Feasibility of a Touch Screen Computer Based Breast-feeding Educational Support Program

NCT03308058

March 5, 2012

I. Background and Significance

Breast-feeding is an effective way to promote infants and mothers health because it has many positive and long lasting impacts on health. The Healthy People 2020 goals set targets for initiation and duration of breast-feeding[1]. Currently, 75% of babies born in the U.S. are initially breastfed, but rates fall to 43% at 6 months and 22% by 12 months[1]. The American Academy of Pediatrics recommends that infants be fed only breast milk for the first 6 months of life, but only 13% of babies in the U.S meet this breast-feeding standard. Healthy People 2020 aims to increase rates to 82% ever breastfed, 61% at 6 months, and 34% at 1 year[1]. Exclusive breast-feeding goals are set for 44% at 3 months and 24% at 6 months[1].

According to data from the National Immunization Survey (NIS), only 30.5% of the children included in the survey who were born in 2004 were exclusively breastfed at 3 months and that number dropped to 11.3% by 6 months of age[2]. These exclusive breast-feeding rates are very similar in Hispanic women in the United States, at 30.9% and 11.6%, respectively[2]. Additionally, no state in the United States met the *Healthy People 2010* objectives for 75% of infants being exclusively breastfed immediately postpartum and 50% by 6 months[2]. Current breast-feeding rates fall short of these goals. Many mothers wean early or initiate complementary feeding of their children before it is recommended and advantages of breast-feeding and breast milk are not realized. The 2006 National Health and Nutrition Examination Survey (NHANES) reported that only 43% of mothers less than 20 years old initiated breast-feeding compared to 65% of mothers in their 20s, and 75% of those older than 30 years[3, 4]. Despite substantial evidence of maternal and infant benefits of breast-feeding, adolescent mothers initiate breast-feeding less often and maintain breast-feeding for shorter durations. The 2006 National Health and Nutrition Examination Survey (NHANES) reported that only 43% of mothers less than 20 years old initiated breast-feeding compared to 65% of mothers in their 20s, and 75% of those older than 30 years[3]. The National Immunization Survey (NIS) reported similar initiation rates of 51%, 71% and 79% respectively[4]. The figures for mothers in these age groups who continued to breastfeed at 6 months were 19%, 36%, and 50%[4].

Significance of Breast-feeding: Breast milk provides the optimal nutrition for infants and offers health benefits as well as immunity from infections. Human breast milk not only provides complete nutrition for the full physical and mental development of healthy infants in the first critical months of life, but also protects against common childhood infections and diseases throughout childhood and into adulthood. Babies who are not fully breastfed for the first 3–4 months of age have been shown to suffer health problems such as gastroenteritis[5, 6], respiratory infection[5], otitis media[7] and urinary tract infection[7]. Maternal benefits of breast-feeding can include more rapid return of postpartum uterine tone and postpartum weight loss, delay of ovulation and decreased risk of breast, ovarian, and endometrial cancers[8].

Challenges of breast-feeding: The correlates of breast-feeding include attitudinal, socio-economic, familial and physiological factors[9-11]. The socioeconomic correlates include maternal education, household income and maternal employment[12-14]. Socioeconomic correlates of breast-feeding are rarely studied for US rural women despite the fact that over 25% of the US population is rural[15]. Rural residents are at a disadvantage compared with urban residents[15] due to lower average education levels, lower incomes, higher fertility, more teen births, geographic isolation, and inadequate economic, social welfare and health resources[15]. Socioeconomic disadvantages faced by adolescent mothers place their infants at greater risk for infant morbidity, mortality and developmental delays[16-18] and increase the importance of protective factors available through breast-feeding. Various factors that hinder breast-feeding duration include breast-feeding knowledge, well-intentioned but inaccurate advice from family members and friends, perceived inadequate quantity of milk supply and perceptions of social disapproval of breast-feeding[19]. There is a decline in breast-feeding in Hispanic women who immigrate to the United States and become acculturated. The degree of acculturation is comprised of various factors including generation, length of time in the United States, and perceived similarity to Americans[20]. The literature on acculturation in Hispanic breast-feeding women is limited. Prior study found that increased years in the US was associated with shorter duration of breast-feeding[21]. Teens raised in the US interpreted public breast-feeding as degrading or embarrassing[22]. Another influence on the decision to breastfeed is that recently immigrated Hispanic women may have fewer family members present to support and guide their decision and positive social support can mediate the challenges mother encounter with breast-feeding[23] and those with greater social support are more likely to breastfeed[24, 25]. Other factors that hinder breast-feeding duration include: (a) lack of support for prolonged breast-feeding[26]; (b) ambivalence and misinformation[27]; (c) younger age[28]; and (d) especially in rural settings[15]. Women who describe themselves as somewhat confident in regards to breast-feeding are three times more likely to discontinue breast-feeding during the first 6 months

postpartum than are those who describe themselves as very confident[29]. Self-efficacy is a dynamic process throughout the postpartum period, especially during vulnerable cessation periods[30]. Low maternal confidence has been associated with the perception of inadequate milk supply and is related to early discontinuation of breast-feeding, especially during the first 2 weeks[30]. Only one descriptive study (n=172) was found on the use of technology to assess breast-feeding knowledge of childbearing families[31]. Lack of knowledge was found related to milk supply and to pumping in special circumstances[31]. Specific individualized interventions, especially during the initial critical 2-6 week period, are needed to prevent deterioration in intention levels for breast-feeding for 6 months and breast-feeding self-efficacy levels within the first 2 weeks postpartum which could lead to the decision to discontinue breast-feeding[31].
A prior study showed significant improvement in the knowledge gained about the chronic illness self management among rural women using computer based health education[32]. Increase in human immunodeficiency virus (HIV)/ acquired immune deficiency syndrome (AIDS) knowledge and self-efficacy was seen when intent to treat model was implemented using internet. The study demonstrated the acceptability and efficacy of the internet for delivering HIV prevention messages to rural men who have sex with men[33].

The objective of the proposed study is to explore acceptance of bilingual, interactive touch screen computer based breast-feeding educational program and also explore its effect on improving breast-feeding knowledge, breast-feeding self-efficacy and partial to exclusive breast-feeding among pregnant Hispanic rural women.

Significance

AHRQ encourages grant applications that propose research that focuses on the health care for AHRQ priority populations with specific emphasis in the following areas (1) explaining disparities in health care and clinical practice; (2) implementation of research and interventions that aim to reduce disparities in priority populations and settings; (3) addressing known gaps in research dealing with priority populations; 4) development of methods to address the heterogeneity of priority populations, small sample sizes and to improve outcomes for priority populations in AHRQ sponsored research; 5) research on cross cutting issues involving mu ltiple priority population groups and settings (for example, disabled children, minority women, rural maternal and child health, etc); and 6) development of innovative service delivery models for settings in which priority populations receive care. The proposed pilot study meets the research priority needs of AHRQ.

