Breastfeeding Education and Support to Improve Breastfeeding Retention

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Abstract

Breastmilk is recognized as the best form of nutrition for infants, aged birth to six months, by the World Health Organization, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics. Health benefits from breastfeeding are numerous for both mothers and infants. The retention of exclusive breastfeeding to six months is a nationally recognized public health issue addressed by Healthy People 2030. This evidence-based exempt research project aimed to improve breastfeeding exclusivity and duration in first time breastfeeders by providing prenatal breastfeeding education paired with postnatal support calls through six weeks postpartum. A quantitative, quasi-experimental two cohort study design was used. Outcomes were measured with data collected from the participants' medical records and throughout the postnatal interactions. Twenty-four participants who were established primigravid prenatal patients intending breastfeeding patients from a local obstetric gynecologic clinic were enrolled. The data from the baseline and intervention cohorts was analyzed using descriptive and inferential statistics. Exclusive breastfeeding was improved by 33.3% (p= .003) and duration of breastfeeding was improved by 11.7% (p= .134) following the interventions. This study suggests that interventions supporting breastfeeding, provided by healthcare professionals, from the clinic setting, can improve breastfeeding outcomes with statistical and clinical significance.

Keywords: prenatal, postpartum, primigravid, breastfeeding education, breastfeeding support, exclusivity, duration, breastfeeding self-efficacy

Breastfeeding Education and Support to Improve Breastfeeding Retention

Breastmilk is the gold standard food for infants, aged birth to six months (Coffman, 2019; M. S. Wong et al., 2021). It provides a complete form of the nutrients for optimal growth, it is individualized by the mother's body for each infant/mother dyad, and it supplies antibodies that help build an infant's immune system from day one (Coffman, 2019; M. S. Wong et al., 2021). Studies show that the occurrence of common childhood illnesses such as otitis media, asthma, and gastrointestinal infections can be decreased by breastfeeding (Coffman, 2019; M. S. Wong et al., 2021). Breastfeeding provides several benefits for the mother including reduction of risk for breast and ovarian cancers, reduction of risk for cardiac disease and metabolic syndrome, improved mental health, and increased bonding with their infant (Coffman, 2019; Louis-Jacques & Stuebe, 2018; M. S. Wong et al., 2021). While breastmilk and breastfeeding provide a long list of benefits to the baby and mother, research suggests there is a lack of knowledge and support for women attempting to exclusively breastfeed their babies to six months of age (Ahlers-Schmidt et al., 2020; Louis-Jacques & Stuebe, 2018; Meedya et al., 2017; M. S. Wong et al., 2021).

Significance

The need for improved long-term breastfeeding rates is documented through national surveys and studies (Center for Disease Control and Prevention [CDC] 2020a, 2020b; US Preventive Services Task Force et al. [USPSTF], 2016). Healthy People 2030 includes an objective to achieve higher rates of exclusively breastfed infants at six months of age (Office of Disease Prevention and Health Promotion [ODPHP], 2020). Rates in 2015 for this objective were 24.9% and the target for Healthy People 2030 is to increase that rate to 42.4% (ODPHP, 2020). Initiation rates for breastfeeding in the United States are considerably high, at 84.1% in

2017, but breastfeeding exclusivity and duration trend down quickly following the early postpartum period. The decrease in breastfeeding is often due to the mother's insufficient breastfeeding knowledge, perception of low milk supply, return to work, and lack of postpartum support (CDC, 2020a; USPSTF et al., 2016; M. S. Wong et al., 2021). While shortened breastfeeding duration may affect a mother-infant dyad physically and emotionally, it can also lead to an unexpected financial burden. Poor breastfeeding retention accounts for over $3 billion in health care expenses per year and a family can save at least $1,000 with six months of exclusive breastfeeding (Coffman, 2019).

Healthcare providers can support the retention of breastfeeding by providing education on breastfeeding to expectant patients in the form of in-person education, take-home materials, supplemental support calls, and links for online education (USPSTF et al., 2016; Wong et al., 2021). Introducing the idea of breastfeeding early in a pregnancy, providing direct hands-on education, and supporting breastfeeding patients throughout the first six months postpartum has been shown to improve breastfeeding exclusivity and duration (McFadden et al., 2017; USPSTF et al., 2016; Wong et al., 2021; World Health Organization [WHO], 2018).

Local Issue

Breastfeeding rates from 2017, as reported by the CDC, show that across the US breastfeeding was initiated for 84.1% of infants but only 25.6% of mother-infant dyads reached the recommended six months of exclusive breastfeeding (CDC, 2020a). Locally, in Kansas, breastfeeding rates for 2017 were similar, with 84.6% initiation and 31.6% reaching exclusive feeding at six months (CDC, 2020a). The national and local rates for exclusive breastfeeding at six months fall below Healthy People 2030's goal of 42.4%.

During observations of the obstetrics and gynecology (OBGYN) clinic, serving as the project site, a need for improved breastfeeding education and support was identified. At the clinic, breastfeeding was briefly discussed and encouraged during prenatal care. Following hospital discharge, patients did not receive breastfeeding support from the clinic other than checking in at the two and six-week postpartum visits.

Diversity Considerations

The site for this project was an urban OBGYN office in Kansas. The office is staffed by OBGYN physicians, physician assistants, and nursing/support staff. Due to the city's large population and a wide variety of ethnic groups, the clinic serves a diverse population of women. Understanding the demographic differences in breastfeeding outcomes is essential when serving a diverse population of women adequately. While breastfeeding rates have significantly improved in the last 20 years, Black, non-Hispanic infants are consistently less likely to have breastfeeding initiated or continued exclusively to six months of age when compared to White, non-Hispanic and Hispanic infants (Anstey et al., 2017). Mothers with education at or less than high school level are less likely to breastfeed than mothers with any college education (Anstey et al., 2017). Age also effects rates of breastfeeding, mothers less than 20 years old are the least likely to breastfeed to six months when compared to mothers 20-29 years old and 30 or greater years old (Anstey et al., 2017). Interventions should be implemented to promote breastfeeding to women from diverse backgrounds and reach them at their level to ensure that these disparities can be minimized.

Problem and Purpose

Problem Statement

While most understand that breastfeeding provides the best nutrition for infants and is a way to help improve childhood health outcomes, breastfeeding exclusivity and duration rates continue to fall below nationally set goals (ODPHP, 2020). This decline in breastfeeding retention can be attributed, in part, to inadequate support for breastfeeding mothers (USPSTF et al., 2016; WHO, 2018). Less than half of mothers in the United States meet their breastfeeding goals due to barriers that include inadequate prenatal breastfeeding education, insufficient postpartum support, difficulty latching, perception of low milk supply, and diminished breastfeeding self-efficacy (Coffman, 2019; McFadden et al., 2017; Parry et al., 2019; USPSTF et al., 2016; Wong et al., 2021).

Purpose Statement

This quantitative, quasi-experimental, exempt research project intended to provide evidence-based breastfeeding education and support to first-time breastfeeders to improve breastfeeding outcomes. The purpose of this project was to determine if the implementation of breastfeeding education provided during a routine prenatal clinic visit and breastfeeding support calls provided throughout the first six weeks of the postpartum period would improve breastfeeding duration and exclusivity for first-time breastfeeders as well as reduce the number of dyads with breastfeeding cessation before six weeks postpartum (Appendix A).

Facilitators and Barriers

The OBGYN physician serving as the project mentor showed interest in improving the breastfeeding education and support for his patients, providing strong support for the project at the site. The clinic manager's endorsement further facilitated the implementation of the project. The only cost for the project was printing the education booklets given to participants during their prenatal breastfeeding education session which was $240 for 50 booklets. Low

implementation and continuation costs increased the chance for successful implementation and sustainability of the project (Appendix B). Sustainability for this project was high due to the strong support from the physician, clinic manager, and nursing staff.

Depending on how closely together participants give birth, a barrier for the project team leader could be allocating enough time and managing when all the needed postpartum support calls should occur. The call schedule was addressed with careful attention to the participants' birth dates and utilization of a Google Sheets document that calculated when calls should be made throughout the six-week postpartum period. A second potential barrier was the loss of postpartum communication between the participants and the project team leader, complicating the ability to provide postpartum breastfeeding support. This barrier was addressed in several ways. First the project team leader provided her phone number at the prenatal education session along with an anticipated call schedule. Then text messages were sent before the support calls to allow participants to choose what time would work best for them that day.

Inquiry

The inquiry guiding this project was: For primiparous patients, intending to breastfeed, does in-person breastfeeding education provided during a third-trimester prenatal visit paired with postnatal follow-up calls improve breastfeeding exclusivity and duration at six weeks postpartum when compared to standard breastfeeding care at an obstetric and gynecologic clinic?

Evidence Review Strategies

A literature review to establish support for the inquiry was performed by searching several databases including Cochrane Review, Cumulative Index to Nursing and Allied Health Literature, JSTOR, Medline, and PubMed. Search engines, Google Scholar and the University of Missouri-Kansas City Health Science Library search engine, were also utilized. Key terms

included breastfeed, primigravid, primiparous nulliparous, prenatal, perinatal, postnatal, postpartum, education, support, and self-efficacy. Manual searches from the reference lists of the included studies were performed for further study identification. Studies were included if they were published between 2012 and 2021, were available in English, and evaluated prenatal and/or postpartum breastfeeding support or barriers to breastfeeding. Excluded studies addressed only hospital-based or web-based breastfeeding support, focused on educating family/support persons, or had education programs that were not practical for this inquiry.

The search yielded 292 distinctive articles. An adaptation of PRISMA was used to analyze and select relevant articles (Appendix C) (Moher et al., 2009). Abstracts were reviewed for relevance, leaving 110 articles to be examined in full. The synthesis of quantitative evidence included 29 articles, categorized by Melnyk's levels of evidence (Appendix D) (Melnyk & Fineout-Overholt, 2019). Articles included two evidence-based practice guidelines (EBPG) with level one evidence, seven systematic reviews with level one evidence, eight single randomized controlled trials with level two evidence, three quasi-experimental studies with level three evidence, three case-control or cohort studies with level four evidence, and six observational or descriptive studies with level six evidence. The inquiry was also supported by two studies that were qualitative/ mixed-method studies and two committee opinion pieces (Appendix E).

Synthesis of Evidence

An understanding of current evidence supporting breastfeeding education and support was obtained during a thorough synthesis of the 29 included studies. The synthesis of evidence revealed five themes relating to the inquiry: (a) timing of the interventions, (b) method for the interventions, (C) breastfeeding exclusivity and duration, (d) education content, and (e)

breastfeeding self-efficacy. The prevalence of each theme, within the selected studies, was determined to illustrate the overall support (Appendix F).

Timing of the Interventions

The timing of breastfeeding education and support interventions for first-time breastfeeders is crucial when improving breastfeeding outcomes. USPSTF published its most recent EBPG on primary care interventions for breastfeeding promotion in 2016, recommending that primary care healthcare providers offer interventions both prenatally and during the postpartum period to help sustain breastfeeding (USPSTF et al., 2016). The WHO provided more detail in their practice guideline, published in 2018, which recommended that interventions should begin during pregnancy and last up to 24 months postpartum (WHO, 2018).

Prenatal Breastfeeding Education

Prenatal breastfeeding education has been shown to provide a strong foundation for primiparous mothers, helping them affirm their intention to begin breastfeeding within hours of birth (Ballesta-Castillejos et al., 2020; Kronborg et al., 2012; Schreck et al., 2017). The evidence shows that prenatal education has successfully increased breastfeeding initiation at birth (Ahlers-Schmidt et al., 2020; Ballesta-Castillejos et al., 2020; Huang et al., 2019; Kronborg et al., 2012; Schreck et al., 2017). However, as a stand-alone intervention, prenatal education was not statistically effective in improving breastfeeding exclusivity or duration up to 12 months in several studies and systematic reviews (Ahlers-Schmidt et al., 2020; Kim et al., 2018; Kronborg et al., 2012; Meedya et al., 2017; Schreck et al., 2017; K. L. Wong et al., 2014).

Postpartum Breastfeeding Support

Postpartum breastfeeding support had a positive impact on breastfeeding exclusivity and duration with the most significant impact occurring with interventions that included several early

postpartum interactions and extended to at least two months postpartum (Huang et al., 2019; McFadden et al., 2019; Skouteris et al., 2017; M. S. Wong et al., 2021). Evidence from included studies suggests several different intervals for postnatal intervention, with no one interval proving the best. Huang et al. (2019) used monthly interactions from birth to four months and Kim et al. (2018) used long-term follow-up with precise interaction protocols. McFadden et al. (2019) determined that four or more interactions were needed to affect exclusivity and duration positively. McFadden et al. (2017) had scheduled postpartum interactions that occurred four to eight times, while M. S. Wong et al. (2021) suggested at least three postpartum interactions with careful consideration for the first two months postpartum. Skouteris et al. (2017) recommended long-duration postpartum follow-up to achieve up to six months of breastfeeding exclusivity.

Prenatal/Postpartum Combination

Strong evidence from the literature review supported a combination of prenatal breastfeeding education and postpartum breastfeeding support as the best option for sustaining breastfeeding exclusivity and duration. This combination of prenatal and postnatal interactions has shown statistically significant improvements to breastfeeding exclusivity and duration in comparison to no interventions and only prenatal or postnatal interventions (Huang et al., 2019; Kim et al., 2018; McFadden et al., 2017, 2019; Meedya et al., 2017; Schreck et al., 2017; USPSTF et al., 2016; M. S. Wong et al., 2021; WHO, 2018).

Methods for the Interventions

A second theme that emerged was the significance of how the interventions were presented. Both the WHO and the USPSTF stated, in their practice guidelines, that to be effective, breastfeeding promotion interventions must include face-to-face interactions and can include additional components such as telehealth, telephone, or web-based exchanges as well

(USPSTF et al., 2016; WHO, 2018). The combination of face-to-face and telephone breastfeeding support was superior to either of these inventions on their own in three articles (Daou et al., 2020; Skouteris et al., 2017; M. S. Wong et al., 2021).

Face-to-Face Support

Several systematic reviews found statistical significance for mothers receiving face-to-face breastfeeding counseling during their pregnancy in association with improved breastfeeding outcomes (McFadden et al., 2017, 2019; M. S. Wong et al., 2021). Face-to-face interventions allow for in-depth discussions and hands-on education, which can be imperative to teaching first-time breastfeeders about correct breastfeeding techniques (Tan et al., 2020; M. S. Wong et al., 2021; Wood et al., 2016; WHO, 2018). Pitts et al. (2015) found that over 90% of their participants preferred one-on-one counseling compared to a group education setting. One-on-one sessions can be easily incorporated into prenatal care visits, allowing for education to be provided routinely to all patients and without requiring a separate office visit for education classes.

Telephone/Video-based Support

Numerous recent research studies included postpartum support via telephone or video-based communication platforms. Evidence showed that when these interactions are provided in early postpartum and the frequency is greater than once in the first six months, breastfeeding exclusivity and duration are positively impacted (Chaves et al., 2019; Daou et al., 2020; Forster et al., 2019; Fu et al., 2014; Huang et al., 2019; Jerin et al., 2020; McFadden et al., 2019; Skouteris et al., 2017; Wood et al., 2016). Another benefit, for both the patient and provider, with regards to supplemental telephone or video-chat interactions, is the ability to provide a financially responsible support intervention, unlike a separate office visit or professional

lactation consultation which can be time-consuming and expensive (American College of Obstetricians and Gynecologists [ACOG], 2021b; Flannery, 2015; Forster et al., 2019; Fu et al., 2014; Huang et al., 2019; Jerin et al., 2020).

Breastfeeding Exclusivity and Duration

Throughout the literature, breastfeeding exclusivity and duration are used to quantify breastfeeding success. Interventions to support these two outcomes vary widely but an overall consensus remains, exclusivity and duration are positively influenced by interventions promoting breastfeeding (McFadden et al., 2019; Nnebe-Agumadu et al., 2016; USPSTF et al., 2016; M. S. Wong et al., 2021; WHO, 2018). The definition for breastfeeding exclusivity differs depending on the source. The WHO's most recently published report states that infants receiving only breastmilk at the breast, expressed, or from a wet nurse without supplementation of any other source with an exception for vitamins and medications qualifies as exclusive breastfeeding (WHO, 2008). This definition was used in several of the articles found in this literature review. Other definition variations included specifying no water given before six months of age and no artificial or non-human milk sources used in the first six months (Daou et al., 2020; Tan et al., 2020; Tseng et al., 2020). Another variation, found in two studies, asked mothers if their infants were breastfed exclusively in only the past 24 hours which created cause for concern in their overall exclusivity results (Forster et al., 2019; Jerin et al., 2020). McFadden et al. (2017) found that definitions differed among several of their included studies during their systematic review, and this heterogeneity caused problems for relatability. There were also studies in this literature review that did not define exclusive breastfeeding. The heterogeneity of the definition for exclusive breastfeeding poses a problem within research and for women attempting to breastfeed exclusively. The use of a unified definition for breastfeeding exclusivity, like the one provided

by the WHO, can help eliminate heterogeneity among results and provide mothers with a firm understanding of what is classified as exclusive breastfeeding.

Education Content

An intervention can only be as successful as the content that it includes. The impact breastfeeding can have on the health outcomes of the mother and infant are well documented and this evidence typically makes up the bulk of traditional prenatal breastfeeding education (Louis-Jacques & Stuebe, 2018; Pitts et al., 2015; Tan et al., 2020; Wood et al., 2016). Education on the positive effects of breastfeeding on health outcomes has been shown to increase the number of women initiating breastfeeding at birth but it has not proved to be enough to impact long-term breastfeeding retention (Kronborg et al., 2012). While the benefits of breastfeeding are an essential piece of education, they need to be coupled with other components to have a more robust impact on breastfeeding exclusivity and duration. ACOG recommends that professional education include the benefits of breastfeeding as well as the mechanics of the skill and that providers need to be open to discussing a patient's breastfeeding goals and the potential barriers that they may encounter (ACOG, 2021b). Evidence has shown that for breastfeeding education to increase breastfeeding outcomes, topics addressed need to include breastfeeding positions, latching techniques, early signs of hunger, estimating milk supply, and troubleshooting techniques (Parry et al., 2019; Pitts et al., 2015; Tan et al., 2020; K. L. Wong et al., 2014). Education should be provided in a way that strengthens the breastfeeders mentally and emotionally, making them feel proud of their breastfeeding journey (Brown, 2016; Jerin et al., 2020; Wood et al., 2016).

Women's Perceptions of Breastfeeding Education

Several studies evaluated women's opinions of their breastfeeding education with varied findings. Brown (2016) evaluated breastfeeding education and promotion, finding that only 10% of participants felt their breastfeeding education had adequately prepared them to breastfeed a baby. The study noted that mothers wanted breastfeeding to be presented as the "normal" way to feed a baby instead of the "best" way, reducing the idea that it will be complicated or an unobtainable skill in addition to removing feelings of resentment and failure that mothers feel when needing to use a combination of breastmilk and formula (Brown, 2016). Participants also stated they wished the ease of access and cost-saving factors of breastfeeding had been emphasized (Brown, 2016). Participants felt overwhelmed by the idea of breastfeeding exclusively for six months, suggesting that helping new mothers first set short-term goals, working towards six days then six weeks of exclusive breastfeeding before trying to tackle six months may help improve maternal confidence and perception of their ability to achieve long-term exclusive feeding (Brown, 2016).

