Learning about Techniques to Create Healthy Infants through Nutrition and proper Growth:

The *LATCHING* Pilot Project

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ABSTRACT

Background: Despite numerous benefits for both mom and baby, early cessation of breastfeeding and introduction of solids is common. Interventions to improve breastfeeding rates and prevent the early introduction of solids often occur in the postpartum period with variable success. Little is known about women's attitudes, perceptions, and knowledge surrounding infant feeding decisions and postpartum weight loss. The purpose of this project was to understand timing of and factors that influence infant feeding decisions (breastfeeding and introduction of solids) and barriers that women face when breastfeeding, introducing solids, and losing weight postpartum to inform future interventions. We then conducted a randomized controlled pilot and feasibility trial to evaluate the effectiveness of a prenatal behavioral lifestyle intervention (PBLI) delivered via group-based phone counseling (GBPC) on rates of breastfeeding, introduction of solids, infant feeding progression, and maternal acceptance of the intervention.

Methods: Eleven women who had recently delivered (infant age 3-10 months) were recruited from a Kansas City Metro pediatric office. All women were currently breastfeeding or had previous breastfeeding experience. Women completed a feeding survey and participated in a group interview to obtain information regarding breastfeeding, introduction of solids, and postpartum weight loss. A content and text analysis was performed to summarize the data. Second, we recruited 41 pregnant women from a Kansas City Metropolitan Obstetrics and Gynecology office and randomly assigned them to a usual care group or a PBLI. Women in the PBLI attended six GBPC sessions where they learned about breastfeeding and introducing solids. Feeding questionnaires to assess breastfeeding and introduction of solids were sent at two weeks, two months, four months, and six months postpartum. Structured interviews were also conducted

after the intervention and at six months postpartum to assess maternal acceptance and intervention feasibility.

Results: Group interviews revealed the following themes: (1) Inadequate knowledge for caring for self and infant (2) Desired knowledge from a Healthcare Provider (3) Feeding decisions were made before pregnancy and preparation took place in the second/third trimesters (4) Unmet breastfeeding goals (5) Clear guidelines on introducing solids were lacking (6) Those that achieve pre-pregnancy weight have a different body shape and weight distribution (7) and Lack of time and energy make postpartum weight loss hard. For the randomized, controlled clinical trial, rates of exclusive breastfeeding and any breastfeeding did not differ between groups at any time point. No between group differences were found for early introduction of solids or infant feeding progression. Participants overwhelming found the intervention acceptable and beneficial, empowering women to feel more prepared to breastfeed and introduce solids.

Conclusions: Overall, women do not feel they have adequate information to successfully breastfeed, introduce solids, or lose weight postpartum. Mothers also discontinue breastfeeding earlier than recommended despite high rates of initiation. Women want basic and practical information on caring for and feeding themselves and their infant. Information should be provided during pregnancy in addition to routine well child visits. In addition, A PBLI may have positive impacts such as maternal empowerment for both breastfeeding and introducing solids, however, future studies should incorporate a postpartum component.

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LIST OF ABBREVIATIONS

CDC: Center for Disease Control

US: United States

SIDS: Sudden Infant Death Syndrome

PBLI: Prenatal Behavioral Lifestyle Intervention

AAP: American Academy of Pediatrics

BF: Breastfed

GDM: Gestational Diabetes

CVD: Cardiovascular Disease

IBCLC: International Board Certified Lactation Consultant

ESPGHAN: European Society of Paediatric Gastroenterology Hepatology and Nutrition

GBPC: Group based phone counseling

BMI: Body Mass Index

CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

Initiatives to improve breastfeeding rates have increased as breastfeeding is now deemed a public health priority [1]. Additionally, the prevention of early introduction of solids is of vital importance. Both national and international experts agree that exclusive breastfeeding should occur for six months of life, at which time solid foods can be introduced, with continued breastfeeding until one year or beyond [1-4]. Despite these recommendations, the Center for Disease Control (CDC) Breastfeeding Report Card reports the United States (US) rates of exclusive breastfeeding rates are suboptimal. In the US, 83.2% of women initiate breastfeeding. However, by three months of age only 46.9% of infants are exclusively breastfed, and by six months only 24.9% are exclusively breastfed [5]. In addition, 40.4% of infants are given solids prior to four months of age [6]. Suboptimal duration of breastfeeding costs the US $13 billion annually in pediatric medical care costs by contributing to the development of childhood obesity and other diseases [7]. Not only are suboptimal feeding practices related to increased healthcare cost, but also poor health outcomes.

Breastfeeding and the appropriate introduction of solids is a public health priority due to the overwhelming evidence of beneficial outcomes for both infant and mother throughout the life span. Breastfeeding is associated with a decreased risk of infant infection [8, 9], childhood obesity [10], diabetes [11], childhood cancer [12], and a reduction in the risk of sudden infant death syndrome by 50% [13]. Breastfeeding also benefits the mother with a reduction in maternal blood loss [14], a reduction in ovarian [15] and breast cancer risk [16], child-spacing [17], postpartum depression [18], and pregnancy related weight retention [19, 20]. Early infant solid food introduction is related to an increased risk of obesity [10, 21-23]. Additionally, early introduction of solids is related to other diseases such as eczema [24], celiac disease [25], and

Type 1 diabetes [26, 27]. The combination of rapidly changing feeding recommendations, inter-provider differences, and inadequate education and support may lead to the suboptimal rates of breastfeeding and early introduction of solid foods that we see. Researchers are investigating efficient interventions to improve feeding practices.

Postnatal interventions to increase breastfeeding rates have shown some success but exclusive breastfeeding rates remain low. Few interventions target the prevention of early introduction of solids. In addition, we do not know when women are making their infant feeding decisions or what information they need to increase success. It is unknown if a prenatal behavioral lifestyle intervention (PBLI) would be successful to help women prepare, plan, and overcome barriers to continue breastfeeding to six months and introduce solids appropriately. Time and energy demands of women are high in the postnatal period, but some women seek information during pregnancy regarding the best care for their infant and to adopt healthy changes [28]. We speculate that equipping women with the knowledge to plan and overcome barriers to breastfeeding prior to delivery will result in an improvement in breastfeeding rates at six months and help prevent the early introduction of solids.

1.2 SPECIFIC AIMS

Aim 1: Conduct group interviews to understand if women would be open to a prenatal breastfeeding intervention, what information they would want to receive, and when they would want to receive it.

Aim 2: Determine if the proportion of women exclusively breastfeeding at six months differs between women participating in the PBLI during pregnancy compared to those receiving usual care.

Hypothesis 2: A greater proportion of women in the prenatal behavior lifestyle intervention will be exclusively breastfeeding at six months when compared to usual care.

Aim 3: Determine if the proportion of women introducing infant solid foods prior to four months of age differs between women participating in the PBLI compared to the usual care group.

Hypothesis 3: A greater proportion of women in the PBLI will delay complementary feeding until after four months of age compared to the usual care group.

Aim 4: Explore differences in infant feeding progression in the first six months of life between infants whose mothers are participating in a PBLI during pregnancy compared to those receiving usual care.

Hypothesis 4*:* A greater proportion of infants in the intervention will have a feeding progression that follows current feeding recommendations.

Aim 5: A process evaluation will be performed to assess subject satisfaction, barriers to recruitment, acceptability, and intervention compliance and study retention. The process analysis data will be used to refine and further develop the intervention. This is important as one of the long term goals is to develop a program that is effective and conserving of clinical resources.

CHAPTER 2

LITERATURE REVIEW

2.1 BREASTFEEDING

2.1.1 The Problem of Breastfeeding Exclusivity

Breastfeeding rates in the United States (US) do not meet expert recommendations for exclusive breastfeeding in the first six months of life and beyond [1-4]. Though still considered suboptimal, current rates for breastfeeding initiation are fairly high at 83.2% [5]. Rates of continued breastfeeding quickly decline in the postpartum period leading to poor rates of breastfeeding duration and exclusivity [5]. This failure to meet recommendations carries a cost, both medically and economically. Suboptimal breastfeeding rates lead to poor public health in the US and result in significant healthcare costs. Not meeting feeding recommendations results in $3 billion dollars in healthcare costs annually [29]. While breastfeeding has gained public attention and monetary resources, we continue to fall short of recommendations that will improve public health and healthcare costs. New and innovative interventions are needed to bridge the gap between the normative standard of exclusively breastfeeding until six months of age and our current breastfeeding practices that include higher rates of formula use.

2.1.2 Current Breastfeeding Rates

The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for the first four to six months of life with complementary foods introduced around six months, while breastfeeding is continued for up to a year and beyond, as desired by mother and infant [1]. Current breastfeeding rates differ throughout the nation. In 2018, the CDC issued its current US Breastfeeding Report Card. The report card breaks breastfeeding rates into national and state statistics of infants ever breastfed, breastfeeding at six months, breastfeeding at 12 months, exclusively breastfeeding at three months, and exclusively breastfeeding at six months. Table 2.1 depicts the most recent breastfeeding statistics for the nation and the state of Missouri. Since the

proposed intervention will take place in Kansas City, Missouri, breastfeeding statistics for Missouri are discussed. Table 2.1 also depicts the breastfeeding goals set forth by Healthy People 2020 and whether those goals have or have not been met. The goal for Healthy People 2020 called for an increase in breastfeeding initiation rates to 81.9%, an increase in exclusive breastfeeding at three months to 46.2%, an increase in exclusive breastfeeding at six months to 25.5% , and an increase in any breastfeeding at one year to 34.1 % [30]. Missouri breastfeeding rates are similar to the national rates. Overall, breastfeeding rates for initiation and any breastfeeding at 12 months were met but goals for any breastfeeding and exclusive breastfeeding at six months were not. The nation and Missouri failed to meet breastfeeding rates of any breastfeeding at six months. Missouri did meet the exclusive breastfeeding goals, but the nation did not. Despite meeting a number of goals, the nation and Missouri are still far from meeting breastfeeding recommendations with only 24.9% and 26.6% of infants being exclusively breastfed at six months, respectively. Healthy People 2030 recommendations are currently being developed and should be announced soon.

2.1.3 Benefits of Breastfeeding

2.1.3.1 Infant Benefits of Human Milk

The benefits of breastfeeding have been widely explored and experts agree that breastfeeding is best for baby and mother [1-4]. The AAP states that breastfeeding and the use of human milk is the "normative standard" for infant feeding [1]. Human milk contains immunologic and anti-inflammatory properties that protect the infant from illness and disease development [31]. In the following sections, we will discuss specific illnesses and diseases that are positively impacted by breastfeeding.

<u>Gastrointestinal Illness</u>

Infants who are breastfed have less incidence of overall gastrointestinal (GI) illnesses [8]. Breastfeeding is specifically associated with decreased rates of diarrhea [32], gastroenteritis, and necrotizing enterocolitis [33, 34]. Breastfeeding also reduces the incidence of Crohn's disease which is a disease causing inflammation in the GI tract [35].

Upper Respiratory Infection

In addition to GI benefits, breastfed infants have a reduction in upper respiratory infections such as ear infections, coughs, and wheezing compared to formula-fed infants [8, 9, 36-41]. Infants who were exclusively breastfed for at least four months had fewer ear infections (10%) than infants who were breastfed for less than four months (20.5%) [36]. Further, a great proportion of human milk intake was related to protection against upper respiratory illness [32]. Five breastfeeding classifications were determined (full breastfeeding, mostly breastfeeding, equal breastfeeding, less breastfeeding, and no breastfeeding) and incidence of illnesses such as coughing and wheezing were compared. Those who were full breastfeeding, mostly breastfeeding, or equal breastfeeding had the lowest incidence of coughing and wheezing compared to those who were classified as less breastfeeding or no breastfeeding. A similar study by Duijts et al. [42] also found that exclusive breastfeeding was more protective against overall illness. Infants exclusively breastfed for at least four months had decreased upper and lower respiratory tract infection risk.

Atopic Disease

Additionally, breastfed infants experienced reduced atopic diseases such as atopic eczema, respiratory allergy, and food allergy [10, 43]. In a study by Saarinen et al. [43], authors found that "prolonged breastfeeding" (which they defined as six months or longer) was protective against food allergy, eczema, and respiratory allergy into childhood and adolescence.

Sudden Infant Death Syndrome

The cause of sudden infant death syndrome (SIDS) is not clearly understood, however evidence regarding breastfeeding and the reduction of SIDS is vast [13, 44-46]. Vennemann et al. [13] found a 50% risk reduction for SIDS in infants exclusively breastfed for at least one month. A 2011 meta-analysis [44] showed a risk reduction of SIDS and reported a greater risk reduction with exclusive breastfeeding.

Cancer

Reduced risk for childhood cancer is another proposed benefit of breastfeeding. Children who were fed formula only or breastfed for six months or less had higher cancer risk when compared to infants who were breastfed for more than six months [12]. A review of nine case controlled studies found that breastfeeding for six months or less was associated with the development of Hodgkin's Disease, hypothesizing that those infants had a suppressed immune system development [47]. A more recent study by Greenop et al. [48] found that any length of breastfeeding was associated with a reduced risk of acute lymphoblastic leukemia.

