

STUDY PROTOCOL

Effects of Social Cognitive Theory Based Health Education Intervention on Exclusive Breastfeeding Practice Among Antenatal Mothers: A Study Protocol

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ABSTRACT

Introduction: Despite the numerous benefits of breastfeeding to mothers and infants, the rate of exclusive breastfeeding (EBF) in Nigeria is still low. **Aim:** This study aims to evaluate the effectiveness of health education intervention to improve EBF among antenatal mothers in the Imo State Specialist Hospital in Nigeria, using the social cognitive theory. **Methods:** This study is a two parallel arm single blinded randomised controlled trial (RCT) that will involve women who come for antenatal check-up in the Imo State Specialist Hospital in Owerri, Nigeria. The primary outcome is EBF practice while secondary outcome is breastfeeding knowledge, breastfeeding attitude, breastfeeding outcome expectancy, breastfeeding social support and breastfeeding self-efficacy. Participants were randomly assigned to either intervention (Health education intervention) or control group. The health education intervention will be developed based on the Social Cognitive Theory and the World Health Organisation guidelines on exclusive breastfeeding. The Social Cognitive Theory in breastfeeding education programme (SCT-BFEP) will be a six-month intervention programme delivered in phases, including a health education session (4 weeks), followed by weekly follow-up WhatsApp messages until eight weeks post-natal. Concealment was determined by using sequentially numbered sealed opaque envelopes. The sample size is 204. In brief, 102 mothers will receive health education alongside standard care for four weeks, while another 102 participants (control group) will receive only standard care. **Discussion:** Studies reported that health education interventions and behaviour change outlines provide an effective basis to increase EBF rates. A health education intervention programme is also a feasible and effective method that may contribute to the national strategy on infant and child feeding practices. This is done through the health education empowerment of mothers and the support of frontline healthcare providers and health programme managers to reinforce the importance and benefits of breastfeeding from early antenatal visits. Data collection will be done at baseline, at three months, and six months post-natal. **Conclusion:** The SCT-BFEP will be effective in positively affecting the outcome variables such as EBF practice, breastfeeding knowledge, attitude, intention, outcome expectancy, social support and self-efficacy. **Trial Registration:** The study has been prospectively registered in the Pan African Clinical Trial Registry with identification number PACTR202307540188312.

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INTRODUCTION

Exclusive breastfeeding (EBF) is defined as feeding

infants only breast milk, be it directly from the breast or expressed, with no other liquids or solids given for the first six months of life, except oral rehydration solutions or drop/syrups of vitamins, minerals, or medicines (1). Breastfeeding is associated with several established health benefits for both the infant and mothers (1) and has considerable potential savings to health services (2). Hence, the World Health Organization (WHO) strongly

recommends EBF for the first six months of an infants' life as the ideal and appropriate infant feeding plan for optimal growth and development (3), followed by ongoing breastfeeding, and combined with timely and appropriate complementary foods for at least two years (4). According to recent assessments, it was revealed that suboptimal breastfeeding practices, encompassing instances of non-EBF, contribute to a mortality rate of 11.6% in children under the age of 5.

From 2000 to 2015, there was an average annual increase of 2.4% in global rates of EBF (rising from 38% to 41% within a 5-year span). However, these rates subsequently declined across most regions. Nonetheless, after 2017, 22 countries documented increase of EBF by 10% or more, mirroring the pace required to meet the overarching global target (5). However, the prevalence of EBF in infants aged 0-6 months remains consistently low in Nigeria, ranging from 17% in 2013 to 23% in 2016 and a slight increase to 29% in 2018. This prevalence displays diversity, both among different regions and within them, with rates that range from 10% to 56% (6-10) suggesting that a considerable number of mothers in Nigeria have not embraced the practice of EBF.

There are numerous factors influencing breastfeeding practices which include maternal age, education, parity, mothers' beliefs about insufficient breast milk, support from family members (such as the husband, mother's mother, mother-in-law, and grandmother), financial insufficiency, household workload, mothers' disinterest, and knowledge and attitude towards breastfeeding (7,11). Furthermore, in previous cross-sectional studies, social support was found to be a strong predictor (AOR 2.18; 95% CI 1.23, 3.87) of EBF (12). In addition, a prospective follow-up study using SCT conducted among 233 primiparous women showed that breastfeeding self-efficacy and outcome expectancy were also strong predictors of EBF with an AOR of 7.32 (95% C.I.: 2.77, 19.36) and 4.12 (95% C.I.: 1.52, 19.32) respectively (13). Therefore, SCT will be used as the foundation for this study, which highlights the importance of a strong support network as well as self-efficacy and outcome expectancies (14). Moreover, SCT has been shown to be effective in previous breastfeeding intervention studies (15).