Cortés-Rúa and Díaz-Grávalos (2019) found that participants felt that both their breastfeeding education and support were inadequate and did not prepare them for the challenges of breastfeeding. In several studies, mothers suggested that the benefits of breastfeeding were well established during provided education but other areas of education involving feeding positions, latching techniques, milk expression, low milk supply, and honest conversations regarding the challenges of breastfeeding should have also been included to improve success (Brown, 2016; Cortés-Rúa & Díaz-Grávalos, 2019; Pitts et al., 2015; Tan et al., 2020). One study, utilizing the Ready, Set, BABY education materials, found that primiparous mothers had improved knowledge regarding Baby-Friendly practices and were able to identify early feeding cues before a baby becomes fussy and begins crying (late feeding cue) (Parry et al., 2019). This

curriculum was well received and described as both useful (98.3%) and informative (98.9%) by the participants (Parry et al., 2019). Over 99% of the participants stated they would recommend it to a friend (Parry et al., 2019).

Breastfeeding Barriers

Breastfeeding education should complement the expressed needs of the mother-infant dyad. For the content to be effective in improving breastfeeding retention, in primiparous mothers, it needs to address the reasons for early discontinuation (Chaves et al., 2019; Daou et al., 2020; Jerin et al., 2020; Wood et al., 2016). Throughout all the relevant studies, perception of low milk supply was a dominant theme for breastfeeding difficulties and cessation (ACOG, 2021a; Brown et al., 2014; Daou et al., 2020; Demirci & Bogen, 2017; Gianni et al., 2019; Wood et al., 2016). Nipple pain related to cracking and mastitis along with incorrect latching techniques and engorgement are other commonly noted barriers to breastfeeding retention (ACOG, 2021a; Daou et al., 2020; Demirci & Bogen, 2017; Gianni et al., 2019; Wood et al., 2016). Studies also found that mothers returning to work with insufficient time to express milk or inadequate knowledge on how to express and store milk created a barrier for breastfeeding success (ACOG, 2021a, 2021b; Brown et al., 2014; Daou et al., 2020; Demirci & Bogen, 2017; Gianni et al., 2019). ACOG acknowledged that there are several barriers encountered during breastfeeding and encouraged healthcare providers who have contact with these mothers to listen and support them in order to help decrease the perceived barriers and increase breastfeeding retention (ACOG, 2021a, 2021b).

Breastfeeding Self-Efficacy

Evidence showed that breastfeeding self-efficacy is an essential component of a successful breastfeeding intervention. Defined in several studies as the confidence a mother has

in her ability to breastfeed her baby, enhanced breastfeeding self-efficacy has the potential to improve breastfeeding retention (Chaves et al., 2019; Piro & Ahmed, 2020; Tseng et al., 2020; M. S. Wong et al., 2021; Wood et al., 2016). Breastfeeding self-efficacy was derived from Bandura's Social Learning Theory which states that strengthened self-efficacy results in an increased ability to respond effectively in a stressful situation (Bandura, 1977; Dennis, 1999). Breastfeeding can be stressful, especially when encountering difficulties and barriers. Piro and Ahmed (2020) reported that a strong breastfeeding self-efficacy increases the chances a new mother will initiate breastfeeding and increases the amount of effort she will put towards breastfeeding. It was also found that mothers with high breastfeeding confidence will work longer and more diligently to master the skill of breastfeeding and respond in a more positive, less emotional way when difficulties arise (Piro & Ahmed, 2020).

Interventions that incorporated breastfeeding self-confidence and breastfeeding self-efficacy theory had higher rates of breastfeeding exclusivity throughout the postpartum period including up to two months and at six months (Piro & Ahmed, 2020; Tseng et al., 2020; M. S. Wong et al., 2021; Wood et al., 2016). These studies focused on providing education both prenatally and in the postpartum period to enhance the mother's confidence in breastfeeding. They found that adequately preparing a woman for the challenges of breastfeeding, in a way that improved her belief in her own ability to perform, positively affected breastfeeding self-efficacy scores along with breastfeeding outcomes (Chaves et al., 2019; Piro & Ahmed, 2020; Tseng et al., 2020; M. S. Wong et al., 2021; Wood et al., 2016). Increased breastfeeding self-efficacy corresponded with a woman's ability to successfully respond and adjust to breastfeeding difficulties she encountered without affecting the exclusivity of her breastfeeding (Piro & Ahmed, 2020; Tseng et al., 2020; M. S. Wong et al., 2021).

Summary and Discussion

Direct Evidence

A review of evidence-based literature showed support for breastfeeding education and postpartum support to improve breastfeeding duration and exclusivity. Through the extensive review of articles, direct evidence was collected on how interventions should be offered, resulting in the most significant positive effect on breastfeeding outcomes. Strong support for the method and timing of the inquiry's interventions to increase breastfeeding exclusivity and duration was found in two EBPGs (level one evidence) and six systematic reviews (level one evidence) along with several studies of lower-level evidence (Kim et al., 2018; McFadden et al., 2017, 2019; Meedya et al., 2017; Skouteris et al., 2017; USPSTF et al., 2016; M. S. Wong et al., 2021; WHO, 2018). The content of the inquiry's breastfeeding education was validated in one systematic review (level one evidence), one randomized controlled trial (level two evidence), two quasi-experimental studies (level three evidence), one case-control study (level four evidence), and two observational studies (level six evidence) (Chaves et al., 2019; Daou et al., 2020; Demirci & Bogen, 2017; Jerin et al., 2020; Parry et al., 2019; Pitts et al., 2015; Wood et al., 2016). The inclusion of breastfeeding self-efficacy as a guiding theme for the interventions in the inquiry was strongly supported by two systematic reviews (level one evidence) and three randomized controlled trials (level two evidence) (Chaves et al., 2019; Piro & Ahmed, 2020; Tseng et al., 2020; M. S. Wong et al., 2021; Wood et al., 2016).

Limitations

Limitations were noted during the literature review. While the WHO suggests a well-accepted definition for exclusive breastfeeding, studies varied in their definitions or did not define this term at all. Only a few studies noted a specific or standardized curriculum that would

be easily reproducible for future use. Most studies were highly heterogenous in the method and timing of their interventions. Interventions ranged from one informal session prenatally to multiple hour-long sessions, some had hospital-based components, and several included postpartum follow-up interventions lasting anywhere from 6 weeks to 24 months. Some studies included multiparous women which left potential for bias from previous breastfeeding experiences and will not be included in this project.

Summary

Current literature supports a combination of prenatal and postnatal interventions to improve breastfeeding duration and exclusivity. Providing these interventions effectively with content that has the potential to improve breastfeeding outcomes is also key for success. Overall, breastfeeding mothers need the help of healthcare professionals from initiation well into the postpartum period to improve successful retention of the skill.

Theory

The Breastfeeding Self-Efficacy Theory was developed by Cindy-Lee Dennis and was first published as a theory by Dennis in 1999. This theory evolved from Bandura's Social Learning Theory. The Breastfeeding Self-Efficacy Theory focuses on an individual's perceived confidence to breastfeed (Dennis, 1999). The theory begins with antecedents, which affect self-efficacy, moves into consequences, and culminates in the initiation and maintenance of breastfeeding (Appendix G) (Dennis, 1999). Before a new behavior begins, a mother will decide whether to pursue breastfeeding through several sources of information or antecedents including performance accomplishments, vicarious experiences, verbal persuasions, and judgments from one's physiologic and affective states (Dennis, 1999). These antecedents have a direct effect on the amount of self-efficacy or confidence a mother has in her ability to breastfeed her infant.

Whether high or low, self-efficacy will impact an individual's choice to breastfeed and their response to mastering this complex skill (Dennis, 1999). Mothers with high self-efficacy are more likely to initiate breastfeeding, establish and work towards breastfeeding goals, put forth more effort and endure difficulties, critically think through problems or seek help related to breastfeeding, maintain positive emotions and thoughts surrounding their ability to breastfeed, and embrace the challenge of breastfeeding without becoming overwhelmed (Dennis, 1999).

The Breastfeeding Self-Efficacy Theory can guide healthcare professionals as they support breastfeeding mothers. Identifying mothers that have low breastfeeding self-efficacy is key to improving breastfeeding retention. Supporting these mothers with direct acknowledgment of the difficulties they may face, providing hands-on education, and using positive reinforcement can help to improve their confidence and breastfeeding outcomes (Dennis, 1999).

Multiple research studies support the application of the application of the Breastfeeding Self-Efficacy Theory as a framework for interventions implemented to improve breastfeeding outcomes. Two studies seeking to improve breastfeeding exclusivity and duration found that including the Breastfeeding Self-Efficacy Theory as a foundation to their interventions improved their rates for both outcomes (Piro & Ahmed, 2020; Tseng et al., 2020). This was also supported by the results of two systematic reviews, which found that higher breastfeeding self-efficacy led to longer periods of exclusivity and duration at both two months and six months postpartum (M. S. Wong et al., 2021; Wood et al., 2016). The application of the Breastfeeding Self-Efficacy Theory to this project's education content and postnatal support enhanced the ability to increase maternal confidence and promote increased exclusivity and duration of breastfeeding (Appendix G).

Methods

Project Approval

Primary approval and site agreement for this evidence-based, exempt research project was granted, on August 20, 2021, by the project sites's Institutional Review Board (IRB) (Appendix H). The University of Missouri-Kansas City IRB and School of Nursing faculty also provided their approval of the exempt research project (Appendix I, Appendix J). An amendment to the project, regarding data use agreements between the project site and the University of Missouri-Kansas City was approved August 31, 2021. The purpose of the project was to improve exclusive breastfeeding rates at six weeks postpartum in first-time breastfeeders. Informed consent was obtained before enrolling participants in the project (Appendix K). Minimal risk was posed to those who chose to enroll.

Ethical Considerations

The project's team leader met with each potential participant before enrollment to provide project information and obtain informed consent. Potential participants were provided information on what to expect as a participant, the data that would be collected throughout the project, the goals of the project, possible risks and benefits of participation, and were ensured that their participation was not mandatory, allowing the option of withdraw at any time. The project site provided a secure laptop for performing chart reviews and storing data. Both of the cohorts' demographic information and data were de-identified for anonymous data reporting and analysis.

A conflict of interest did exist with the project team leader, who was acquiring clinical hours at the project site during 2021 and 2022. Efforts to reduce the nurse practitioner-patient relationship between the participants and the project team leader included informing the participants about the conflict of interest and providing information on consent as noted above.

Funding

The project's only cost was printing the Ready, Set, BABY educational booklets (Appendix L). This cost was estimated at $240 for 50 booklets (Appendix B). This expense was fully covered by a grant received from the University of Missouri-Kansas City Women's Council Graduate Assistance Fund in February of 2022. The grant received were provided by the Planned Parenthood of Kansas City Award and the Martha Jane Starr Award.

Setting and Participants

The project was implemented at a hospital affiliated OBGYN clinic in Kansas. The clinic was staffed by several OBGYN physicians, physician assistants, nurses, and support staff. Potential participants were primiparous patients of the project's mentor, a physician at the project site. Inclusion criteria for participants were primiparous patients, with singleton pregnancies, who intended to breastfeed, were 34-38 weeks gestation at the time of enrollment, English speaking, and who had a means of communication for postpartum support. Exclusion criteria for the project included any or all of the following: any previous breastfeeding experience, 40 weeks gestation or more at the time of enrollment, no intention to initiate breastfeeding, and no means of communication for postpartum support.

Participants were selected through consecutive sampling, offering enrollment to all who met the project's criteria. This type of sampling helped to reduce bias created by non-probability selection. It provided the project with the largest sample possible, increasing the reliability and validity of the results. An offer to be included in the project was provided to all eligible participants from September to December of 2021, with a goal of recruiting 40 mother-infant dyads to participate in the interventions.

Evidence-Based Practice Interventions

Recruitment for the project began with a chart review of all upcoming prenatal visits for the project's supporting physician (Appendix M, Appendix N). Potential participants were determined based on the inclusion/exclusion criteria. The project team leader met with each potential participant during a prenatal visit to inform them about project and obtain informed consent for those that agreed to participate (Appendix K). Recruitment and enrollment began in September of 2021 and continued throughout the implementation of the prenatal intervention. Following enrollment, the project team leader provided the prenatal education session to each participant during one routine prenatal visit between 36 and 39 weeks gestation. The prenatal education detailed breastfeeding positions, how to determine if an infant is latched to the breast properly, benefits for breastfeeding mothers and infants, early feeding cues, and information about milk supply. An educational booklet, called Ready, Set, BABY, was given to each participant to take home to help reinforce the face-to-face education (Appendix L). The Raygor reading level for this booklet was fifth grade. The prenatal education sessions began in September of 2021 and continued through December of 2021.

Following the first participant birth in September of 2021, the project team leader began providing postnatal support calls on postpartum days 5, 12, 19, 26, and 42. These calls provided participants with breastfeeding support both technical and emotional as well as allowed time for the participants to ask their own questions. These calls were individualized, content depended on the concerns or questions posed by each participant during the call. If the project team leader felt the participant could use hands-on breastfeeding support, the participant was encouraged to make an appointment with the hospital-affiliated lactation clinic. To determine breastfeeding exclusivity for that week, participants were asked during the support calls if they had used any

formula in the past week. The postpartum support calls continued through February of 2022. Evaluation and analysis of the project began after all the project's data has been collected.

Change Process Theory

Kotter's Leading Change Model provided a guide for this project's organizational change process. Proposed changes fail for a variety of reasons, buy-in and follow-through are challenging obstacles to overcome, but Kotter provided a model for making organizational-level changes successful (Kotter, 2018). Kotter's Leading Change Model proposes eight steps to successfully integrated a change (Kotter, 2018). These steps include creating a sense of urgency, developing a solid team, forming and sharing the vision, empowering others to make the change, accomplishing and celebrating short-term wins, proceeding through revisions and improvements, and establishing the change (Kotter, 2018). The project had a strong team, made up of the project team leader, the supporting physician, and his nursing staff. During implementation the team reviewed the interventions and participant feedback to determine if the interventions were successful. Improvements and revisions were made to increase sustainability following the project's completion. The steps laid out by Kotter's model have not only helped with the development and implementation of this project, but they supplied a guide for the team to promote long-term sustainability for the clinic.

Evidence-Based Practice Model

The Stetler Model of Evidence-Based Practice was the evidence-based practice model chosen to guide this project. The Stetler model places significant importance on the critical thinking skills of the practitioner in the implementation of the evidence-based intervention (Stetler, 2001). It contains several phases that helped the project team leader move from preparing the project through research and defining outcomes to applying and evaluating the

project (Stetler, 2001). Throughout the model, several spots allow the project team leader to stop, review the progress, and decide if proceeding with the project is the best course of action (Stetler, 2001). The Stetler Model can be effectively utilized to implement change in a private medical clinic, making it a good choice for the current project and it's site (Stetler, 2001).

Project Design

A quantitative, quasi-experimental study design was used for the project (Appendix O). Two cohorts, baseline and intervention, helped to determine the project's success. The baseline cohort consisted of patients of project's mentor who were seen prenatally and postnatally before the project's implementation. The intervention cohort consisted of a consecutive sample of all the project mentor's patients who were willing to participate and met the project's inclusion and exclusion criteria.

Validity

Internal Validity

The causality of the interventions was supported by providing the same prenatal education content, breastfeeding booklet, and number of postnatal interactions to all participants. Both cohorts were care for prenatally and postnatally by the same physician and nursing support staff as well as gave birth in the same Baby-Friendly designated hospital.

Potential confounding variables that could threaten a breastfeeding project include family and peer breastfeeding support or lack thereof, breastfeeding barriers encountered, and the health status of both the mother and infant following birth. Unexpected events such as damage to a phone or loss of phone service could threaten the project's validity and could be attributed to either socioeconomic disadvantage or technological difficulties. Selection bias is another threat to internal validity. Participants were selected if they intended to breastfeed which could have

falsely increased the outcomes being measured. Attrition may be affected positively or negatively by personal feelings towards breastfeeding or the personal breastfeeding experience of the participant.

External Validity

The transferability of the project depends on the variation in demographics achieved in the participant sampling and the ability of any OBGYN clinic to implement the intervention successfully. The project site's setting, a large OBGYN practice in an urban city, increased the transferability and external validity. To enhance transferability, project and intervention flow models were developed (Appendix M, Appendix N). Differences in education styles or content may threaten successful transferability but using a preplanned education session and providing identical evidence-based education booklets can help to reduce this factor.

Outcomes

Two outcomes were assessed during the project. The first was exclusive breastfeeding at six weeks postpartum. Exclusivity was based on the response to how much breastmilk was received by the infant each week. Exclusive breastfeeding was designated for dyads with 100% breastmilk that week whether at the breast or from a bottle. Partial breastfeeding was defined as any supplementing with formula, and no breastfeeding was defined as the use of only formula, with no breastmilk given.

The second outcome measured was breastfeeding duration. This was measured by the continuation of any breastfeeding (exclusive or partial) each week. Anticipated results, following project's implementation, included an approximately 15% increase in number of infants exclusively breastfed at six weeks postpartum and an approximately 10% increase in the duration of any breastfeeding.

Quality of Data

An *a priori* power was calculated with G*Power (Faul et al., 2007) with a one-sided difference between two independent proportions with proportions of 0.5 and 0.8, alpha 0.05, power of 0.8, and an allocation ratio of one revealed the need for a sample size of 62 participants, 31 in each cohort. An additional nine participants were added to each cohort to account for possible attrition, creating a total target sample size of 80.

Twenty-four participants enrolled in the project's intervention cohort. Two participants were lost to attrition during the postpartum support calls. These two did not answer several of the attempts at communication and did not attend their six-week postpartum visit at the clinic, leaving no way for the project leader to collect breastfeeding data. To match the intervention cohort size, 24 past patients were selected during a retrospective chart review to serve as the baseline cohort.

Quality of data collected was enhanced by collecting demographic and birth-related data for both cohorts from the same electronic medical record system. Demographic data collected included maternal age, ethnicity, mode of birth, gestational age at birth, and birth complications (Appendix P). Breastfeeding exclusivity data was collected from the participants during their weekly postpartum support calls and at their six-week postpartum clinic visit (Appendix P). Both cohorts were cared for by the same physician and nursing staff, therefore the electronic medical charts were similar in content and form.

Project Analysis

Project data was analyzed by the project leader with descriptive and inferential statistics (Appendix Q). Demographics assisted in establishing the similarities of the cohorts' compositions and evaluating descriptive differences in breastfeeding outcomes by age, race, birth

mode, gestational age at birth, and birth complications (Table R1, Table R2). Breastfeeding exclusivity was categorized by full, partial, and none. Breastfeeding duration was described as any breastfeeding whether exclusive or partial during each week postpartum. The exclusivity of the intervention cohort was evaluated for each week of the postpartum follow-up period (Chart R1). IBM's SPSS used the Wald HO independent- samples proportions z-test to compare breastfeeding duration and exclusivity between the baseline and intervention cohorts (Table R3). The project's breastfeeding exclusivity results, at six-weeks postpartum, was compared to national and state data from the CDC on exclusive breastfeeding rates at three months postpartum (Table R4). Six weeks postpartum data was not available from the CDC for a closer comparison.

