

Lactation Counseling for Maintaining Exclusive Breastfeeding in Adolescent Mothers: A Trial Protocol

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Study Protocol

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Abstract

Adolescent mothers have lower rates of initiation, continuation, and exclusivity of breastfeeding, and even more so in the first pregnancy. Current interventions target adult women, and little evidence is available for breastfeeding promotion among adolescents. This is a pilot study protocol with a parallel, single-blind, randomized, controlled trial design, to evaluate the effectiveness of the intervention “Lactation Counseling” in first-time adolescent mothers to maintain exclusive breastfeeding in the first six months of life. The control group will receive routine education in prenatal care and prenatal and childbirth classes and, the experimental group will receive additionally the intervention “Lactation Counseling”, for four weeks, both conducted by trained nurses. The primary outcome will be the exclusive breastfeeding rate; and the secondary, the breastfeeding knowledge. Measurements will be taken at baseline, post-intervention, and two, four and six months after childbirth. This study will allow the evaluation of the feasibility of an intervention in low-income, Latin American population adolescents.

Introduction

Breast milk is the natural and optimal source of nutrition for the newborn; it is associated with multiple health benefits (1,2), providing nutrients, hormonal immunoactives, and microbiomes necessary for growth and development (3). Furthermore, in the mother, it reduces the probability of breast and ovarian cancers, improves birth spacing, prevents type-2 diabetes, obesity and hypertension, among other benefits (4,5).

Countries have made efforts to protect, promote and support exclusive breastfeeding (EB). It is expected that by 2025 the prevalence of EB will be 50% (6), although globally only about 38% of children benefit from it (7). The outlook is worse in developing countries, such as Colombia with a prevalence of 36.1% in children under 6 months, and only 52.2% of children 6 to 12 months continued to receive breastfeeding (8).

Exclusive breastfeeding is one of the most important cost-effective strategies in the prevention of maternal and infant morbidity and mortality. An estimated 823,000 deaths of children under 5 years of age and 20,000 deaths of women from breast cancer could be prevented each year if breastfeeding were a universal practice (2).

The optimal practice of breastfeeding in adolescent mothers is determined by a range of personal and cultural factors such as attitudes about breastfeeding, perceived benefit, knowledge, previous experiences, self-efficacy, and affective or social support. All these factors significantly influence the duration of breastfeeding in adolescent mothers (9).

The development of educational strategies that intervene in the factors that influence breastfeeding in adolescent mothers is key. Therefore, nurses must acquire a commitment and responsibility in the implementation of educational interventions, motivating the mother to generate positive thoughts and

commitments, as well as providing a support network and knowledge that contribute to the significant improvement of breastfeeding practices and indices of initiation, exclusivity and duration (10–14).

The Global Breastfeeding Scorecard 2019 urges that primary care facilities offer individual advice on infant and child feeding, seeking the goal of 80% of countries whose health institutions provide this advice by 2030. It emphasizes in the importance of improving access to qualified breastfeeding counseling by providing specialized guidance that helps to make informed decisions and overcomes difficulties for breastfeeding, focusing on new mothers who have the greatest lack of knowledge and confidence (15).

To carry out educational interventions, the nurse must implement the nursing care plan, as it provides patient-centered care and improves the expected results. To implement this care plan, the use of the Nursing Intervention Classification (NIC) (16) is recommended, which includes the nursing intervention “Lactation Counseling”; however, available evidence on the use of the classification in clinical trials is scarce especially in the adolescent maternal population (17).

Purpose: This article describes the methodology of intervention design based on the nursing intervention “Lactation Counseling” that aims to determine the effectiveness of this intervention in first-time adolescent mothers for maintaining exclusive breastfeeding in the first six months of child-life.