To our knowledge, this is the first ever study to deliver breast-feeding education through use of a touch screen computer based program in a rural setting. The study will help to develop breast-feeding educational modules tailored to the needs of the Hispanic women living in rural settings. The study further explores the feasibility of utilizing bilingual; touch screen computer based breast-feeding educational programs to promote breast-feeding among Hispanic rural women who are difficult to reach, have limited access to health information and language barriers. The current proposed study will help advance our understanding to use health information technology as a medium to disseminate bilingual health education programs in rural settings. The proposed computer based breast-feeding educational program will continue even after the duration of the grant. The research team will continue to update the educational content and develop new educational modules necessary to make program adoption successful. The findings of the program will be presented to the relevant stakeholders including AHRQ six months post completion of the grant. Further, this approach can be used to disseminate tailored health educational programs for various other health conditions in underserved populations across various other settings. This exploratory study will lay a foundation for a larger multicenter randomized controlled clinical trial to evaluate the impact of computer based educational intervention to promote sustainability of breast-feeding among women across diverse settings. The proposed study will help demonstrate the utilization of telecommunications technology as an effective means for reaching geographically and socially isolated individuals.

I. Conceptual framework

The framework for the proposed study is the Sustained Breast-feeding Framework based on Fishbein and Ajzen's Predicting and Changing Behavior Theory [PCBT] [34]. PCBT proposes that attitudes, perceived norm, and perceived behavioral control are inter-related and that together they influence intention to engage in the behavior which is proposed to be the primary determinant of behavior. The PCBT has been used previously to predict behaviors such as weight loss, physical activity and self-efficacy for healthy eating in Mexican American populations[35-37].

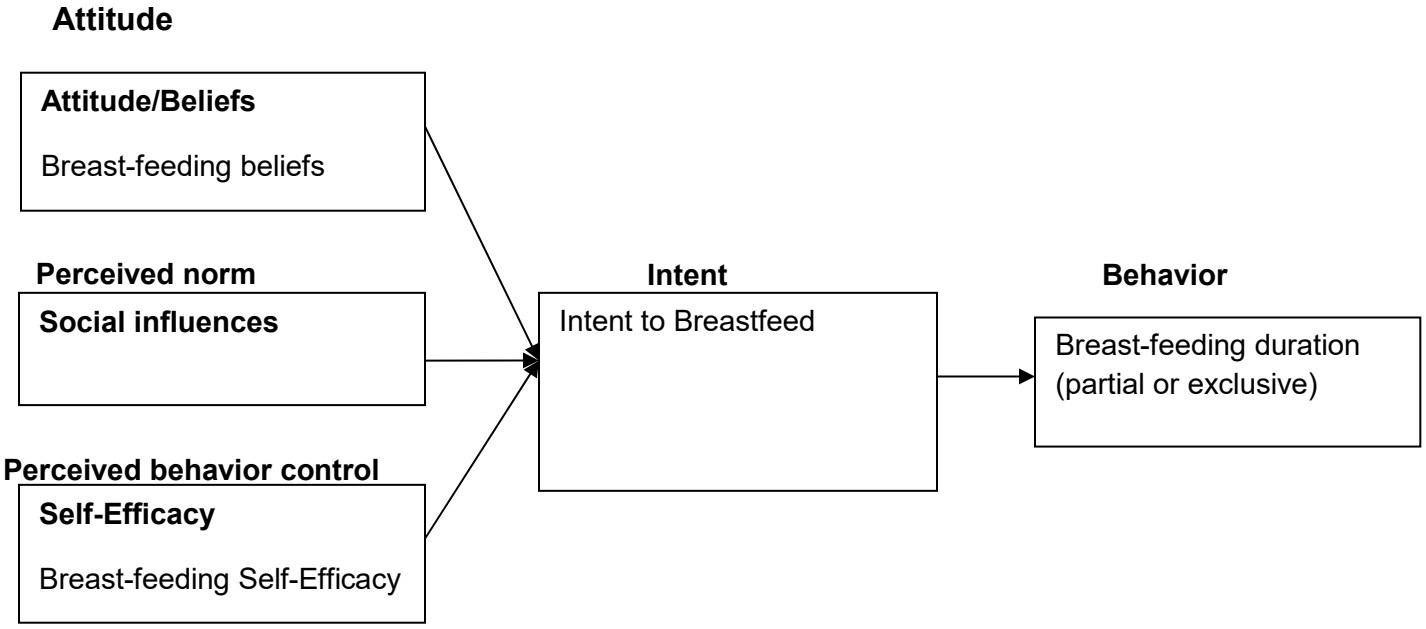


Figure1. Sustained Breast-feeding framework

Attitude/Beliefs. Attitude is defined as an individual's evaluation either favorably or unfavorably for a specific behavior[34]. This study will measure this concept using survey questions from the revised breast-feeding attrition prediction scale [BAPT] [38, 39], and will be adapted for the PEMT to determine the mother's attitude about breast-feeding.

Perceived Norms. The framework variable perceived norm or social pressures is described as the pressures to perform a given behavior. The mother's perception of influence by her social network to perform a specific behavior will be measured by questions developed for the PEMT. Mexican American mothers have been found to follow nutritional advice of family members over that of their health care providers, (e.g., doctors, nurses, WIC educators) [40]. Questions from the revised BAPT[38, 39] will be adapted for the PEMT to measure the mother's perception of influence from her social network.

Perceived behavioral control, (self-efficacy). It is proposed to be the extent that an individual (mother) believes that they are capable of performing a behavior including access to all resources. This concept will be measured using the breast-feeding self-efficacy scale [BSES] [41, 42], that reflects past experiences and anticipated obstacles.

Intent. It is defined as readiness to engage in a behavior. It will be measured by an intention question related to the mother's perceived intent to breastfeed for the recommended 6 months. The question has been developed based on Fishbein & Ajzen's guidelines[34] and is "How likely do you intend to breastfeed for 6 months?"

Behavior. It is observable events directed at a target in the context of which it is performed and the time that it is performed. The behavior outcome is partial or exclusive breast-feeding.