METHODS

This study is a two parallel arm single blinded randomised controlled trial (RCT) involving mothers attending an antenatal clinic in Imo State Specialist Hospital in Owerri, Nigeria. The primary outcome will be EBF until 6 months post-natal. The trial will involve pregnant mothers recruited in the third trimester of pregnancy. Eligible pregnant mothers will be randomly assigned to an intervention or control groups and outcomes will be measured before delivery, 3 months after delivery, and up to 6 months follow-up. The sample size is 204,

therefore 102 participants (intervention group) will receive four session of newly develop breastfeeding education and standard care, remaining 102 participants (control group) will receive standard care.

Randomisation and patient recruitment

Simple randomisation technique using a random number generating programme by an independent project biostatistician will be used to randomly allocate the sample population into intervention and control groups at a ratio of 1:1 respectively using the opaque sealed envelope method. The opaque sealed envelopes will be coded with unique codes. The codes will be, for instance, "IX" for the first intervention group participant and "CX" for the second participant of the control group. There will be 204 envelopes with 102 for the intervention group and 102 for the control group. The envelopes will then be handed to the medical records staff from the antenatal clinic who will enrol and assign participants into intervention and control group. To prevent contamination, the intervention group will receive breastfeeding health education in the antenatal clinic, while the control group will receive the standard health education in a different location (paediatric clinic).

Participant's eligibility

The eligibility criteria will be the basis for the selection of study participants. Only pregnant mothers who meet these criteria will be included in the study. The researchers will recruit a total of 204 participants from the Imo State Specialist Hospital in Owerri, Nigeria.

This study will exclude the following mothers: mothers who are not in their third trimester; mothers with known medical condition(s) including mental illness that might hinder breastfeeding; mothers who had a complicated pregnancy (defined as one with an underlying medical condition such as hypertension, diabetes and obesity); and antenatal mothers who cannot speak and understand English. The researcher will explain to the participants that they can leave this study at any time when they demand to do so, without any consequences.

Intervention

The two groups are intervention group and control group. Participants of the intervention group will receive health education to improve EBF and standard care, while participants of the control group will receive standard care. Standard care includes (routine physical examination, physical activities, maternal weight and blood pressure measurement at all visits, and fetal heart rate scan). All the participants will be followed up for six months after recruitment into the study. Health education will be given to the intervention group immediately after administering the baseline questionnaire, and follow up will be done at 3 and 6 months post-natal. The researcher will explain the aims, justification, and process of the intervention to the participants.

Development of intervention programme

The social cognitive programme is a new programme that was developed by the researcher. It is developed for antenatal mothers based on the SCT (12, 13, 16). The theory assumes that human behaviour is the product of the dynamic interplay of personal, behavioural, and environmental factors. The theory illustrates the exceptional way in which individuals acquire and maintain certain behaviours, as well as the social environment in which individuals perform the behaviour. This intervention is formulated to improve mother's knowledge, attitude, intention outcome expectancy, social support and self-efficacy, recognises how environments shape behaviour and focuses on people's potential abilities to alter and construct environments to suit the purposes they devise for themselves (12, 13). This in turns facilitates and influences the mother's engagement in improving EBF.

The contents of the SCT module recently developed by the researcher are in the table below. The SCT breastfeeding education session will be based on WHO guidelines and from previous intervention studies (17, 18, 19).

The SCT intervention module will use four behaviour change techniques, namely knowledge- intention, outcome expectancy, social support and self-efficacy, Mothers will be advised to report any difficulties encountered and any misconception to the WhatsApp group. The table below shows the application of SCT's behaviour techniques in the SCT intervention programme.

Table I: Protocol: Content of Social Cognitive theory

Units	Topics and Contents in SCT programme	Units	Topics and Contents in SCT programme
1	Introduction and exclusive breastfeeding* • Introduction of program • Breastfeeding and Exclusive breastfeeding • Information on Nigeria exclusive breastfeeding guideline	2	Knowledge • What is EBF • Benefit of EBF • Target of EBF • What is Baby friendly hospital initiative (BFHI)
3	Goal/Intention • What is goal/intention • Why is important to inform pregnant mothers about compliance of BFHI • How to encourage them to set the goal	4	Self-efficacy • Why do we empower mothers with knowledge to comply with EBF? • How to properly position and latch? • How to express breastfeeding and milk storage? • Target of frequency feeding • How to determine adequate intake. • Manage to keep up with breastfeeding demand • Deal with time consuming

CONTINUE

Table I: Protocol: Content of Social Cognitive theory. (CONT.)