Materials And Methods

Design: This is a pilot study protocol for a randomized controlled trial using a parallel-group design with a 1:1 allocation ratio, to evaluate the effect on exclusive breastfeeding rates of the intervention “Lactation Counseling” described in the Classification of Nursing Interventions (NIC) (16) (n=59), versus usual education and nursing interventions not related to breastfeeding (n=59) in first-time pregnant adolescents, attending the control prenatal, and followed-up with for up to 6 months after delivery.

Participants: Eligible participants are first-time teenage mothers; between 14 and 19 years old, between 20 to 30 weeks gestation. Adolescents with psychiatric and/or communication disorders will be excluded and who have obtained a score less than or equal to 3.8 on the Knowledge outcome: Breastfeeding (1800), described in the Nursing Outcomes Classification (NOC) (18).

Settings and locations: The study will be carried out in two public hospitals in the cities of Girón and Piedecuesta in Santander, Colombia, which mainly provide care for low-income people. The recruitment of participants began in 2019 and is expected to end in 2021 due to delays caused by quarantines and restrictions to control the COVID-19 pandemic. The protocol is approved by the research ethics board of the Industrial University of Santander and is covered by the inter-institutional agreement between the participating hospitals; it has obtained approval and funding from the university’s Research and Extension Directorate (#2453) and additional funding from young research program from the Ministry of Science, Technology and Innovation(#8009).

Pregnant women attending prenatal controls will be invited to participate in the study. Pregnant women who meet the inclusion criteria will fill out a questionnaire designed based on the Knowledge outcome: Breastfeeding (1800). Adolescents who obtain a score on the knowledge test less than or equal to 3.8 points will be invited to participate in the intervention, with prior informed consent. Pregnant women scoring above 3.8 in breastfeeding knowledge will not be invited as they are considered to have extensive breastfeeding knowledge.

Interventions: Control group: This group will receive the usual education given in prenatal control and maternity preparation classes, using the interventions: Infant Care (6820) and Prenatal Care (6960), taken from the Nursing Interventions Classification (16). This group will not receive specific interventions in breastfeeding and the information on this aspect will be that which is usually offered in prenatal control.

This group will receive the interventions in four educational sessions with the following topics: physical-psychological changes and care during pregnancy, the process of labor, delivery and postpartum in its different stages, care of the newborn at home, and family planning. The sessions will be carried out in groups of a maximum of ten pregnant women, led by a nurse trained in maternal and perinatal care. The frequency of each session will be weekly, lasting between 45-60 minutes each. The sessions will be supported by audiovisual materials like slides, photography, videos, and educational games.

Experimental group: In addition to the usual education given in prenatal control and maternity preparation classes, this group will receive the intervention “Lactation counselling” (5244) defined as “assisting in the establishment and maintenance of successful breastfeeding” (16).

The intervention will consist of four educational sessions with seven topics (See Table 1). The frequency of each session will be weekly, lasting 45-60 minutes each. Each session contains three parts: 1) introduction to the topic where the objective of the session is explained and the pre-knowledge and usual practices in the community on the topic are explored, 2) development of the topic using PowerPoint presentations, audiovisual material such as photographs and videos, simulation material as well as strategies to encourage the participation of mothers such as games and challenges, and 3) end of the session reviewing the main lessons, addressing doubts and concerns and carrying out an evaluation with questions on the topic of the session.

Participants will not receive educational material about interventions, neither will they be encouraged or prohibited from seeking information about breastfeeding by other means. All mothers will be called before each session to encourage their attendance and another phone call will be made near to childbirth to know the health status of mother-child binomial.

Outcomes: The primary outcome will be the exclusive breastfeeding rate in the first 6 months postpartum. We use the WHO definition of exclusive breastfeeding: “exclusive breastfeeding for at least 6 months in

all infants,” meaning that the infant receives only breast milk and no other liquids or solids, not even water, except for oral rehydration solution or drops/syrups of vitamins, minerals, or medicines(19).