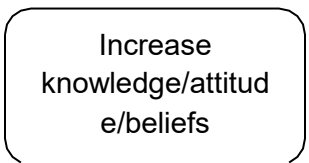
Design of Patient Education and Motivation Tool (*PEMT)*: PEMT is a touch screen, computer based interactive health education program designed based on a variety of cognitive-behavioral theories[43]. PEMT facilitates health information and messages to be adapted depending on the psychosocial elements including attitude, self-efficacy, expectations, personal norms and social influences[44-46] (Table1). PEMT has 3 key components including (a) *screening* gathers individual socio-demographics, knowledge, attitudes and practice through a series of questions; (b) learning component delivers educational material in a structured format. The entire educational material is broken down into series of modules, each module into sub-modules and each sub-module into a series of educational messages. Each message is then presented using various multimedia formats (such as audio, video, text and images) and (c) evaluation component gauges effectiveness of the program by assessing change in knowledge, attitudes and practices of the individuals. The main objective of the PEMT is to

present health information in an interactive tailored manner considering multiple factors influencing health status and health behaviors.

Theory	Purpose	PEMT Learning Component
Information Processing theory[47]	Information chunking means presenting information as a meaningful unit and short term memory is limited 5 to 9 chunks of information	Each screen has a series of short educational messages
Constructivist Theory[48]	Present information in a structured format simple to understand	The information is presented in a structured format with a series of several educational modules. Each module is broken down into sub-modules and each sub-module is broken down into a series of educational messages.
Cognitive Flexibility theory[49]	The information presented should be highly interconnected so that it is relevant to the learner	The information is presented related to the responses to the questions provided during the screening component.
Cognitive Flexibility theory[49]	Multiple Content Formats should be available including audio, images and text	The information is presented in multiple formats including text, audio, images, and animation. The patients can turn on/off the audio at their own will
Cognitive load theory[50]	Minimize working memory load	The information on the screen is presented as text enhanced using images and animation to make it easy to understand
Behavioral theory and operant conditioning[51]	Feedback given based on responses	The positive prompts or encouragement is given based on a correct response and an educational message is reinforced during an incorrect response.

Table1. Conceptual framework of existing PEMT

PEMT interaction metrics: Another important aspect of PEMT is that it captures individual's interactions with this interactive educational support program and generates usage metrics. These cluster of usage metrics include user id, session id, screen id, number of screens viewed, screen viewing time, chunk viewing time, navigational patterns assessed by capturing the buttons clicked on the screen. Usage is clearly an important characteristic in assessing the popularity of a computer mediated health education programs with most usage data being derived from the digital logs that record user activity on a continuous and real time basis. The logs provide data on what people have done; this gives logs their strength, and differentiates them from other data capture methods like interviews and questionnaires. Considerable knowledge extracted from these digital usage logs and knowledge is used to decide what content need to be presented, the media that will be used to present the content, and the order in which the content will be presented based on user preferences. Further, this information is used as an indirect measure of motivation to assess individual's engagement to the program, learning pathways, preferences and their receptiveness to learning. We will improve breast–feeding related attitudes, self-efficacy and knowledge by implementing sustained breast-feeding framework to the existing PEMT to improve partial or exclusive breast-feeding (Figure2)



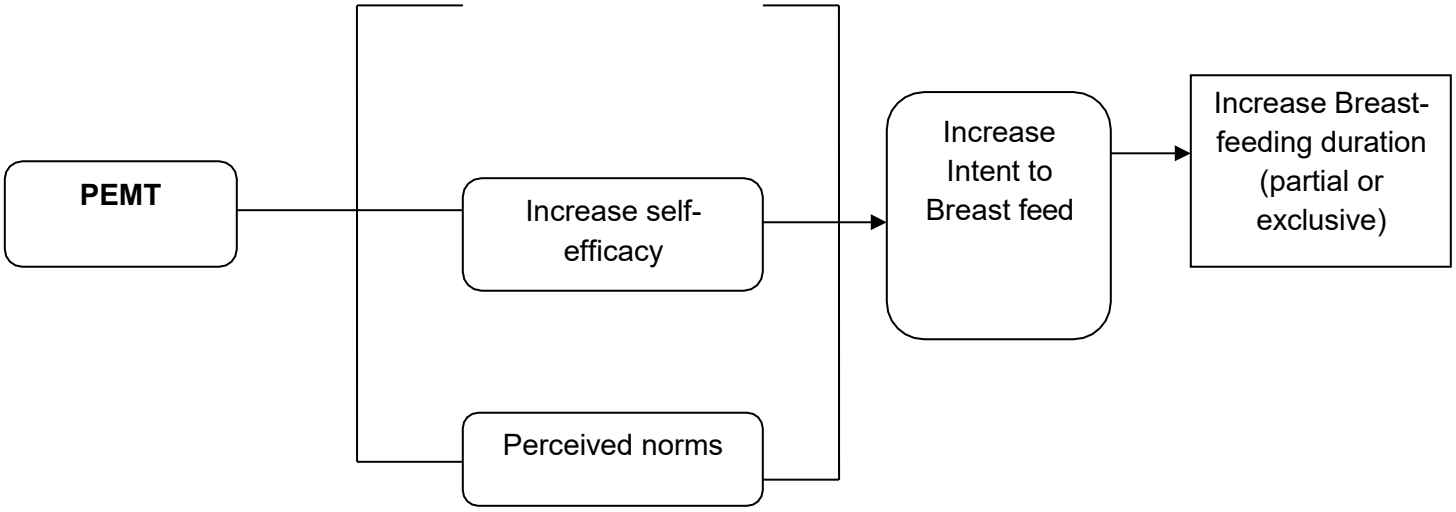


Figure2. Adapting PEMT to Sustained breast-feeding framework

II. Preliminary Data

PEMT was designed by Joshi (PI) and has been previously implemented for various disease conditions such as asthma, influenza, multiple myeloma, multiple sclerosis and bilingual nutrition education program for Spanish speaking mothers[44- 46](Figure3).