Units	Topics and Contents in SCT programme	Units	Topics and Contents in SCT programme
5	Social support/Social-structural factors • What is social support • Why is it important to initiate breastfeeding and establish support? • Why is encouragement from spouse important? • Why creating an enabling environment?	6	Outcome expectancies • What is outcome expectancies • YTarget of EBF • How to Solve any BF related problem • Why do we need to clear misconception • Consequences of not exclusive breastfeeding both the infant and mothers

Table II: Session of health education which address the constructs of SCT

Week	SCT Constructs	Content	Mode of Delivery	Time duration
Week 1	Knowledge	- Introduction of breastfeeding - Benefit of exclusive breastfeeding.	Lectures and discussion (PowerPoint)	30 minutes
Week 1	Goal/intention	- Importance of goal setting/intention - Individual opinion toward breastfeeding	Discussion	
Week 2	Outcome expectancies	- Breastfeeding benefit	Lectures and discussion	30 minutes
Week 3	Social support/ socio-structural	- Motivational support - Guidance	Lectures and Discussion	30 minutes
Week 4	Self-efficacy	- Practical demonstrations of breastfeeding technique - Steps to successful breastfeeding - Managing breastfeeding difficulties - Successfully cope with breastfeeding challenging tasks. - Discussion of issues or problems that may arise	Lectures (PowerPoint) and demonstration-vid- eo session	30 minutes
Problem solving		- To answer breastfeeding related questions and how to handle them	Brief discussion whatsapp follow-up	10 minutes

Delivery of the intervention

The SCT intervention will be a six-month intervention programme, which will be delivered in phases via health education sessions during antenatal visit starting from the second week of the programme. Health education

will be given to the intervention group immediately after administering the baseline questionnaire, the health education phase will involve a face-to-face session of 30 minutes, followed by WhatsApp messages weekly until 8 weeks post-natal for intervention group. Past literature showed that the duration of intervention by other RCTs that have significant increase on EBF were those conducted between three and six months. The SCT module intervention is designed to be delivered for 4 weeks, followed by a weekly WhatsApp message that will impart knowledge and skills as part of the training phase. The WhatsApp group will also serve as a platform for question and answer sessions and feedback on progress of the mothers in EBF their babies.

Educational sessions will be conducted by the researcher and one research assistant (RA). The RA will also help provide lectures and demonstrations and assist with the organising of the intervention. The intervention will be delivered to mothers in the intervention group as highlighted in the randomisation and allocation concealment.

Sample size determination

A two-proportion sample size formula (20) will be utilised to calculate the sample size, as given below: In the formula, $P_1=0.68$ and $P_2=0.47$. This proportion is based on a randomised control trial study by Puharic (21) titled "The effect of a combined intervention on exclusive breastfeeding in primipara". From the study, the EBF rate at 3 months between intervention control and standard care will be used for the calculation of the sample size.

For calculating the sample size, the following formula is used:

$$n = \frac{\left\{ Z_{1-\alpha/2} \sqrt{2\tilde{p}(1-\tilde{p})} + Z_{1-\beta} \sqrt{p_1(1-p_1) + p_2(1-p_2)} \right\}^2}{(p_1 - p_2)^2}$$

Where

n = sample size

$Z_{(1-\alpha/2)}$ = Z statistic for level of confidence of 95% = 1.96

$Z_{(1-\beta)}$ = Z statistic for 80% power = 0.842

p_1 = Proportion of EBF at 3 months in intervention control group
= 68% (0.68)

p_2 = Proportion of EBF at 3 months in standard group
= 47% (0.47)

$\tilde{p} = (p_1 + p_2)/2 = 0.575$

$$n = \frac{\left\{ 1.96 \sqrt{2 \times 0.575(1-0.575)} + \sqrt{0.68(1-0.47) + 0.47(1-0.47)} \right\}^2}{(0.68-0.47)^2}$$

$n = 85$

$n \times 2 = 85 \times 2$
=170

Hypothesis testing, 2 groups: As there are two groups, the intervention and control groups among the sample size estimated are multiplied by a factor of two.

To calculate for attrition rate of 20% based on previous study by Valentine & Coopern (18)

$170 \times 20/100 = 34$

Sample size = $170 + 34 = 204$

Sample = 204

Training of research team

A two-day training will be done for selected nurses (who will serve as RA) using the developed health education intervention training module. Training on each day will last for three hours. The selection of RAs will be based on volunteerism as well as inclusion criteria. The first session covers aspects on education, types of health education, importance of health education, and health education materials. This ends with a role play and discussion on health education. The second session covers the basics of EBF.