Cognitive Development

Improved cognitive development is another proposed benefit for infants who are breastfed. However, this concept is controversial. A 2011 cluster randomized controlled trial investigated differences in cognitive ability at age six and a half years between infants receiving a breastfeeding promotion intervention and those receiving usual feeding care [49, 50]. About 17,000 healthy breastfed infants in Belarus were enrolled into the study, and about 14,000 children were followed up at six and a half years of age. Mother infant dyads in the intervention received breastfeeding assistance in the hospital and early postnatal period. Cognitive ability was

assessed by Wechsler Abbreviated Scales of Intelligence scores and teacher assessment of reading and writing. The intervention group was significantly more likely to be exclusively breastfed at three months of age (43.3% versus 6.4%) and to engage in any amount of breastfeeding at 12 months. At six and a half years, children who received the intervention had significantly higher mean scores on all outcomes of the Wechsler Abbreviates Scales of Intelligence. The authors concluded that increased exclusivity and duration of breastfeeding lead to higher cognitive development.

Obesity and Diabetes

Finally, infants who are breastfed experience a reduced risk of chronic diseases such as diabetes [11, 51] and obesity [10, 52, 53]. A systematic review of seven studies examined the odds of developing type 2 diabetes later in life between breastfed and formula-fed infants [11]. Results indicated a significantly lower risk for developing diabetes in those infants who were breastfed. Mayer et al. [51] found a decreased risk for type 1 diabetes in a retrospective study looking at infants who were breastfed for one year or longer. Obesity is another chronic condition affected by breastfeeding, however, the relationship is somewhat controversial. In 1981, Kramer et al. [10] conducted a case control study on 639 children between the ages of 12 and 18. Breastfeeding was protective and the effect rose slightly with increased duration of breastfeeding. A more recent systematic review by Cordero et al. [52] concluded that there is a causal relationship between breastfeeding and childhood obesity prevention. The highest level of benefit was found in infants who were breastfed exclusively for six months and then continued until two years of age. Li et al. [53] found that higher breastfeeding intensity was negatively associated with excess weight in infants greater the six months. Low and medium intensity breastfeeding (less than half of feedings from human milk or about half of feeding from human

milk, respectively) increased the risk for excess weight in later infancy (> six months). The authors concluded that this could contribute to obesity development. The association between breastfeeding and obesity continues to be a hot topic for research and we will continue to learn about any role breastfeeding may have in the prevention of childhood obesity.

According to experts, exclusive breastfeeding for the first six month of life is the normative standard of feeding a woman should strive to attain. As previously discussed, the benefits of breastfeeding for the infant are unmatched by alternative feeding methods such as formula. Not only does breastfeeding benefit the infant, but also the mother. As such, the maternal aspects of breastfeeding will now be reviewed.

2.1.3.2 Maternal Benefits of Breastfeeding

The maternal benefits of breastfeeding are numerous. Immediate benefits include less blood loss in the postpartum period [14]. Benefits also extend much later after the postpartum period to later in life. Women who exclusively breastfeed for a duration of at least one month have a decreased risk of developing type 2 diabetes [54]. A reduction in type 2 diabetes risk is particularly important for those mothers who experienced gestational diabetes (GDM) because they are at an increased risk for developing type 2 diabetes later in life [55]. Breastfeeding in women who experienced GDM during pregnancy is associated with improved insulin response and glucose tolerance [56]. A reduction in the risk of certain cancers is another maternal benefit of breastfeeding. Mothers who breastfeed decrease their risk of breast cancer by 4% for every year of breastfeeding [57] and BRCA1 mutation carriers can decrease their risk of breast cancer by 37% with one to two years of breastfeeding [58]. In addition, a meta-analysis of 40 epidemiological studies found a protective affect for ovarian cancer with breastfeeding [15, 59, 60]. An inverse association between breastfeeding duration and cancer risk was found [59].

Cardiovascular disease (CVD) is the top killer of women throughout the world [61]. Breastfeeding offers a reduced risk of hypertension, hyperlipidemia, and overall cardiovascular disease [62]. Breastfeeding is also associated with a decreased risk of maternal weight retention which will be discussed in more detail in the coming sections. Finally, breastfeeding is associated with a decreased risk for postpartum depression (PPD) [20]. In a study by Borra et al. [18] it was suggested that the PPD association with breastfeeding depended upon the mother's intent to breastfeed and if she was then able to breastfeed successfully. The lowest rates of PPD occurred in women who intended to breastfeed and went on to breastfeed successfully, and the highest rates occurred in women who expressed intention to breastfeed but did not follow through or were unable to breastfeed. It is clear that breastfeeding provides a variety of benefits to both mother and baby.

2.1.4 The cost benefit of breastfeeding

2.1.4.1 Infant benefits

Formula feeding in the US is a large financial burden for the public and for individual families. The cost to purchase standard infant formula for an exclusively formula-fed infant is between $750 and $1200 per year [63]. In addition, healthcare costs are more expensive for formula-fed infants. When compared to breastfed infants, formula-fed infants had excessive office visits, hospitalizations, and prescription usage costing between $331-$475 in the first year of life [64]. Further, suboptimal breastfeeding rates cost the US $13 billion dollars and 911 excess deaths annually [7]. A simulated cost analysis using Monte Carlo simulation models found that suboptimal breastfeeding rates account for $3 billion dollars in medical costs, $1.3 billion in non-medical costs, and $14.2 billion in costs associated with premature death [29]. Another cost analysis concluded that if 90% of women met current breastfeeding

recommendations the economy would save $3.7 billion dollars in both direct and indirect infant health care costs [65]. Additionally, $10.1 billion dollars would be saved with reduced premature death from pediatric diseases.

2.1.4.2 Maternal benefits

Another cost analysis looked at maternal disease development in women who met breastfeeding recommendations compared to women who did not meet recommendations. In those not meeting recommendations, they found higher rates of breast cancer, hypertension, and heart attacks costing $17.4 million dollars [66]. Meeting breastfeeding recommendations has a significant financial benefit for both for individual families and the nation.

2.1.5 Reasons for Early Breastfeeding Cessation and Maternal Needs for Success

Breastfeeding cessation is common, and the reasons associated with cessation are varied. Many studies attempted to capture characteristics of women who stop breastfeeding early, practices that lead to early breastfeeding cessation, and maternal reasons for terminating breastfeeding early. Studies found that women who do not initiate breastfeeding or do not meet breastfeeding recommendations were single, younger than 25 years, a current smoker, less educated, multiparous, delivered a low birth weight infant, and a WIC participant [67-69]. In addition to maternal characteristics predicting breastfeeding cessation, policies and behaviors at the hospital can play a role in breastfeeding duration.

There are certain practices in the hospital that can hinder establishment of breastfeeding leading to decreased breastfeeding exclusivity and duration. Examples of these practices include foregoing skin to skin contact early after delivery, separation of mother and infant, and unnecessary formula supplementation [70]. In-hospital formula supplementation is another example of a practice that reduces breastfeeding success. Regardless of reported initial intent to

breastfeed, mothers of infants who received formula supplementation in the hospital were three times more likely to stop breastfeeding by day 60 [71]. The top three reasons women were given formula in the hospital were perceived maternal insufficient milk supply, signs of inadequate infant intake such as poor weight gain or decreased urine and stool output, and poor latching or breastfeeding [71]. Legler-Leblanc et al. [72] conducted a study on women participating in a prenatal nutrition program that included information on healthy nutrition practices and breastfeeding. Breastfeeding initiation and duration rates were low with no women breastfeeding to six months. The study found factors positively associated with breastfeeding initiation were primiparity, attending prenatal classes, having been breastfed themselves, and intention to breastfeed at 36 weeks gestation. Breastfeeding duration was positively associated with paternal education, intention to breastfeed at 36 weeks gestation, no formula or water supplementation in the hospital, and maternal hemoglobin levels above 127 g/L. As we can see, many factors in the hospital can affect the establishment of and thus continuation of breastfeeding.

Infant mode of delivery and maternal complications may also play a role in breastfeeding cessation. A study conducted in the United Kingdom found that women with delivery complications breastfed for a shorter duration than those with no complications [73]. Specifically, women who delivered via caesarian section, experienced fetal distress, failed to progress in labor, or experienced postpartum hemorrhage breastfed for a shorter time period. These same women were also more likely to cite reasons for cessation, such as pain and breastfeeding difficulties, if they experienced delivery complications, with no difference in perceived support.

Successful breastfeeding in the first few days of life is critical as it may predict breastfeeding cessation, of which the reasons are variable. The top reasons for breastfeeding

cessation included perceived maternal nipple pain, inadequate milk supply, infant difficulties, and a notion that the infant was not full [68]. Women also cite cessation of breastfeeding early in the postpartum period due to sore nipples and a delay in milk "coming in". After the first few weeks of breastfeeding, up to six months postpartum, the most common reasons for cessation included difficulty with latching and poor milk supply [74]. Thus, there are several reasons that women stop breastfeeding early, and this can often lead to a woman not reaching her own breastfeeding goals.

While meeting expert feeding recommendations is important, it is also vital to understand if women are meeting their own breastfeeding goals. In 2013, Odom et al. [67] conducted a study aimed at determining whether or not mothers met their own breastfeeding duration goals (despite meeting current recommendations) and reasons behind success or lack of success. In a sample of almost 1200 women (taken from the Infant Feeding Practices Study II), researchers found that 60% of mothers did not meet self-established breastfeeding goals. The top four reasons cited for early termination were difficulties with lactation, infant nutrition and weight gain, illness or need to take medication, and the effort associated with pumping. A more recent study by Brown et al. [75] examined why women stopped breastfeeding prior to six months. They found that most women (73%) had stopped breastfeeding prior to six weeks. The most common reasons were inconvenience or tiredness related to breastfeeding, milk supply concerns, or returning to work or school. Balogun et al. [76] found that women in developing countries also cited return to work or school as a barrier to breastfeeding duration. Appropriately tailored education and adequate support for women is necessary, particularly in the early weeks, to improve success at meeting breastfeeding recommendations.

2.1.6 Maternal Needs for Successful Breastfeeding

Breastfeeding can be difficult, and women may have specific needs to help them be successful. Recurring themes from research suggest a lack of education regarding the breastfeeding experience and maternal support are contributing factors to early breastfeeding cessation. A survey from the Pregnancy Risk Assessment Monitoring System (PRAMS) asked women if "During any of your prenatal care visits, did a doctor, nurse, or healthcare worker talk with you about breastfeeding my baby?" Overall, 82.7% of women responded yes [77]. This indicates that most women have at least had a brief encounter with a healthcare professional to discuss breastfeeding during pregnancy. However, this brief encounter is inadequate for achieving optimal breastfeeding duration as evidenced by suboptimal breastfeeding rates. It is vital that we determine what education and support is needed to facilitate women reaching breastfeeding recommendations. Deitrich Leurer et al. [78] distributed a survey to determine what information was helpful and what information women wished they had received while breastfeeding. For those women who expressed unmet needs, they cited the following topics for which additional information was desired; milk supply management, frequency and duration of feedings, proper latch and feeding positions, nipple care, expressing human milk, nutrition sources, and practical advice regarding common concerns. Provider and familial support in the prenatal period is also important for improving breastfeeding success [79]. Additionally, women express a desire for prenatal breastfeeding education that sets up realistic expectations for the upcoming breastfeeding experience [80]. This information regarding maternal needs for successful breastfeeding is imperative for developing future interventions to improve breastfeeding rates. Current interventions aimed to improve breastfeeding rates will be discussed next.

2.1.7 Current Interventions to Improve Breastfeeding

2.1.7.1 Postpartum Interventions to Improve Breastfeeding

Many breastfeeding interventions are conducted in the postpartum period. A systematic review of postpartum interventions designed to increase breastfeeding rates at six months was conducted by Skouteris et al. [81]. Seventeen randomized trials were analyzed, of which 15 were conducted in the postpartum period. Results of the review were mixed and they cited poor assessment of intervention fidelity as a reason. Researchers found the most successful interventions performed in the postnatal period were substantial in duration and involved peer support programs or additional support provided by trained lactation consultants in the home or via phone. Lavender et al. [82] completed a Cochrane Review of randomized control trials to assess the effectiveness of telephone support during pregnancy and up to six weeks postpartum for maternal and infant outcomes. When looking specifically at breastfeeding as an outcome, nine studies were reviewed with all but one being conducted in the postpartum period. Overall, studies with longer-term breastfeeding outcomes showed that telephone support increased the rates of any breastfeeding and the length of exclusive breastfeeding. Simonetti et al. [83] conducted structured telephone interviews with 115 new mothers on a weekly basis for six weeks after delivery. Women receiving telephone interviews were significantly more likely to be exclusively breastfeeding at one, three, and five months. Giglia et al. [84] found that an internet support site was an effective intervention for improving breastfeeding rates at six months. Four hundred fourteen women from the Regional Infant Feeding Study in Western Australia were randomized into a control versus intervention group. The intervention group was given access to an internet site providing "best practice" feeding recommendations for 12 months. Participants were able to post discussions, email other study participants, and contact a lactation consultant

through the website. At six months, women in the intervention were significantly more likely to be exclusively breastfeeding. Fu et al. [85] conducted a multicenter, three arm, randomized control trial in the postpartum period. The study consisted of 772 first-time mothers and their infants who were randomized into one of three groups; standard care, standard care plus three in-hospital sessions conducted by a breastfeeding professional, or standard care plus weekly breastfeeding telephone support for four weeks. Overall, women in either intervention arm had high rates of any or exclusive breastfeeding across the first six months. The telephone support intervention specifically had a significant impact on rates of any breastfeeding at one and two months and on rates of exclusive breastfeeding at one month. In contrast, a randomized control trial by Bunik et al. [86] found that women who received daily telephone calls about breastfeeding by a nurse for two weeks after hospital discharge had the same rates of breastfeeding as women who received standard care. A perceived insufficient milk supply was the primary reason given by women for early cessation in both the control and intervention group. Researchers determined that early supplementation of formula prior to discharge and the start of the phone calls, may have been a contributing factor resulting in insignificant results.