Figure3. Existing PEMT programs and bilingual nutrition program for Spanish speaking mothers

The objective of these initial evaluation studies of PEMT were five–fold: (i) to assess the feasibility of a touch screen computer based educational program in diverse settings such as Emergency room, waiting rooms of the outpatient clinics, and primary care settings (ii) to gauge change in knowledge, attitudes and practice towards diseases such as asthma and influenza, (iii) to gather and describe user interactions with the computer, (iv) to understand health information seeking patterns of the individuals and (v) to assess acceptance of PEMT. PEMT has been easy to use even in low income Spanish speaking Latino immigrant populations with no prior computer experience. However, this study only assessed feasibility of using touch screen kiosk as a medium to facilitate delivery of health education and did not include any algorithm for tailored messages. The study was also conducted in an urban tertiary setting and did not include any participants from a rural setting. Analysis of the usage data of the computer based program showed association between the times spent to view the various educational topics, the specific educational topics viewed, the demographic characteristics and asthma knowledge[44]. PEMT interaction metrics data gathered during individual interactions with the PEMT helped identify the educational modules that were most viewed by the diverse users. The research team (SW, TA & KR) has also conducted a variety of studies in multi-rural sites related to prevention of chronic illnesses in infants and

children[19]. They have performed studies to promote sustained breast-feeding in rural Caucasian, Native American, and Hispanic mothers[19]. A multi-site rural intervention study for sustaining breast-feeding in primiparous women at three sites in Wyoming and Nebraska was also conducted; therefore they are aware of some of the challenges of multi-site rural research.

III. Procedures for pilot testing Computer based Breast-feeding educational support program

The major objectives of this pilot study is to (a) develop breast-feeding educational content both in English and Spanish (b) Modify existing PEMT to develop interactive tailored, computer based breast-feeding educational support program and (c) pilot test the Computer-based Breast-feeding Educational Support program to educate Hispanic rural pregnant women to improve breast-feeding knowledge, breast-feeding self-efficacy and partial breast-feeding. The following tasks will be performed to achieve the proposed study aims.

(a) Developing and Finalizing Breast-feeding educational content

The expert panel comprising of multidisciplinary team of researchers including Drs. Joshi, Wilhelm, Aguirre, Rodehorst, Brigitan and Wambach will work closely to develop a detailed outline of the educational modules. Qualitative data gathered during the 2 focus groups can add an important dimension for research on facilitating behavior change. One highly valued and widely-used method for qualitative inquiry is the use of focus group interview. This method can capture evolutionary and transformational developmental dynamics. These are typically based on homogenous groups (people of similar backgrounds and experiences to participate in a group interview about major issues that affect them) [52]. Two separate focus groups one in English and Spanish will be performed with six Hispanic rural women with history of previous pregnancy will be enrolled at the Regional West Medical Center (RWMC), Scottsbluff, NE. The focus group of 2 hours duration will be performed at the antenatal clinic at RWMC during months 2 and 3 of the study. The focus group will help examine factors that affect the decision to continue breast-feeding in pregnant Hispanic rural women and will guide development of bilingual (English and Spanish) breast-feeding educational modules during months 4 and 5 of the study (Appendix A). Dr. Aguire and Lupe Salazar (Consultant) will be responsible for subject recruitment, focus group assessments and would act as a moderator and respond to questions and comments during the focus groups. Ms. Salazar is a community person who has worked with Minority Health, Nebraska Dept of Health and Human Services and is certified in Spanish translation. The focus group interviews, analysis and development of Breast-feeding Educational modules in English and Spanish will be finalized during first 5 months of the study. Each subject will receive $50 gift card for their participation in the focus group.

(b) Computer-based Breast-feeding educational Support Program

We will modify existing touch screen, computer based interactive PEMT platform to deliver bilingual, Breast-feeding educational support program. The existing PEMT platform allows users to dynamically change the educational content either to English or Spanish. The modification of the existing PEMT will occur during months 5-7 and will include several stages:

- **PEMT modification design**: The research team including Drs. Joshi, Wilhelm, Aguirre, Rodehorst, Brigitan and Wambach will work closely to facilitate computerized tailoring based on the developed breast-feeding educational modules discussed previously (Section IV a). The finalized breast-feeding educational content will be available both in Spanish and English and the subject can use either language to navigate through the program. The modification of the existing PEMT to adapt it to deliver computer based breast-feeding educational support program will be done during months 5 and 6 of the study.

- **Tailoring:** It is a process of creating individualized communication and is an assessment-based approach in which individuals provide personal data related to a given health outcome[53]. Those data are then used to determine the most appropriate information or strategies to meet each individual unique need. An important theoretical basis for tailoring comes from Elaboration Likelihood Model[54], which states that people are more likely to actively and thoughtfully process information if they perceive it to be personally relevant[53]. Messages processed in this way tend to be retained for a longer period of time and are more likely to lead to permanent attitudinal change. The entire finalized breast-feeding educational content will be broken down into series of modules, each module into sub-modules and each sub-module into a series of educational messages. The computer based program will have the ability to deliver breast- feeding education in varied learning styles such as text-only, audio and text, or text, audio and images to

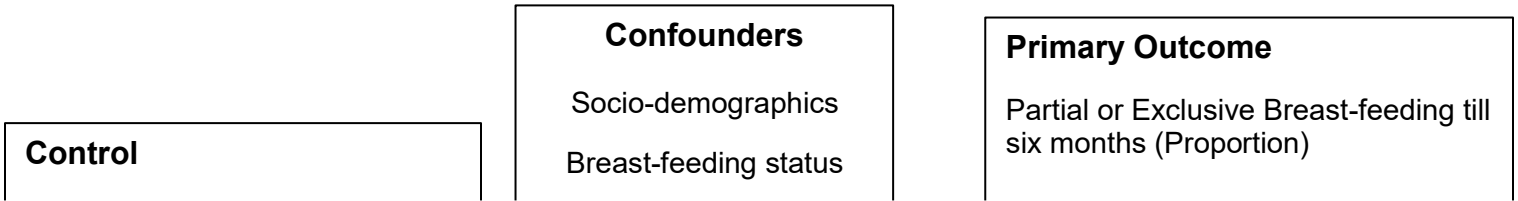
account for health literacy of the individuals. The program will simplify the design and create multiple tailored versions of printed materials instead of using a single standardized version. The tailoring algorithm will be developed based on health literacy levels, prior breast-feeding knowledge and attitude towards breast-feeding practices. For e.g. If a person has low literacy the information will be presented as images and graphics. Similarly information specific to those topics will be presented in which the individual has poor breast-feeding knowledge. Messages will be tailored to perceived breast-feeding concerns. Tailored educational messages might focus on subjects with poor breast-feeding skills and will educate and empower individuals through use of motivational prompts. The program aims to deliver specific messages as computer provides a medium to adopt tailoring with no time lag and multimedia capabilities.