Study Instrument

Data on health education intervention on EBF practice will be obtained using validated and pre-tested questionnaires at baseline and follow-ups. The questionnaire will be administered in English. The questionnaire consists of two main parts which include baseline questionnaire and follow-up questionnaire which will be administered at different points of time in the course of data collection. It will be pre-tested among 20 antenatal mothers, where amendments to the final questionnaire will be based on findings from the pre-test. The adapted and modified version of the infant feeding practice questionnaire (IFPQ) will be used as an instrument for data collection in this study to determine the effects of the intervention on the primary outcome at 3 and 6 month post-natal (22). The primary outcome will be EBF practice. The covariates are demographic profile. The secondary measures are knowledge of EBF, attitude, and SCT constructs, all questionnaire for the secondary outcomes was adapted and modified from previous studies (13, 23, 24, 25). In this study, all instruments will be reviewed by a panel of experts from the field of community health, maternal care, and child care in public health.

Ethics approval and consent to participate

Ethical approval will first be obtained from the ethics committee *Jawatankuasa Etika Universiti Putra Malaysia* (JKEUPM). Then, another ethical approval will be obtained from the local Ethics Committees at the Imo State Specialist Hospital. Informed consent forms will be administered to all pregnant mothers who are willing to participate in the survey. These documents contain information about the research, including the purpose

and procedures, benefits, risks, confidentiality, how the data and results obtained would be used, and freedom to withdraw at any point of the research. Also contained is the name and contact of the researcher. All documents will be in English. The study has been prospectively registered in the Pan African Clinical Trial Registry with identification number PACTR202307540188312.

Data collection

The participants will be required to fill up a structured baseline questionnaire in English language. The participants will be required to fill up another follow-up questionnaire at 3 and 6 months (follow-up). Information on mothers will be obtained from the antenatal register. The questionnaires will be distributed and collected by the RA. Internal consistency reliability using Cronbach's alpha will be assessed, where reliability values of 0.70 or higher is considered valid and will be used as the standard for reliability. Data will be self-administered collected at baseline, 3 and 6 months. The researchers will ensure data quality by pretesting the questionnaire among 30 mothers who will not be part of the study and for completeness and accuracy; the researcher will ensure that the questionnaire is completed by the mothers, no questions will be left partially unanswered or skipped, the researcher and research assistant will ensure all questions are answered by the participants.

Data analysis

Data collected will be collated, checked, cleaned, and analysed using Statistical Package for Social Sciences software (SPSS) version 25. The participants' selection process and flow throughout the study will be summarised and presented in a flow-diagram. The intention to treat (ITT) analysis concept will be employed for final analysis. Thus, based on the concept, all participants in the intervention group will be analysed using the randomised treatment assignment. This will be irrespective of the noncompliance status, deviation from protocol, attrition, and/or any other occurrences after randomisation. The results will present descriptive analysis including calculations of means, 95% confidence intervals (CI) of means, and frequencies of categorical variables. Chi square and fisher exact will be used to test categorical variables, to compare between intervention and control groups at baseline and t-test for continuous variables at baseline. ANOVA will be used for the changes within the intervention and control group from baseline to 3- and 6-months follow-up, t-test will also compare the changes between the intervention group and control group at 3 and 6 months follow-up. Meanwhile, the General Linear Mixed Model (GLMM) will be used to determine the final results and to check the effectiveness of the intervention at 6 months post-natal.

DISCUSSION

Recommendation by WHO stated that infants should

be breastfed exclusively for at least 6 months and to continue breastfeeding combine with complementary feeding in order to avoid communicable illnesses, when this is achieved, infant morbidity and mortality will potentially reduce.

Previous RCT studies show that written information regarding breastfeeding and follow up telephone calls during pregnancy at 3, 4 and 6 months postpartum improved EBF (21, 26, 27, 28, 29). Studies from Lebanon, China, Croatia, Bangladesh, and Nigeria demonstrated that health education interventions and behaviour changes frameworks, the rate of effective EBF increases (18, 21, 30). In this study, the intervention group will receive health education that will help the participants improve their EBF. Given the low breastfeeding rate worldwide especially in developing countries like Nigeria, there is need to validate, disseminate and implement efficient strategies to promote breastfeeding among the people. However, implementing the intervention may present potential challenges, particularly in recruiting mothers. In many African communities, cultural beliefs and traditional practices strongly influence infant feeding decisions, often favouring formula feeding, early introduction of solid foods, or the belief that breast milk alone is insufficient for the baby. To effectively recruit participants, researchers must collaborate closely with local community leaders to build trust and address these concerns. Another challenge could be the use of mobile technology, which may not be widely adopted by many mothers. To mitigate this, the study will be conducted in an urban setting where access to mobile technology is more common.

The purpose of this study is to provide scientific evidence that may support public policies, which include to implement programmes and decrease delivery cost strategies for EBF counselling among pregnant mothers. The health education intervention programme is a feasible and effective method. Hence, this research may contribute to the scientific knowledge in the study area and can also serve as a basis of child health policies implementation.

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