After reviewing current evidence regarding postpartum interventions to improve breastfeeding rates, it is clear that postpartum interventions have had some success. However, it is not clear what support is most effective and having support such as a lactation consultant in the postnatal period is not always feasible and can be cost-prohibitive. Given that breastfeeding rates at six months of age remain significantly below recommendations with postnatal interventions, further interventions need to be explored. We hypothesize that starting an intervention during pregnancy will increase breastfeeding rates. Therefore, a review of prenatal interventions that have been completed will be discussed next.

2.1.7.2 Prenatal Interventions to Improve Breastfeeding

The prenatal period is a logical time to intervene to improve breastfeeding rates because previous research suggests the prenatal period is a "critical time" for infant feeding decisions [87]. In a secondary analysis of the National Maternal Infant Health Survey with a sample of 5,143 black mothers, Timbo et al. [87] found breastfeeding advice from a medical provider during the prenatal period and breastfeeding education during prenatal birth classes was associated with increased breastfeeding rates. Additional studies indicate a lack of prenatal education as a barrier to improved breastfeeding rates [77, 88]. In the 2005 AAP Policy Statement from the Section on Breastfeeding, Gartner et al. [88] highlights inadequate prenatal breastfeeding education as a root cause for poor rates of breastfeeding initiation and duration. Additionally, Lind et al. [77] conducted a study using 2010 PRAMS data to determine how many women received breastfeeding education during the prenatal period. Eighty-two percent of women indicated breastfeeding was discussed during the prenatal period. However, rates differed by ethnicity, income level, and level of education. Only 79.4% of non-Hispanic white women, 76.9% of higher income women, and 77.9% of women with a high school education reported receiving advice from a provider during the prenatal period. While these rates are high, it indicates that about 20% of women receive no information at all in the prenatal period regarding breastfeeding. Authors concluded that inadequate prenatal education regarding breastfeeding is a primary factor related to poor breastfeeding rates. These studies provide the rationale to support an intervention in the prenatal period aimed at improving exclusive breastfeeding rates.

Data support that educational interventions are effective at increasing breastfeeding initiation rates [89], and therefore we hypothesis that an educational intervention would also be effective at improving exclusive breastfeeding rates. However, current evidence on prenatal

interventions to improve exclusive breastfeeding rates or duration of breastfeeding is unclear. Lumbiganon et al. [90] completed a Cochrane systematic review of prenatal breastfeeding education interventions to evaluate the effectiveness on breastfeeding duration. The review focused on breastfeeding education and not breastfeeding support, which is aimed at an individual person given, as the need arose, by an individual, group, or organization. Interventions that appeared within the review included breastfeeding education, formal breastfeeding education, printed information, video, peer counseling, and lactation consultation. Overall, authors found significant methodological differences in the types of studies but concluded that peer support, formal breastfeeding education, and the use of lactation consultations may be effective at increasing breastfeeding duration. Due to methodological differences, they urged conducting additional randomized control trials with adequate power to further investigate the effectiveness of prenatal breastfeeding education interventions. Previous studies suggest a prenatal breastfeeding intervention is an effective way to improve breastfeeding rates [91-93]. Kistin et al. [92] found prenatal breastfeeding education sessions and individual counseling sessions improved breastfeeding rates in the early postpartum period. This US trial randomized 159 low SES, black women less than 24 weeks gestation into a control group, prenatal classes group, or prenatal individual counseling group. Women in the class intervention attended at least one 50-80 minute group breastfeeding education session led by study investigators. Women in the individual counseling group attended a face to face 15-30 minute session led by a study investigator. The measured outcomes were breastfeeding (at least one session of breastfeeding per day) in the hospital and at two weeks, six weeks, and 12 weeks. Authors found that both interventions improved breastfeeding rates in the hospital (45% classes, 50% individual sessions, 22% control). Participants in the individual session intervention were more likely to be

breastfeeding at two weeks compared to the control group (36% vs 18%). No differences were found at six weeks but at 12 weeks, women in the class intervention were significantly more likely to be breastfeeding. Authors cited the higher rates of breastfeeding at 12 weeks within the class intervention could be due to more contact hours associated with the breastfeeding class or the effect of peer support within a group setting. Mattar et al. [93] conducted a study in Singapore to assess the effect of simple prenatal education on breastfeeding rates. A total of 401 healthy women who were at least 36 weeks gestation were randomized into one of the following groups: Group A – educational material with a 15 minute face to face session conducted by a lactation counselor, Group B – educational material only, or Group C – no intervention. Exclusive and predominant breastfeeding at two weeks, six weeks, three months, and six months were the primary outcomes. Women receiving a combination of educational materials and a one-on-one session with a lactation consultant were more likely to be exclusively or predominantly breastfeeding at three months compared to those receiving no intervention or educational materials alone.

The previous studies indicate improved breastfeeding rates with prenatal education. In contrast, we will now discuss two reviews and a randomized control trial that showed no effect on increasing breastfeeding rates. A recent review by Patnode et al.[94] looked at primary care interventions to support breastfeeding. When looking specifically at the four prenatal only intervention studies that were reviewed, no significant differences were seen in breastfeeding rates. One limitation was that all studies were short in duration (three lasted a single day and one lasted two weeks). A systematic review by Wong et al. [95] compared individual versus group education interventions, looking at both breastfeeding duration and exclusivity. Inclusion criteria required studies to be randomized control trials or quasi-experimental and to report on rates of

"any breastfeeding" or "exclusive breastfeeding." Studies had to occur during the prenatal period. Definitions of "any breastfeeding" and "exclusive breastfeeding" were developed using current WHO definitions. A total of 19 studies were reviewed providing a sample size of 6931 healthy, pregnant women. Overall, authors found both group and individual prenatal education only improved breastfeeding rates in populations at risk for suboptimal breastfeeding (ie. low-income or low-education participants). Authors could not draw conclusions on the effectiveness of either method due to methodological differences and a limited number of high-quality studies. In a randomized controlled trial by Wong et al. [96], 469 first-time Hong Kong mothers who were at least 35 weeks gestation were recruited and randomized to one-on-one prenatal breastfeeding education or standard care. The one-on-one intervention consisted of a single 20 to 30 minute breastfeeding education session delivered by the author who was a registered nurse with breastfeeding experience. Participants were encouraged to ask questions throughout the session and were also given 10-15 minutes for additional questions after the education session ended. The primary outcome was exclusive breastfeeding at six weeks. Thirty seven and a half percent of women in the intervention group were exclusively breastfeeding at six weeks postpartum compared to 36.4% in the control group, showing no significant differences. Secondary outcomes included exclusive breastfeeding at three and six months and the duration of any breastfeeding at six months. No significant differences were found between the intervention and standard care groups for any outcomes. Authors hypothesized that a single education session was inadequate for improving breastfeeding outcomes and more intensive prenatal education may be beneficial.

In conclusion, more research is needed to determine when to initiate education, information to be discussed (such as practical information for common breastfeeding concerns,

milk supply management, etc.), and the intensity level required to improve breastfeeding rates. Prenatal education to increase breastfeeding rates is an interesting approach that requires further research to validate effectiveness and determine what method is best for information dissemination.

2.1.7.3 Combination Interventions to Improve Breastfeeding

Previous sections have discussed both postpartum and prenatal interventions separately to improve breastfeeding rates. However, some interventions utilize the combination of prenatal breastfeeding education and postpartum breastfeeding support. Bonuck et al. [97] conducted a randomized control trial in Bronx, New York on 304 women that combined prenatal and postnatal care to improve breastfeeding rates. The study compared usual care to an intervention where lactation consultants provided two prenatal visits, a hospital visit postpartum, and/or home visit, and telephone calls. Researchers found the intervention group was more likely to be breastfeeding (53% intervention vs 39% control) at 20 weeks postpartum with a higher level of intensity (a higher proportion of human milk versus formula). However, exclusive breastfeeding rates did not differ between groups. The authors noted that a low number of lactation consultant contact hours with the intervention participants as a possible reason for their lack of success at improving exclusive breastfeeding rates. Only 44% of participants received assistance from a lactation consultant during both the prenatal and the postnatal period, and about 24% of intervention participants received no lactation assistance at all. Low contact was due to circumstances such as declined lactation consultant assistance, difficulty in locating participants, and lactation consultants only working half-time. A more recent study by Schreck et al. [98] tested the effectiveness of a hospital based prenatal and postnatal breastfeeding intervention. Six hundred and fifty low-income women were recruited from a Detroit teaching hospital prenatal

clinic and randomized to control or intervention. Women in the intervention received 10 optional breastfeeding education lessons taught by an International Board Certified Lactation Consultant (IBCLC) while in the prenatal clinic waiting room and had a breastfeeding support group made available to them after delivery. Women who received the prenatal intervention were significantly more likely to initiate breastfeeding, however, there were no differences in breastfeeding continuation. Only 42 women in the intervention group received both the prenatal education and attended an average of 3.15 sessions at the breastfeeding support group. Participation in both the prenatal and postnatal intervention increased the length of breastfeeding continuation. Approximately ninety-two percent of women indicated that prenatal education influenced their feeding decision and 79.5% indicated that it was helpful in prolonging breastfeeding. Further, 95.2% of women indicated that attending breastfeeding support groups was helpful in prolonging breastfeeding. Combination interventions may have some advantage in providing both education prior to delivery and physical support in the postnatal period. However, despite this potential advantage and some success at improving breastfeeding rates, combination interventions place a large burden on both time and monetary resources. The implementation of combination interventions is often not realistic or cost-efficient in research or primary care settings.

In conclusion, more research needs to be done regarding appropriate interventions to improve breastfeeding rates. To date, postpartum interventions alone have been inadequate to improve breastfeeding rates. A recurrent theme from research is that interventions would be more effective beginning in the prenatal period. Therefore, we aim to implement a prenatal intervention with a high level of contact hours to increase rates of exclusive breastfeeding at six months.

2.2 INTRODUCTION OF SOLID FOODS

As reviewed previously, breastfeeding is recommended for the first six months of life followed by the introduction of complementary foods (also referred to as solid foods). Next, the discussion will consist of the purpose of introducing solid foods, historical and current recommendations regarding solid foods, problems associated with inappropriate introduction of solid foods, reasons for early introduction of solid foods, and current interventions to promote appropriate introduction of solid foods.

Complementary feeding is defined by the AAP as "providing nutrient-containing foods or liquids along with human milk, and includes both solid foods and infant formula" [99]. A complementary food is defined as "any energy containing food that displaces breastfeeding and reduces the intake of human milk" [100]. Typically, the introduction of complementary food is viewed as the time when you begin offering solid foods such as infant cereal or pureed fruit and vegetables in addition to human milk. A complementary food can also include the introduction of formula, but for the purpose of this review, we will focus on the introduction of solid foods. Solid foods are started to complement the diet with nutrients that may not be sufficient in human milk alone [101]. Recommendations on introducing solid foods have changed throughout the years and will be discussed in detail in the next section.

2.2.1 Historical and Current Recommendations for the Introduction of Solid Foods

In the US, current infant feeding recommendations come from the AAP Committee on Nutrition. This committee was formed in 1954 to address important feeding concerns related to infants and children. Their first report outlining infant feeding recommendations was delivered in 1958 due to rising concerns of very early introduction of solid foods, based on opinion and not science [102]. Their aim was to review the current evidence and give guidance on introducing

complementary foods. In their report, the committee points out that complementary foods were not introduced before 12 months of age prior 1920. However, as of 1954, 88% of pediatricians were recommending solids before three months of age and 66% before eight weeks. After reviewing available evidence, the committee concluded that healthy, term infants could be sustained by human milk or formula alone with iron-containing foods being introduced during the third month. In 1980, the committee published another report with new recommendations [103]. This report concluded that infant feeding needed to include both a nursing period and a transition period. The nursing period should last for a minimum of four to six months followed by the transitional period which included complementary foods. The recommended time for introduction of solids changed from three months to four to six months. This change was due to evidence suggesting infants did not have the neuromuscular development needed to safely eat solids before four months. These recommendations remained stable until 2001.

In 2001 [104], Kramer and Kumar conducted a Cochrane review of 16 studies from both developed and developing countries. They compared the effect of exclusive breastfeeding for six months versus three to four months on infant growth, development, and overall health. They concluded that exclusive breastfeeding should occur for six months because evidence supported that infants who were exclusively breastfed for six months, as comparted to exclusive breastfed for three to four months, experienced less gastrointestinal illnesses without any noted deficiencies in growth or nutrients. Women also experienced a longer period of lactational amenorrhea helping with child spacing. Predominant health organizations, such as the AAP and WHO, adopted these new recommendations. To date, the current recommendations from the AAP is “exclusive breastfeeding for about six months followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding one year or longer as

mutually desired by mother and infant" [1]. Delaying introduction of solids until six months is also recommended because there is evidence suggesting that introducing solid foods prior to six months of age can reduce human milk intake [105, 106].