- **Expert Pretesting using Heuristic evaluation:** The proposed Computer based Breast-feeding Educational Support program will undergo usability assessment during modification of the existing PEMT program. Heuristic evaluations, which are often referred to as "expert reviews" or "usability audits", are an efficient way of assessing the usability of information technologies and are particularly useful early in the development process when it is least expensive to make changes. Dr. Sears (Consultant), a well known expert in usability will formalize this process while working with Dr. Joshi (PI). We will employ a variant of this technique, often referred to as a heuristic walkthrough, where evaluators (Joshi and Sears) are given a set of representative tasks to guide their assessments. These reviews are conducted independently and the results are subsequently combined. The severity of the issues identified can then be assessed and modifications to the system prioritized. One advantage of this methodology is that it can be employed as soon as a mock-up of the system is available, allowing issues to be identified and corrected before a semi-functional prototype is developed. Computer based Breast-feeding Educational Support program will provide modular, culturally relevant, bilingual (English/Spanish) breast-feeding education tailored to the needs of the mothers. For these assessments, we will identify representative tasks including both critical and high frequency activities. This expert pre-testing using heuristic evaluation will be performed during months 5-6 of the study.

- **Usability and User testing**: We will recruit six Spanish speaking pregnant Hispanic rural women at the RWMC, Scottsbluff to interact with the system. They will be enrolled at the Regional West Medical Center (RWMC), Scottsbluff, NE. Dr. Aguire and Lupe Salazar (Consultant) will be responsible for subject recruitment. Information flyers will be available at the RWMC to inform the subjects about he study. These subjects will not be part of the actual study. After a brief introduction to the system, study subjects will be asked to complete a predefined set of tasks by interacting with the system and the duration of this interaction will be around 30 minutes. We will have a think aloud protocol that will involve participants thinking aloud as they perform a set of specified tasks. Users will be asked to say whatever they are looking at, thinking, doing, and feeling, as they go about their task. This will enable observers to see first-hand the process of task completion. Notes and test sessions will be audio taped of everything that users' say, without attempting to interpret their actions and words will be taken. During these assessments, we will gather basic quantitative results including information about the time required to complete tasks and the errors encountered using the usage data metrics as described previously (Section II. Conceptual framework). A likert scale survey will be used to assess user satisfaction with the computer program and any recommendations study subjects may have to improve the system. The results of the user testing will be followed by incorporating the recommended changes to the design of the Computer-based Breast-feeding educational support program during months 6 and 7. The final program will be deployed during month 8 of the study period.

IV.Research Design and Methods

The proposed pilot study is a two-group repeated measures quasi-experimental design that will be used to explore the effect of using Computer based Breast-feeding Educational Support program to promote breast-feeding in rural Hispanic women. (Figure4)



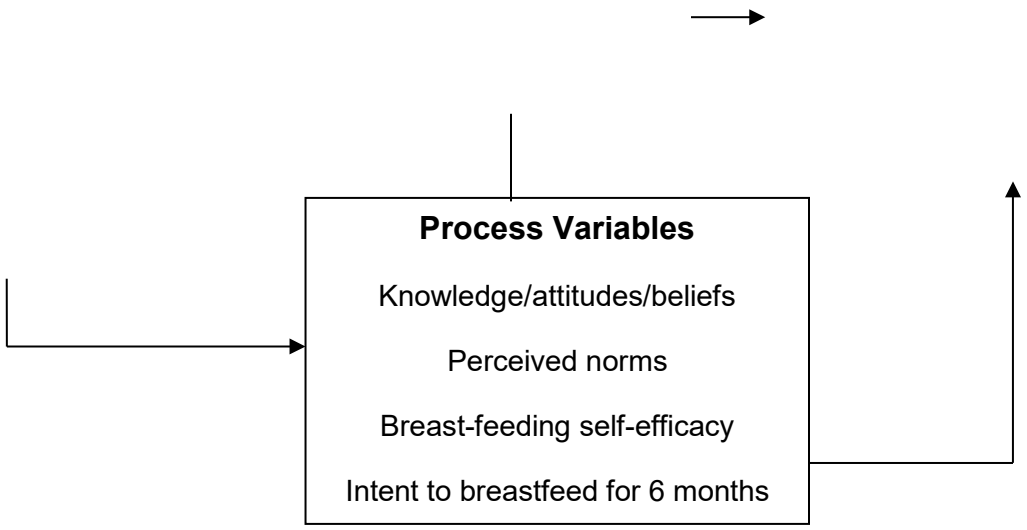


Figure4. Research Design

The subjects will be enrolled at RWMC, Scottsbluff and randomly assigned to either intervention (bilingual Computer based Breast-feeding Educational Support program) or attention control (bilingual breast-feeding printed educational material) groups during the subject's prenatal visit (i.e. anytime during last six weeks of their pregnancy). Once randomized, baseline information will be gathered in both the groups as outlined in Figure5. The difference between the two study groups is that subjects in the intervention (bilingual Computer based Breast-feeding Educational Support program) will record their baseline assessment on a computer and receive tailored breast-feeding education compared to the attention control (bilingual printed breast-feeding educational materials) who will record their baseline information on paper (Figure5) and receive printed breast-feeding educational material. Using self report responses of the individuals in the intervention group (bilingual computer based breast-feeding educational support program), the decision logic and algorithm will process the information and deliver tailored breast-feeding educational messages in varied multimedia formats using a combination of text, images, and animations to account for the literacy levels of the subjects. Appropriate feedback will be given in the form of reinforced educational messages and encouragement and motivational prompts for those using the computer based program. Educational session in both the groups will last for 30 minutes. The first educational session will be performed during the post partum period, one day before the discharge from the hospital followed by week 6, months 3 and 6. Specific individualized interventions, especially during the initial critical 2-6 week period, are needed to prevent deterioration in intention levels for breast-feeding for 6 months and breast-feeding self-efficacy levels within the first 2 weeks postpartum which could lead to the decision to discontinue breast-feeding[31]. Subjects in both the groups will be given telephone reminders for follow up educational sessions. The touch screen computer based Breast-feeding Educational Support program will be placed on a mobile cart in the outpatient clinic of the RWMC, Scottsbluff. A research assistant will be available to guide the subjects in both the intervention (during the use of the tablet pc program) and the control groups (printed educational material) if needed. The breast-feeding educational modules and data collection instruments will be both in English and Spanish.