This result will be evaluated by phone call at 2, 4 and 6 months postnatal and a checklist will be applied to evaluate the following: offer exclusive breastfeeding, offer food or fluids other than breast milk, ensure breastfeeding even when separated from your child (express), describe correct breastfeeding technique, and recognize the importance of breastfeeding for the growth and development of the newborn.

Additionally, mothers will be invited to continue breastfeeding and participating in the study.

Secondary outcomes: The secondary outcome will be the level of knowledge about the breastfeeding process using a questionnaire based on the nursing Knowledge outcome: Breastfeeding (1800) defined as the “Extent of understanding conveyed about lactation and nourishment of an infant through breastfeeding”(18). For questionnaire design 7 indicators were selected for each topic taught in the 4 sessions, with a Likert-type scale with a score from 1 to 5 (1: no knowledge, 2: little knowledge, 3: moderate knowledge, 4: substantial knowledge and 5: extensive knowledge). Each of the indicators selected will be quantifiable constructing a questionnaire with a single answer, multiple choice question (Table 2). The internal consistency of the instrument was 0.8712 Cronbach's Alpha coefficient.

At the end of the intervention, the level of knowledge acquired will be verified and a phone call will be made at 2, 4 and 6 months after the birth of the babies. Instrument 1 will be used again in each of the visits to evaluate the level of knowledge over time and Instrument 4 will be used to verify the adherence and maintenance of mothers to breastfeeding.

Sample size: We used STATA-12 to calculate the sample size with the following statistical parameters: a rate of exclusive breastfeeding of 70% in the experimental group and 60% in the control group, a power of 80%, an alpha error of 5%, and the rate of abandonment of exclusive breastfeeding being 2.5 times higher in the control group compared to the experimental group. Additionally, for the knowledge level outcome, we considered a delta or expected difference of 0.4 in the knowledge assessment result score between both groups, a power of 95%, an alpha of 5%, a standard deviation of the result scores of 0.5, an average of correlations between the first and second assessment of 0.5. Finally, the sample size estimated was n=118 primigravidae mothers including 20% of the possible losses; distributed by simple randomization with a ratio of experimental group/control group 1:1 (n=59 pregnant women in the experimental group and n=59 pregnant women control group).

Randomization and blinding: We will use simple randomization with an allocation ratio of 1:1. The generation of the allocation sequence will be carried out using a succession of true random numbers stored in tables of random digits. A person who does not know the participants will access this table to find out which group each participant belongs to, depending on whether the number was odd or even and will inform the nurses who will carry out the intervention. The nurse who will perform the intervention “Lactation Counselling” will only maintain contact with the experimental group, and the nurse who will carry out the initial and final measurements along with the person who will perform the data analysis will

be blinded to the group assignment. Study participants, nurses conducting the interview and statistical analysis of data will be masked in group assignments.

Ethical consideration: This research is based on the World Medical Association Declaration of Helsinki and the research guidelines in Colombia (Resolution 008430/1993 and Law 911/2004) and has the approval of the Ethics Committee in Scientific Research of the Industrial University of Santander. The parents of the participants must sign the informed consent, as well as a consent for those under 18 years of age because they are considered a population of minors.

Statistical analysis: The information will be recorded in EPIDATA 3.1. An intention-to-treat analysis will be performed. The categorical and continuous variables will be compared according to the treatment group using chi-square tests or Fisher's exact tests and Student's T-test or Mann Whitney's U test, respectively. The exclusive breastfeeding rate will be calculated at 2, 4 and 6 months of follow-up with their respective confidence intervals. To evaluate the effect of the intervention on the level of Knowledge: Breastfeeding, two approximations will be made by different statistical methods: mean differences through an independent samples Student's t-test and repeated measures ANOVA. Additionally, the effect of the intervention on the abandonment of exclusive breastfeeding will be calculated in terms of relative risk by means of a binomial regression.