Results

Setting & Participants

The setting for this study was a hospital-affiliated OBGYN clinic in Kansas. Participants were enrolled in the intervention cohort from September to December of 2021 (Appendix M). Age range for the participants varied from 22 to 32 with a mean age of 26.0 years. The participants were 87.5% Caucasian and 12.5% Hispanic. The average gestational age for the participants' babies at birth was 38.8 weeks. Vaginal births were experienced by 91/7% of the participants; 8.3% underwent cesarean section (Table R1). Birth-related complications were encountered during six of the births including pre-eclampsia, shoulder dystocia, vacuum-assisted birth, infection, postpartum hemorrhage, pre-term labor, failed induction of labor, neonatal resuscitation and need for transfer. The baseline cohort was created from a retrospective chart review, matching patients of the project site prior to the project's implementation as closely demographically as possible with intervention participants (Table R2). Age range for the

baseline cohort was 20 to 33 with a mean age of 25.2 years. The participants were 87.5% Caucasian and 12.5% Hispanic. The average gestational age for the participants' babies at birth was 38.6 weeks. Vaginal births were experienced by 91.7% the participants and 8.3% underwent cesarean section. Birth-related complications were encountered during six of the births including fetal distress, neonatal resuscitation, postpartum hemorrhage, failed induction of labor, and pre-eclampsia.

Intervention Course

Following enrollment, demographic data for the participants was collected from the electronic medical record and input into the Google Sheets document created by the project leader. Next participants were provided with a 15-minute breastfeeding education session. This session took place during one routine prenatal clinic visit between gestational age 36 weeks and 39 weeks. These education sessions were provided to all 24 participants from September to December of 2021 (Appendix M, Appendix N). Participants were allowed time to asked questions following the education session.

Each participant's pregnancy course was followed by the project leader by monitoring their electronic medical record for their hospital admission and birth-related notes. Participants gave birth between September of 2021 and January of 2022. Following birth, postpartum support calls were made to each participant starting on postpartum day five and continuing weekly for weeks two, three, and four and a final call was made at six weeks postpartum, for a total of five calls. Calls were preceded by a text message, to the participants the morning of a scheduled call to identify what time would work best for the team leader to call them that day. If participants did not answer the text message, a second message was sent the following day. If this message was unanswered, a phone call was placed the next day and voice message was left. Participants

who did not answer any messages or calls were marked as no response for that week and messages and calls were attempted at their next scheduled date.

Postpartum support calls began in September of 2021 and concluded in February of 2022. Data collected during the postpartum support calls included current breastfeeding exclusivity and notes were made about topics discussed during each call. All the data was input into the project's Google Sheets document. Two participants did not respond to several of the postpartum support calls including the final one at six weeks. The project team leader was unable to collect accurate breastfeeding data for those two participants. No participants formally withdrew from the project.

The baseline cohort was selected during a retrospective chart review beginning in December of 2021 and concluding in February of 2022. Patients receiving prenatal and postpartum care prior to the project implementation going back until January of 2020 were eligible for chart review. Inclusion and exclusive criteria for the baseline cohort was similar to the intervention including: primiparous patient with a singleton pregnancy and an intention to breastfeed. Charts were reviewed and matched as closely as possible to the demographics of the intervention cohort participants. This included reviewing their prenatal care notes for intention to breastfeed and their delivery notes for birth details. After establishing the baseline cohort, their six-week postpartum clinic visit note was reviewed for comments on breastfeeding exclusivity.

Outcome Data by Subtopic

Following the completion of the project's interventions, data collections, and baseline cohort chart review, an analysis of the data collected was performed. The outcomes of breastfeeding exclusivity and duration were examined with descriptive and inferential statistics. Demographic data was used to assess for any differences in breastfeeding exclusivity per

demographic category. The two participants lost to attrition were used in the demographic data total calculations but were not included in the analysis of breastfeeding exclusivity or duration.

Demographic Comparison

The average age of those breastfeeding at six weeks postpartum was similar in both cohorts: 26.1 years for intervention and 26.5 years for baseline (Table R1, Table R2). The same was true for average gestational age at birth: 39.0 weeks for intervention and 39.3 weeks for baseline. Due to the increased number of dyads exclusively breastfeeding at six weeks following the interventions, the analysis of race, birth mode, and birth complications are elevated for the intervention cohort when compared to the baseline cohort. Overall, the demographics appeared similar for both cohorts, suggesting that demographics had little effect on breastfeeding exclusivity or duration.

Exclusivity

Exclusive breastfeeding at six weeks postpartum was improved by 33.3% from 41.7% at baseline to 75.0% following the project's interventions (Chart R2, Table R3). When evaluated for statistical significance by IBM's SPSS software, the Wald HO independent- samples proportions z-test produced a one-sided p value of 0.003. This showed statistical significance for the increased number of participants exclusively breastfeeding at six weeks postpartum.

While the CDC's earliest reports on breastfeeding exclusivity are at three months postpartum, the participants of this study, at six weeks postpartum, were exceeding the national and state of Kansas rates at three months by 23.4% and 28.1% respectively (Chart R4).

Duration

Duration of breastfeeding was defined as any breastfeeding (exclusive or partial). There was an increase in duration of breastfeeding for the intervention cohort when compared to the

baseline cohort with an increase of 11.7% from 79.2% to 90.9% (Table R3). The Wald HO independent- samples proportions z-test produced a one-sided p value of 0.134. This does not support a statistical significance for increased duration of breastfeeding however increasing breastfeeding by over 11% to almost 91% of participants is clinically significant.

Support Calls Content

While the content of the calls was not a measured outcome, there is value in knowing what topics the participants frequently talked about. The topics participants most frequently voiced concerns about included pumping, sore nipples, newborn sleep schedules, milk supply, and engorgement. Other topics discussed during the support calls included maternal exhaustion, difficulty with latch, cluster feeding, introduction of a bottle or pacifier, returning to work, and building a frozen breastmilk supply. These topics align with the topics discovered in the project's literature review.

Discussion

Successes

The outcomes for this project were met. A statistically significant increase in exclusive breastfeeding (p= .003) for the intervention cohort in comparison to the baseline cohort suggests the project's interventions were successful in improving breastfeeding retention with education and support. While the total duration of breastfeeding from baseline to intervention was not statistically significant, clinically an increase in total duration of breastfeeding at six weeks from 79.2% to 90.9% provides support for continuing the interventions. This increase suggests that breastfeeding support and education can decrease the number of dyads with total breastfeeding cessation.

Participants expressed gratitude for the education and the individualized support provided during the interventions. They found the calls encouraging and appreciated having scheduled calls, stating that knowing the project leader would be calling to check-in gave them something to look forward to.

Strengths

An important strength of this project was the support given by the project site's physician and nursing staff. Without staff buy-in, the implementation of the educational session in the clinic could have been less successful. As participants began expressing their gratitude for the project's interventions to the physician and his staff, buy-in continued to grow.

Another strength of the project was the low-cost of implementation. The PDF of the booklet provided to participants was obtained at no cost from the University of North Carolina. Printing these booklets was the only cost of implementation. The ease of implementation also supported the success of the interventions. Adding an additional 15 minutes of breastfeeding education to one prenatal visit caused little change to the flow of the clinic's schedule and did not require the participants to makes extra trips to the clinic.

Scheduled postpartum phones calls were another strength for this project. The day five postpartum support call was scheduled purposefully to make contact with the participants around the time they were settling in at home following discharge from the hospital. During their hospital stay they had continuous lactational support but following discharge, which is typically day two or three postpartum, they arrive home to find that their lactational support may be lacking. Weekly calls during the first four weeks served the purpose of collecting breastfeeding outcome data but also provided weekly support to these first time breastfeeders during some of the most trying weeks of the breastfeeding journey. Participants appreciated knowing that the

project leader would be calling to check-in each week, commenting that it removed the stress of attempting to reach out for help.

The support calls were placed with the convenience of the participants in mind, allowing them to pick what time of day would best work with their schedules. Using the project leader's personal phone allowed for the calls to be made from wherever the project leader was at the time, decreasing the burden and time consumed making them. Data from the support calls was input into the project's Google Sheets document. This document was a strength of the project because it kept track of all the participants' demographics, due dates, birth dates, call schedule, and data from all support calls. Without the call schedule, the project leader may have had trouble keeping up with the approximately 120 calls.

Finally, the project was strengthened by a low attrition rate. Of the 24 participants who enrolled in the project, all 24 participated in the prenatal breastfeeding education session and only two did not interact with the project leader during the postpartum support period.

Comparison to Published Literature

The results from the project were compared to evidence from the project's literature review. Huang et al. (2019) found that after providing prenatal breastfeeding education and postnatal support, 74.5% of their invention group was breastfeeding exclusively at six weeks postpartum. This finding is similar to the percentage of participants reporting exclusive breastfeeding at six weeks in this project.

Fu et al. (2014) found that the telephone support group had statistically significant improvement in breastfeeding duration compared to standard care with approximately 58% of the intervention group versus 48% of the standard care group breastfeeding at two months postpartum. Jerin et al.'s (2019) intervention of postnatal telephone support had statistically

significant improvement of breastfeeding exclusivity at two months. These two studies suggest that postpartum support is effective for improving breastfeeding outcomes which was congruent with this project's results.

Limitations

Internal Validity

While the inclusion criteria of intention to breastfeed was necessary due to the limited time of the project, it may have affected the internal validity of the results. Confounding factors may have also affected the validity of the project. A major factor that could affect breastfeeding retention is inaccurate breastfeeding information obtained from family, friends, the internet, and social media. During support calls, some participants did mention when they had heard conflicting advice or had less support than they expected from their significant other/family/friends. Another factor to consider is the implementation of the interventions being over Thanksgiving and Christmas, which may have increased stress on the breastfeeding dyad. Internal validity may have also been affected by participants self-reporting their breastfeeding exclusivity.

External Validity

External validity was affected by a small sample size and low ethnic variation but could be improved by greater variation in the project's participant demographics. The participants were nearly all Caucasian woman and none of the participants were African American or Asian. The age range of the participants was 22 to 32, which may help to improve external validity. The project site was a large, urban OBGYN clinic with a wide variety of patient demographics. With a longer timeframe, it is possible that enrollment would have included a larger variation of participants.

Minimize Limitations

Consecutive sampling was used to increase the number of potential participants. While the project only had 24 participants, this reflected 100% enrollment of the potential participants available during the project's timeframe. A longer timeframe may have increased the intervention sample size and ethnic variation.

The project leader preplanned the contents of the prenatal education session to reduce the variation in information provided to the participants. All participants gave birth at the same Baby-Friendly hospital and had access to the same hospital-affiliated breastfeeding clinic. In an effort to decrease limitations related to self-reported data, participants were all asked if they had used any formula in the past week during each support call. The question was posed in a direct and similar way to decrease confusion and increase accuracy of reporting.

Sustainability and Maintenance

Sustainability of these interventions depends on several factors. The low cost of implementation supports sustainability. The booklet used in this project could be substituted for literature the clinic currently provides to increase sustainability. Finding knowledgeable staff who have time available to provide the interventions may decrease sustainability. Once there is plan in place for continuing the interventions, the only maintenance that may be required would be when revisions are needed.

The satisfaction experienced by the participants and the success perceived by the supporting physician has led to a search for a lactation consultant to continue providing the interventions at the project site after implementation by the project leader has commenced. The supporting physician felt that the importance of supporting breastfeeding for his patients was far

greater than the barriers that may be encountered as he works through the onboarding process of hiring a lactation consultant.

Interpretation

Expected and Actual Outcomes

The expected outcome for this project was an improvement in the retention of breastfeeding measured by breastfeeding exclusivity at six weeks postpartum. The project leader anticipated the interventions provided would lead to improved breastfeeding exclusivity and duration at six weeks postpartum. The actual increase in percentage for exclusive breastfeeding at six weeks postpartum, 33.3%, was more than the project leader expected. Duration of any breastfeeding was also increased at six weeks postpartum by 11.7%. This was also more than originally anticipated.

The increase in exclusive breastfeeding was notable for statistical significance and both outcomes were clinically significant. When compared to three-month breastfeeding data reported by the CDC, the intervention cohort at six weeks postpartum exceeded the rates of exclusive breastfeeding for both national and state records. The lack of statistical significance for the improvement of the duration of breastfeeding may have been caused by the small sample size and short timeframe of the project.

Intervention Effectiveness

Both the statistical analysis and the clinical analysis of the interventions suggest that the prenatal education and postpartum support calls were effective in improving the rates of exclusive and any breastfeeding for first-time breastfeeders. The project was also effective in decreasing the number of dyads that had total breastfeeding cessation before six weeks postpartum. The effectiveness of these interventions will likely be heightened in settings where

breastfeeding is already supported and encouraged. While these interventions were implemented in a hospital-affiliated OBGYN clinic, they could be effectively implemented in any women's health clinic that is caring for pregnant and postpartum patients.

Revisions

There are some improvements that could be made to this project. Increasing the postpartum support period to either three or six months would align the postnatal intervention more closely with the recommendation to continue exclusive breastfeeding to six months. Providing a second prenatal breastfeeding session explaining the benefits of breastfeeding earlier in pregnancy may help increase number of patients opting to initiate breastfeeding. The project's participants recommended including information about engorgement and clogged milk ducts in the prenatal education session, as this was something they had concerns about within the first few weeks of breastfeeding but had received little information about.

Expected and Actual Impact to Healthcare and Cost

The interventions of this study were expected to provide breastfeeding support from the clinic setting to first-time breastfeeders to improve their breastfeeding retention. The study found, as literature suggests, that providing prenatal breastfeeding education and postpartum support to first-time breastfeeders can help to improve rates of exclusive breastfeeding and breastfeeding duration.

The actual cost of the project was more than the expected cost. This is due in part to the project team leader having little experience in printing large numbers of booklets. Overall, the actual cost of the project, $239.56 for 50 booklets, was low. This cost could be reduced by a clinic that contracts with a printing company or in a clinic that already has suitable breastfeeding education materials available. While not calculated in the project's budget, the cost of the time

donated by the project team leader would need to be considered when determining feasibility of implementation (Appendix B).

Conclusion

Breastfeeding retention is a significant public health issue that could be addressed in the clinic setting. Great strides have been made in achieving a high percentage of initiation of breastfeeding at birth, but more focus is required to help support breastfeeders, especially those attempting for the first time, as they continue their breastfeeding journeys. High rates of non-exclusive breastfeeding and cessation are often due to barriers encountered during the early postpartum period including the perception of low milk supply, difficulty with technique, low breastfeeding self-efficacy, nipple pain, fatigue, and return to work (ACOG, 2021b; Brown, 2016; Cortés-Rúa & Díaz-Grávalos, 2019; Daou et al., 2020). These barriers could be addressed and even avoided with proper breastfeeding education and support from healthcare providers, starting in pregnancy and extending into the postpartum period (McFadden et al., 2019; Skouteris et al., 2017; M. S. Wong et al., 2021; Wood et al., 2016).

Implementation of this project, a face-to-face prenatal breastfeeding education session coupled with several postpartum support interactions, suggests the potential of these interventions to increase breastfeeding outcomes and improve public health. Future endeavors could include extending the postpartum support time frame or increasing the number of prenatal breastfeeding education sessions to further improve breastfeeding retention.

Dissemination of the project included a poster presentation at the Midwest Nursing Research Society's conference in April of 2022 and submission for publication in Women's Healthcare: A Clinical Journal for NPs, the official journal of the National Association of Nursing Practitioners in Women's Health (Appendix S). Following graduation, the project will

be submitted for presentation at the Nurse Practitioners in Women's Health national conference held in the fall of 2022.

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Appendix A

Definitions of Project Terms

Exclusive breastfeeding- infants receiving only breastmilk at the breast, expressed milk, or from a wet-nurse without supplementation of any other source with an exception for vitamins and medications (World Health Organization, 2008)

Primigravid/ primiparous- first-time mother (World Health Organization, 2018)

Breastfeeding self-efficacy- confidence a mother has in her ability to breastfeed her baby (Dennis, 1999)

Postpartum period- first 12-weeks following birth (Paladine et al., 2019)

Appendix B

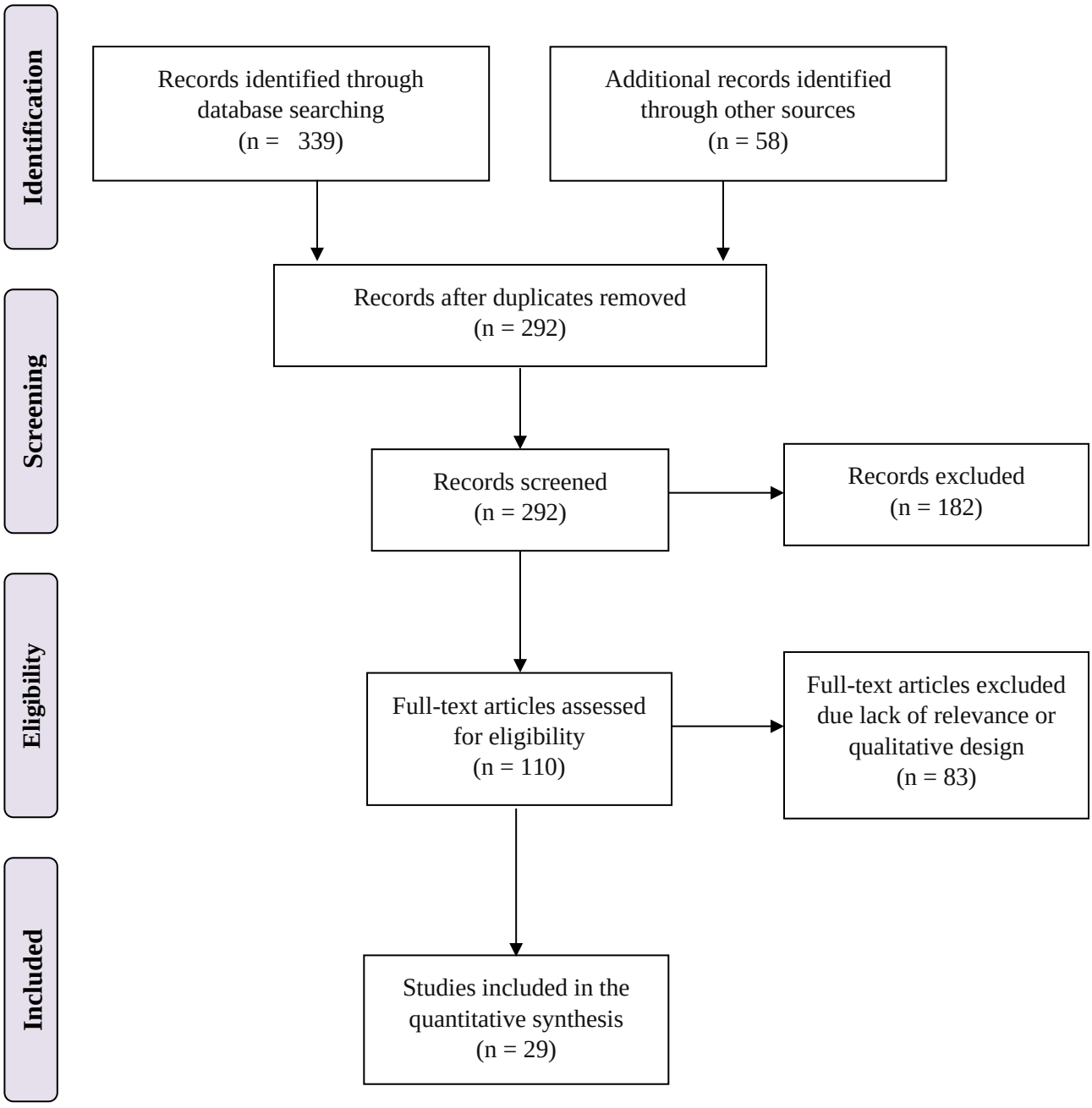
Project Cost Table

Item	Description	Quantity	Unit Cost	Anticipated Cost	Revenue
Printed Booklet	Breastfeeding education booklet	50 booklets	$4.79/book	$239.56	
Student Time	Hours used for education in office and follow-up interactions	Est. 60hrs	$48/hr	$2,880	
Postpartum Call	Telehealth Call	5 calls per patient			$20-$200 per call *