Study Subject enrollment

Inclusion Criteria

- Hispanic females 15 years and above
- Agreeing to participate in the study
-

Exclusion Criteria

- Mental & physical challenge
- Unavailability on telephone for follow up
- Included in other Clinical trial on breast-feeding
- Not willing to participate
- Mothers who are admitted to ICU during

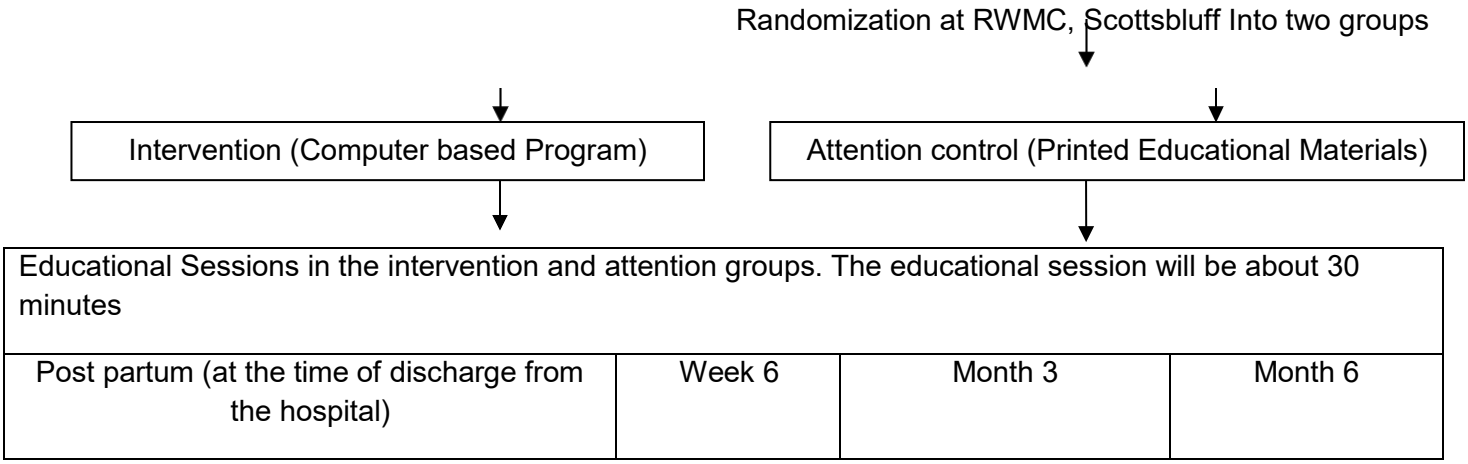


Figure5. Flow chart and education sessions in intervention and attention control groups

Description of the variables

The relevant study variables include (i) independent variables, (ii) process variables, (iii) potential confounding variables and (iv) dependent variables (outcomes). All the data gathering instruments will be available both in English and Spanish.

a. Independent variables

The study will have two groups: intervention group will receive bilingual Computer based Breast-feeding Educational Support program while attention control group will receive bilingual printed breast-feeding educational materials

b. Process variables

Variables impacting breast-feeding duration include;

Breast-feeding Knowledge: The *Breast*-feeding Questionnaire (BKQ)[24] was used in a randomized clinical trial of education and support for adolescent mothers[24]. Items from two tests of breast-feeding knowledge[55, 56,] were combined to provide a 30-item measure. Nineteen items developed for use with adolescent girls as a measure of laypersons' breast-feeding knowledge[55], were used in combination with 11 items from the Breast-feeding Knowledge Questionnaire (BKQ) [56]. The questionnaire includes multiple-choice and true-false items on the components of breast milk, colostrums, weaning and breast-feeding techniques. Reliability (internal consistency alpha coefficient-KR20) of the measure was .70 (Appendix B).

Breast-feeding Attitude/Beliefs: The Breast-feeding Attrition Prediction Scale (short-form) [BAPT] Spanish and English[38, 39]. This 35 item scale is based on theory of planned behavior[57]. It includes 4 sub-scales:1) positive breast-feeding sentiment (PBS); 2) negative breast-feeding sentiment (NBS); 3) social support and professional support (SPS) and 4) perceived behavioral control (PBC) for breast-feeding. Two International Board Certified lactation consultants reviewed the revised BAPT and judged the items to be both relevant and appropriate. Reliability was good with sub-scales scoring .67-.88 Cronbach's alpha. The overall scale demonstrated predictive validity by differentiating sustained breast-feeding at 8 weeks [38] (Appendix C)

Perceived norms: Is described as the perceived pressure to perform a behavior[34]. Social pressure will also be measured by a sub-scale of the revised BAPT. It is critical that perceived norms be measured for Hispanic

mothers since familism is an important cultural social structure in which the needs of the family as a group are more important than the needs of any individual family member and may include nutrition behaviors[58]. This strong cultural value in Mexican American families embodies social support within the extended family[59, 60] (Appendix C)

Breast-feeding Self-Efficacy: Self-efficacy is the personal belief that one can effectively perform a given behavior and that the behavior will result in the desired outcome. Self-efficacy has also been identified as a modifiable psychosocial variable in predicting behavior performance[61], including sustained breast-feeding[62]. We will use Breast-feeding self-efficacy scale short form (BSES-SF). The BSES-SF is a 14-item 5-point Likert scale questionnaire that has response categories that range from 1 = not at all confident to 5 = always confident. An internal consistency alpha coefficient of .97 was obtained for the revised total scale. Predictive validity was demonstrated by significantly higher breast-feeding self-efficacy scores in breast-feeding mothers compared to bottle-feeding mothers at 4 ($p < .001$) and 8 ($p < .001$) weeks postpartum. Content validity of 86% was established with a review by an expert panel[62] (Appendix D)

Intent to breastfeed for 6 months: -is defined as readiness to engage in a behavior. It will be measured by an intention question related to the mother's perceived intent to breastfeed for the recommended 6 months. The question has been developed based on Fishbein & Ajzen's guidelines[34] and is "How likely is that you intend to breastfeed for 6 months is measured by a 7 point Likert scale (extremely likely to extremely unlikely)?"

c. Dependent Variables

Primary outcome: Primary outcome is partial (combined formula and breast milk feeding) or exclusive breast-feeding at six months[63] and will be assessed using breast-feeding assessment questionnaire[64] (Appendix E). The questionnaire will also assess information about the timing of introducing solid food during the first six months. Exploratory analysis will also be performed to determine the proportion of Hispanic rural women who continue to do exclusive breast-feeding at six months in both the intervention (bilingual computer based breast- feeding educational support program) and control (bilingual printed breast-feeding educational materials)

Acceptance of Computer-based Breast-feeding Educational Support program: We will adapt and use previously published questionnaire used to assess acceptance of computer based asthma educational program[46] (Appendix F). Feedback will be gathered on ease of use of program, navigation patterns, and feedback during the program, future use of program and recommendation to others to use the program. Usage data analysis will help to understand learning patterns during use of the computer program by gathering the amount of time an individual spent on viewing the educational modules.

d. Potential Confounders

Socio-demographics: Include age, income levels, employment status, and education level, smoking status, prior pregnancies and previous history of breast-feeding. Information is also gathered about prior use of computers, its frequency of usage prior use of internet and sources of health information (Appendix G). Health literacy is the ability to perform basic reading and numerical tasks required to function in the health care environment[65]. Studies have shown an association between limited health literacy and worse health outcomes such as poorer knowledge about health conditions[66, 67]. The 3 health literacy screening questions, which performed optimally in a previous study[68], will be used to assess health literacy assessments of Hispanic rural women (Appendix H) and include: "How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?" (Help Read), "How often do you have problems learning about your medical condition because of difficulty understanding written information?" (Problems Reading), and "How confident are you filling out forms by yourself?" (Confident with forms). Responses will be scored on a Likert scale from 0 to 4 and were asked to choose between all of the time, most of the time, some of the time, a little of the time *or* none of the time[68].