Discussion

We detail the design of a nursing intervention to standardize breastfeeding counseling, as well as the evaluation of its effect on adolescent mothers. This intervention has the advantage of having been designed using standardized language from the Nursing Intervention Classification and using the same standardized language to evaluate its effect through the Nursing Outcome Classification, using standardized language facilitates the use of interventions and the measurement of their effect in different populations, as well as consolidating the use of a specific nursing language.

Educational interventions in first-time mothers has shown effectiveness in maintaining exclusive breastfeeding in the first six months of life (13) and an increase in the level of knowledge about breastfeeding (20,21). However, these interventions were not carried out on adolescent mothers, despite the fact that pregnancy at this stage of the life cycle is considered a global public health problem given that nearly 16 million adolescents give birth every year in the world. which is equivalent to 11% of all births worldwide, a figure that increases in developing countries. Likewise, Latin America and the Caribbean have the second highest adolescent fertility rate in the world, estimating 67 births per 1000 girls between the ages of 15 and 19 between 2010-2015 (22). The above figures denote the urgency of providing counseling support to sustain breastfeeding in these young mothers, with appropriate methodologies for these ages.

Additionally, it should be considered that the adolescent mother is generally not prepared to carry out effective breastfeeding, and in developing countries it is working mothers who can put breastfeeding at risk. Different studies have established that adolescent mothers, compared to adult mothers, are less

likely to initiate breastfeeding and those who initiate it are more likely to abandon it. Among the reasons for dropping out, causes such as hypogalactia, returning to school, medical indication, causes related to the nipple, maternal illness, maternal labor, and acid reflux in the newborn have been described (23). In a study carried out in adolescent mothers, 39.4% lactated for 6 months and 9.8% lactated for more than 6 months; the reasons why they do not feed their child with only breast milk are: 9.5% produce little milk, 12% the child is left hungry, and 20.7% other causes (24). On the other hand, a study in South Africa found that adolescent mothers knew the benefits of breastfeeding but abandoned it easily due to its lack of practicality when faced with the need to go to school (25) as was found by Acosta Silva in Ecuadorian adolescents (26), adding as a barrier the insufficient breastfeeding education during prenatal or in the early postpartum period (26,27). The foregoing highlights the importance of designing interventions that promote exclusive breastfeeding and therefore evaluating its effect.

On the other hand, a review by Lumbiganon et al. in 2016 found that the majority of intervention studies to promote exclusive breastfeeding had been done in high-income countries (28). This is a pilot study that seeks to know the efficacy of a nursing intervention in low-income adolescent mothers in a developing country, considering that sustaining breastfeeding depends on social and cultural factors and in view of the need to explore an intervention that is low cost and easy to perform by nurses.

Even though this pilot uses a randomized design, with the aim of preventing potential biases, some measures will be taken to reduce their appearance: Offer the possibility of participation to all adolescents in maternity classes, Have strict measures for the random assignment of mothers to groups. Ensure blinding of nurses who will assess the results and those who analyze the data. It is worth highlighting the importance of the intervention activities being standardized and supervised with prior training of the nursing staff.

It is important to note that mothers will be able to access information or training on breastfeeding in a complementary way through different means and could bring the levels of knowledge about breastfeeding closer to those of the intervention group. There can also be a potential contamination of the groups in the event that some mothers who are in different intervention / control groups have a close relationship given the proximity of their homes and the similarity in age and share the learning and experiences acquired during the interventions.

This study, given nature of intervention, also provides a higher level of scientific evidence, which will undoubtedly support the advancement and training of professionals in the discipline of Nursing, by basing knowledge and thinking to take actions and decisions that form part of the practice and assistance of nursing care in maternal and child health.

Finally, the findings of this study will be a valuable resource for the management of nursing care, which will support the formulation, implementation, monitoring and evaluation of national policies aimed at the promotion, support, and protection of breastfeeding, by involving the educational component as an important strategy that guarantees respect and protection of the act of breastfeeding as a human right appropriate for women and their children.