*Depending on insurance billing, coding, and reimbursement

Appendix C

Adaptation of PRISMA Flow Diagram



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Appendix D

Melnyk Rating System for Level of Evidence

Rating System for the Hierarchy of Evidence For an Interventional Inquiry (*Additions* by Dr. Lindholm for course N5555 and N5613)*	
Evidence Level	**Study Designs**
Level I	• Systematic review or meta-analysis of all relevant RCTs. • *Evidence-based clinical practice guidelines based on systematic reviews of RCTs and other quantitative designs*.*
Level II	• Well-designed RCT. • *Quantitative systematic review of well-designed controlled trial without randomization.*
Level III	• Well-designed controlled trial without randomization *(quasi-experimental).* • *Quantitative systematic review of case-control, cohort, or correlational studies.*
Level IV	• Well-designed case-control or cohort study *or cross-sectional study.*
Level V	• Systematic review of *quantitative* descriptive *(no relationships to examine)* or systematic review of qualitative studies.
Level VI	• Single *quantitative* descriptive *(no relationships to examine in the study) or* single qualitative study
Level VII	• Opinion of authorities and/or reports of expert committees, *clinical practice guidelines based mostly on expert opinion, integrative reviews, review of literature*

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Appendix E

Synthesis of Evidence Table

First author, Year, Title, Journal	Purpose	Research Design[1], Evidence Level[2] & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
THEME: Timing of Interventions						
Ahlers-Schmidt et al. (2020) Impact of Prenatal Education on Breastfeeding Initiation Among Low-Income Women **American Journal of Health Promotion**	Determine if participants receiving prenatal education-initiated breastfeeding at a higher rate.	Retrospective, descriptive cohort study. Level 6 evidence. -Prenatal education program. -Breastfeeding at hospital discharge.	1489 mothers with a singleton pregnancy. Consecutive sampling. Sedgwick County, Kansas.	Report of breastfeeding at discharge per the birth certificate report.	Intervention participants were significantly more likely to initiate breastfeeding than controls. 93.65% vs. 87.48% $X^2(1)=9.077$, p= 0.003	One county, relied on birth certificate accuracy. Intervention shows potential to increase breastfeeding initiation, especially in vulnerable populations.
Ballesta-Castillejos et al. (2020) Factors that influence mothers' prenatal decision to breastfeed in Spain **International Breastfeeding Journal**	Identified reasons that influence mothers' decision to breastfeed.	Cross sectional, observational study. Level 4 evidence. -Prenatal intention. -External influences. -Main reason for breastfeeding.	5671 women who had given birth 2013-2018. Convenience sample. Breastfeeding associations in Spain.	Questionnaire with 5 yes/no, 16 Likert scale, and 1 open response questions. Reliability not reported.	Maternal education that included breastfeeding training increased likelihood to breastfeed. aOR 2.10, CI 1.32 -3.34	Voluntary participation bias and sampling from breastfeeding associations. Breastfeeding education has a positive effect on intention to breastfeed.
Huang et al. (2019) Individualized intervention to improve rates of exclusive breastfeeding **Medicine**	Effectiveness of individualized intervention compared with routine care in improving exclusive breastfeeding.	Randomized controlled trial. Level 2 evidence. -Individualized prenatal breastfeeding education and postnatal lactation support.	293 women. Blinded, simple random sampling. Obstetrics office and Baby-Friendly hospital	Breastfeeding attrition prediction scale, breastfeeding knowledge scale, breast-feeding assessment scale, and self-reported	Exclusive breastfeeding rate at 4 months was increased for the intervention group. RR 1.78, CI 1.12-2.82 Increased likelihood to breastfeed on demand with intervention. RR 9.00, CI 4.09-19.74	Only followed to 4 months, did not evaluate different forms of support. Prenatal and postnatal education/support can be effective in improving exclusive breastfeeding rates. Face-to-face interventions more likely to detect maternal problems. Phone calls can

		-Duration of exclusive breastfeeding.		breastfeeding data. Reliability not reported.		reduce economic cost of breastfeeding support.
McFadden et al. (2019) Counselling interventions to enable women to initiate and continue breastfeeding: a systematic review and meta-analysis **International Breastfeeding Journal**	Examine effectiveness of different breastfeeding counseling interventions.	Systematic Review/ Meta-analysis. Level 1 evidence. -Breastfeeding counseling -Breastfeeding practices from birth to 24 months	63 trails, total of 33,037 women Randomized, cluster-randomized, and quasi-randomized controlled trials.	GRADE approach used to assess quality of evidence. Reliability not reported.	Counseling reduced risk for breastfeeding cessation from 4 to 6 weeks postnatal RR 0.85, CI 0.77-0.94. Interventions of both prenatal and postnatal reduced risk of stopping exclusive breastfeeding RR 0.71, CI 0.55-0.93	Intervention heterogeneity, trials included were mostly from high-income countries, no trials included caesarean birth. Overall findings suggest prenatal face to face counseling and prenatal/postnatal telephone support.
Kim et al. (2018) Interventions promoting exclusive breastfeeding up to six months after birth: A systematic review and meta-analysis of randomized controlled trials. **International Journal of Nursing Studies**	Review how effectively interventions can help sustain exclusive breastfeeding to 6 months.	Systematic Review/ Meta-analysis Level 1 evidence. -Intervention type -Intervention time -Intervention provider type -Intervention setting -Breastfeeding exclusivity and duration	27 randomized controlled trials, total of 36,051 women Randomized, cluster-randomized, and quasi-randomized controlled trials.	Meta-analysis with Comprehensive Meta-analysis version 3.0. Cochrane Collaboration's Risk for Bias tool used to determine each study's risk of bias.	Breastfeeding interventions have positive effect on 6-month exclusivity. OR 2.77, CI 1.81-3.76 Most effective interventions started at birth and extended into postpartum. OR 3.32, CI 1.83-6.03	Exclusion of several RCTs due to data collection stopping before 6 months or poor definition of breastfeeding exclusivity, cultural influences, intervention heterogeneity. Recommends use of prenatal/postnatal intervention combination with well-defined protocols.
World Health Organization (2018) Guideline: counselling of women to improve breastfeeding practices **WHO Library**	Guide global, evidence-informed recommendations on breastfeeding counseling, as a public health intervention, to improve breastfeeding practices.	Evidence-based practice guideline. Level 1 evidence. -Breastfeeding initiation -Breastfeeding exclusivity and duration -Supplementation	48 randomized controlled trials, 15 cluster randomized trials, 36 qualitative studies. Included 26 countries.	Developed per the WHO handbook for guideline development and the DECIDE framework.	Breastfeeding interventions prenatally and postnatally reduce likelihood of not breastfeeding at 4-6 weeks RR 0.91, CI 0.76-1.05 and at 6 months RR 0.79, CI 0.67-0.93	Intervention heterogeneity, lack of support for pregnancy/delivery complications, returning to work, with trauma, stress, or inadequate food resources. Counseling should be in the prenatal/postnatal periods, face-to-face with telephone support, and the first weeks

		-Artificial nipples and bottle use				postpartum are critical for breastfeeding establishment.
Meedya et al. (2017) Effect of educational and support interventions on long-term breastfeeding rates in primiparous women: a systematic review and meta-analysis **Joanna Briggs Institute Database of Systematic Reviews**	Review effect of professional breastfeeding education and support interventions on duration and exclusivity of breastfeeding.	Systematic Review/ Meta-analysis. Level 1 evidence. -Professional breastfeeding education interventions. -Breastfeeding support interventions. -Breastfeeding rates at 6 months and up to 2 years postpartum.	10 studies on primiparous mothers who intended to breastfeed. Randomized controlled trials.	Standardized critical appraisal instrument created by Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument Adequate quality threshold= mean quality score minus one standard deviation 14, (12-18)	Interventions with both prenatal education/support and postnatal education support increased breastfeeding at 6 months postpartum. OR= 0.91. CI 0.64-1.30 p=0.28 Prenatal only and postnatal only interventions showed little difference in breastfeeding duration.	Only included articles in English, small number of included studies, variance in outcome measures in each study. Overall findings support prenatal/postnatal combination for breastfeeding education and support.
Schreck et al. (2017) Both Prenatal and Postnatal Interventions Are Needed to Improve Breastfeeding Outcomes in a Low-Income Population **Breastfeeding Medicine**	Determine the effect of a hospital-based prenatal intervention combined with postnatal interventions on breastfeeding outcomes.	Quasi-experimental study, pre/post intervention groups. Level 3 evidence. -Prenatal breastfeeding education. -Hospital-based breastfeeding support. -Breastfeeding initiation. -Breastfeeding continuation.	650 women from prenatal clinic/local hospital. Randomized pre/post intervention selection. Detroit, Michigan.	IRB-approved telephone survey including infant feeding methods, breastfeeding continuation, influences, experiences, goals, barriers, and how helpful they found the intervention. Reliability not reported.	Increased breastfeeding initiation for postintervention group p<0.0001. Participation in both prenatal education and postnatal breastfeeding support group increased breastfeeding duration, 59% breastfed to at least 6 months vs 28% with prenatal only.	Interested in breastfeeding prenatally could influence participation, reliance on self-report, population difficult to contact via telephone. The prenatal education aided in increasing initiation and was deemed helpful, but the postnatal support was necessary to affect duration.
Skouteris et al. (2017)	Review interventions	Systematic Review.	12 studies with follow-up of at	Cochrane Collaboration's	Combination of education and support	Intervention heterogeneity, cultural influences, no

Interventions Degined to Promote Exclusive Breastfeeding in High-income Countries: A Systematic Review Update **Breastfeeding Medicine**	designed to promote exclusive breastfeeding up to 6 months.	Level 1 Evidence. -Intervention components. -Effect on breastfeeding exclusivity and duration.	least 4 months postpartum. Randomized controlled trials. United States, China, Australia.	Risk for Bias tool used to determine each study's risk of bias. GRADE approach used to assess quality of evidence.	was significantly successful. Four studies with successful outcomes included long-term postpartum support.	statistical comparison of the studies. Supports the use of a prenatal/postpartum intervention with a strong focus on long-term postpartum support.
K. L. Wong et al. (2014) Antenatal Education to Increase Exclusive Breastfeeding- A Randomized Controlled Trial **Obstetrics and Gynecology**	Assess the success of a healthcare provider one-to-one breastfeeding intervention on breastfeeding exclusivity and duration.	Randomized Controlled Trial. Level 2 Evidence. -Exclusive breastfeeding -Duration, any breastfeeding	469 primiparous mothers of Hong Kong. Block random sampling. Hong Kong, China.	Self-administered questionnaire. Reliability not reported.	No significant change in control and intervention group for exclusivity p=0.77, CI -0.08- 0.11 or any breastfeeding at 6 weeks. p=0.49, CI -0.13- 0.06	High breastfeeding initiation rates in setting, self-recall bias, did not measure postnatal support. This study shows that prenatal education alone cannot sustain breastfeeding 6 weeks.
Kronborg et al. (2012) Antenatal training to improve breast feeding: a randomised trial **Midwifery**	Effect of a prenatal training program on knowledge, self-efficacy and problems related to breastfeeding and on breastfeeding duration.	Randomized controlled trial. Level 2 evidence. -Prenatal education program at 30-35 gestational weeks. -Duration, exclusive, any breastfeeding. -Breastfeeding knowledge. -Breastfeeding self-efficacy scores. -Problems encountered.	1193 primigravid women from prenatal clinic. Blinded, simple random sampling. Prenatal clinic.	Yes/No questions for breastfeeding duration and problems. Breastfeeding knowledge, coping, management-Likert scale. Self-efficacy with validated BSES-SF scale. Reliability not reported.	Breastfeeding confidence increased with intervention at 36 weeks gestation. p= 0.05 Increased breastfeeding knowledge with intervention at 6 weeks postpartum. p= 0.02 No differences in self-efficacy, reported problems, or duration at 6-weeks postpartum.	Homogeneous participant population, method of questioning breastfeeding problem. Higher expressed knowledge and self-efficacy in the intervention group correlated with longer breastfeeding duration. May need postnatal intervention to help support confidence, self-efficacy, and duration.
THEME: Method of Interventions						
Wong et al. (2021) Effectiveness of educational and	To examine the effects of different approaches to	Systematic Review, meta-analysis.	13 articles on primiparous women, who	Meta-analysis performed by	Education and support interventions had a significant effect on	Generalizability decreased due to narrow scope for studies populations, studies

supportive intervention for primiparous women on breastfeeding related outcomes and breastfeeding self-efficacy: A systematic review and meta-analysis **International Journal of Nursing Studies**	educational and supportive interventions that can help sustain breastfeeding and improve breastfeeding self-efficacy for primiparous postnatal women.	Level 1 evidence. -Exclusive and partial breastfeeding rates. -Breastfeeding self-efficacy. -Breastfeeding knowledge. -Maternal satisfaction. -Cost of intervention.	delivered vaginally at term. Randomized controlled trials.	Review Manager 5.3. Heterogeneity measured by I^2 statistic; outcome data assessed with odds ratio, confidence interval, and standard mean difference.	exclusivity. OR 1.68, CI 1.2-2.34, p= 0.002 Self-efficacy theory implementation had a significant effect on exclusivity. OR 2.5, CI 1.55-4.03, p= 0.0002 Prenatal/postnatal components were 3x more likely to increase exclusivity. OR 3.06, CI 1.22-7.66, p= 0.02	had high heterogeneity, insufficient data follow up for self-efficacy. This review supports all points of the inquiry including time frame, intervention style, breastfeeding education component, and self-efficacy.
Jerin et al. (2020) Mobile phone support to sustain exclusive breastfeeding in the community after hospital delivery and counseling: a quasi-experimental study **International Breastfeeding Journal**	Determine if breastfeeding support, following a hospital delivery and by mobile phone after discharge can be effective in improving exclusive breastfeeding.	Quasi-experimental study. Level 3 evidence. -Exclusive breastfeeding rate.	241 women who intended to breastfeed, delivered at Centre for Women and Child Health, and owned a mobile phone. No randomization. Pre-intervention: April-September. Intervention: July to December. Dhaka, Bangladesh.	Medical records and telephone questionnaire. Reliability not reported.	Intervention infants were exclusively breastfed at a higher rate than pre-intervention 78% vs 58% p=0.000 Intervention exclusive rate 1-mon=89%, 5-mon=71% Pre-intervention rate 1-mon=85%, 5-mon=42%	Seasonal effects of breastfeeding in area, no randomization, self-recall bias. Mother with mobile phone support breastfed their infants exclusively for longer periods. Phone calls were made every 15 days.
Chaves et al. (2019) Telephone intervention in the promotion of self-efficacy, duration and exclusivity of breastfeeding: randomized controlled trial	Evaluate effectiveness of telephone intervention to increase breastfeeding self-efficacy, duration, and exclusivity.	Randomized controlled trial. Level 2 evidence. -Breastfeeding self-efficacy.	132 postpartum mothers, breastfeeding, one-term infant. Blinded, simple random sampling.	Breastfeeding Self-Efficacy Scale- Short Form (BSES-SF) Cronbach's alpha 0.74.	Long term self-efficacy was increased (4 months). p= 0.01 Did not statistically impact exclusivity (2-mon & 4-mon).	High sample loss rate, decreased generalizability. Shows that telephone support can help but is not enough to impact breastfeeding retention.

Revista Latino Americana de Enfermagem		-Exclusivity and duration.	Fortaleza, Ceara, Brazil.		p= 0.98 & 0.573	
Forster et al. (2019) Proactive Peer (Mother-to-Mother) Breastfeeding Support by Telephone (Ringing up About Breastfeeding Early [RUBY]): A Multicentre, Unblinded, Randomised Controlled Trial **EClinicalMedicine**	Evaluate a proactive, postnatal telephone-based intervention for breastfeeding outcomes at 6 months.	Randomized controlled trial. Level 2 evidence. -Breastfeeding rate. -Time of breastfeeding cessation.	1157 primiparous women intending to breastfeed. Non-blinded, simple random sampling. Victoria, Australia.	Medical records and self-administered questionnaire. Reliability not reported.	Intervention group had lower rates of cessation and higher rates of breastfeeding at six-months. HR 0.77 CI 0.61-0.97 and RR 1.10 CI 1.02-1.18.	Breastfeeding motivation bias, self-recall bias. Telephone support given postpartum improved breastfeeding rates; peer support offers low-cost intervention.
McFadden et al., (2017) Support for healthy breastfeeding mothers with healthy term babies **Cochrane Database of Systematic Reviews**	Examines forms of interventions that provide extra support to breastfeeding mothers and to assess the impact on breastfeeding duration, exclusivity, health outcomes, and maternal satisfaction.	Systematic Review/ Meta-analysis. Level 1 evidence. -Types of breastfeeding interventions. -Breastfeeding exclusivity and duration. -Related health outcomes. -Maternal satisfaction.	100 studies, healthy pregnant mothers intending to breastfeeding or already breastfeeding. Randomized and quasi-randomized controlled trials.	GRADE approach used to assess quality of evidence. Considers study limitations, consistency of effect, imprecision, indirectness, and publication bias.	Those receiving support were significantly less likely to quit breastfeeding. RR 0.91, CI 0.88-0.95 Intervention increased breastfeeding likelihood at six weeks. RR 0.87, CI 0.80-0.95 Face to face appears to have most positive effect on breastfeeding duration. $Chi^2 = 10.63$ df=2 (P=0.005), I^2= 81.2%	Heterogeneity of articles, bias of studies due to lack of blinding. Review suggests that breastfeeding support and face to face interventions help to improve duration and exclusivity.
Fu et al. (2014) Professional breastfeeding support for first-time mothers: a multicenter cluster randomised controlled trial	Assess the differences between two postpartum support interventions on breastfeeding outcomes.	Randomized controlled trial. Level 2 evidence. -Breastfeeding rates, any/exclusive. -Duration of breastfeeding.	724 primiparous women who intended to breastfeed without serious complications.	Written and telephone questionnaires. Reliability not reported.	Telephone support increased likelihood of exclusive breastfeeding at 3-months and lower overall risk for cessation. OR 1.89 CI 1.24-2.90 and HR 0.79 CI 0.64-0.98	Unequal participants in each group, 24hr breastfeeding recall bias, self-report bias, inability to blind participants. Postpartum support increases maternal confidence and increases breastfeeding rates. Telephone support is easier to

