science (SPSS version 25). Descriptive statistics will be used to summarize and present demographic and clinical characteristics. Graphs and charts will be appropriately used to present socio-demographic variables where necessary. Categorical variables will be expressed as frequencies or percentages and quantitative variables as means and standard deviations if normally distributed and as median and inter-quartile range if not normally distributed. An intention-to-treat analysis will be conducted. All observations will be analyzed in the arm to which they will be randomized. Multivariate binary logistic regression will be used to predict the level of EBF practice using the related associated factors as independent variables between the control and intervention arms. Adjusted odds ratio will be reported as the baseline parameter using the practice of EBF as an outcome variable while adjusting for age, type of family, marital status, education, family income, occupation, number of successful deliveries, type of delivery, and number of an ante-natal clinic visit(s) as cofounders in the regression model. In the analysis, the reference category will be those who did not practice EBF. A p -value of <0.05 will be used to indicate statistical significance.

Low birth weight will be defined as birth weight below 2500 g. WHO 2019 child growth standards will be used to calculate WHZ and HAZ WHO Anthro Survey Analyser [44]. Children with a WHZ below -2 will be considered wasted, and those with a HAZ below -2 will be considered stunted [44,45]. All analyses will be by intention-to-treat. Comparisons between study arms on participants' baseline characteristics will be performed using binary logistic regression.

An In-Depth Interview (IDI) with all the study personnel in the intervention arm will be conducted at the end of the study to assess the mothers' and study personnel's experiences,

and limiting factors associated with the intervention. The IDI instrument to be used will be developed using the Pathfinder International Tool Series guideline on conducting IDI [46]. During the interview, notes will be taken, and data will be transcribed verbatim into English by the researcher and research assistant independently. A thematic content approach, guided by the Graneheim and Lundman framework, will be utilized for qualitative data [47]. Responses from the IDIs will be read systematically through to identify the meaning units. A meaning unit will be defined as a string of text that expresses a single coherent thought, up to the point that the coherent thought changes [1]. The meaning units will be coded using a describing cue related to the content of the meaning unit. Codes concerning the same subject will be grouped into categories. The interview guide will be used as a point of departure for grouping information deductively. Information obtained during the IDIs will be analyzed and merged according to the codes and themes. Original data will be reassessed after analysis to detect any concepts or information that may be missed.

Monitoring

Data monitoring: The Data and Safety Monitoring Board (DSMB) is composed of one of the authors, a biostatistician, and four external, independent experts on child and maternal health. The members are listed in Appendix 3. Specifically, the committee will: (1) review and evaluate the accumulated study data every two months for participant safety and (2) study the conduct and progress of the trial and make appropriate recommendations to the trial team.

Harms: The major risk envisaged in this trial will be the exposure of the data of study participants. To mitigate this risk, participants' data will be treated with confidentiality.

Auditing: Not applicable

Ethics and dissemination

Research ethics approval: The protocol and the template informed consent forms contained in Appendix 4 were reviewed and approved first by the Ethics Committee (EC) of the 12 included hospitals and then by approved Chukwuemeka Odumegwu Ojukwu University Teaching Hospital Amaku Awka Anambra State Ethics Committee (COOUTH/CMAC/ETH.C/VOL.1/FN:04/202) concerning scientific content and compliance with applicable research and human subjects regulations. The protocol, site-specific informed consent forms (local language and English versions), participant education and recruitment materials, and other requested documents—and any subsequent modifications—also were reviewed and approved by the ethical review bodies. After initial review and approval, the responsible local Institutional Review Boards/Ethical Committees (IRBs/ECs) will review the protocol at least annually. The Investigator will make safety and progress reports to the IRBs/ECs at least annually and within three months of study termination or completion at his/her site. These reports will include the total number of participants enrolled and summaries of each DSMB [data safety and monitoring board] review of the safety and/or efficacy.

Patients and public involvement: Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research

Protocol amendments: Any modifications to the protocol that may impact the conduct of the study, the potential benefit of the participant, or may affect participant safety, including changes in study objectives, study design, participant population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by the investigators and approved by the Ethics Committee/IRB [institutional review board] before implementation and notified to the health authorities per local regulations. Administrative changes to the protocol are minor corrections and/or clarifications that do not affect how the study is conducted. These administrative changes will be agreed upon by the investigators and will be documented in a memorandum. The Ethics Committee/IRB may be notified of administrative changes at the discretion of the investigators.

Consent or assent: Trained Research Nurses will introduce the trial to participants who will receive a trial information sheet and the hospital-based counseling guide on EBF. Research Nurses will discuss the trial with participants in light of the information provided in the information sheets. Participants will then be able to have an informed discussion with the participating research assistant/investigator. Research Nurses will obtain written consent from participants willing to participate in the trial.