Despite the official AAP policy statement outlining recommendations for the introduction of complementary foods, disagreement within the AAP exists. The AAP Committee on Nutrition, and the AAP Section on Breastfeeding have different recommendations. The AAP Pediatric nutrition handbook states that complementary feeding can begin between four and six months of age, with developmentally readiness as a guide [99]. The APP Section on Breastfeeding recommends exclusive breastfeeding until "about" six months [1]. To add to confusion, in 2010, Baker et al. and the AAP Committee on Nutrition [107] developed recommendations for the prevention of iron deficiency and iron deficiency anemia in infants. Recommendations included supplementing healthy term infants with iron or introducing iron containing complementary foods at four months. Backlash quickly ensued, and several responses were submitted in disagreement with these recommendations [108-110]. Furman et al. [108] argued that the recommendations were premature as they were based on a single study with limited ability to draw conclusions. Seventy-seven term infants between the age of one month and six months received either 7.5 mg of daily iron or a placebo. Furman points out that 34% of participants did not complete the study, 19% were non-compliant with the recommendations, the majority were not exclusively breastfeeding, and all but three participants were receiving iron fortified cereal. Hernell et al. [109], also voiced concern on the change in recommendations based on a single study. The authors discussed a Swedish study in which breastfed infants were given the same level of supplementation as the study in which recommendations were based. Those infants displayed poor linear growth showing potential adverse effects of iron

supplementation for all infants. Finally, on behalf of the AAP Section on Breastfeeding [110], additional concerns were voiced about universal iron supplementation recommendations and called for a retraction of the recommendations. In addition to concerns with recommendations being formed based on one study, they pointed out that the recommendations had been submitted to the committee for review but had been rejected. This rejection was not mentioned in the official recommendations. There was also concern that the recommendations failed to address any potential harms of universal iron supplementation. This debate has added to the ongoing confusion surrounding the timing of introducing complementary foods.

The AAP Committee on Nutrition is not alone in questioning the six-month guideline for exclusive breastfeeding. Emerging evidence discusses the benefit of starting solids prior to six months of age for the reduction of allergies. Symon et al. [111] reviewed evidence regarding the introduction of complementary foods from four months of age and argued that recommendations should be changed back to four to six months instead of six months. He hypothesizes that the gut may have a specific window for introducing solids to allow the development of immunological tolerance and our currently delayed recommendations are leading to an increase in allergy prevalence.

Evidence is mixed and remains controversial regarding whether complementary foods should be introduced at four or six months of age, and which infants might benefit from different timing of introduction. For the most part, experts appear to be deferring to the recommendation of exclusive breastfeeding for six months to protect breastfeeding and avoid adverse complications associated with early weaning [112]. However, these differing recommendations cause parents and healthcare providers' frustration and confusion. While research is needed to clarify and define recommendations, we can certainly see that solid foods are not recommended

prior to four months of age. Therefore, we will now discuss incidence of early introduction of complementary foods and the problems associated with early introduction.

2.2.2 The Problem of Inappropriate Introduction of Solid Foods

Research reports between 20-40% of parents in the US are introducing solid foods prior to four months of age [6, 113, 114]. According to a sample of 1334 mothers drawn from the Infant Feeding Practices Study II, 40.4% of women introduced solids prior to four months of age [6]. Previous studies documented rates of solid food introduction prior to four months of age between 19% and 29% [113, 114]. There are many reasons, both developmentally and medically, to delay the introduction of solid foods until four to six months of age as recommended by pediatric authorities. Developmentally, infants are unable to handle solids until they reach four to six months of age due to the tongue extrusion reflex and poor neuromuscular development [115]. Medically, current recommendations were implemented due to evidence that the introduction of solid foods prior to four months of age is associated with an increased risk of obesity [10, 21-23], eczema [24], celiac disease [25], and diabetes [26, 27] which will now be discussed in more detail.

Early introduction of solid foods can have a vast and far reaching impact. Currently, obesity prevention is of interest. Research shows that early introduction of solid foods puts infants at risk for later obesity [21-23]. A secondary analysis of Infant Feeding Practices Survey II data by Gaffney et al. [22], including 691 infants, examined four feeding behaviors and their relationship to weight-for-age at one year. The four behaviors were no bottles to bed, minimal juice consumption, breastfeeding throughout the first year, and no solid foods prior to four to six months of age. Gaffney et al. found early introduction of solid foods, juice consumption, and not breastfeeding in the second six months of life to be associated with elevated weight for length at

one year of age. Another study by Huh et al. [21] examined the age at introduction of solid foods and obesity risk at three years of age. This study was conducted in Massachusetts with 847 participants. Infant/child feeding information was obtained from the mother via questionnaire at birth, six months, and three years and child weight and height was measured by research staff at three years. Introduction of solid food was broken down into three age ranges; less than four months, four to five months, and greater than or equal to six months. Huh et al. found that among formula-fed infants or infants who discontinued breastfeeding prior to four months of age, introduction of solids prior to four months of age was associated with a six-fold increase in obesity risk at age three.

Reducing the risk of future obesity is not the only reason to prevent the early introduction of solid foods. In a systematic review by Tarini et al. [24], the early introduction of solid foods was associated with an increased risk of eczema. Additionally, evidence suggests that celiac and diabetes risk can be reduced by appropriate introduction of solid foods. Agostoni et al. [26] suggested that prevention of celiac disease, type 1 diabetes, and wheat allergy requires abstaining from introducing gluten prior to four months of age or delaying until after six months of age. Additionally, gluten should be introduced while breastfeeding is continued. A study by Rosenbauer et al. [27] found that preschool children who were introduced to solid foods after five months of age, in comparison to before five months of age, had a reduced risk of type 1 diabetes.

Evidence suggests that early introduction of solid foods prior to four to six months may have health related ramifications. Due to this, most committee and organization recommendations encourage delaying solid food introduction until six months of age. However, new evidence is emerging that delaying introduction of solid foods until six months or later may

be contributing to the recent increase in the prevalence of food allergies. Nwaru et al. [116] analyzed the data of 994 children from a prospective birth cohort in Finland. The association between age at introduction of solid foods and allergic sensitization at five years of age was the primary outcome. Nwaru et al. found that delayed introduction of solid food was related to increased allergic sensitization to food and inhalant allergens at 5 years old. In 2008, Agostoni et al. [26] authored a commentary from the European Society of Paediatric Gastroenterology Hepatalogy and Nutrition (ESPGHAN) outlining recommendations for feeding solid foods based on a review of current literature. Specific recommendations were made regarding delayed introduction of gluten. Gluten is recommended to be introduced gradually before seven months (but after four months) while the infant is still breastfeeding to reduce the risk for celiac disease, type 1 diabetes, and wheat allergy. As discussed previously, there is some concern that delaying iron containing solid foods until six months of age can lead to decreased iron levels; however, this is controversial [117]. Further research should be done to determine if recommendations to delay solids until six months of age is still appropriate in populations such as the United States.

2.2.3 Reasons for Early Introduction of Solid Foods

Solid foods are introduced early for a variety of reasons. Clayton et al. [6] conducted an observational study of 1334 mothers and their infants to determine adherence to current recommendations and reasons for non-adherence. They found that overall, 40.4% of participants gave solids earlier than four months. Additionally, they found that early introduction was affected by feeding type. Amongst breastfeeding women, 24.3% of women introduced solid foods prior to four months in comparison to formula-fed and mix-fed infants (52.7% and 50.2%, respectively). The most common cited reasons for introduction of solids prior to four months of age were “my baby was old enough,”, “my baby seemed hungry,”, “I wanted to feed my baby

something in addition to breast milk or formula,", "My baby wanted the food I ate,", "A doctor or other healthcare professional said my baby should begin eating solid food", and "It would help my baby sleep longer at night." Over 90% of these mothers chose "my baby was old enough to begin to eat solid food" as the reason for early introduction which indicates a need for accurate education on the appropriate age to introduce solid foods. It should also be noted that 55% of women indicated their healthcare provider told them to introduce foods prior to four months of age. This is concerning and potentially suggests needed education for healthcare providers, but also highlights their impact on parental choices regarding the introduction of solid foods.

Given the short-term and long-term consequences of early introduction of solid foods and the fact that such a large proportion of solid foods are being introduced to infants prematurely, interventions aimed to educate parents regarding the proper introduction of solid foods are needed.

2.2.4 Current Interventions for Appropriate Introduction of Solid Foods

Current interventions to encourage appropriate introduction of solid foods are lacking despite the strong evidence of their health impact. In 2008, Dewey et al. [118] conducted a systematic review of 42 papers discussing solid feeding interventions in developing countries. They found that interventions are generally begun between the ages of six to 24 months and are primarily initiated due to health problems such as growth stunting, infectious illnesses, and micronutrient deficiencies. They concluded that there were no "best package" regarding needed components for the intervention, but the intervention depended greatly on the needs of the targeted population. Unfortunately, these results have little implication for the target of preventing childhood obesity. A more recent systematic review was conducted by Arikpo et al. [119] in 2018 to determine the effectiveness of educational interventions on complementary

feeding practices. Included studies primarily looked at outcomes related to appropriate age at introduction of solids, types and amounts of foods introduced, and hygiene. They found that educational interventions are effective for improving the timing of introducing solid foods. Another study by Taveras et al. [120] used a pediatric primary care intervention to promote healthy behaviors in mothers and their infants, age birth to six months. Targeted infant health behaviors included improving feeding, improving sleep duration, and decreasing TV viewing. The six-month intervention enrolled 60 mother infant dyads recruited from two Boston pediatric offices. Twenty-four dyads were enrolled in the usual care group which attended the standard schedule for pediatric visits in the first six months of life (two weeks, one, two, four, and six months). The intervention group attended the same visits, but was given additional infant health information from a health educator using brief focused negotiation skills, which is a form of motivational interviewing. No differences were found between breastfeeding duration or exclusivity but there were significant differences between groups for the introduction of solids. Infants in the intervention group were less likely to start solids before four months of age (57%) compared to the usual care group (82%). Oliveira et al. [121] conducted a randomized control trial aimed at preventing non-human milk and solid foods in the first six months of life. Adolescent mothers (n=163) received education from a health provider trained in lactation and appropriate introduction of solid food. Information was received at time of discharge and at seven, 15, 30, 60, and 120 days of age. The intervention delayed both the introduction of non-human milk and solid foods. In the control group at four months, 41% of infants had already received solid food as compared to 22.8% in the intervention. Another randomized control trial by Edwards et al. [122] found that in young, low-income, African American mothers a combination of prenatal and postpartum education by Doulas on breastfeeding and introducing

solids increased breastfeeding rates and reduced early introduction of solids foods. Mothers introducing solids before six weeks was 6% in the intervention group as compared to 18% in the control group. Twenty-one percent of mothers in the intervention waited until at least four months to introduce solids as compared to 13% in the control group. On average, the mothers received 10 prenatal visits and 12 postpartum visits. This indicated a high level of needed resources. Additionally, there was no set curriculum, leaving it hard to determine what messages were delivered at what time in the prenatal and postpartum period.

It is possible that multicomponent educational and behavior interventions are effective at improving parental knowledge of infant feeding behaviors and effective at changing some health behaviors in the infancy period. It is unknown whether a prenatal behavior intervention would improve outcomes. To our knowledge, there are currently no educational interventions occurring in the prenatal period only with the primary goal of reducing the incidence of solid foods being introduced prior to four months of age. This presents a novel opportunity to conduct research to not only improve health outcomes, but also add to the scientific body of knowledge.

2.3 GROUP BASED PHONE COUNSELING FOR INTERVENTION DELIVERY

A prenatal behavioral lifestyle intervention (PBLI) to improve breastfeeding duration and exclusivity and appropriate timing for the introduction of solid foods is a novel approach that efficiently uses both time and resources of the participants and educators. Traditional interventions often involve face-to-face education. These methods have shown effectiveness, but they also present a higher cost and an increased number of barriers for participants [123]. We hypothesize that delivering a PBLI via group-based phone counseling (GBPC) sessions will be an effective method that reduces study costs and barriers for participants. Previous studies have shown delivering intervention information via technology to be feasible and effective [124]. In a

study by Davis et al. [124], the feasibility of a technology based intervention was tested in 68 pregnant women between the age of 16 and 43. Over a three week period, women were sent daily educational text messages and asked to watch three 20 minute PowerPoint presentations. At the conclusion of the study, 26.5% of women "strongly agreed" and an additional 40% "agreed" that they were interested in having health information delivered to them at home via technological modalities. Previous studies have shown that GBPC is an effective method for delivering a weight loss intervention in non-pregnant women [125-127]. Donnelly et al. [127] conducted a study comparing the delivery of a weight loss intervention via face-to-face contact or GBPC. Weight change at six months was not significantly different between groups. The cost of offering face to face contact for intervention delivery was $790 more per participant. Authors concluded that GPBC was a feasible and cost-effective method for delivering a weight loss intervention. It is unknown if GBPC is also an effective method for intervention delivery in pregnancy, but it is hypothesized that it will be.

2.4 CONCLUSIONS

Increasing the duration and exclusivity of breastfeeding is a public health priority. It is clear from this review of literature that novel interventions are needed to improve the duration and exclusivity of breastfeeding through six months. It is also clear that there are educational gaps that need to be filled for a mother to feel equipped for a successful breastfeeding experience. Advice regarding milk supply management, relief of common breastfeeding problems, return to work, etc. need to be provided to women for them to succeed at breastfeeding. In addition, more focus on practices regarding the appropriate introduction of solid foods are necessary to reduce poor infant and maternal outcomes. An intervention focusing on increasing exclusive breastfeeding rates and improving the appropriate introduction of solid

foods is novel and a logical combination for an intervention to improve health outcomes. Group-based phone counseling appears to be an effective and novel way to deliver an intervention to women while reducing barriers to participation.