Royal College of Obstetricians and Gynecologists		-Breastfeeding cessation.	Clustered random sampling. Hong Kong, China.		Telephone support increased breastfeeding rates compared to in-hospital intervention but without statistical significance.	manage and financially responsible.
THEME: Breastfeeding Duration and Exclusivity						
US Preventive Services Task Force et al. (2016) Primary Care Interventions to Support Breastfeeding: US Preventive Services Task Force Recommendation Statement **JAMA**	Updated recommendations on primary care interventions to promote breastfeeding.	Evidence-based practice guideline. Level 1 evidence.			Systematic review to update recommendations from 2008. Focused on effectiveness of interventions promoting and support breastfeeding initiation, duration, and exclusivity.	Grade B recommendation. Breastfeeding education and support interventions improve likelihood of breastfeeding at less than 3 months and 3 to 6 months.
Nnebe-Agumadu et al. (2016) Associations between perceived value of exclusive breastfeeding among pregnant women in the United States and exclusive breastfeeding to three and six months postpartum: a prospective study **International Breastfeeding Journal**	To what degree does the mother's value of exclusive breastfeeding effect exclusivity and duration of breastfeeding.	Prospective, descriptive cohort study. Level 6 evidence. -Value of exclusive breastfeeding. -Duration of exclusive breastfeeding.	1799 women with prenatal intention to breastfeed. Consecutive sampling from United States Infant Feeding Practices Study II. United States.	Questionnaires from month seven of pregnancy through one year postpartum. Maternal attitude towards breastfeeding measured with survey Likert style question. Reliability not reported.	Exclusive breastfeeding- 3 months= 34% 6 months= 9% Those who significantly valued exclusive breastfeeding were more likely to do so. OR 2.22, CI 1.82-2.72	Survey may not represent whole of population well, lack of heterogeneity, more intention to breastfeeding than national average, self-report survey prone to bias. Breastfeeding education can influence mother's value of breastfeeding leading to improved duration and exclusivity.
THEME: Breastfeeding Education Contents						
ACOG (2021) Barriers to Breastfeeding:	Identify and address barriers to breastfeeding.	Committee Report with supportive research.			Substantial amount of research and support	Provides several case scenarios for providers to

Supporting Initiation and Continuation of Breastfeeding- Committee Opinion No. 821 **Obstetrics & Gynecology**		Level 7 evidence.			articles used to create this report. Committee on Health Care for Underserved Women & Breastfeeding Expert Work Group	relate to their own patient care.
ACOG (2021) Breastfeeding Challenges- Committee Opinion No. 820 **Obstetrics & Gynecology**	Identifies common challenges faced by people who breastfeed.	Committee Report with supportive research. Level 7 evidence.			Substantial amount of research and support articles used to create this report. Committee on Obstetric Practice & Breastfeeding Expert Work Group	Each challenge is examined and a case study is provided.
Daou et al. (2020) Assessing the impact of professional lactation support frequency, duration, and delivery form on exclusive breastfeeding in Lebanese mothers **PLoS ONE**	Investigates association between exclusive breastfeeding and the timing, type, duration of professional support.	Retrospective case-control study of previous RCT. Level 4 evidence. -Exclusive breastfeeding at 6 months. -Breastfeeding barriers/facilitators.	174 pregnant women, 1st-2nd trimester, interested in breastfeeding. Simple randomized sampling. Lebanon.	Questionnaire, Breastfeeding Knowledge Questionnaire (BFK-A), Iowa Infant Feeding Attitude Scale (IIFAS-A). Reliability not reported.	Face-to-face with telephone support increased odds for exclusive breastfeeding at 6 months. OR 1.15, CI 1.04-1.27 More contact with professional support was associated with exclusive breastfeeding at 6 months. Early cessation was associated with thoughts of low milk supply, more breastfeeding difficulties, and latching techniques.	Cannot state causal relationship due to study design, bias of breastfeeding intention, demographic bias. Early cessation is associated with poor technique, perception of low milk supply, pain, and fatigue. Study supports use of face-to-face and telephone support.
Tan et al. (2020) Postpartum women's perception of antenatal breastfeeding education: a descriptive survey	Determine perception of antenatal breastfeeding education experience during	Single descriptive, observational study. Level 6 evidence.	282 up to 8 weeks postpartum women at MOH clinics.	Questionnaire developed by the investigators and revised following small pilot.	Useful topics included infant positioning for breastfeeding and correct latch technique/ recognition.	Closed ended questionnaire, reliance on self-report, sample size, interest in breastfeeding prenatally could influence participation.

International Breastfeeding Journal	the early postpartum period.	-Prenatal breastfeeding education. -Postpartum perception of usefulness. -What else should be included in education. -Infant feeding practices.	Volunteer sampling. Penang State, Malaysia.	Reliability not reported.	Topics requested included milk expression techniques, milk storage, and tips for low milk supply. Attendees of antenatal sessions had higher rates of breastfeeding duration. aOR 8.1 CI 1.7-38.3 Most frequently sited reasons for stopping exclusive breastfeeding were insufficient milk and returning to work.	Provides insight into what information to include during prenatal education.
Gianni et al. (2019) Breastfeeding difficulties and risk for early breastfeeding cessation **Nutrients**	Evaluated breastfeeding mothers during first few postpartum months and associated early breastfeeding cessation.	Prospective observational study. Level 6 evidence. -Feeding method at 3-months. -Breastfeeding difficulties. -Post-hospital support.	792 breastfeeding mothers of term singleton infants. Convenience sampling. Milan, Italy.	Online and telephone questionnaires. Reliability not reported.	95% exclusive breastfed at initiation,73% at 1-month, 68% at 3-months. 70.3% reported difficulties including cracked nipples, perception of low milk supply, pain, fatigue. Lack of postpartum support increased risk for non-exclusive breastfeeding OR 1.367 CI 1.09-1.70 p=0.005 Perception of low milk supply increased risk for non-exclusive breastfeeding OR 9.23 CI 5.961-14.301 p<0.0001	High dropout, self-recall bias, single region limits generalizability. Shows possible connection between lack of postpartum support and lack of breastfeeding education leading to non-exclusive breastfeeding before 6-months.
Parry et al. (2019) Evaluation of Ready, Set, BABY: A prenatal	Determine if curriculum would be acceptable to	Quasi-experimental study, pre/post questionnaire.	416 pregnant women.	Pre/post-questionnaire included Infant	Education was found to useful (98.3%), informative (98.9%),	Small sample size, lack of heterogeneity, social desirability bias with

breastfeeding education and counseling approach **Birth**	mothers, if strength of intention would increase, and if idea of formula feeding would decrease.	Level 3 evidence. -RSB curriculum. -Acceptability of the education. -Intention to breastfeed. -Comfort with formula feeding.	Convenience sampling. North Carolina, Louisiana, Puerto Rico.	Feeding Intentions (IFI) scale. Study states tool was validated. Reliability not reported.	plan to refer back to the booklet (98.6%). IFI scores improved with significance after the education $p<0.001$ Improved early feeding cue recognition $p<0.001$	anonymous answering of questionnaires. Supports the use of the RSB education booklet during prenatal breastfeeding education.
Cortés-Rúa & Díaz-Grávalos (2019) **Early interruption of breastfeeding. A qualitative study** **Enfermeria Clinica**	Explore personal experience and feelings of primiparous women who did not meet their breastfeeding goal.	Qualitative study. Level 6 evidence. -Experience of breastfeeding. -Causes of early cessation. -Feelings about early cessation. -Opinion of healthcare professional role.	15 primiparous women with early breastfeeding cessation. Convenience sampling. Health Centres of Orense, Spain.	Semi-structured interview. Reliability not reported.	Breastfeeding was more challenging than expected. Reported will not breastfeeding with future infants, insecurity about milk supply frequent guests reduced time for uninterrupted breastfeeding. Support from healthcare professionals was inadequate.	Sampling bias, reduced generalizability. First-time mothers feel they do not have adequate support or education to breastfeed to their goal. Education should include milk supply and how challenging breastfeeding can be.
Demirci and Bogen (2017) **An ecological momentary assessment of primiparous women's breastfeeding behavior and problems from birth to eight weeks** **Journal of Human Lactation**	Explore early breastfeeding behaviors and problems of primiparous mothers.	Observational, prospective study. Level 6 evidence. -Breastfeeding duration/exclusivity. -Perceived problems.	61 primiparous mothers, intention to breastfeeding ≥2 months, owned smartphone. Convenience sampling. Northeast United States.	Iowa Infant Feeding Attitude Scale (IIFAS), PROMIS Emotional Distress-Anxiety Scale Short Form, Perceived Stress Scale. Reliability not reported.	Infants given formula in hospital less likely to breastfeed exclusively at 2 weeks. uOR 0.3, CI 0.1-0.9, $p=0.04$ Only 22% on track to meet exclusivity goal at 8 weeks. Problems included latching, perception of low milk supply, pain, and frequent feedings.	Missing data from feeding app, unable to tell why entries is low/missing, loss to follow up. View of duration and exclusivity of primiparous mothers and includes problems associated with breastfeeding difficulties.

A. Brown (2016) What Do Women Really Want? Lessons for Breastfeeding Promotion and Education **Breastfeeding Medicine**	Explored new mothers' attitudes toward their breastfeeding education and promotion.	Retrospective, mixed method. Level 6 evidence. -Experiences of breastfeeding education and promotion. -Intention, initiation, duration, and exclusivity.	1100 mothers with infant 0-2 years with intention to breastfeed at birth. Convenience sampling. United Kingdom.	Questionnaire open and closed-ended questions. Reliability not reported.	10.4% felt prepared after education. Strongly supported prenatal breastfeeding education. Thought breastfeeding introduced should be normal not "best". Tell the truth about breastfeeding being challenging and to take it one day at a time.	Sampling bias, internet recruitment leading to demographic bias. Provides experience information about how mothers' felt about breastfeeding and the promotion provided to them.
Wood et al. (2016) Interventions that Enhance Breastfeeding Initiation, Duration, and Exclusivity: A Systematic Review **The American Journal of Maternal/Child Nursing**	Determine which breastfeeding interventions have been used to date and created recommendations for future breastfeeding research.	Systematic review. Level 1 evidence. -Interventions that enhance initiation, exclusivity, and duration. -Limits of known strategies for enhancing breastfeeding.	6 studies focused on breastfeeding outcomes from mothers of term singletons. Randomized controlled trials. Singapore, Denmark, Canada, France, Brazil.	Does not specify analysis used.	Five limits to what is known about breastfeeding practices: 1. Difficulty applying knowledge and skills acquired to breastfeeding problems. 2. Maternal perception of infant feeding behaviors is a skill that needs more attention. 3. Lack of self-confidence and infant crying contribute to perception of low-milk supply, no clear ways to address 4. A need for theory guided interventions, suggests breastfeeding self-efficacy theory. 5. Healthcare providers need to be knowledgeable about the interventions they provide.	Heterogeneity of studies, small number of included studies, studies only written in English, variations of breastfeeding definitions. Provides guidance in what is needed in breastfeeding education and support including increased maternal self-efficacy, interventions guided by theory, and knowledgeable providers.

Pitts et al. (2015) **Incorporating Breastfeeding Education into Prenatal Care** **Breastfeeding Medicine**	Identify evidence-based breastfeeding education that promotes initiation and continuation of exclusive breastfeeding up to 6-months.	Descriptive study. Level 6 evidence. -Maternal utilization and perception of education program. -Breastfeeding initiation and plans for retention. -Rate of provider documentation of education.	23 women at 32 weeks gestation. Convenience sampling. New Hampshire.	Short questionnaire following education and summative questionnaire at 6-weeks postpartum. Reliability not reported.	67% reported education modules promoted breastfeeding for them. 90% were exclusively breastfeeding at 6-weeks. Most helpful contented included latching and positioning, benefits of breastfeeding, milk supply, and maintaining lactation.	Small sample size, no control group or randomization, short time frame for follow-up, previous breastfeeding experience. Majority of women had a preference for individual education, the content of education aligns for other studies and breastfeeding barriers.
C. R. L. Brown et al. (2014) **Factors influencing the reasons why mothers stop breastfeeding** **Canadian Journal of Public Health**	Evaluate why mothers ceased breastfeeding before 6 months and determine factors and timing associated with early cessation.	Longitudinal cohort study. Level 4 evidence. -Breastfeeding duration. -Factors affecting cessation. -Timing of cessation.	500 women who stopped breastfeeding before 6-months. Convenience sampling. Nova Scotia.	Databases records combined with telephone or face-to-face interviews. Reliability not reported.	26.4% breastfed for at least 6-weeks, 48.2% for 1-6 weeks, 25.4% for ≤ 1 week. Most frequently cited reasons for cessation: 22% inconvenience/fatigue 21% insufficient supply 12% return to work 8.8% difficulty with technique 7.6% planned to stop	Limited by forced-choice answers, self-recall, public database use. Provide insight in reasons for cessation and topics for education. Almost half of the women stopped between 1 and 6 weeks, this a vulnerable time for breastfeeding mothers.
THEME: Breastfeeding Self-efficacy						

Piro & Ahmed (2020) Impacts of antenatal nursing interventions on mothers' breastfeeding self-efficacy: an experimental study **BMC Pregnancy and Childbirth**	Evaluate the role of a professionally provided intervention on a breastfeeding self-efficacy.	Randomized controlled trial. Level 2 evidence. -Prenatal breastfeeding education sessions -Breastfeeding self-efficacy -Exclusivity -Breastfeeding duration	130 pregnant women Blinded, random sampling. Primary health care center in Iraqi Kurdistan.	Questionnaire developed with literature review, WHO, and UNICEF. Iowa Infant Feeding Attitude Scale Cronbach 0.85-0.86. Prenatal Breastfeeding Self-Efficacy Scale Cronbach 0.89. Breastfeeding Self-Efficacy Scale-Short Form Cronbach 0.97.	Accurate breastfeeding knowledge, attitude scores, and self-efficacy were all significantly higher following intervention $p<0.0001$ for all three.	Subjective data, influences from personality and environment. Increased breastfeeding self-efficacy is linked to increased breastfeeding duration. Self-efficacy can be increased through breastfeeding education.
Tseng et al. (2020) Effectiveness of an integrated breastfeeding education program to improve self-efficacy and exclusive breastfeeding rate: A single-blind, randomised controlled study **International Journal of Nursing Studies**	To develop a self-efficacy based breastfeeding education program.	Randomized controlled trial. Level 2 evidence. -Level of breastfeeding self-efficacy. -Feeding attitude. -Exclusive breastfeeding rate. -Any breastfeeding rate. -Satisfaction with program.	93 mothers (12-32 weeks gestation). Convenience sampling and block-randomization. Taipei, Taiwan.	Breastfeeding Self-Efficacy Scale-Short form Cronbach's alpha 0.95. Iowa Infant Feeding Attitude Scale Cronbach's alpha 0.74. Questionnaire to determine breastfeeding rates and satisfaction with program developed by researchers.	Intervention had significant difference in improved self-efficacy from control group and baseline results $p<0.001$ and $p<0.001$, $p<0.05$. Intervention group exclusive breastfeeding rates significantly higher than control group OR 4.7, CI 1.2-1.68, $p = 0.5$.	Limited geographically, participants may have been influenced by cultural "doing the month" tradition, self-report bias. Improved breastfeeding self-efficacy from breastfeeding education program involving self-efficacy theory. Breastfeeding exclusivity was also improved.

Appendix F

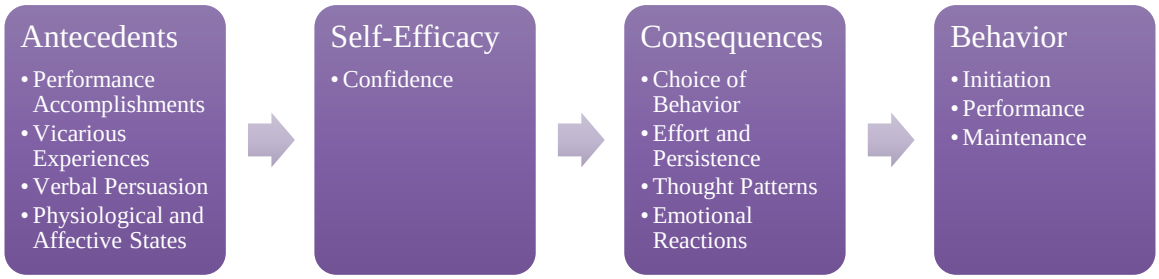
Evidence Grid

Article	Method of the Interventions	Timing of the Interventions	Breastfeeding Duration and Exclusivity	Breastfeeding Self-Efficacy	Breastfeeding Education Contents
Ahlers-Schmidt (2020)		X			
Ballesta (2020)		X			
C. Brown (2014)			X		X
A. Brown (2016)					X
Chaves (2019)	X		X	X	X
Cortés-Rúa (2018)					X
Daou (2020)	X		X		X
Demirci (2017)			X		X
Forster (2018)	X		X		
Fu (2014)	X		X		
Gianni (2019)			X		X
Huang (2019)	X	X	X		
Jerin (2020)	X	X	X		X
Kim (2018)		X	X		
Kronberg (2012)		X			X
McFadden (2017)	X	X	X		
McFadden (2019)	X	X	X		
Meedya (2017)		X			
Nnebe-Agumadu (2016)			X		
Parry (2019)					X
Piro (2020)		X		X	
Pitts (2015)	X		X		X
Schreck (2017)		X	X		
Skouteris (2017)	X	X			
Tan (2020)		X	X		
Tseng (2020)		X	X	X	X
K. L. Wong (2014)	X	X			
M. S. Wong (2021)	X	X	X	X	
Wood (2016)	X	X	X	X	X
Total	13	17	19	5	13

Appendix G

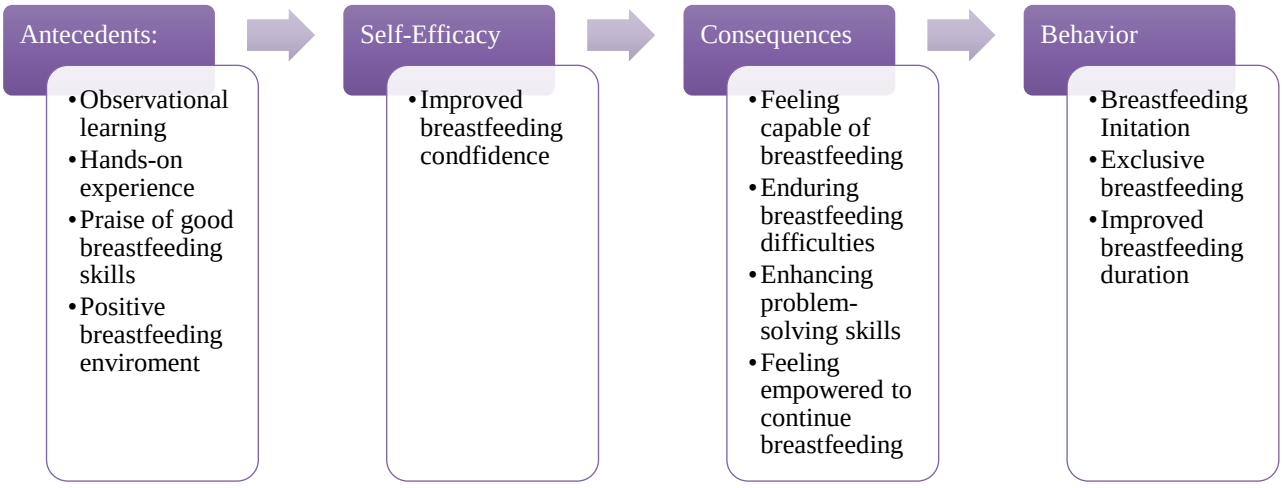
Application of Breastfeeding Self-Efficacy Theory

Breastfeeding Self-Efficacy Theory Diagram



Adapted from Dennis, Cindy-Lee. 1999. "Theoretical Underpinnings of Breastfeeding Confidence: A Self-Efficacy Framework." Journal of Human Lactation 15(3):195–201. doi: 10.1177/089033449901500303.