Declarations

Ethics approval and consent to participate. The pilot protocol is approved by the Ethics Committee in Scientific Research of the Industrial University of Santander (Acta 014-August 17/2018). The parents of the participants must sign the informed consent, as well as a consent for those under 18 years of age because they are considered a population of minors.

Consent for publication: Consent was not obtained to publish personal data because it is not expected to be used.

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Trial Registration: ClinicalTrials.gov NCT04655846, Registered December 7, 2020.

<https://www.clinicaltrials.gov/ct2/show/record/NCT04655846>

Authors' contributions: All authors contributed to the design of the study, and the preparation of the article.

Competing/Conflict of Interest Statement: The authors declared not to have conflicts of interest.

Availability of the data: The datasets generated and analyzed during the current study will be available from the corresponding author on reasonable request.

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Tables

Table 1. Summary description of educational sessions for Lactation Counseling intervention.

Session	Content	Methodologies	Materials
1	<ul style="list-style-type: none"> • Composition of breast milk • Psychological and physiological benefits of breastfeeding 	<ul style="list-style-type: none"> • Lecture method • Audiovisual Presentation • Group assignment 	PowerPoint presentations Breast milk production video Breastfeeding benefits video Breastfeeding kit with educational elements such as games and models (bottles with types of breast milk) Explanatory sheets with each of the components of breast milk. Sheets with text to identify the benefits of breast for the mother, baby, family and society.
2	<ul style="list-style-type: none"> • Technique positions and for breastfeeding 	<ul style="list-style-type: none"> • Audiovisual Presentation • Demonstration • Practical exercise 	Simulated models (baby dolls) Video on breastfeeding and nipple latch technique
3	<ul style="list-style-type: none"> • Extraction, conservation, administration and of breast milk 	<ul style="list-style-type: none"> • Lecture method • Audiovisual Presentation • Demonstration • Practical exercise 	PowerPoint Presentations Video on storage, conservation, and administration of breast milk. Vest-type simulators for breast milk extraction
4	<ol style="list-style-type: none"> 1. • complications Breast during breastfeeding • Lactating mother needs (rest, hydration and a balanced diet) 	<ul style="list-style-type: none"> • Lecture method • Audiovisual Presentation • Demonstration • Practical exercise • Group activity 	PowerPoint Presentaciones Breastfeeding kit with educational elements such as games and models (Breast models) Lottery game on care and complications during breastfeeding Memory game on nutrition and hydration during breastfeeding Video on care for the prevention of breast complications

Table 2. Items and Indicators to Quantify the Nursing Knowledge Outcome: Breastfeeding (1800)

INDICATOR 180003: Composition of breast milk, milk outlet process, and initial vs late milk

1. Occurs between 5 and 10 days after delivery
 2. Contains less sugar, fats, and vitamins of B complex and vitamin C
 3. Contains proteins, sugar, fats, minerals such as sodium, calcium, iron, selenium, zinc and B complex vitamins and vitamins such as C, A, E, K.
 4. Its composition contains between 88% to 90% water
 5. Occurs in the first 3 to 4 days after delivery
 6. It is yellow, thick and of little amount
 7. Contains more sugar, fats, calories and B Complex vitamins and vitamin C
 8. It occurs progressively up to about 100 milliliters a day
 9. Contains fewer proteins, antibodies and vitamins A, E, K
 10. It occurs in an amount of 400 to 600 milliliters per day
 11. Occurs from the tenth day after delivery
 12. Contains more protein, minerals such as sodium, iron, selenium, zinc, and vitamins such as A, E, K
 13. Its composition contains 87% water
 14. It is produced in an amount of 700 to 800 milliliters per day
-