Table 2.1 National, State, and Healthy People 2020 Breastfeeding statistics

	Ever BF	BF @6 m	BF @ 12 m	EBF @ 3 m	EBF @ 6m
National	83.2%	57.6%	35.9%	46.69%	24.9%
Missouri	82.3%	57.8%	36.8%	46.5%	26.6%
HP 2020	81.9% ✓ Nation ✓ MO	60.6%	34.1% ✓ Nation ✓ MO	46.2% ✓ Nation ✓ MO	25.5% ✓ MO

CHAPTER 3
METHODS

3.1 Group Interviews

3.1.1 Subjects

Four group interviews were completed with a total of 11 women who had recently delivered (infant age 3-10 months) and were currently breastfeeding or had previous breastfeeding experience. Participants were recruited from Priority Care Pediatrics, a Kansas City metro pediatric office. Flyers were put up at the clinic and women were approached at a weekly breastfeeding support group run by the clinic. Informed consent was obtained in a private exam room at the pediatric office, either at a regular pediatric appointment or before the group interview. Women did not receive any compensation for their participation.

3.1.2 Data Collection

Demographic and infant feeding surveys were administered after participants provided consent and prior to the start of the group interviews.

Questionnaires

Women were given questionnaires to collect demographic information and infant feeding practices. The demographic questionnaire collected data including pre-pregnancy BMI based on self-reported height and pre-pregnancy weight, age, sociodemographics (income, education, and employment status), number of prior pregnancies, and whether they were currently or recently pregnant. The feeding questionnaire collected data regarding breastfeeding plan and initiation, breastfeeding goals, formula introduction, age of solid food introduction, and amount of postpartum weight loss.

Group Interviews

Group interviews were held at the pediatric office where recruitment took place. A moderator's guide to provide a standard set of questions was developed by the principal investigator (PI; HH) and the research coordinator, who is a lactation consultant. Questions were asked about barriers, knowledge, and experiences related to infant feeding and postpartum weight loss. The same research coordinator moderated all group interviews. Group sessions lasted 30-60 minutes and were recorded and transcribed verbatim. Once transcripts were produced, a research assistant (AH) reviewed all transcriptions for accuracy. Any discrepancies were modified as necessary by the research coordinator (JC) until agreement was reached.

3.1.3 Statistical Analysis

Aim 1 Analysis: Group Interviews

Content Analysis: Verbatim transcripts were coded by hand by the research coordinator and topics were identified within each question to create a key for analysis. Final transcripts and the analysis key were given to three individual study personnel (the research coordinator, research assistant, and PI), who deductively abstracted the data into topics. The study team then met and reviewed each question individually. Frequencies were determined to summarize the data.

Text analysis: Each of the three members of the research team deductively coded the transcripts. All coders identified preliminary themes which were sent to an outside researcher to develop thematic statements. The outside researcher and the study team then met to check and discuss final themes. All illustrative quotes were identified by the moderator/research coordinator (JSC).

Questionnaire

Using data from the demographic questionnaire, proportions were calculated to describe the population. Rates and percentages calculated from the infant feeding questionnaire provided

information on quantifiable goals and practices of the women regarding breastfeeding, introducing solids, and postpartum weight loss. These data allowed us to determine if women met national recommendations for feeding practices and was used to supplement the group interview data.

3.2 Prenatal Behavior Lifestyle Intervention

3.2.1 Subjects

Inclusion/Exclusion Criteria

Pregnant women, 18-35 years old, who were 9-30 weeks in gestation were recruited from Priority Care Pediatrics, LLC and Northland Obstetrics & Gynecology, Inc. Due to the effect on pregnancy and potential complications related to breastfeeding after delivery (i.e. poor milk production), women with pregnancies conceived using fertility treatments, those at high risk for pre-term delivery, those with multiple gestation (i.e., twins, triplets, etc.), or pregnancies complicated by morbid obesity (BMI>40), diabetes (pre-gestational or gestational), hypertension, metabolic dysfunction, etc. were excluded. If women developed these conditions during pregnancy, they were excluded from the final analysis. Women whose pregnancies ended with a preterm infant (<37 weeks) were also excluded from the final analysis. Women who had previously exclusively breastfed for three or more months were excluded from the study since our focus was to increase duration and exclusivity of breastfeeding in women who had not previously met breastfeeding recommendations

Recruitment procedures at Priority Care Pediatrics

Women were recruited at the pediatric clinic by posting flyers and by approaching women at regular pediatric follow-up visits in which they had indicated to the doctor or staff that

they were pregnant. Women were either checked into their appointments manually with a staff member or using a Phreesia Pad. Women who were checked in manually were given an interest sheet to fill out by hand, and those that checked in using the Phreesia pad answered identical questions on their Phreesia pad. Women who indicated that they were pregnant and interested in the study had their information given to research staff who made every effort to connect with them prior to leaving the clinic. The patient was then given more information about the study and given an eligibility screener. If research staff could not meet with potential participants, they were contacted using the contact information provided.

Recruitment procedures at Northland OBGYN

Providers and staff at Northland Obstetrics & Gynecology, Inc. referred women from their practice to the study. Women were approached at their scheduled appointments if they met eligibility criteria. If interested in participating in the study, a research team member came to discuss the study with the women while still in clinic. If unavailable to meet in clinic, women were provided a study flyer, and with consent of each individual patient, Northland OBGYN provided the patients' contact information to research staff to be contacted in regard to study recruitment/enrollment. In addition to meeting women at their scheduled appointments, research staff monitored clinic schedules and were given a daily list of participants that met eligibility criteria. Research staff then called eligible women to discuss possible interest in the study. Northland OBGYN also added a letter to their online prenatal packets that was accessed by newly pregnant women, and they posted information about the study on their website and social media outlets. There were also flyers available in the lobby and exam rooms for women to contact the research staff on their own if interested in study participation.

Additional Recruitment Avenues

Women were recruited by posting recruitment flyers on websites, social media outlets, and community channels. Social media sites included Priority Care Pediatrics, Northland OBGYN, Meritas Health OBGYN, Meritas Health Pavilion, Northland Women's Healthcare, and businesses that are geared toward the pregnancy and breastfeeding period. Women interested in the study were asked to contact staff using the information listed on the flyer.

Randomization

Participants were randomized to intervention (n=20) and usual care group (n=20). Block randomization occurred so that group-based phone counseling (GBPC) groups contained 6-10 participants each.

Description of Intervention:

Usual care group: Participants received the standard education given by their OBGYN or other healthcare provider. No additional breastfeeding or nutrition education was provided to participants by the investigators during pregnancy, however, they were not asked to avoid any outside resources (breastfeeding/birthing classes, lactation support inside/outside the hospital, etc.) that were provided. After delivery, participants received a REDcap survey to answer feeding questions at two weeks, two months, four months, and six months. We also assessed use of any lactation support.

Intervention Group: The intervention was delivered via GBPC. Women attended six weekly sessions starting between 16-30 weeks of pregnancy until 22-36 weeks. Participants were encouraged to follow a balanced diet emphasizing fruits and vegetables, whole grains, low-fat

dairy, and lean protein. Sessions were approximately 60 minutes and led by a dietitian who was also certified as an International Board Certified Lactation Consultant (IBCLC). Separate groups were run to keep group numbers reasonable at 6-10 participants each. All sessions were recorded. The weekly group sessions provided women the opportunity to discuss potential challenges associated with breastfeeding and introducing solids, encouraged problem solving skills needed after delivery, and provided educational information related to eating healthy and being physically active both during and after pregnancy. Examples of topics included benefits of breastfeeding, latching techniques, pumping, healthy eating during pregnancy, self-monitoring, portion control, infant feeding, and postpartum weight loss. Participants received a comprehensive notebook containing handouts and assignments specific to each weekly topic. The group leader had training and experience in nutrition, weight loss, breastfeeding, infant-toddler feeding, and psychology. After delivery, participants followed a normal pediatric visit schedule with their primary care physician.

Phone logistics: For this study, we used the Acano Audio Conferencing System through KUMC. Participants were given a phone number that allowed them to enter the group session each week. Participants were asked to call the number five minutes before the start of group and participate during the duration of the meeting. For safety reasons, we asked that participants not join the conference call while driving. All conference calls were recorded (via Acano) for quality assurance and to serve as additional training for the group leader.

3.2.2 Data Collection

The primary outcomes included exclusive breastfeeding status at six months and timing of the introduction of solid foods (before four months). Secondary outcomes included the infant feeding progression from birth to six months, and maternal compliance and satisfaction with the

intervention. At enrollment, all participants provided self-reported pre-pregnancy weight and highest weight during pregnancy. Confounding variables such as use of breastfeeding support in the hospital or after discharge were collected and used in exploratory analyses due to the small sample size.

Breastfeeding and Introduction of Solid Foods: At two weeks, two months, four months, and six months women were sent a REDCap survey and asked to complete a feeding questionnaire answering questions regarding breastfeeding, introduction of formula, and any introduction or use of solid foods. This information was used to classify breastfeeding status and to assess timing of any solid foods that had been introduced. Exclusive breastfeeding was defined as follows: 1. Infants four months of age or younger who received all of their nutrition from human milk with the exception of supplementation of formula for medicinal purposes (excessive weight loss, hypoglycemia, jaundice, etc) for a brief period of time (less than two weeks in length). 2. Infants between four and six months of age who received all of their nutrition from human milk or solid foods with the exception of supplementation of formula for medicinal purposes (excessive weight loss, hypoglycemia, jaundice, maternal/infant illness, etc) for a brief period of time (less than 2 weeks in length). If women did not meet the criteria for "exclusive breastfeeding" but were offering human milk to some extent, they were classified as "any breastfeeding."

Questionnaires: Questionnaires were given via REDCap at baseline after the consent process to assess maternal pre-pregnancy and pregnancy characteristics. Examples of other information collected included maternal health (medical and obstetric history), race/ethnic background, pre-pregnancy weight, income, education, and smoking history, etc.

Process Evaluation: Data were collected throughout the intervention to assess barriers to recruitment and study retention, participant acceptability and intervention compliance, and how

well the intervention was implemented. Compliance was assessed based upon GBPC attendance of at least four sessions. Structured interviews were conducted by research staff after completion of the intervention and at six months postpartum to evaluate program satisfaction and to solicit feedback on how well the intervention promoted breastfeeding and the appropriate introduction of solid foods. Interviews were audio recorded and transcribed verbatim. Participant comments were coded, categorized into themes, and used to refine and further develop the intervention.

3.2.3 Statistical Analysis

This was a pilot study aimed to provide pilot and feasibility data. A sample size of 40 equally divided across the two groups ensures an exact 95% confidence interval on the proportion of women exclusively breastfeeding at six months will have a margin of error no larger than 0.1 overall, and 0.2 within a group. Due to the small sample size, the role of data analysis was to determine meaningful trends to direct future research and grant submissions. An intent-to-treat analysis was performed, including all subjects that dropped. A secondary analysis included those considered compliant, attending at least four of the GBPC sessions. Use of breastfeeding support services at the hospital and post discharge was explored as a confounding variable (see description of intervention).

Aim 2 Analysis: Exact binomial confidence intervals were computed overall and by group. A Fisher's Exact test was used to determine the difference in the proportion of women exclusively breastfeeding at six months in the prenatal behavioral lifestyle intervention (PBLI) compared to usual care.

Aim 3 Analysis: Exact binomial confidence intervals were computed overall and by group. A Fisher's Exact test was used to determine the difference in the proportion of women who introduced solids before four months of age in the PBLI compared to usual care.

Aim 4 Analysis: A Kaplan-Meier analysis was performed to explore differences in infant feeding progression between infants whose mothers participated in a PBLI during pregnancy compared to usual care.

Aim 5 Analysis: A process evaluation was performed to assess subject satisfaction, barriers to recruitment, acceptability and intervention compliance to the intervention and study retention. The process analysis data will be used to refine and further develop the intervention. This is important as one of the long-term goals is to develop a program that is effective and conserving of clinical resources.

CHAPTER 4

MATERNAL OPINIONS ON BREASTFEEDING, INTRODUCING SOLIDS, AND POSTPARTUM WEIGHT LOSS

4.1 Abstract

Background: Early cessation of breastfeeding, inappropriate introduction of solids, and postpartum weight retention are associated with negative health outcomes for mother and infant. Breastfeeding interventions primarily occur in the postpartum period with limited success, however, little is known about women's attitudes, perceptions, and knowledge surrounding infant feeding decisions and postpartum weight loss. The purpose of this study was to understand timing of and factors that influence infant feeding decisions (breastfeeding and introduction of solids) and barriers that women face when breastfeeding, introducing solids, and losing weight postpartum to inform future interventions.

Methods: Eleven women who had recently delivered (infant age 3-10 months) were recruited from a Kansas City Metro pediatric office. All women were currently breastfeeding or had previous breastfeeding experience. Women completed a feeding survey and participated in a group interview to obtain information regarding breastfeeding, introducing solids, and postpartum weight loss. A content and text analysis were performed to summarize the data.

Results: Predominant emerging themes were: (1) Inadequate knowledge for caring for self and infant (2) Desired knowledge from a Healthcare Provider (3) Feeding decisions were made before pregnancy and preparation took place in the second/third trimesters (4) Unmet breastfeeding goals (5) Clear guidelines on introducing solids are lacking (6)) Those that achieve pre-pregnancy weight have a different body shape and weight distribution (7) and Lack of time and energy make postpartum weight loss hard.

Conclusions: Overall, women do not feel they have adequate information to successfully breastfeed, introduce solids, or lose weight postpartum. They would like basic and practical information on both caring for and feeding themselves and their infant. They would like this information provided to them both during pregnancy and during well child visits.