Theory Application Diagram



Adapted from Dennis, Cindy-Lee. 1999. "Theoretical Underpinnings of Breastfeeding Confidence: A Self-Efficacy Framework." Journal of Human Lactation 15(3):195–201. doi: 10.1177/089033449901500303.

Appendix H

Project Site's IRB Approval Letter

Ascension Via Christi

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Institutional Review Board

Exempt Research Application

Project / Study Title:	Breastfeeding Education and Support to Improve Breastfeeding Retention
Name of Principal Investigator:	Dr. Jonathan Scrafford
Is the Principal Investigator a member of the Via Christi Staff or an Employee:	Yes _X___ No _____
Names of Associate Investigators:	Ashley Brinker, Student Investigator, UMKC
Study Site Primary Contact, Phone Number and Email Address:	Victoria Parris BSN, RN, Physician Practice Manager 316-274-1550 victoria.parris@ascension.org
Sponsor (if any):	
Any Financial Interest or Conflict of Interest for any Investigators:	Yes _____ No ___X___ If Yes, describe:
Brief description of methodology including patient / subject selection:	This project began after identifying a specific need at the project site. Currently, there is no breastfeeding support/education provided to patients beyond encouraging it as good practice for mother and infant. This project plans to address this gap in care by improving breastfeeding support for first-time mothers. A quantitative, quasi-experimental design with two cohorts (baseline and intervention) will be used for this quality improvement project. The project has a goal of 40 participants per cohort, for a total of 80 participants. The intervention group will be a consecutive sample of all the patients willing to participate, who meet the project's inclusion and exclusion criteria. The baseline group will be comprised of patients that are as similar demographically to those in the intervention group as possible. The intervention cohort will be provided a face-to-face breastfeeding education session during a routine prenatal visit at 36-39 weeks gestation by the student investigator. The education will be provided in approximately 10 minutes and participants will be provided with an educational booklet to take home for further review. Postnatal support calls will begin after that first intervention cohort birth. They will be placed on postpartum days 5, 12, 19, 26, and 42 using either Zoom, Google Duo, or a verbal-only telephone call and last approximately 5-20 minutes. These calls will not be recorded. They will provide participants with breastfeeding support and allow time for participants to ask questions regarding breastfeeding. Demographic and breastfeeding data to be collected includes name, age, medical record number, phone number, race, due date, birth date, birth mode, gestational age of the baby at birth, birth complications, breastfeeding status throughout first six weeks postpartum, and reason for breastfeeding cessation. During the prenatal intervention, the intervention cohort participants' goals for the duration of exclusive breastfeeding will be written down and then followed-up on postnatally.
Any known and anticipated risks (include incidence if known):	None are known or anticipated. Confidentiality risks will be reduced by storing study data only on the clinic computer and in the UMKC REDCap system.
Currently approved alternate treatment(s):	N/A
Brief description of how study population will be obtained or identified:	A query will be ran on the clinic's EMR to identify potential participants. The list will be retained on the clinic's computer. The student investigator will then perform a review of the potential charts to determine participation qualification. Inclusion criteria for participants of both cohorts include 18 years or older, primiparous patients, with singleton pregnancies, who intend to breastfeed. Intervention participants will need to be English speaking, 34-38 weeks gestation at the time of enrollment, have a personal telephone or computer available for postpartum follow-up. Availability of communication device will be determined when speaking with potential participants, at the time of consent, before the prenatal education session. Exclusion criteria for both cohorts will include any or all of the following: 17 years of age or younger, any previous breastfeeding experience, and no intention to initiate breastfeeding. Further exclusion criteria for the intervention cohort includes 40 weeks gestation or more at the time of enrollment and no personal telephone or computer for postpartum follow-up.
Description of how confidentiality of study population will be maintained:	Confidentiality risks will be reduced by storing study data only on the clinic computer and in the UMKC REDCap system. Original signed consent forms and handwritten notes from the investigator will be scanned into the UMKC REDCap system and the original documents placed in the clinic's shred-bin. Data collected during the chart reviews and protocol will be put directly into REDCap, accessed on the student investigator's computer through the UMKC's server.
Include with this completed form a copy of the complete project plan / protocol and all supporting documents.	

GENERAL EXCLUSIONS FROM EXEMPTIONS (Check if **"Yes"**. If any in this section are checked, the research is not exempt.)	
☐	The research is FDA-regulated.
☐	The research involves Prisoners, conducted or funded by DHHS, Department of Defense (DOD), or Veterans Administration (VA), and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.
☐	The research involves interactions with Prisoners.

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☐	The research is classified and conducted or funded by the Department of Energy (DOE) (may be reviewed by convened IRB only).

The research falls into one or more of the following categories (One or more categories must be checked)

☐	1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of the educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
X	2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met, ☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; **OR** X (ii) Any disclosure of human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **OR** ☐ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or indirectly through identifiers linked to the subjects, **AND** an IRB conducts **limited IRB review** to determine that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
☐	If the research involves children and is conducted, funded, or subject to regulation by DHHS, Department of Defense (DOD), Department of Education (ED), Environmental Protection Agency (EPA), or Veterans Administration (VA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed or (2) the use of educational tests and at least one of the following criteria is met: ☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects; **OR** ☐ (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational achievement, or reputation.
☐	3(i). Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: ☐ (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; **OR** ☐ (B) Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **OR** ☐ (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, **AND** an IRB conducts **limited IRB review** to determine that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (ii) For purposes of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples include subjects playing an online game, solving puzzles under various noise conditions, or deciding how to allocate a nominal amount of cash between themselves and someone else.

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	(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
X	4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if <u>at least one</u> of the following criteria is met: ☐ (i) The identifiable private information or identifiable biospecimens are publicly available; **OR** ☐ (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **OR** X (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **OR** ☐ (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
☐	5. Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
☐	6. Taste and food quality evaluation and consumer acceptance studies, ☐ (i) if wholesome foods without additives are consumed **OR** ☐ (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Department of Agriculture.

NOTE: Categories 7 and 8 are not available as implementation of broad consent has not been approved for research overseen by the VCH-W IRB.

Criteria for approval of exempt research (Check if **"Yes"**)	
X	The research involves no more than Minimal Risk to subjects. **(Must be checked.)**

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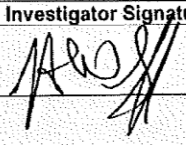
X	Selection of subjects is equitable. (That is, the research is appropriate for the population being studied.) **(Must be checked.)**	
X	There are interactions with subjects: **(If checked the following must be checked.)**	
	X	There will be a consent process
	X	The consent process will disclose that the activities involve research.
	X	The consent process will disclose the procedures to be performed.
	X	The consent process will disclose that participation is voluntary.
	X	The consent process will disclose the name and contact information for the investigator.
	X	There are adequate provisions to maintain the privacy interests of subjects.

Investigator Acknowledgement

I attest that the information provided in this application is true and accurate. I will promptly report proposed changes in a research activity to the VCH-W IRB, and must conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject. I will notify the VCH-W IRB when the project / study is permanently closed.

Principal Investigator Signature	Date
	2|12|21

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Exempt Research Application

VCH-W IRB USE ONLY

The above Request for Exempt Research Application has been reviewed by me and I find the research study to meet the qualifications for Exempt Research in the following category(s):

The research falls into one or more of the following categories (One or more categories must be checked)

☐ 1. Conducted in established or commonly accepted educational settings

☒ 2. Educational tests, survey procedures, interview procedures, or observations, **if at least one** of the following criteria is met,

- ☐ (i) Information recorded so that the identity of the subjects cannot be ascertained, directly or indirectly through identifiers linked to the subjects; **OR**
- ☒ (ii) Disclosure would not reasonably place subjects at risk of criminal or civil liability or be damaging, **OR**
- ☐ (iii) Information recorded by the investigator so that the identity of the subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, **AND** an IRB conducts **limited IRB review.**

☐ If the research involves children and is conducted, funded, or subject to regulation by DHHS, DOD, ED, EPA, or VA, the procedures are limited to (1) the observation of public behavior **OR** (2) the use of educational tests **AND** at least one of the following criteria is met:

- ☐ (i) Information recorded so that the identity of the subjects cannot be ascertained, directly or indirectly through identifiers linked to the subjects; **OR**
- ☐ (ii) Disclosure outside the research would not place subjects at risk criminally or civilly or be damaging.

☐ 3. Benign behavioral interventions in conjunction with collection of information from adult subjects if the subjects prospectively agree to the intervention and information collection and at least one of the following criteria is met:

- ☐ (A) Information recorded so that the identity of the subjects cannot be ascertained, directly or indirectly through identifiers linked to the subjects; **OR**
- ☐ (B) Disclosure outside the research would not place subjects at risk criminally or civilly or be damaging; **OR**
- ☐ (C) Information recorded by the investigator so that the identity of the subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, **AND** an IRB conducts **limited IRB review.**

☒ 4. Secondary research for which consent not required - of identifiable private information or identifiable biospecimens - if at least one of the following criteria is met:

- ☐ (i) Publically available; **OR**
- ☐ (ii) Information recorded so that the identity of the subjects cannot be ascertained, directly or indirectly through identifiers linked to the subjects, no contact with subjects, and the investigator will not re-identify subjects; **OR**

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	[X] (iii) Research involves only involving the use of identifiable health information for the purposes of "health care operations" or "research" or for "public health activities and purposes"; **OR** ☐ (iv) Research conducted by, or on behalf of, a Federal department or agency.
☐	5. Research conducted or supported by a Federal department or agency that are designed to study, evaluate, improve or otherwise examine public benefit or service programs. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision and must be published on this list prior to commencing the research involving human subjects.
☐	6. Taste and food quality evaluation and consumer acceptance studies, ☐ (i) if wholesome foods without additives are consumed **OR** ☐ (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Department of Agriculture.

[ ] Not approved - Refer for Full Board Review

Explanation_____

Benefit / Risk: [ ] Less Than Minimal Risk [X] Minimal Risk

Informed Consent is: [X] Required (for Interventional Cohort) [X] Not Required (for baseline cohort)

IRB Chair or Designee: John L Jones **Date** 27 Aug 2021

FULL BOARD VCH-W IRB REVIEW

The above Request for Exempt Research Application has been reviewed by the full board VCH-W IRB and is determined to meet the qualifications for Exempt Research in the following category(s):

☐	1. Conducted in established or commonly accepted educational settings
☐	2. Educational tests, survey procedures, interview procedures, or observations, **if at least one** of the following criteria is met, ☐ (i) Information recorded so that the identity of the subjects cannot be ascertained, directly or indirectly through identifiers linked to the subjects; **OR** ☐ (ii) Disclosure would not reasonably place subjects at risk of criminal or civil liability or be damaging, **OR** ☐ (iii) Information recorded by the investigator so that the identity of the subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, **AND** an IRB conducts **limited IRB review.**
☐	If the research involves children and is conducted, funded, or subject to regulation by DHHS, DOD, ED, EPA, or VA, the procedures are limited to (1) the observation of public behavior **OR** (2) the use of educational tests **AND** at least one of the following criteria is met: ☐ (i) Information recorded so that the identity of the subjects cannot be ascertained, directly or indirectly through identifiers linked to the subjects; **OR** ☐ (ii) Disclosure outside the research would not place subjects at risk criminally or civilly or be damaging.
☐	3. Benign behavioral interventions in conjunction with collection of information from adult subjects if the subjects prospectively agree to the intervention and information collection and at least one of the following criteria is met:

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	☐ (A) Information recorded so that the identity of the subjects cannot be ascertained, directly or indirectly through identifiers linked to the subjects; **OR** ☐ (B) Disclosure outside the research would not place subjects at risk criminally or civilly or be damaging; **OR** ☐ (C) Information recorded by the investigator so that the identity of the subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, **AND** an IRB conducts **limited IRB review.**
☐	4. Secondary research for which consent not required - of identifiable private information or identifiable biospecimens - if at least one of the following criteria is met: ☐ (i) Publically available; **OR** ☐ (ii) Information recorded so that the identity of the subjects cannot be ascertained, directly or indirectly through identifiers linked to the subjects, no contact with subjects, and the investigator will not re-identify subjects; OR ☐ (iii) Research involves only involving the use of identifiable health information for the purposes of "health care operations" or "research" or for "public health activities and purposes"; **OR** ☐ (iv) Research conducted by, or on behalf of, a Federal department or agency.
☐	5. Research conducted or supported by a Federal department or agency that are designed to study, evaluate, improve or otherwise examine public benefit or service programs. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision and must be published on this list prior to commencing the research involving human subjects.
☐	6. Taste and food quality evaluation and consumer acceptance studies, ☐ (i) if wholesome foods without additives are consumed **OR** ☐ (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Department of Agriculture.

[ ] Disapproved for Exempt Status

Benefit / Risk: [ ] Less Than Minimal Risk [ ] Minimal Risk

Informed Consent is: [ ] Required [ ] Not Required

IRB Chair or Designee:_____ **Date**_____

Ascension Via Christi
Via Christi Hospitals Wichita, Inc.
Institutional Review Board

Appendix J Page 1 of 1

Waiver or Alteration of Informed Consent

I. **Protocol Number and Title:** __**Breastfeeding Education and Support to Improve Breastfeeding Retention**___
Principal Investigator: __**Dr. Jonathan Scrafford**_____

II. Waiver of Informed Consent

Please respond to each of the following:

1. The research involves no more than minimal risk to the subjects. [X] Yes
2. The research could not practicably be carried out without the requested waiver or alteration. [X] Yes
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. [X] Yes
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects. [X] Yes
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. [X] Yes

Comments: _____

_____ 8/13/21
Principal Investigator Signature Date

VCH-W IRB USE ONLY
In order to approve a request to waive the requirement for informed consent, or to omit or alter one or more basic or additional elements of consent (at "Alteration"), the VCH-W must determine and document the five criteria are satisfied.

[X] Approved (Meets all five criteria.)

THIS SIGNIFIES NOTIFICATION OF IRB APPROVAL OF THE PROJECT DESCRIBED ABOVE.

[ ] Disapproved for Waiver of Informed Consent; Informed Consent Required.

This is to confirm that the following member(s) of the Institutional Review Board abstained from voting on any submissions for the above mentioned study: N/A

IRB Chair or Chair Designee Signature **Date of Action** 28 July 2021

Pilot Form: Appendix J (Version 1/21/2019)

ASCENSION VIA CHRISTI HOSPITALS WICHITA, INC.
INSTITUTIONAL REVIEW BOARD

APPENDIX C (2) – PAGE 1

WAIVER OF AUTHORIZATION OF DISCLOSURE of PHI***

Protocol #: _____

Protocol Title: Breastfeeding Education and Support to Improve Breastfeeding Retention

Principal Investigator: Dr. Jonathan Scrafford

1. The use or disclosure of Protected Health Information (PHI)* involves no more than a minimal risk to the privacy of individuals. Explain why. Include a detailed list of the PHI to be collected and a list of the source(s) of the PHI.

Data to be collected includes name, age, medical record number, race, date of education session, due date, birth date, birth mode, gestational age of the baby at birth, birth complications, dates of postpartum support calls, breastfeeding status throughout first six weeks postpartum, and reason for breastfeeding cessation. Some data will be found during a chart review, in the clinic, of patients care for by the principal investigator and some will be collected directly from the patients in the intervention cohort.

2. Describe the plan to protect identifiers and indicate where PHI will be stored and who will have access. (Researchers must list all of the entities that might have access to the study's PHI such as IRB, Institutional representatives, sponsors, FDA, DSMBs and any others given authority by law.)

A list of potential participants will be created through a query of the clinic's EMR. This list will be stored on a clinic computer. The data collected from the patients medical records will be input directly from the clinic's EMR into REDCap provided by the University of Missouri-Kansas City. Scanned copies of the signed consent forms and notes written by the investigator during the prenatal and postnatal interactions with the patients will be scanned into UMKC REDCap. The original signed consent forms and written notes will be placed in the clinic's shred-bin for confidential destruction. The student investigator and her professors will have access to the data stored in REDCap. PHI will also be available for review if required under authority of law by federal authorities, and the AVCH-W IRB.

3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is: (*explain below*).

Once the project has been accepted for publishing, all data and scanned documents, both on the UMKC REDCap system and the clinic computer, related to this project will be deleted, but no later than May 14th, 2023.

Please describe the procedure used to destroy all the data collected during the study (electronically, paper, audio/video, photography, other). OR

Original consent forms and hand written notes of the investigator will be placed in the clinic's shred-bin after being scanned into REDCap. The original list of potential participants will be deleted from the clinic's computer and all the records for this project stored in the UMKC REDCap system will be destoyed May 14th, 2023.

Alternatively, the identifiers collected during the study will not be destroyed because: (*explain below*).

N/A

4. The research could not practicably be conducted without the waiver because (*explain below*).

*PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that related to the past, present or future physical or mental health or conditions of an individual.
**Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.
***HIPAA Regulations allow IRBs to waive use of authorization form if all the criteria listed above is met.

The patients whose data will be accessed under the waiver will no longer be a prenatal/postpartum patient at the clinic at the time of the protocol implementation.

5 The research could not practicably be conducted without access to and use of the PHI because (*explain below*)

This data will serve as a baseline to compare the protocol's implementation to Without this data the protocol's success, within the clinic, will not be able to be determined.

6 The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Please note that researchers are **accountable** for any PHI released under a waiver. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives.

The data to be collected has been specifically selected to allow for comparison to the protocol implementation participants' data. There is no data being collected that will not be used in comparing the two cohorts.

The information listed in the waiver application is accurate and all research staff** will comply with the HIPAA regulations and the waiver criteria. I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the Ascension Via Christi Hospitals Wichita, Inc. Institutional Review Board.

Jonathan Scrafford
Principal Investigator Name Typed or Printed

8/18/21
Date

Principal Investigator Signature

3/8/2019 Updated Hospital Name

*PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that related to the past, present or future physical or mental health or conditions of an individual.
**Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.
***HIPAA Regulations allow IRBs to waive use of authorization form if all the criteria listed above is met.

ASCENSION VIA CHRISTI HOSPITALS WICHITA, INC.
INSTITUTIONAL REVIEW BOARD

APPENDIX C (2) – PAGE 3

AVCH-W IRB USE ONLY

The Ascension Via Christi Hospitals Wichita, Inc. – IRB, has determined that the project meets all of the following criteria for waiver of authorization:

X The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:

X An adequate plan to protect the identifiers from improper use and disclosure;

X An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

X Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA/Privacy regulations:

X The research could not practicably be conducted without the alteration or waiver.

____ The research could not practicably be conducted without access to and use of the protected health information.

Use or access to the following information is approved:

_____

_____

_____

_____

_____

This waiver was approved under:

____ **Full IRB Review** **X Expedited IRB Review**

IRB Chair or Chair Designee Signature

20 Aug 2020

Date of Action

3/8/2019 Updated Hospital Name

*PHI: individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that related to the past, present or future physical or mental health or conditions of an individual.
**Note: Research staff is defined as ALL study personnel (including PI) that is involved in the research.
***HIPAA Regulations allow IRBs to waive use of authorization form if all the criteria listed above is met.