Confidentiality: All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. To maintain participant confidentiality, all reports, data collection, process, and administrative forms will be identified by a coded ID [identification] number. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number. All local databases will be secured with a password-protected access system. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access. Participants' study information will not be released outside of the study without the written permission of the participant, except as necessary for monitoring by DSMB or in-country government and regulatory authorities.

Declaration of interests: None to declare

Access to data: The Data Management Coordinating Center will oversee the intra-study data-sharing process, with input from the Data Management Subcommittee. All Principal Investigators will be given access to the cleaned data sets. Project data sets will be housed on the Project Accept website and/or the file transfer protocol site created for the study, and all data sets will be password-protected. Project Principal Investigators will have direct access to their own site's data

sets and access to other sites' data by request. To ensure confidentiality, data dispersed to project team members will be blinded to any identifying participant information.

Ancillary and post-trial care: Not applicable

Dissemination policy: Publication Policy

The Publications subcommittee will review all publications following the guidelines given below and report its recommendations to the Steering Committee.

A. Data analysis and release of results

The scientific integrity of the project requires that the data from all HOME [Hospital-based counseling guide on exclusive breastfeeding] trial sites be analyzed study-wide and reported as such. Thus, an individual center is not expected to report the data collected from its center alone; all presentations and publications are expected to protect the integrity of the major objective(s) of the study; data that breaks the blind will not be presented before the release of mainline results. Recommendations as to the timing of the presentation of such endpoint data and the meetings at which they might be presented will be given by the Steering Committee.

B. Review process

Each paper or abstract, as described below, must be submitted to the appropriate Subcommittee for review of its appropriateness and scientific merit before submission. The Subcommittee may recommend changes to the authors and will finally submit its recommendations to the Steering Committee for approval.

C. Primary outcome papers

The primary outcome papers of HOME Trial are papers that present outcome data. The determination of whether or not a particular analysis represents a primary outcome will be made by the Steering Committee on the recommendation of the Publications Subcommittee.

D. Other study papers, abstracts, and presentations

All studies other than those designated as "Primary Outcome" fall within this category. The Publications Committee must approve all papers and abstracts before they are submitted. In certain instances, HOME Trial may be asked to contribute papers to workshops, symposia, volumes, etc. The individuals to work on such requests should be appointed by the Executive Committee, but where time permits, a proposal will be circulated soliciting other participants as in the case of other study papers described in the Application Review Process.

Close-out procedures

HOME Trial may terminate at the planned target of nine months after the last participant has been randomized or at an earlier or later date if the circumstances warrant. Regardless of the timing and circumstances of the end of the study, close-out will proceed in two stages:



- Interim period for analysis and documentation of study results.
- Debriefing of participants and dissemination of study results.

A. Interim

Every attempt will be made to reduce to an absolute minimum the interval between the completion of data collection and the release of the study results. We expect to take about % to & months to compile the final results paper for an appropriate journal.

B. Reporting of study results

The study results will be released to the participating nurses, participants, and the general medical community

Biological specimens: Not applicable

Declarations

Ethics approval and consent to participate

The study will be conducted according to the Helsinki Declarations on ethical principles for medical research involving human subjects [48]. Ethical approval was obtained from Chukwuemeka Odumegwu Ojukwu University Teaching Hospital Amaku Awka Anambra State Ethics Committee. Oral and written consent will be obtained from all participants. Unique identifiers and a password-protected database will be used to protect the personal information of the study participants. Participant's data will be domiciled with the PI. Participants will be free to purposely leave the study at any time, without any effect on the care received in the study hospital. Ethical approval for any amendments to the protocol will be sought before implementing any changes if necessary.

Trial registration: Pan African Clinical Trial Registry (PACTR) with registration number PACTR202203618023651

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Roles and responsibilities

This includes the roles and responsibilities of the principal investigator and research physician, steering committee (SC), trial management committee (TMC), data manager, and lead investigators (Appendix 5).

Roles of authors/protocol contributors

ILE and OIE conceived the study, and ILE, OIE, and GUE refined it. The hospital-based counseling guide on EBF was

produced by ILE, BMA, and NEA and validated by LIE. The questionnaire was developed by ILE, MUA, ATN, CCA, BMA, ROA, and IBU, and the interview guide was by ILE and MUA. All authors initiated the study design and implementation. CGC, ILE, OIE, and GUE provided statistical expertise in clinical trial design and primary statistical analysis. ILE, NEA, and MUA provided training for the nurses. The trial will be monitored by CUO, ILE, MUA, IBU, BOO, and CMO. All authors contributed to the refinement of the study protocol and approved the final manuscript.

(Supplementary-Files)

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