4.2 Background

The transition to motherhood can be challenging. Infant feeding and postpartum weight loss are two areas that can be difficult to navigate. Breastfeeding is the recommended standard for infant feeding and provides mother and baby many health related benefits[1]. Infants who are breastfed have a decreased risk of infant infection [8, 9], childhood obesity [10], diabetes [11], childhood cancer [12], and also a 50% reduction in the risk of sudden infant death syndrome [13]. Maternal benefits include a reduction in maternal blood loss [14], ovarian [15] and breast cancer risk [16], postpartum depression [18], pregnancy related weight retention [19, 20], and encourages child-spacing [17].

Exclusive breastfeeding is recommended by the American Academy of Pediatrics (APP) for the first six months with continued breastfeeding to 12 months [1, 2, 4]. At about six months, solid foods can be introduced. In the United States (US), only 24.9% of babies are exclusively breastfed at six months [5] and 40.4% of infants are given solids before the recommended age [6]. Early introduction of solids is associated with a number of medical issues such as eczema [24], celiac disease [25], and diabetes [26, 27]. There is also an associated increased obesity risk with early introduction of solids [10, 21-23]. Weight retained from pregnancy can lead to increased rates of maternal obesity at one year postpartum [128] and is linked to poor health outcomes such as diabetes, cardiovascular disease, and depression [129]. Furthermore, maternal weight retention increases the chance of entering a subsequent pregnancy overweight or obese, thus predisposing the infant to obesity, and perpetuating obesity generation to generation.

Interventions to improve breastfeeding rates [81, 119] and postpartum weight loss [130] provide mixed results and interventions to improve the timing of introducing solids are lacking. Overall, little is known about when women make their infant feeding decisions, what

information is desired, or how and when they would like the information delivered to improve success rates. To our knowledge, no studies have addressed how mothers feel about introducing solids to their infant for the first time. Furthermore, additional work needs to be done to understand what information women need to achieve weight loss in the postpartum period. This knowledge is important to inform effective intervention development. Therefore, the purpose of this study was to gain knowledge on when women make their infant feeding decisions, what factors influence infant feeding decisions, and gain understanding from experienced women regarding barriers surrounding successful breastfeeding, introduction of solids, and postpartum weight loss to help inform future interventions.

4.3 Methods

4.3.1 Study Aim and Design

This project was completed to understand maternal attitudes and beliefs surrounding breastfeeding, introduction of solids, and postpartum weight loss to help inform future interventions. Specifically, the study was developed to;

1. Identify barriers faced during breastfeeding, introduction of solids, and postpartum weight loss.
2. Identify what information or support would be helpful regarding breastfeeding, introduction of solids, and postpartum weight loss.
3. Identify at what stage of pregnancy would be best to receive information on breastfeeding, introduction of solids, and postpartum weight loss.

Both qualitative and quantitative methods were used for this project. The primary data collection and analyses were qualitative, using group interviews to understand barriers, when women need additional support or education, and what information would be beneficial.

Quantitative data collection to supplement the group interviews included questionnaires to obtain demographic information and infant feeding practices. The group interview data were also analyzed quantitatively with a content analysis to summarize the data.

4.3.2 Sampling Frame

Four group interviews were conducted with a purposive sample of 11 women who had recently delivered (infant age 3-10 months) and had previous breastfeeding experience. While purposive sampling is a nonprobability technique, it was appropriate for this study because only women who had previously delivered an infant with breastfeeding experience would be able to identify specific needs and barriers to infant feeding and postpartum weight loss. One scheduled group had only one participant attend; an interview was conducted using the group interview questions. Informed consent was obtained in a private exam room at the pediatric office, either at a regular pediatric appointment or before the group interview. Demographic and infant feeding surveys were administered after participants provided consent and prior to the start of the group interviews.

4.2.3 Recruitment

Study protocols were approved by the University of Kansas Medical Center's Human Subjects Committee (HSC # STUDY00003055). Participants were recruited from a Kansas City metro pediatric office. Flyers were put up around the clinic and women involved in a weekly breastfeeding support group run by the clinic were approached by the support group leader.

4.2.4 Data Collection

Group Interviews

Group interviews were held at the pediatric office where recruitment took place. Sessions were in the evenings to accommodate women's work schedules. The moderator's guide was

developed by the principal investigator (PI; HH) and the research coordinator (JSC), who is a lactation consultant. Structured questions were asked about barriers, knowledge, and experiences related to infant feeding and postpartum weight loss (see table 4.1 for questions). The same research coordinator moderated all group interviews. Group sessions lasted 30-60 minutes and were recorded and transcribed verbatim. The study was not designed to reach saturation, but to provide a needs assessment to inform intervention development. Once transcripts were produced, a research assistant (AH) reviewed all transcriptions for accuracy. Any discrepancies were modified as necessary by the research coordinator (JC) until agreement was reached.

Questionnaires

Women were given questionnaires to collect demographic information and infant feeding practices. The demographic questionnaire collected data including pre-pregnancy BMI based on self-reported height and pre-pregnancy weight, age, sociodemographics (income, education, and employment status), number of prior pregnancies, and whether they were currently or recently pregnant. The feeding questionnaire collected data regarding breastfeeding plan and initiation, breastfeeding goals, formula introduction, age of solid food introduction, and amount of postpartum weight loss.

4.2.5 Data Analysis

Group Interviews

Content Analysis: Verbatim transcripts were coded by hand by the research coordinator and topics were identified within each question to create a key for analysis. Final transcripts and the analysis key were given to three individual study personnel (the research coordinator; JSC, research assistant; AH, and PI; HH), who deductively abstracted the data into topics. The study

team then met and reviewed each question individually. Frequencies were determined to summarize the data.

Text analysis: Each of the three members of the research team deductively coded the transcripts. All coders identified preliminary themes which were sent to an outside researcher to develop thematic statements. The outside researcher and the study team then met to check and discuss final themes. All illustrative quotes were identified by the moderator/research coordinator.

Questionnaire

Using data from the demographic questionnaire, proportions were calculated to describe the population. Rates and percentages calculated from the infant feeding questionnaire provided information on quantifiable goals and practices of the women regarding breastfeeding, introducing solids, and postpartum weight loss. These data allowed us to determine if women met national recommendations for feeding practices and was used to supplement the group interview data.

4.4 Results

Four group interviews were held yielding eleven women ranging in age from 21-43 years (mean 32.0 $\pm$ 6.9) with current or previous breastfeeding experience participated. All women had recently delivered and had infants between the age of three and 10 months. Most women already had children, with the following sample distribution; one child (27.3%), two children (36.4%), three children (18.2%). All women had at least a high school diploma with 63.7% of women having an undergraduate or postgraduate degree, 45.5% had full-time or part-time employment, and all women were white and non-Hispanic. Participant demographics are displayed in Table 4.2. Women reported the following plans for breastfeeding. Ten women planned to breastfeed

prior to delivery and all 10 women initiated breastfeeding in the hospital. Over 70% of women planned to breastfeed for at least one year, however, 30% of women only breastfed for 0-3 months, 20% breastfed for 9-12 months, and 40% were still breastfeeding at the time of the group interview (age nine months). Sixty percent of women introduced formula at some point. Forty percent of women did not feel they met the breastfeeding goal they set for themselves. Regarding introducing solids, 22% of women stared at four months, 11% at five months, and 67% at six months. Forty percent of women stated they achieved pre-pregnancy weight. One woman achieved pre-pregnancy weight before three months, one at four months, one at six months, and one after six months.

Thematic analysis of group interview data revealed seven overarching themes: (1) inadequate knowledge for caring for self and infant (2) women desired knowledge from a Healthcare Provider (3) feeding decisions were made before pregnancy and preparation took place in the second/third trimesters (4) breastfeeding goals were not met (5) clear guidelines for introducing solids were lacking (6) in those achieving pre-pregnancy weight, their body shape and weight distribution changed (7) and a lack of time and energy make postpartum weight loss hard. Exemplary quotes are described in Table 4.3.

4.4.1 Theme 1 and 2: Inadequate Knowledge for Caring for Self and Infant; Desired knowledge from a Healthcare Provider

Women do not feel knowledgeable on how to feed their infant or how to generally care for their babies and themselves. They indicated that they wanted resources to help become educated on basic information regarding being a mother, caring for and feeding a new infant, and caring for themselves in the postpartum period. Women wanted this information during pregnancy in addition to receiving education at standard pediatric or postpartum visits.

Breastfeeding education was preferable during pregnancy, but they also appreciated anticipatory guidance on introducing solids, maternal health, and postpartum weight loss. Mothers felt introducing solids should be thoroughly reviewed at a standard four-month pediatric visit. Specific information included feeding problems such as constipation or picky eating, appropriate weight gain and growth expectations, allergies, and baby led weaning. Regarding postpartum weight loss, women wanted information on realistic weight loss expectations and the effect of weight loss on milk supply. Women were already seeking out the desired information from a variety of sources including family, friends, the internet, books, etc. However, they preferred this information come from a trusted healthcare professional. Women did not agree on how they would like to receive this information, but several options were discussed including verbal information, printed information, or via technology such as phone, internet, or email.

4.4.2 Breastfeeding Theme 3 and 4: Feeding decisions before pregnancy and preparation in the second/third trimesters; Unmet breastfeeding goals

All 11 participants indicated that they made their feeding decision prior to pregnancy. Ten of the 11 women who participated in the study planned to breastfeed. When asked about this decision, a comment from one mother on the topic was "It's a funny question because I think it was just always known you should breastfeed your baby. My mom had talked about it, and other friends had done it. You just heard in your head that breastfeeding is best. I liked the idea of bonding and just wanted that relationship with my baby so breastfeeding was on my mind." Seventy percent of women set breastfeeding goals for up to one year or longer. Despite many women having goals that aligned with breastfeeding recommendations, 40% of the women did not meet their goal for breastfeeding length. One mom indicated that "My plan was to nurse her for a year and I did not meet my goal, and I was not even close. The reason was because I did not

have enough milk, and I supplemented her with formula until she was done nursing and then went to formula only." Milk supply issues was a top stated barrier for not meeting breastfeeding goals. In addition to milk supply issues, women named several other barriers including latching issues (n=3), maternal health (n=2), nipple pain (n=1), and other (n=2). "Other" reasons included mother being pregnant and an infant milk allergy. To address these barriers, women wanted basic information on breastfeeding, difficulties experienced while breastfeeding and how to handle problems that arise, and where they can find support. Specific breastfeeding information desired included proper use of a nipple shield, guidance for moms who are exclusively pumping, how often to feed their baby, hunger cues versus other reasons the baby may cry, latching techniques, and how to access a lactation consultant. Women also indicated that it is important for mothers to have an understanding that facing barriers is normal and it does not make them a bad mother. One mom stated that "I think it is important for new mothers who have never breastfed to understand it is not easy because it is one of the most difficult things I have ever done, and you really have to be persistent at it."

4.4.3 Introducing Solids Theme 5: Clear recommendations on introducing solids

The primary message from women regarding introducing solids was that they wanted clear guidelines on when and how to introduce solids. In general, women planned to introduce solids around six months of age. Seventy-two percent of women indicated that a healthcare provider or expert committee recommendations influenced their decision on when to start solids. Despite this, women sought out information on introducing solids from a source other than their provider such as a technological source (i.e., internet, video, etc.), book/article, or friend. When asked if they would utilize a specific manual provided from their doctor, all women indicated that they would like and utilize this. The standard four-month pediatric visit was the favorable

time to receive this resource. When asked what barriers the women faced when introducing solids, the most common response was being overwhelmed with information or that their child was not interested in food in general; however, they also cited barriers such as medical problems like eczema and allergies or difficulty getting the child to sit still for a meal. One mom said "I think there is too much information out there and I get tired of other people's opinions. So I selected my doctor carefully so I can put my trust in him and I won't have to worry about every little thing I read and every little trend because it's too overwhelming." Another mom said "I am frustrated because of his total disregard for food. He will put anything in his mouth besides food. So that was a struggle." Women indicated wanting practical information for how often to feed their baby and how much to offer, recipes for making baby food, information on picky eating, how to combat constipation, guidelines related to food allergies, and information about appropriate growth and weight gain.

4.4.4 Postpartum Weight Loss Theme 6 and 7: Those that achieve pre-pregnancy weight have a different body shape and weight distribution; Lack of time and energy make postpartum weight loss hard

Many women in this study were able to achieve pre-pregnancy weight, but three women specifically mentioned that their bodies were not the same. Women stated this was not an expectation prior to pregnancy. One woman said "Weight wise I was back to my pre-pregnancy weight, but my clothes no longer fit. That was a shock." Another said "I am back to pre-pregnancy weight, but my clothes still don't fit right. It's the worst." The women indicated that they wanted to be informed of realistic expectations regarding postpartum weight loss as well as the fact that their bodies may not be the same despite achieving pre-pregnancy weight. Women named several barriers related to postpartum weight loss including hunger related to

breastfeeding, milk supply concerns, a lack of ability to exercise, and turning to convenience junk food. However, the most consistent barriers were lack of time and/or energy. One mom stated "The biggest barriers are time and energy and the desire to do it, and sometimes the resources of finding things that you want to do with groups." Another said "Time for exercise is a barrier. I just can't seem to fit it in." Women indicated that they would like support to help overcome these barriers. Examples of information women wanted included time management strategies, support systems, childcare options during exercise, available exercise programs, and practical information on diet and nutrition. Many women commented on being interested in some type of postpartum group and felt that having appropriate support or a community of other mothers would improve their postpartum weight loss experience.