ASCENSION VIA CHRISTI HOSPITALS WICHITA, INC.
INSTITUTIONAL REVIEW BOARD

APPENDIX E – PAGE 1

REQUEST FOR REVISION/AMENDMENT OR MISCELLANEOUS REPORT SUBMISSION

I. **Title of Protocol:** Breastfeeding Education and Support to Improve Breastfeeding Retention.

II. **Principal Investigator:** Jonathan Scrafford MD **Phone:**

IV. **Office Research Coordinator or contact person (for IRB):** Ashley Brinker **Phone:**

Address:

IV. **Submission Description:**

[x] Revision to currently approved protocol
[ ] Revision to currently approved consent form
[ ] Miscellaneous Report (such as Advertisements, Status Change, Site or Monitoring Visit Report, Audit Report, Annual Report, Note to File, or Report of Protocol Violation or Deviation, etc.)

V. **Will enrolled subjects or participants be notified of study changes or re-consented? [ ] Yes [x] No**
If yes, please indicate method: [ ] Re-consent [ ] Written notification [ ] Telephone notification
[ ] In-person notification at next appointment [ ] Other, please describe:

VI. **Check one:**

[x] This revision/submission *does not* increase risks to participants enrolled in the study.
[ ] This revision/submission *does* increase risks to participants enrolled in the study. (Include explanation in revision description.)

VII. **Describe revision request or submission:**

A Data Use Agreement (DUA) is needed prior to sharing any data outside of the covered entity, AMG-VC. As the execution of the DUA is anticipated to take some time to get in place, once the IRB Authorization Agreement (IAA) is executed, the study can begin but instead of inputting any data into UM REDCap, it will be stored at the AMG-VC entity on an Ascension-owned laptop. Paper documents (signed consent forms, handwritten notes, and any records from the EMR) will all be stored in a secure location within the principal investigator's office, at the covered entity, accessible only to investigators on this study. Once the DUA has been executed, data from handwritten notes and data from the EMR will be uploaded into the UM REDCap system.

Signed consent forms will not leave the AMG-VC covered entity. They will instead be scanned into the individual patient's EMR, rather than being scanned into the UM REDCap system. The hardcopy of the signed consent forms, or scanned copies, will be retained in the principal investigator's office or AMG-VC computer system. Signed consent forms will not be transferred or uploaded to the UM REDCap system as they must be retained for six years under federal regulations.

VIII. **Attach revised documents *(HIGHLIGHT ALL REVISIONS)***

I ATTEST THAT THE INFORMATION PROVIDED ABOVE IS TRUE AND ACCURATE.

Investigator Signature **Date** 8/31/21

IRB REVIEWER RECOMENDATIONS

4/4/2019 Hospital name change

ASCENSION VIA CHRISTI HOSPITALS WICHITA, INC.
INSTITUTIONAL REVIEW BOARD

APPENDIX E – PAGE 1

IRB REVIEWER RECOMENDATIONS

BENEFIT/RISK: [X] Less than Minimal Risk [ ] Minimal Risk [ ] More than Minimal Risk

[X] **Approve**

NOTE TO REVIEWER: PLEASE CONTACT THE IRB STAFF WITH COMMENTS FOR FOLLOW-UP ON OTHER OPTIONS

[ ] Conditionally Approve [ ] Disapprove [ ] Defer

Reviewer: _____ **Review Date** 31 Aug 2024

AVCH-W IRB USE ONLY

[x] Approved by Expedited Review
[ ] Approved by Full Board Review

THIS SIGNIFIES NOTIFICATION OF IRB APPROVAL OF THE REVISION DESCRIBED ABOVE.

[ ] Conditionally Approved
Letter attached describing requirements for approval.
[ ] Disapprove
[ ] Deferred

[X] **Yes** **[ ] No** With this revision, the study retains its EXEMPT status under **Category 2ii** – Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if any disclosure or human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation **AND Category 4iii** – Secondary research for which consent is not required – of identifiable private information where the research involves only involving the use of identifiable health information for the purposes of "health care operations" or "research" or for "public health activities and purposes."

This is to confirm that the following member(s) of the Institutional review Board abstained from voting on any submissions for the above mentioned study; N/A

The Board requests to be notified within five working days of any unexpected adverse reaction as a result of the use of this protocol.

This submission was reviewed and approved by expedited review in accord with 45 CFR 46.110(b)(1)(ii), "an IRB may use expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized."

IRB Chair or Designee: _____ **Date** 31 Aug 2024

3/8/2019 Hospital Name Change

Appendix I

University of Missouri-Kansas City IRB Approval Letter

UMKC Institutional Review Board
University of Missouri-Kansas City

5319 Rockhill Road
Kansas City, MO 64110
816-235-5927
umkcirb@umkc.edu

Dear Lyla Jo Lindholm,

A member of the UMKC Research Compliance Office screened your QI Questionnaire to project #2062803-QI entitled "Breastfeeding Education and Support to Improve Breastfeeding Retention" and made the following determination:

QI Determination: **The project has been determined to be a quality improvement activity not requiring IRB review.**

If you have any questions regarding this determination, please feel free to contact our office at 816-235-5927, umkcirb@umkc.edu, or by replying to this notification.

Note Regarding Publications: It is appropriate to disseminate and replicate QI/program evaluation successes, including sharing the information external to an organization. This may include presentations and publications. The mere intent to publish the findings does not require IRB review as long as the publication does not refer to the activity as research.

Thank you,
UMKC Institutional Review Board

Appendix J

Faculty Approval Letter

UMKC School of Nursing and Health Studies

June 29, 2021

UMKC DNP Student: Ashley Brinker

Congratulations. The UMKC Doctor of Nursing Practice (DNP) faculty has approved your DNP project proposal, *Prenatal/Postpartum Breastfeeding Education and Support*.

You may proceed with IRB application

Sincerely,

Cheri Barber

Cheri Barber, DNP, RN, PPCNP-BC, FAANP
Clinical Assistant Professor
DNP Program Director
UMKC School of Nursing and Health Studies barberch@umkc.edu

Lyla Lindholm

Lyla Lindholm, DNP, RN, ACNS-BC
Clinical Assistant Professor, DNP Faculty
MSN-DNP Program Coordinator
UMKC School of Nursing and Health Studies lindholml@umkc.edu

Debbie C. Pankau DNP, APRN, FNP-BC
Clinical Assistant Professor
DNP Faculty
UMKC School of Nursing pankaud@umkc.edu

DNP Faculty Mentor Sherri Sellers, DNP, RN, WHNP-BC
UMKC School of Nursing and Health Studies

UNIVERSITY OF MISSOURI-KANSAS CITY
2464 Charlotte • Kansas City, MO 64108-2718 • p 816 235-1700 • f 816 235-1701 www.umkc.edu/nursing
• nurses@umkc.edu
an equal opportunity/affirmative action institution

Appendix K

Participant Informed Consent Document

AGREEMENT TO PARTICIPATE IN A RESEARCH STUDY MEDICAL RESEARCH INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSEPROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Title of research study: Breastfeeding Education and Support to Improve Breastfeeding Retention.

Investigators: Jonathan Scrafford MD, Principal Investigator; Ashley Brinker, Student Investigator

Key Information: The following is a short summary of this research study to help you decide, voluntarily, whether or not to be a part of this study. This project plans to improve breastfeeding support for first-time mothers. Possible benefits include improved breastfeeding knowledge, breastfeeding practices, improved breastfeeding self-confidence, and longer duration of breastfeeding. If you choose to participate, you will be provided a face-to-face breastfeeding education session during a routine prenatal visit at 36-39 weeks gestation by the student investigator. The education will be provided in approximately 10 minutes and participants will be provided with an educational booklet to take home for further review. Following the birth of your baby, postnatal support calls from the student investigator will begin on postpartum days 5, 12, 19, 26, and 42 using either Zoom, Google Duo, or a telephone call and are expected to last approximately 5-20 minutes. These sessions are planned to provide participants with breastfeeding support and allow time for participants to ask questions regarding breastfeeding. The student investigator will take notes during these sessions and collect information from your medical records at the clinic. Specifically, data to be collected include your name, age, medical record number, phone number, race, due date, your breast feeding goals, birth date of your baby, birth mode, gestational age of the baby at birth, birth complications, breastfeeding status throughout first six weeks postpartum, and reason for breastfeeding cessation. Your participation will end after approximately 42 days after your delivery. There are no anticipated risks to participating in the study other than a very small risk of disclosure of your information to someone outside this research study. Complete confidentiality cannot be guaranteed but safeguards are in place to protect your confidentiality. Your data will be stored on the clinic computer and the University of Missouri secure computer system and all documents and computer records will be destroyed no later than May 14, 2023. Your records will only be accessible by the investigators, the student investigator's instructors overseeing this educational activity, the IRB overseeing this study, and governmental authorities where required by law. If you decide not to participate in this study, you will continue to receive the standard care provided at this clinic.

Why am I being invited to take part in a research study?

We invite you to take part in this research study because you are a first-time mother intending to breastfeed your baby.

Why is this research being done?

Research has shown that breastfeeding mothers benefit from education and support during their breastfeeding journey. This study is being implemented to provide breastfeeding education and support with the intention of improving breastfeeding duration and exclusivity of first-time adult mothers and their babies.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 7-12 weeks depending on the date of your prenatal breastfeeding education and the birth of your baby.

You will be provided a 10-minute breastfeeding education session before or after one of your regularly scheduled prenatal visits at 36-39 weeks gestation. Following the birth of your baby you will receive 5 postpartum breastfeeding support calls.

More detailed information about the study procedures can be found under **"What happens if I say yes, I want to be in this research?"**

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this study. However, possible benefits include improved breastfeeding knowledge, improved breastfeeding practices, improved breastfeeding self-confidence, and longer duration of breastfeeding.

Are there any risks to participating in this study?
There is expected to be no risks to participating in this study other than a possible risk of loss of confidentiality. Procedures are in place to help protect your personal information from unauthorized disclosure, but confidentiality cannot be guaranteed. Data collected will be stored electronically in secure computer systems at the clinic and at the University of Missouri. Paper documents, once scanned into the computer system will be destroyed at the clinic. Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization. The researchers agree to protect my health information by using and disclosing it only as permitted by me in this Authorization and as directed by state and federal law.

Ascension Via Christi Hospitals Wichita, Inc., does not provide free medical treatment or payment for injuries resulting from participation in biomedical or behavioral research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate. Standard medical care will be provided regardless of your participation in this study.

How many people will be studied?

We expect about 80 mothers and their babies will be in this research study.

What happens if I say yes, I want to be in this research?
Participants will be provided a 10-minutes breastfeeding education session either before or after one of your regularly scheduled prenatal visits at 36-39 weeks gestation. The student investigator will cover topics that include benefits of breastfeeding, breastfeeding positions, milk supply, and more. During this session that student investigator will ask you to make a goal for exclusive breastfeeding duration.
After the birth of your baby, the student investigator will call you during your first 6-weeks postpartum to see how breastfeeding is going and allow time for questions. You will receive calls on postpartum days 5, 12, 19, 26, and 42. These calls can be made over the phone or via a video messaging platform (Zoom or Google Duo). During the support calls the student investigator will ask you if you are exclusively breastfeeding, breastfeeding with supplementation, and has stopped breastfeeding. Breastfeeding status changes will not affect your ability to participate in the postpartum support calls. None of these sessions will be recorded.

There is no cost nor payment for participating in this study.

What happens if I say yes, but I change my mind later?

Your authorization will automatically expire on May 14, 2023. However, you can decide to leave the study, at any time. Send written notice of your decision to the student investigator at ambn2w@mail.umkc.edu. Your study participation and collection of your data will cease at the time your notice to withdraw your authorization is received. Data collected up to that point will continue to be used in the study, but no additional data will be collected. In case of an adverse event, your information may still be disclosed if required by law.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, and to keep it confidential, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB, other representatives of this organization, professors of the student investigator and federal authorities where required by law. The data collected will be stored in a secure online server provided by the University of Missouri. Paper records will be scanned at the clinic and stored in the UMKC computer system and the paper records destroyed. This data will be accessible to the above parties until May 14, 2023, at which time it will be destroyed. Your information that is collected as part of this research will not be used or distributed for future research studies, even if all your identifiers are removed. You will not have access to the information collected for this research project, however, your medical records are accessible through standard procedure at the clinic.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the student investigator at ***785-336-1196 or ambn2w@mail.umkc.edu***

This research study has been reviewed and approved by the Ascension Via Christi Hospitals Wichita, Inc. Institutional Review Board. You can contact them at (316) 291-4774 if:

- Your questions, concerns, or complaints are not being answered by the research team.

- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Your signature documents your permission to take part in this research. If you do not sign this form, you cannot participate in this study.

You authorize the investigators to use and disclose your protected health information for the purposes of the research study described above.

You will be given a copy of this signed consent and authorization form for your records.

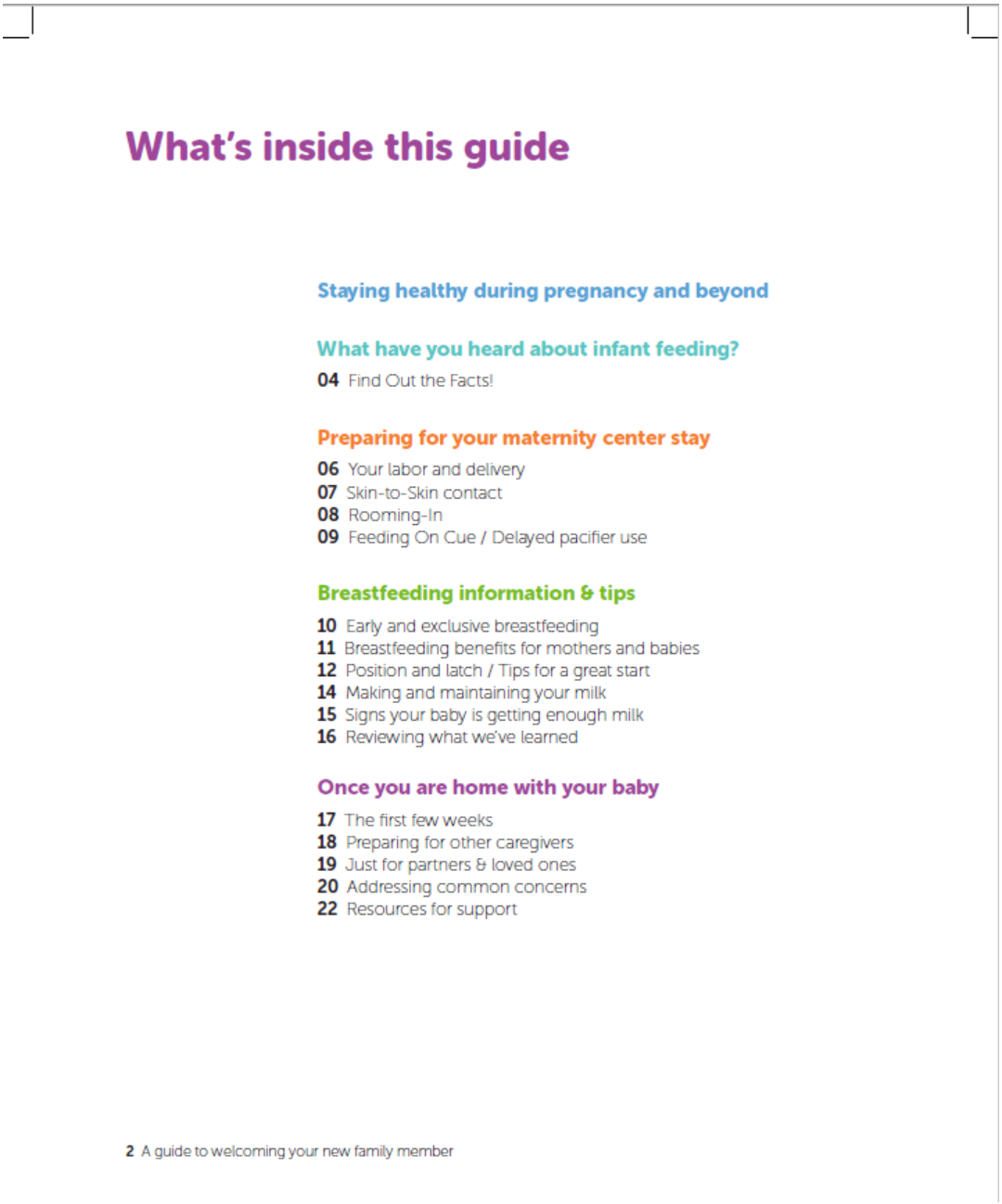
Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date

Appendix L

Education Booklet

Ready, Set, **Baby**

A guide to welcoming your new family member

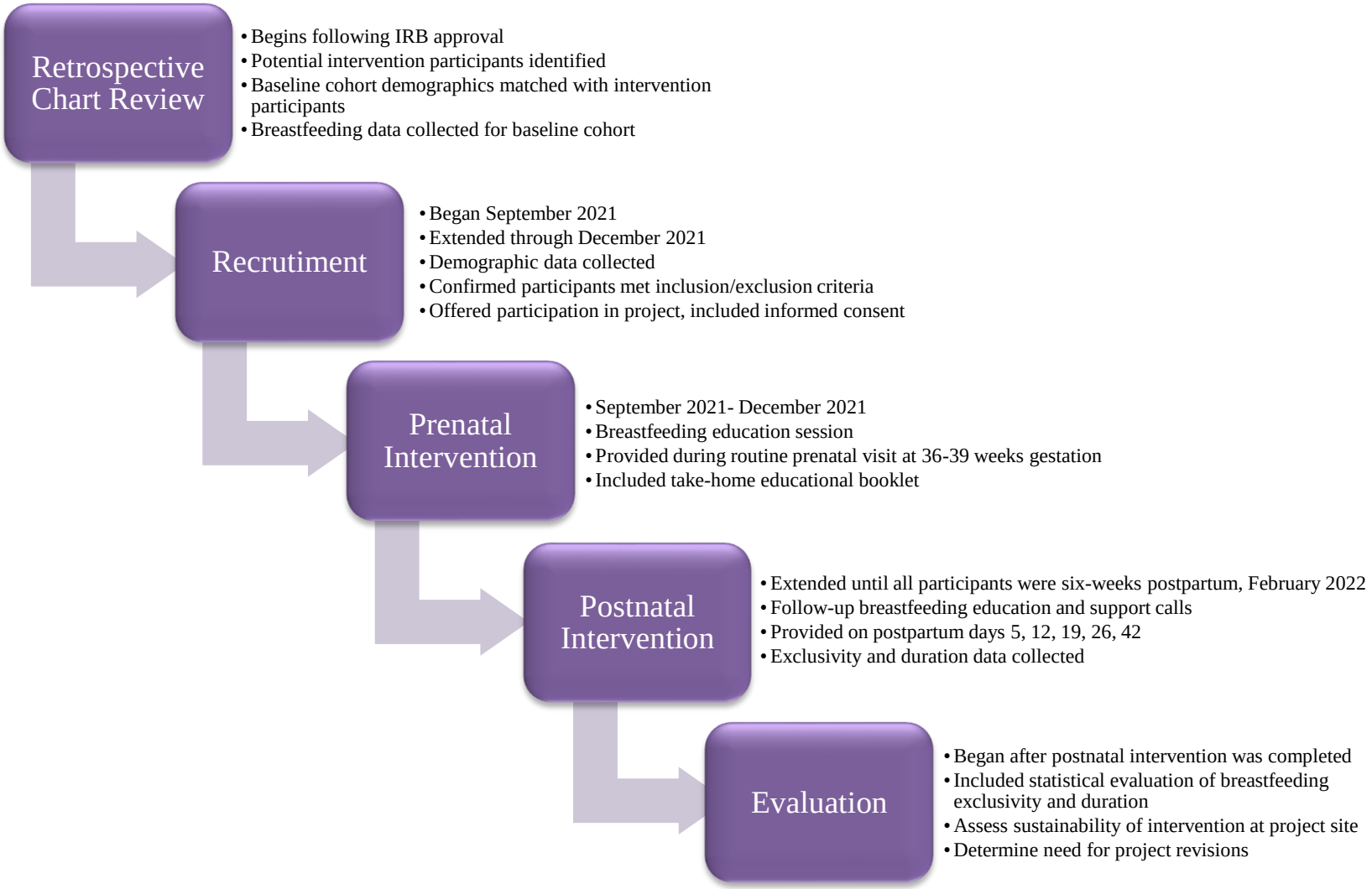


What's inside this guide

These two images are the cover and contents pages of the 24-page booklet that will be provided to participants during the prenatal breastfeeding education session. The booklet was developed by the University of North Carolina and is available to the public (https://sph.unc.edu/cgbi/resources-ready-set-baby/). The Raygor reading level for this booklet is fifth grade.