In addition, Newest Vital Sign (NVS) consisting of a nutrition label with 6 accompanying questions to assess literacy will be used[69]. It takes approximately 3 minutes to administer, and is meant to allow healthcare providers to make a quick assessment of patients' literacy, which can then allow them to adapt communication to achieve better outcomes. It assesses literacy and numeracy, and is available in both English and Spanish versions. The

NVS has good reliability and validity for both English (Cronbach's alpha=0.76) and Spanish versions (Cronbach's alpha=0.69)[69] (Appendix I)

Subject recruitment

We will recruit subjects for focus groups, usability studies and the final evaluation from antenatal clinic at RWMC, Scottsbluff. The study information will be provided to the prospective subjects by the physicians and the other staff at the RWMC, Scottsbluff. Information about the study will also be disseminated through information flyers. The research staff at the College of Public Health (COPH) and College of Nursing (CON) Scottsbluff will gather data during the study months (Appendix J).

Subject eligibility

The inclusion criteria include; (1) Hispanic females age 15 years and above, (2) agreeing to participate in the study (3) telephone contact and (4) available for follow-up interview. The rationale for including 15 year old teen mothers is because Scottsbluff County has highest teen pregnancy rate in the State of Nebraska[70-72]. We will include only mothers in the proposed study as the focus of the study is to analyze her attitudes, beliefs, her perceived norms towards breast-feeding; breast-feeding self-efficacy and intend to breast-feed her baby for 6 months. Subjects will be excluded if any of the following criteria are met including; (1) mental and physical challenge that makes it difficult to use the touch based computer program, (2) unavailability for telephone follow-up and (3) involvement in other clinical trials or protocols related to breast-feeding, (4) Mothers who are admitted to ICU during their hospital stay, (5) Birth weight of <2500 gms, (6) <36 weeks gestation, (7) a bilirubin >15 mg%, (8) NICU admission to provide a sample of stable infants and (9) still birth.

Data Collection procedures

Baseline data will be gathered during the enrollment prenatal visit (anytime during last six weeks of pregnancy) and follow up data will be collected on postpartum day 3, week 6 and months 3 and 6 resulting in overall five data collection time periods. The postpartum day 3 data collection will be done over the telephone while other follow up data collection including week6 and months 3 and 6 will be done when the individuals in both the groups will come to the hospital for follow up educational sessions. Almost all women who initiate breast-feeding plan to continue for at least 6 weeks; however, one of every five women quits breast-feeding within the first days after delivery[73]. This finding supports the notion that 2–4 weeks postpartum is a vulnerable period for breast- feeding cessation[74]. Baseline evaluation will be done during the prenatal visit (last trimester). The research assistant will schedule a follow up interview to administer the study questionnaires at a convenient time over the telephone. Subjects will receive gift vouchers worth $15 for baseline and for every follow up postpartum visit (Table2).

Pre and Post educational Session data collection	**Baseline**	**Day 3**	**Week 6**	**Month 3**	**Month 6**
Socio-demographics	X				
Health Literacy	X				
Breast-feeding Knowledge	X	X	X	X	X
Breast-feeding self-efficacy	X	X	X	X	X
Intent to Breast-feed	X	X	X	X	X
Breast-feeding attitudes	X	X	X	X	X
Perceived norms	X	X	X	X	X
Program acceptance	X				X

Table2. Data Collection in intervention and attention control groups

Informed Consent

Lupe Salazar (Consultant) is a bilingual and certified Spanish translator and will administer the informed consent and assent forms at the RWMC, Scottsbluff after the eligible subjects have agreed to participate in the study. The research staff members will read the UNMC IRB-approved consent and assent forms to subjects describing the study, the measures used by the researchers to protect the confidentiality of the responses, and the voluntary nature of the study. Those who agree to participate will be asked to sign the consent and the assent forms as appropriate. The research staff member will countersign the consent and the assent forms and copies will be given to the participant.

Data Entry and Quality Assurance

The research assistants will perform data entry and Dr. Meza (Co-Investigator) will be responsible for data management. Data will be entered into a relational database structure using Microsoft Access Forms and inconsistencies will be generated automatically by the system for verification with original forms. To ensure efficiency and high quality data collection and processing, we will have (1) well trained team of research assistants (2) clearly defined study manual (3) weekly meetings with the research staff, (4) logs of all patient contacts. To ensure efficient and accurate data management, we will (1) maintain logs of all the data instruments filled during each visit for every patient (2) central data processing and (3) weekly data checks. Minimal risks of anxiety related to filling out instruments and demographic forms may be experienced by the participants. Methods of recruitment consistent with ethical access will be used to identify patients who meet eligibility criteria and to invite them to participate in the study. All data collected with be kept confidential. Data files will be coded by number to retain the anonymity of the participants between focus groups. All data will be stored in a password protected computer in a locked office of the PI for 3 years from the point of the study completion at which time they will be destroyed. Security of the data will be maintained through regular backups, and all computers and specific data files will be password protected and kept in a locked file cabinet (Appendix K).

VII. Analysis Plan

The study will produce a very rich database consisting of a spectrum of outcome variables including the primary and secondary outcomes; it also contains information on many potential confounders and process variables. The overall objective is to investigate the impact of the intervention of using touch screen computer based breast-feeding educational support program compared to the traditional methods of informing the subjects regarding breast-feeding during their prenatal visit at the hospital. A detailed statistical analysis plan is outlined below.

Focus Group Analysis

Analysis will be systematic, sequential, verifiable, and continuous in order to minimize the potential bias introduced in analyzing and interpreting focus group data. The main source of data analysis will be the recorded spoken language. We will use Framework analysis approach as it provides a clear series of steps, which could help to manage the large amount and complex nature of qualitative data much more easily[75]. The other distinctive aspect of this analysis approach is that although it uses a thematic approach, it allows themes to develop both from the research questions and from the narratives of research participants[75]. The analytical process involves a number of distinct though highly interconnected stages including: familiarization; identifying a thematic framework; indexing; charting; mapping and interpretation[75].