4.5 Discussion

The primary goal of this study was to gain an understanding of when women make their infant feeding decisions, what factors influence those decisions, and understand what barriers women face when breastfeeding, introducing solids, and returning to pre-pregnancy weight to inform future interventions. Effective interventions need to be tailored to the targeted population to improve breastfeeding rates, introduction of solids, and postpartum weight loss. This study found women feel inadequately educated on these areas. Women desire the education; however, the education is not being provided by the healthcare professionals at the appropriate time. The lack of education and support hinders the ability to meet personal or recommended breastfeeding goals, feel confident to introduce solids appropriately, and have the resources and tools to overcome barriers to facilitate postpartum weight loss. Women want to be educated by a healthcare professional on infant feeding and caring for themselves while they are still pregnant

and they want additional resources after the baby has arrived to complement the knowledge they have.

Breastfeeding

To our knowledge, this is the first study to report on when women are making infant feeding decisions. Study participants unanimously indicated they decided before becoming pregnant if they were going to breastfeed or formula feed. Only one woman planned to formula feed and this was due to medical complications and a negative previous breastfeeding experience. This finding may suggest public health messages or societal norms related to breastfeeding have an impact on a women's decisions before she becomes pregnant. Therefore, interventions to target improved breastfeeding rates may need to occur pre-conception. Further research should investigate this finding further as there is the potential that outcomes would be different based on maternal age, parity, and status of a planned or unplanned pregnancy.

Current interventions to improve breastfeeding rates are primarily delivered during the postpartum period [81]. We found that women make their infant feeding decision prior to pregnancy but would like educational information during the prenatal period. Data suggest that prenatal interventions improve breastfeeding rates. A recent study by Schreck et al. compared a control group to an intervention that combined one on one prenatal education by an International Board Certified Lactation Consultant (IBCLC) combined with a free breastfeeding support group in the postpartum period. When compared to the control group, women who received the intervention had higher breastfeeding initiation rates but breastfeeding duration rates did not differ. However, women who received the intervention and attended postnatal breastfeeding support groups had both higher breastfeeding initiation rates and prolonged breastfeeding [98]. This suggests that the educational component is beneficial for both initiation and early

breastfeeding struggles but additional hands on support (that is typically offered at a breastfeeding support group) may be required for continued breastfeeding or addressing struggles that occur further into the postpartum period.

Women often encounter a number of breastfeeding struggles that lead to early cessation including sore nipples, inadequate milk supply, infant problems, and the perception that the infant is not satiated [68]. Similarly, the primary issues women faced in this study were latching issues and milk supply issues [37]. Our study expanded on the barriers and investigated the information that would be beneficial to improve these struggles. Some struggles may require a different mode of delivery for the information. For example, teaching women about appropriate milk supply and breastfeeding basics can occur prenatally via educational material or classes; however, teaching appropriate latching techniques may need to be taught in person. Some women indicated that learning theoretical information about proper latching technique is simply not enough, they need hands on support once their baby has arrived. In summary, women want to be educated during pregnancy in preparation for breastfeeding, but feel they may also need additional hands on support if/when struggles arise.

Introducing Solids

The current recommendation for introduction of solids is about six months in conjunction with breastfeeding or formula feeding [1]. However, according to the Infant Feeding Practices Study II data, about 40% of infants are given solids prior to four months of age [6]. This is concerning due to the associated medical complications related to early solid introduction [21-27]. We found no women started solids prior to four months of age. Even though they followed the current recommendation for timing of solids introduction, women indicated feeling unprepared for the transition and cited barriers of feeling overwhelmed by information from a

combination of sources such as family, friends, and online baby forums, with no clear guidance from their healthcare providers. This is not surprising given there is disagreement between expert committees on when solids should be introduced. The AAP Committee on Nutrition recommends the introduction of solid foods between four and six months of age, with developmentally readiness as a guide [99], while the AAP Section on Breastfeeding recommends exclusive breastfeeding until "about" six months [1]. In addition, neither the AAP Committee on Nutrition nor the AAP Section on Breastfeeding offer clear guidelines on what foods to start with or the frequency and amount of food to provide. These conflicting recommendations cause inappropriate introduction of solids due to confusion or misunderstanding of the guidelines and contribute to a lack of maternal confidence in the ability to properly feed her child.

Interventions aimed at the appropriate introduction of solid foods are lacking. A recent review by Arikpo et al. found educational interventions decrease the risk for early introduction of solids, but they are limited and are occurring primarily in the postpartum period [119]. The lack of interventions aimed at improving both the timing of introduction of solids and maternal self-efficacy presents a novel opportunity to develop an effective intervention to both improve health outcomes and add to the scientific body of knowledge. Our study provides the specific informational framework for what should be included in such an educational intervention.

Postpartum Weight Loss

Postpartum weight loss is difficult. Thirteen to twenty percent of women retain five kg or more at 12 months [131]. This is concerning as it may progress a women into a higher BMI category and expose her to negative health outcomes such as gestational diabetes with a subsequent pregnancy [132], type 2 diabetes later in life [55], cardiovascular disease, and depression [129]. Forty percent of participants reported returning to their pre-pregnancy body

weight. Even though they returned to their pre-pregnancy body weight, it was clear many felt their body weight was redistributed to different locations. Further, participants indicated they wanted to exercise or that they understood exercise would aid in postpartum weight loss. Despite this, participants stated they could not find the time or did not have the desire to exercise. Other studies have found similar results. Ostbye et al. [133, 134] randomized women to 10 group physical activity sessions, eight healthy eating classes, and six phone counseling sessions or to a control group over a nine-month period. No between group difference was found for weight change at 12 months postpartum. Authors cited reasons for the null results were low intervention participation due to time barriers. The authors suggested a home-based intervention (via mail, email, telephone, internet, etc) would be a more viable option for new mothers as it would address barriers such as time and childcare. Authors also discussed offering the intervention in the prenatal period to address time and childcare barriers; however, it is unknown if behaviors learned prenatally would be implemented postpartum. To our knowledge, no studies have investigated prenatal interventions to address postpartum weight loss. Overall, women want information to help them lose weight in the postpartum period and are receptive to prenatal education regarding postpartum weight loss. They desire practical information on time management, healthy eating, maintaining a milk supply while losing weight, and tips for exercising with baby.

Limitations

Our study is limited by the small sample size and lack of diversity in our participants. The study participants were older and had multiple children. First time mothers may require or desire different information for success when compared to women with multiple children. Further, a first-time mother may be more interested in gaining new knowledge and have more

time to participate in a pregnancy intervention when compared to women who already have children. Additionally, more tech savvy women may prefer to receive information in different ways (ie. technology based versus in person). Women in our study did not introduce solids early but nationwide 40.4% of infant are given solids too early [6]. It would be important to understand what influences early introduction of solids. This knowledge would complement the results of our study. While we feel our findings of what women want to be successful are representative, additional research with a larger sample composed of a larger variety of women would be beneficial.

4.6 Conclusions

Overall, women would like more information to manage their own health and the health of their infant. Women do not feel they have adequate information or support to reach their goals. Educational interventions during pregnancy could help fill this knowledge gap. Interventions should provide practical tips and basic information on how to be a mother and care for an infant, basics of breastfeeding, clear cut guidelines on when and how to introduce solids, and information on healthy eating, exercise, and time management to aid in postpartum weight loss. These tips and resources should be developed by a healthcare provider and delivered by a knowledgeable professional in breastfeeding, introducing solids, and postpartum weight loss. There are several ways that this information could be delivered, but it should be tailored to the specific population.

Table 4.1 Group Interview Questions

1. "At what point did you decide you were going to breastfeed your child?" a. Did this time differ if this was not your first child? 2. "Prior to delivery what was your plan on how long you wanted to breastfeed your child?" a. Did you meet your goals? b. If you did not meet your goals, what do you think affected this? 3. "What was the length of time that you breastfed your infant and what barriers did you face?" 4. "At what time would you have liked information on breastfeeding?" • During pregnancy? (If so, when?) • After the baby was born? (If so, when?) 5. "What were the most difficult points in time regarding breastfeeding and how long did it take before you felt you had things under control?" 6. "If formula was introduced at any time, at what time was it introduced and what was your reason for introduction?" 7. "What were your plans for introducing solids foods prior to delivery and how did you determine this plan?" 8. "If you did not introduce solids as planned, when did you introduce solids and why did your plan change?" 9. "What barriers did you encounter while attempting to get back to pre-pregnancy weight?" 10. "Were you able to achieve pre-pregnancy weight and if so at what time point postpartum did you reach it? 11. "If you had access to a weekly support group via phone led by a Registered Dietitian/Lactation Consultant, with information and support regarding breastfeeding, postpartum weight loss, and introduction of solid foods would you use this support group?"

Table 4.2 Maternal Characteristics (n=11)

Age (in years, mean, SD)	32.0, ± 6.9
Race	
White	100.0%
Ethnicity	
Non-Hispanic/Latino	100.0%
Education Level	
High School Diploma	27.3%
Associates Degree	9.1%
Undergraduate Degree	36.4%
Postgraduate Degree (masters, PhD)	27.3%
Employment Status	
Stay at home to watch children	45.5%
Part-time	27.3%
Full-time	27.3%
Number of Pregnancies	
1	18.2%
2	27.3%
3	36.4%
4	18.2%

Table 4.3 Thematic Statements

Cross Cutting Statements

1. Women do not have adequate knowledge on feeding and caring for their infants or themselves. Women want practical information, both during pregnancy and during standard well child visits, on how to be a mother, caring for a feeding a new infant and caring for themselves.
2. Women actively seek information from family, friends, internet, and books but would like the information to be obtained from their healthcare provider.

Breastfeeding Statements

3. Women make decisions about infant feeding prior to pregnancy and desire information about breastfeeding during the 2nd or 3rd trimester

"I thought before I was pregnant that I knew how I wanted to feed my baby."

"The second trimester…In the first trimester I was too busy worried about ya know, getting sick all the time and trying to survive the day and then third trimester I was, you know, laying in bed."

4. Women set goals to breastfeed for 1 year or longer but do not reach these goals due to the primary barriers of milk supply and latching issues

"My goal was to nurse for a year, and no, I did not meet my goal. Like not even close. It was because of milk supply, just not having enough."

Introducing Solids Statements

5. Women want clear guidelines on when and how to introduce solids to their infants

"I think there is too much information out there and I kind of get tired of all the people's opinions."

Postpartum Weight Loss Statements

6. Some women achieve pre-pregnancy weight but do not feel their bodies are the same. Women are unprepared for this.

"I am back to pre-pregnancy weight, but my clothes still don't fit right. It's the worst."

"Weight wise I was pre-pregnancy, but my clothes no longer fit. That was a shock."

7. Women face many barriers related to postpartum weight loss but the most important are time and/or energy

"The biggest barriers are time and energy and the desire to do it, and sometimes the resources of, you know, finding things that you want to do with groups and whatever."

CHAPTER 5

IMPACT OF A PRENATAL GROUP BASED PHONE COUNSELING INTERVENTION ON BREASTFEEDING RATES AND THE INTROCUTION OF SOLIDS: A RANDOMIZED, CONTROLLED PILOT AND FEASIBILITY TRIAL

5.1 Abstract

Background: Despite numerous benefits for both mom and baby, few infants are exclusively breastfed for the recommended first six months. Additionally, infants are given solids too early. Interventions to improve breastfeeding rates and prevent the early introduction of solids often occur in the postpartum period with variable success. Prenatal education increases rates of breastfeeding initiation and we hypothesize it can also improve exclusive breastfeeding rates and prevent the early introduction of solids. We conducted a randomized controlled pilot and feasibility trial to evaluate the effectiveness of a prenatal behavioral lifestyle intervention (PBLI) delivered via group based phone counseling (GBPC) on rates of exclusive breastfeeding up to six months postpartum. Secondary aims included rates of any breastfeeding up to six months, rates of early introduction of solids, infant feeding progression, and the feasibility and maternal acceptance of the intervention.

Methods: Forty-one pregnant women were recruited from a Kansas City Metropolitan Obstetrics and Gynecology office and randomly assigned to a usual care group or a PBLI. Women in the PBLI attended six GBPC sessions where they learned about breastfeeding and introducing solids. Feeding questionnaires to assess breastfeeding and introduction of solids were sent at two weeks, two months, four months, and six months postpartum. Structured interviews were also conducted after the intervention and at six months postpartum to assess maternal acceptance and intervention feasibility.

Results: Rates of exclusive breastfeeding and any breastfeeding did not differ between groups at any time point. No between group differences were found for early introduction of solids or infant feeding progression. Participants overwhelmingly found the intervention acceptable and beneficial.

Conclusions: Mothers discontinue breastfeeding earlier than recommended despite high rates of initiation. A PBLI may have positive impacts such as maternal empowerment for both breastfeeding and introducing solids. Future studies should incorporate both prenatal and postpartum components.

5.2 Background

Meeting infant feeding recommendations is a public health priority due to the numerous benefits for both mom and infant. This includes both duration and exclusivity of breastfeeding and preventing early introduction of solids. The benefits of breastfeeding for both mom and baby are well established [8-20]. Introducing solid foods prior to four months is related to childhood obesity development [22] as well as eczema [24], celiac disease [25], and diabetes [26, 27]. In addition to suboptimal health outcomes, not meeting infant feeding recommendations costs the US $13 billion annually in pediatric medical costs by contributing to the development of childhood obesity and other diseases [7]. Exclusive breastfeeding is recommended by the American Academy of Pediatrics (APP) for the about six months, at which time solids can be introduced, with continued breastfeeding to 12 months [1]. Current breastfeeding initiation rates are high at 83.2%, but by three months of age, only 46.9% of infants are still exclusively breastfeeding and at six months only 24.9% are still exclusively breastfeeding [5]. About 40.4% of infants are currently receiving solids before four months of age [6].