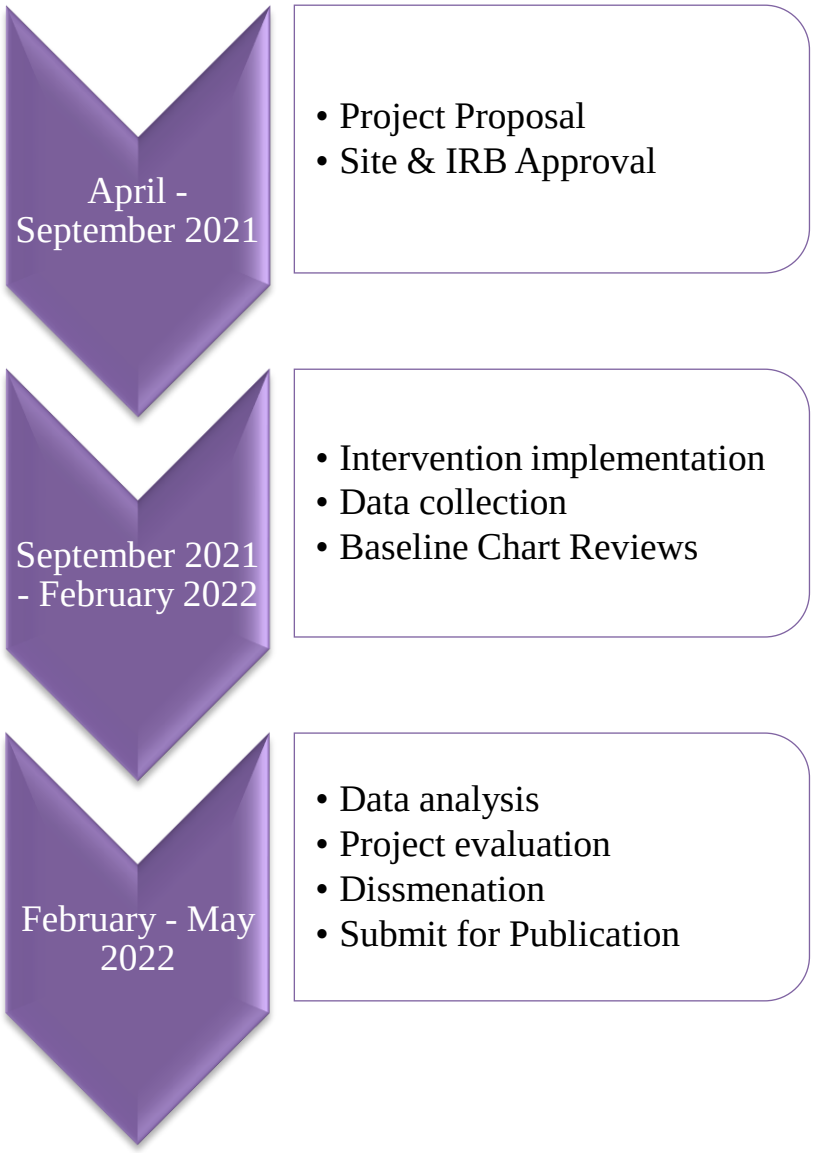
Appendix M

Intervention Flow Model



Appendix N

Project Timeline Flow Model



Appendix O

Logic Model

Inquiry: For primiparous women, intending to breastfeed, does in-person breastfeeding education provided during a third-trimester prenatal visit paired with postnatal follow-up calls improve breastfeeding exclusivity and duration at six weeks postpartum when compared to standard breastfeeding care at an obstetric and gynecologic clinic in Kansas?

Inputs	**Interventions -- Outputs**		**Outcomes -- Impact**		
	Activities	***Participation***	**Short**	**Medium**	**Long**
Evidence, sub-topics 1. Exclusivity and duration 2. Provided during prenatal and postnatal 3. Face-to-face and phone/video calls used for contact 4. Education addresses breastfeeding barriers 5. Self-efficacy impacts outcomes **Major Facilitators or Contributors** 1. Support of staff 2. Minimal expense 3. Minimal outside commitment needed **Major Barriers or Challenges** 1. Time management for education and postpartum session 2. Loss of phone or computer access	**EBP intervention:** Education and support of first-time breastfeeding mothers **Major steps of the intervention:** 1. Enrollment 2. Prenatal education session at 36-39 weeks gestation 3. Postpartum follow up calls on days 5, 12, 19, 26, and 42	**The participants:** Primiparous patients intending to breastfeed their singleton infant following delivery. **Site:** OB/GYN Clinic **Time Frame:** September 2021-January 2022 **Informed consent obtained from all participants.** **Project team leader will collect all data:** • Breastfeeding exclusivity • Cessation reasons	**Primary:** Breastfeeding exclusivity and duration to 6-weeks **Statistical analysis to be used** 1. Descriptive statistics 2.Two independent proportions z-test	Exclusive breastfeeding to 6-months. Reduced economic burden on mother-infant dyads.	Reduced infant morbidities and mortality. Reduced maternal morbidities and mortality. Reduced economic burden on healthcare system.

Appendix P

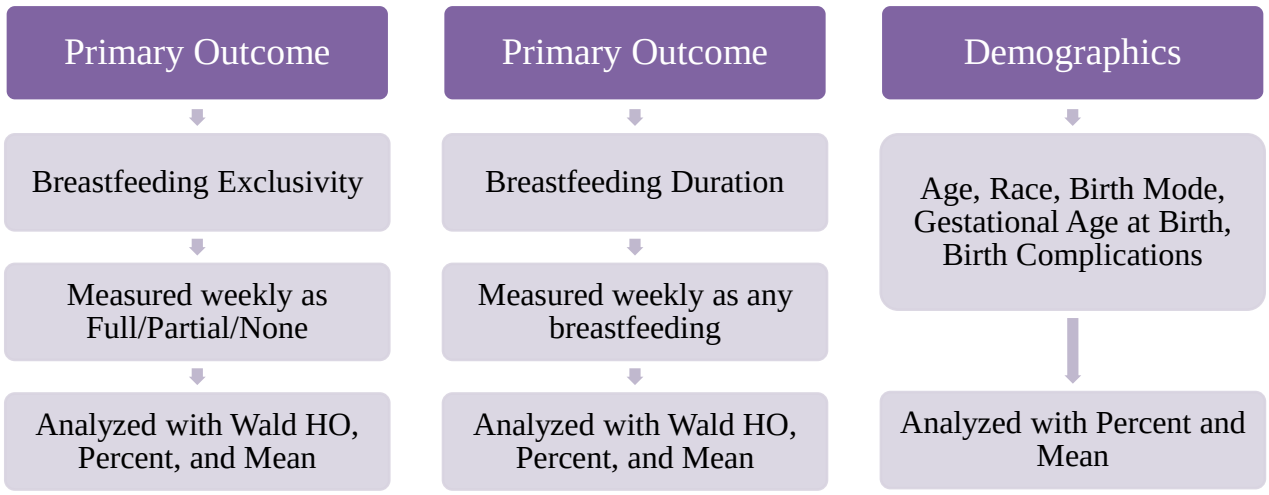
Data Collection Template

Demographics: Baseline and Intervention Cohorts					
ID	Age	Race	Birth mode	Gestational Age at Birth	Birth Complications

Weekly Breastfeeding Exclusivity					
Week 1 Exclusivity	Week 2 Exclusivity	Week 3 Exclusivity	Week 4 Exclusivity	Week 5 Exclusivity	Week 6 Exclusivity

Appendix Q

Outcome through Analysis Model



Appendix R

Statistical Analysis Tables and Charts

Table R1

Intervention Cohort Demographics				
	6-week Exclusive Breastfeeding	6-week Partial Breastfeeding	6-week No Breastfeeding	Total
Average Age (in years)	26.1	27.3	25.5	26.0
Race				
Caucasian	66.7%	12.5%	4.2%	87.5%
Hispanic	4.2%	--	4.2%	12.5%
Birth Mode				
Vaginal	66.7%	12.5%	4.2%	91.7%
Cesarean Section	4.2%	--	4.2%	8.3%
Average Gestational Age at Birth (in weeks)	39.0	40.1	38	38.8
Births with Complications				
Yes	4	1	1	6
No	13	2	1	18

Table R2

Baseline Cohort Demographics				
	6-week Exclusive Breastfeeding	6-week Partial Breastfeeding	6-week No Breastfeeding	Total
Average Age (in years)	26.5	24.2	24.4	25.2
Race				
Caucasian	37.5%	33.3%	16.7%	87.5%
Hispanic	4.2%	4.2%	4.2%	12.5%
Birth Mode				
Vaginal	41.7%	33.3%	16.7%	91.7%
Cesarean Section	--	4.2%	4.2%	8.3%

Average Gestational Age at Birth (in weeks)	39.3	39.2	38.3	38.6
Births with Complications				
Yes	2	3	1	6
No	8	6	4	18

Chart R1

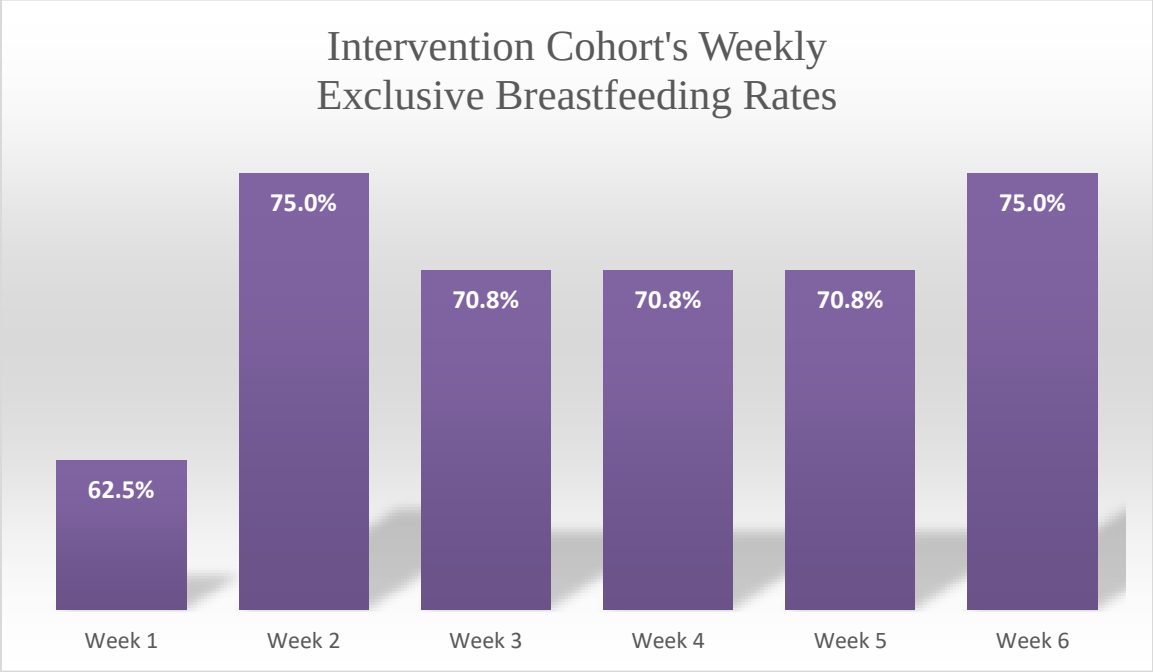


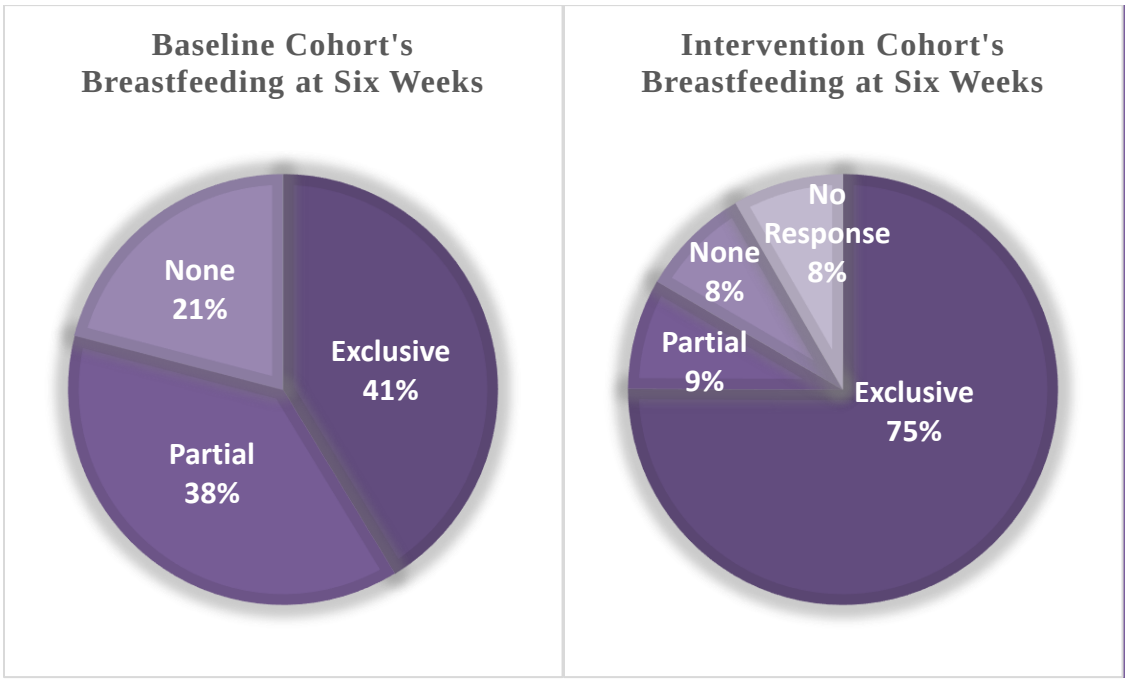
Table R3

Wald HO Independent Samples Proportions Test					
	Baseline Cohort		Intervention Cohort		One-Sided p
	Participants	Percentage	Participants	Percentage	
EBF at 6 weeks	10	41.7%	18	75.0%	p= .003
Any BF at 6 weeks	19	79.2%	20	90.9%	p= .134

Table R4

Results Comparison	EBF	Partial BF	No BF
Intervention Group ***(at 6wks)***	75.0%	8.3%	8.3%
Baseline Group ***(at 6wks)***	41.7%	37.5%	20.8%
State- Kansas ***(at 3 mon.)***	51.6%	--	--
National ***(at 3 mon)***	46.9%	--	--

Chart R2



Appendix S

Executive Summary

Background

Breastmilk is the gold standard food for infants, aged birth to 6 months (M. S. Wong et al., 2021). It provides a complete form of the nutrients for optimal growth, it is individualized by the mother's body, and it supplies antibodies that strengthen an infant's immune system (Coffman, 2019). While breastmilk and breastfeeding supply both mother and infant with a long list of health benefits, research suggests that a lack of knowledge and support inhibits dyads from reaching exclusive breastfeeding to six months (M. S. Wong et al., 2021; Coffman, 2019).

Problem

Initiation rates for breastfeeding, in the United States, in 2017, were considerably high, 84.1%, but breastfeeding exclusivity and duration trended down quickly following the early postpartum period (Centers for Disease Control and Prevention, 2020a). Locally, in Kansas, breastfeeding rates in 2017 were 84.6% initiation and 31.6% exclusively breastfeeding at six months (Centers for Disease Control and Prevention, 2020a). The problem that the project attempted to answer was: what interventions can help improve breastfeeding exclusivity and duration for first-time breastfeeders who are patients at an OBGYN clinic in Kansas?

Purpose

The purpose of this project was to improve the retention of breastfeeding by first-time breastfeeders at six weeks postpartum. The project's two interventions were developed based on current research and guidelines. Participants were provided one in-person breastfeeding education session at a routine prenatal visit and following birth they received five postpartum

breastfeeding support calls intended to answer questions, address concerns, and provided mental support.

Methods of Analyzing the Problem

A quantitative, quasi-experimental two-cohort study design was used to determine the success of the project's interventions. The project site's Institutional Review Board (IRB) and University of Missouri-Kansas City IRB approved the project as an exempt research project. The intervention cohort, 24 participants, was provided with the project's interventions. The baseline cohort, 24 prior patients, provided pre-intervention data for comparison. Both cohorts were matched as closely as possible demographically. Data from the CDC's report on breastfeeding was also used for comparison.

During the postpartum support calls, each participant was asked about their breastfeeding exclusivity status for the week (exclusive, partial, none). Data for breastfeeding exclusivity was recorded for each participant, each week. The baseline cohort's breastfeeding status at six weeks postpartum was extracted from their medical records. The collected data was analyzed with descriptive and inferential statistics.

Results of Analysis

Exclusive breastfeeding at six weeks postpartum was improved by 33.3% (p= .003) from 41.7% at baseline to 75.0% following the project's interventions. Duration of breastfeeding was noted as any breastfeeding (exclusive or partial). There was an increase in the duration of breastfeeding for the intervention cohort when compared to the baseline cohort with an increase of 11.7% (p= .134) from 79.2% to 90.9%. While the CDC's earliest reports on breastfeeding exclusivity are at three months postpartum, the participants of this study, at six weeks

postpartum, were exceeding the national and state of Kansas rates at three months by 23.4% and 28.1% respectively (Centers for Disease Control and Prevention, 2020a).

Recommendations

A statistically significant increase in exclusive breastfeeding (p= .003) for the intervention cohort suggests the project's interventions were successful in improving breastfeeding exclusivity to six weeks postpartum. While the total duration of breastfeeding from baseline to intervention was not statistically significant (p= .134), clinically an increase in total duration of breastfeeding at six weeks to 90.9% provides support for continuing the interventions. This increase suggests that breastfeeding support and education can decrease the number of dyads with total breastfeeding cessation.

This project's results suggest that breastfeeding outcomes can be affected through professional support from the healthcare clinic setting. Breastfeeding support interventions provided in and from the primary care setting, can improve the quality of care being provided, improve breastfeeding outcomes, reduce healthcare-associated costs, and positively impact public health. Next steps for this project could include extending the postpartum support period to either three or six months to align with national recommendations for exclusive breastfeeding or providing a second, earlier prenatal education session on the benefits of breastfeeding to help the initiation rate.