We will conduct this analysis on the audio recorded data and the observational notes gathered during the focus group interviews. The aim will be to immerse in the details and get a sense of the interview as a whole before breaking it into parts. Themes will emerge lifting the quotes from the original context and re-arranging them under the newly-developed appropriate thematic content. One of the most important aspects of this task is data reduction, which is achieved by comparing and contrasting data and cutting and pasting similar quotes together. The data are now ready for the final stage of analysis, i.e. mapping and interpreting and prior studies have suggested the following headings as a framework for interpreting coded data: words; context; internal consistency; frequency and extensiveness of comments; specificity of comments; intensity of comments; big ideas. Computer-based approach will be employed for cutting, pasting, sorting, arranging and rearranging data through comparing and contrasting the relevant information using specialized software such as nVIVO[76].

Exploratory Data Analysis

In the first step of exploratory analysis, we will present a table to summarize the distribution of all variables, including outcomes, confounding, and process variables. This table will also serve the purpose of quality control of the original data, to mine missing data patterns and outliers. The distributions of the continuous outcomes will be explored for normality and transformations will be used if warranted. Continuous variables will be summarized using means, medians, standard deviations and ranges while categorical variables will be examined using frequencies and percentages. Exploratory analysis on process variables will be used for post-hoc analysis. Inter-rater reliability of knowledge, attitudes/beliefs, self-efficacy and intent to breast feed will be examined using the kappa statistic.

Sample Size Justification

The optimum number of participants for a focus group is typically 6-10 people with similar backgrounds who participate in the interview for one to two hours may vary[52]. The number generally suggested as being manageable is between six and ten participants as smaller groups show greater potential and large enough to gain a variety of perspectives and small enough not to become disorderly or fragmented[52]. For the intervention effect analysis, a comparison of two independent binomial proportions using Pearson's Chi-square statistic with a two-sided significance level of 0.05, a sample size of 23 per group achieves a power of at least 0.8 when the proportion with partial breast-feeding at 6 months are 0.3 for the control group and 0.7 for the intervention group. To account for anticipated attrition of 15%, the sample size will be increased to 54 subjects (27 per group). This is a pilot study to explore the possibility of promoting breast-feeding using computer based breast-feeding tailored educational program among Hispanic rural women.

Statistical Analysis

Baseline characteristics will be summarized by intervention group. A chi-square test will be used to compare baseline categorical variables between the intervention and control groups and a t-test will be used for continuous variables. The primary outcome of proportion partial or exclusive breast-feeding at 6 months will be compared between groups using a Chi-square test. The primary outcome will be assessed at 6 months; however, we will also conduct these analyses at 6 weeks and 3 months. A generalized linear mixed model using a binomial distribution and logit link function will be used to examine partial breast-feeding at day 3, week 6 and months 3 and 6 postpartum, with intervention group as a fixed effect and subject as a random effect using a Variance Components covariance structure. In exploratory analyses, covariates will be added to the model to adjust for confounders that differ significantly between both the intervention and attention control groups at the 0.20 level of significance. Similar analyses will be conducted to examine exclusive breast-feeding. Breast-feeding knowledge, self-efficacy, will be compared between groups using a t-test. In exploratory analyses, a general linear mixed model with intervention group as a fixed effect and subject as a random effect using an AR (1) covariance structure will be examined. Covariates will be added to the model to adjust for confounders that differ significantly between both the intervention and attention control groups at the 0.20 level of significance (Table3).

Variables Assessment	Variable types	Data Analysis	Anticipated Outcomes
Focus groups	Qualitative	Framework analysis	Breast-feeding educational modules and functionality of the computer based program established
Socio-Demographics	Continuous & Categorical	T test for continuous and Chi-square tests for categorical variables.	Distribution of population characteristics
Intent to Breast-feed	Categorical	Chi-Square test	Assess intent to breast-feed

Breast-feeding knowledge	Continuous	T test	Improve Breast-feeding knowledge (intervention)
Breast-feeding attitudes and beliefs	Continuous and categorical	T test for continuous and Chi-square tests for categorical variables.	Change Breast-feeding related attitudes and beliefs
Breast-feeding perceived norms	Continuous and categorical	T test for continuous and Chi-square tests for categorical variables.	Change Breast-feeding related behavior
Breast-feeding self-efficacy	Continuous	T test	Improve self-efficacy (intervention)
Breast-feeding assessment	Categorical	Chi-square test	Better breast-feeding practices (intervention)

Table3. Analysis Plan

VII. Project Timelines and Milestones

The research plan entails the performance of the following tasks: (a) Modify and enhance the PEMT to deliver breast-feeding education to the Hispanic rural women about major topics such as: review the benefits of breast-feeding, principles of lactation, myths, common problems, solutions and skills training appear to have the greatest effect, (b) deliver education tailored to individual profiles including demographics age and health literacy,
(c) Other variable information gathered will include breast-feeding knowledge, attitudes and practices, (d) implement tailoring strategies, (e) assess the impact on the study outcomes and (f) perform data analysis and report the results. The Research investigators will coordinate a meeting once every month. The meeting points will be mailed to the members of the research team 72 hours before the meeting so that enough time is available to review and provide appropriate suggestions as needed. The research analysts will be responsible for the overall coordination of the meetings. The timeline of the study has been presented in the Table below (Table4).

Tasks involved	Timeline	Objectives
Research Team meet	Month 1	To formulate and strategize the study implementation plan
Focus group and Analysis	Months 2&3	Identify relevant breast-feeding educational modules
Breast-feeding Educational Content developed (English and Spanish)	Months 3-5	Develop breast-feeding educational modules based on initial findings of the focus group and investigators' expert opinion.
Modify existing PEMT	Months 5-6	Modify and integrate the breast-feeding educational modules into a computer format
Computer program redesign using heuristic principles	Months 5-6	Modify and integrate the breast-feeding educational modules into a computer format
User testing	Months 6	Usability evaluation of the system
System deployment	Months 7	System modified based on users feedback and final deployment of the computer program
Subject Recruitment	Months 8 to 13	Subject Enrollment initiated

Data Collection	Months 8-20	Baseline and follow up data collection
Analysis and Results	Month 6, 12, 20	Data entry, data analysis and initial findings reported
Dissemination	Month 6, 12, 18, 24	Final study findings disseminated to the funding and other key agencies

Table4. Project Timeline