INDICATOR 180001: Benefits of breastfeeding

15. Prevents breast, uterine and ovarian cancer
 16. Prevents respiratory diseases such as bronchitis, pneumonia, and gastrointestinal diseases such as diarrhea and dehydration
 17. Prevents the onset of diseases such as allergies, obesity, high blood sugar, high blood pressure and cancer
 18. Prevents postpartum depression states (mood affecting women after giving birth, characterized by feelings of extreme sadness and anxiety)
 19. Prevents constipation and cramping
 20. Prevents child malnutrition
 21. Facilitates the affective bond between mother and child
 22. Strengthens self-appreciation, self-confidence and emotional satisfaction
 23. Contributes to postpartum weight loss
 24. Lowers the risk of osteoporosis (a disease that thins and weakens bones, causing them to break easily)
 25. Promotes better growth and development of physical, language and social capacities
 26. Reduces risk of postpartum hemorrhaging or bleeding
 27. Lowers the risk of heart disease
 28. Improves intelligence
 29. Delays the return of ovulation and menstruation
-

INDICATOR 180005: Proper technique for breastfeeding the baby

30. The mother should select the most comfortable position
 31. The baby's body must be attached to the mother's body
 32. The baby's head and body are in the same direction
 33. The mother should grab the breast with her C-shaped hand (placing her thumb above the breast and the other four fingers below the nipple and behind the areola (ring of pigmented skin around the breast))
 34. The mother should bring the child closer to the breast and not the breast to the child
 35. The mother should stimulate the baby to have a search reflex, bringing the nipple closer to the baby's lip and when it opens its mouth to insert the nipple and the areola
 36. The baby's lips should remain outside like the mouth of a fish
 37. The baby's mouth should coat the entire areola (dark area of the breast)
 38. The baby's chin must touch or almost be touching the mother's chest
-

INDICATOR 180006: Adequate position of the infant during breastfeeding

39. Stretched or cradle position (classic or traditional)

40. Cross-cradle position

41. Parallel stretched position (side lying down)

42. Rugby ball or football position (inverted)

43. Sitting or horse position

44. Face-up position

45. Vertical or standing position

INDICATOR 180014: Signs of mastitis, duct obstruction and nipple trauma

46. Breast skin is shiny, red, tense and warm

47. Formation of a mass or lump in the breast that is palpable and painful, often with redness of the skin in that area

48. Painful cracks or wounds on the nipple

49. Uncontrolled fever, chills, general discomfort, nausea, vomiting, headache

50. Formation of a mass or lump in the breast, severe pain, swollen and hardened sinus, obstruction at the milk outlet (milk does not flow), pus secretion

51. Inflammation or swelling in the breast with a feeling of warmth

52. Nipple pain

53. Cracks or nipple wounds that may bleed

54. Decreased milk flow

55. No fever or symptoms of general discomfort

INDICATOR 180015: Appropriate techniques for the extraction and storage of breast milk

56. Massage into the breast before breast milk extraction

57. At room temperature: Breast milk is preserved for up to 4 hours, it is advisable to leave it in a dry place, protected from sunlight and heat.

58. In the freezer: Breast milk is kept frozen for up to 15 days, so it is recommended not to constantly open and close the freezer. If the refrigerator is two doors, breast milk can be stored for up to 3 months.

59. With your hand in the shape of a C, place it on breast (placing your thumb above the breast and the other four fingers below the nipple and behind the areola (dark area of the breast))

60. In a refrigerator or refrigerator: Breast milk is stored for up to 12 hours, it is advisable not to place it in the refrigerator door to avoid temperature changes every time the door is opened or closed.

61. Lean the body forward, squeeze the breast without swiping your fingers and gently push against the ribs

62. Then move your fingers forward and repeat the procedure as many times as necessary simultaneously and smoothly

INDICATOR 180020: Need for fluid intake by the mother

63. It is advisable to increase the consumption of liquids, preferably water, as it is the largest component of breast milk

64. Water intake during lactation should be sufficient to compensate for the loss of water through milk

65. Vitamin C-rich juices are recommended

66. The most recommended liquids for women during breastfeeding are water, fruit juices, and milk

67. Avoid drinking alcoholic beverages, excessive coffee, and tea (more than 2 cups a day, during the term of breastfeeding)

Figures

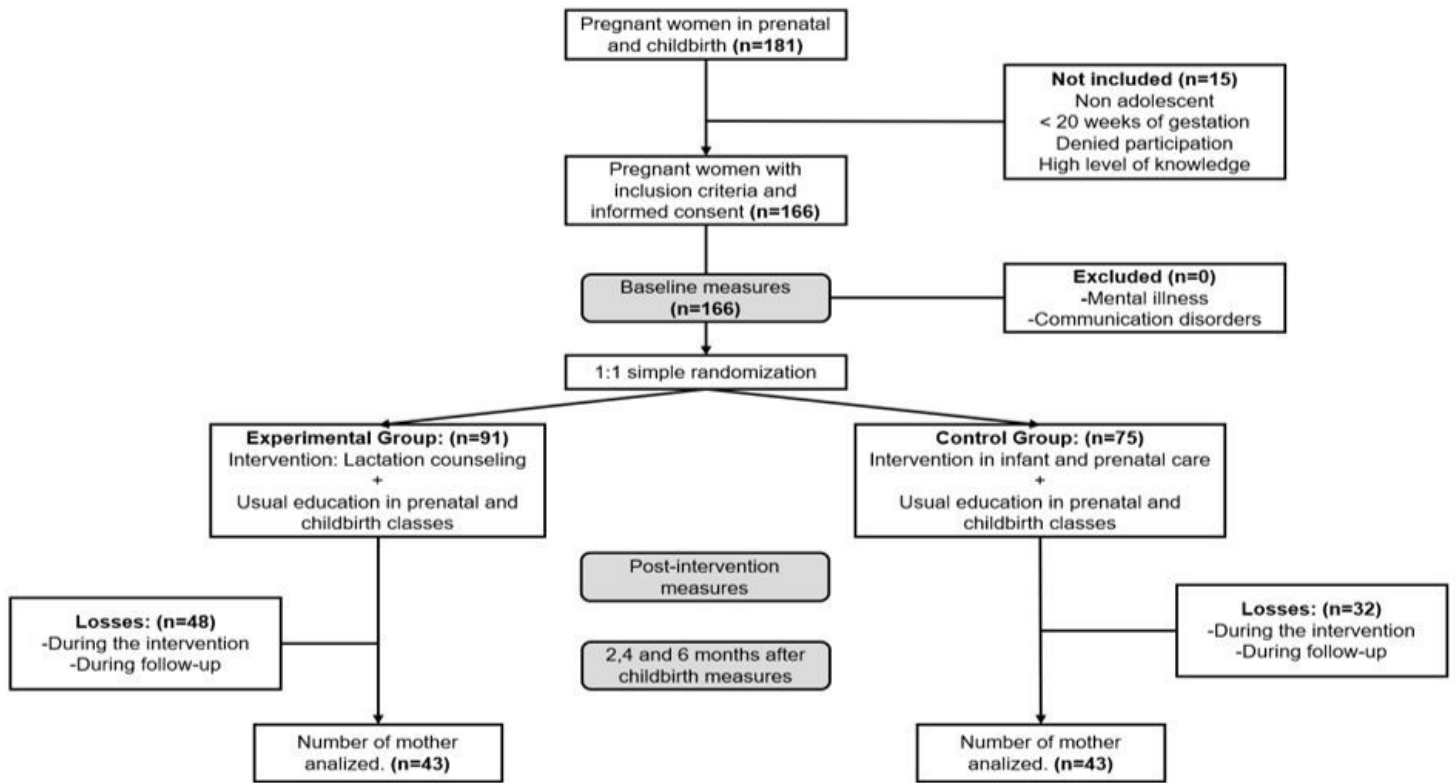


Figure 1

Flowchart of study protocol