Despite current interventions to improve breastfeeding rates and early introduction of solids, breastfeeding rates remain low and infants are given solids too early [5, 6]. A review of interventions to improve breastfeeding rates [81] and the timing of solid food introduction [119] reveals that the majority of interventions occur in the postpartum period, but have variable success rates. Addressing barriers and concerns in the postpartum period may be too late. Mothers face new barriers in the postpartum period such as limited time, prioritizing other familial needs, and poor support from family, friends, or coworkers [135]. A lack of prenatal education is a barrier to improved breastfeeding rates [77, 88]. However, advice from a medical professional and breastfeeding education during the prenatal period is associated with increased

breastfeeding rates [87]. Therefore, novel interventions in the prenatal period are needed to reduce barriers so mothers receive appropriate infant feeding education and support.

We designed a pilot study to understand if a prenatal lifestyle intervention (PBLI) delivered using group based phone counselling (GBPC) would impact rates of exclusive breastfeeding and any breastfeeding at two weeks, two months, four months, and six months. Secondary aims were to understand if the intervention would impact the rates of early introduction of solids and result in differences in infant feeding progression up to six months. Lastly, we conducted structured interviews to understand maternal acceptance of the PBLI.

5.3 Methods

5.3.1 Study Design

The present study is a pilot randomized clinical controlled trial. Women were recruited from a local Kansas City Metropolitan Obstetrics and Gynecology office between January 2018 and May 2018. Study protocols were approved by the University of Kansas Medical Center's Human Subjects Committee (STUDY00140506) and registered at ClinicalTrials.gov (NCT03442517, retrospectively registered). All subjects provided written informed consent prior to study participation. Participants were not compensated.

5.3.2 Subjects and randomization

Pregnant women, 18-35 years old, who were 9-30 weeks in gestation and pregnant with their first child or who had exclusively breastfed for less than three months with a previous child were recruited from Northland Obstetrics & Gynecology, Inc. Due to the effect on pregnancy and potential complications related to breastfeeding after delivery (i.e. poor milk production), women with pregnancies conceived using fertility treatments, those at high risk for pre-term delivery, those with multiple gestation (i.e.. twins, triplets, etc.), or pregnancies complicated by

morbid obesity (BMI>40), diabetes (pre-gestational or gestational), hypertension, metabolic dysfunction, etc., were excluded. Women who developed any of these conditions during pregnancy or had a preterm infant (<37 weeks) were excluded from the final analysis. A CONSORT diagram is included in Figure 5.1.

Participants were block randomized in groups of 6-10 into either the intervention or usual care group at a 1:1 ratio. Randomization was computer-generated using excel software by the study statistician. If women indicated to their provider they were interested in hearing about a breastfeeding study, they were approached at their regularly scheduled OBGYN clinic appointment. A research team member discussed the study with the women while still in clinic. If unavailable to meet in clinic, women were provided a study flyer, and with consent of each individual patient, the OBGYN office provided the contact information to research staff. Research staff called women to discuss study participation. Once women indicated interest, they were screened for eligibility. Eligible women that agreed to participate were consented in person or via phone using a REDCap [136, 137] link.

5.3.3 Intervention

Intervention participants attended six weekly GBPC sessions starting between 16-30 weeks gestation. Phone calls were conducted using the Acano Audio Conferencing System. Each session was approximately 60 minutes and was led by an IBCLC and registered dietitian (JSC). Participants were given a comprehensive manual that outlined weekly lessons discussing breastfeeding, latching techniques, pumping, return to work, introduction to solids, and healthy eating during pregnancy. Each lesson allowed for participant questions and assigned tasks for the next week. Participants in the usual care group received standard pregnancy and pediatric

education provided by their healthcare provider. They received no additional breastfeeding or nutrition education.

5.3.4 Data Collection

Demographic Questionnaire

Women were emailed a REDCap questionnaire to collect demographic data [136, 137]. The questionnaire collected data including height, pre-pregnancy weight, age, sociodemographic information (income, education, and employment status), and previous number of pregnancies.

Breastfeeding and Introduction of Solids

At two weeks, two months, four months, and six months, women were sent a REDCap [136, 137] survey. Women answered questions regarding breastfeeding, use of formula, and introduction or use of solid foods. This information was used to classify breastfeeding status and to assess timing of solid food introduction. For infants less than four months of age, exclusive breastfeeding was defined using WHO guidelines, which state that exclusively breastfed infants only receive human milk. No other liquids or solids are a given, not even water, with the exception of oral rehydration solutions, drops/syrups, minerals, or medicine [2]. We altered our definition of exclusive breastfeeding after four months to encompass infants being provided human milk only (no formula) but also receiving solid foods. This was based on current recommendations from the AAP stating that in combination with providing only human milk, solid foods can begin between four and six months of age, with developmental readiness as a guide [99]. If women did not meet the criteria for "exclusive breastfeeding" but were offering human milk to some extent, they were classified as "any breastfeeding."

Structured Interviews

Immediately following intervention completion and at six months postpartum, a structured interview was completed to understand maternal acceptance of the intervention including benefits and potential improvements. Structured interview questions are displayed in Table 5.1. Structured interviews were recorded using the Acano Audio Conferencing System. A content and text analysis was completed. Verbatim transcripts were created using Temi Transcription service (Temi.com, San Francisco, CA). The research coordinator coded the transcripts and identified topics within each question to create an analysis key. Three individual study personnel (the research coordinator (JSC), research assistant (AH), and PI (HH)), used the transcripts and the analysis key to deductively abstract the data into topics. Each team member inductively coded the transcripts. All coders identified preliminary themes which were sent to an outside researcher (CMD) to develop thematic statements. All illustrative quotes were identified by the moderator/research coordinator (JSC).

5.3.5 Data Analysis

Frequencies and proportions were calculated for all categorical variables. Means and standard deviations were calculated for all continuous variables. Exact binomial confidence intervals were calculated for rates of exclusive breastfeeding and any breastfeeding, and $\sqrt{x^2}$ or Fisher's exact tests were used to compare rates between groups. Mean duration and 95% CI of exclusive breastfeeding and introduction of solids were obtained via Kaplan-Meier survival curves. An intent-to-treat analysis was conducted, including any subjects that did not participate in the GBPC sessions. A secondary analysis included those considered compliant to the protocol, attending at least four of the GBPC sessions. Data were analyzed using SPSS version 25.0 and SAS 9.4 with a p-value ≤ 0.05 considered statistically significant.

5.4 Results

5.4.1 Demographics

Sixty-seven women were screened, and 53 were eligible (Figure 5.1). The primary reason for exclusion was previous breastfeeding experience (7%) or elevated BMI (6%). Of the eligible women (n=53), 45 women consented, for an enrollment rate of 85%. Twenty-three women were randomized to the usual care group and 22 were randomized to the intervention. Prior to the start of the intervention, two women in the intervention group were lost to follow up. Post-delivery, one participant in the control group and one participant in the intervention group were excluded due to a preterm delivery. Overall, 41 women (usual care n=22 and intervention n=19) were used for analysis. For the usual care group, all women completed the two week questionnaire, one woman did not complete the two month, four month, and six month feeding questionnaires and two women did not complete the four and six month feeding questionnaires. For the intervention group, all women completed all feeding questionnaires at all time points.

No between group differences were found for the baseline characteristics (Table 5.2). The mean participant age was 26 years (SD: 4.3 years) with an average BMI of 27.3 kg/m^2 (SD: 4.5). Most women were white (95.1%) and 65.9% had an Associate's degree or higher. Women were primarily married or co-habitating with their significant other (82.9%) with 46.3% having a household income less than $75,000 per year. Most women were having their first child (70.7%). Infants were primarily born via vaginal delivery (84.2%). The mean gestational age at birth was 39.5 weeks (SD: 1 week) and mean birthweight was 7.8 lbs (SD: 1.0 lbs). Infant gender was evenly split with 48.8% of infants being female.

5.4.2 Lactation Support

Most women (usual care=94.7%, intervention =73.7%) received lactation support in the hospital after delivery. Post-discharge, 47.7% of the women in the usual care group received lactation support compared to 73.7% of women in the intervention. Women primarily received post-discharge lactation support from a lactation professional (usual care=36.8%, intervention=63.2%) but also received support from their OBGYN (usual care=5.3%, intervention= 5.3%) and the Women Infants and Children (WIC) program (usual care=0%, intervention=10.5%).

5.4.3 Intervention Compliance

Intervention compliance was defined as attending a minimum of four phone meetings. Eighty-five percent of the sample (n=16) attended four or more phone meetings. Only three women did not attend the minimum of four phone meetings. Missed sessions were primarily due to work commitments or appointments that interfered with the session time.

5.4.4Rates of breastfeeding initiation, any breastfeeding, and exclusive breastfeeding

Rates of exclusive breastfeeding at six months were similar in the intervention group (31.6%, 95% CI = 12.6%-56.6%) and the usual care group (31.8%, 95% CI = 13.9%-54.9%). Rates of initiation, exclusive breastfeeding, and any breastfeeding at two weeks, two months, four months and six months are displayed in Table 5.3 and Figure 5.2. No between group difference was found for initiating breastfeeding. All women in the usual care group initiated breastfeeding, while all but one of the women in the intervention initiated breastfeeding. Next, the results related to any breastfeeding will be discussed. No between group difference was found for any breastfeeding at any time point. Overall, as the infant aged, breastfeeding rates declined at each successive time period in the usual care group and intervention. Next, the rates

for exclusive breastfeeding (no formula) will be discussed. No between group difference was found for exclusive breastfeeding at any time point. Exclusive breastfeeding rates declined until four months and then remained stable at six months in the usual care group and intervention group. The largest drop in exclusive breastfeeding for both groups occurred after two months.

In a secondary analysis of women compliant to the intervention, we found that all women initiated breastfeeding. No difference was found for rates of any breastfeeding or exclusive breastfeeding at any time point. Exclusive breastfeeding rates also declined at two weeks, two months, and four months, but then remained stable from four months to six months.

5.4.5 Reasons for Formula Introduction

During the first six months, women were asked to identify if they had introduced formula and reasons for formula introduction (Table 5.4). At two weeks the main response was "other" (n=8) and "following advice from a healthcare provider" (n=6). The most common listed reasons for "other" were milk supply (n=3) and latching issues (n=2). At two months, the primary answer was "other" (n=9) and "baby did not gain enough weight on breastmilk alone" (n=6). Listed "other" reasons were all related to milk supply problems (n=5) or poor support (n=1) with three women giving no response. At four months, the primary reason for formula introduction was "other" (n=14) and "easier to fit into daily routine." The main listed reason under "other" was milk supply (n=8). At six months, the primary reason for formula introduction was "other" (n=10) and "easier to fit into daily routine" (n=9). The main listed reason under "other" was milk supply (n=7).

5.4.6 Introducing Solids

No between group difference was found for the timing of solid introduction. Most infants in both the usual care group (94.7%, 95% CI = 74%-99%; n=18) and intervention group (94.7%,

95% CI = 74%-99%; n=18) started solid foods appropriately and no infant received solids at or before two months. One infant in both the usual care group and intervention group started solids prior to four months of age. The remaining infants in the usual care group and intervention were given solids after four months. When asked to mark all options that influenced their decision to start solid foods, 28 women (usual care n=13, intervention n=15) indicated "baby was showing interest," 17 women (usual care n=6, intervention n=11) indicated they were "following the advice of a healthcare provider," six women (usual care n=3, intervention n=3) indicated that "breastmilk or formula alone was not enough," one woman in the intervention indicated she was "following advice from family or friends," and one woman in the usual care group indicated "other" but did not specify her reason.

5.4.7 Feeding Progression

Figure 5.3 presents the overall time until the cessation of exclusive breastfeeding over the six month follow up period for each group. There were no between group differences for rates of exclusive breastfeeding at any time points (log-rank $p = 0.87$). Overall, exclusive breastfeeding dropped dramatically between birth and two weeks and then continued to decline until six months. In the usual care group, the mean age for discontinuation of exclusive breastfeeding was nine weeks (SD± 1.5weeks) versus 10 weeks (SD± 1.6 weeks) in the intervention group. Seven women in the usual care group and six women in the intervention group were still exclusively breastfeeding at six months.

Figure 5.4 presents the overall time to introduction of solids between groups. No differences between groups were found regarding the time for introduction of solids (log-rank $p = 0.57$). One infant in both the usual care and intervention started solids early, prior to four months. The mean age for introduction of solids in the usual care group was 4.9 months (SD±

0.75 months) and 4.7 months (SD± 0.65 months) in the intervention. At six months, three infants in the usual care group and two infants in the intervention group had not started solids.

5.4.8 Maternal Perception of Intervention

Post Intervention

Four primary themes emerged from the thematic analysis of the structured interview responses immediately after the intervention concluded. The first theme was that women liked the program including the format, accompanying manual, the diversity of experiences represented from group members, having an expert available for discussion, and the comprehensiveness of the information received. They also mentioned several other positive factors such as having the information broken into sections, not having to travel anywhere for group meetings, and having an hour set aside to focus on learning about the topic, to name a few. Overall, women felt the amount of information provided was appropriate and were positive about their GBPC experience. The second theme was that women would participate in another intervention delivered via GBPC. When asked about participating in another PBLI delivered with GBPC, one woman stated that the intervention "made me feel more empowered as a woman who is going into taking care of their first child. I feel like I have more tools, and it's crazy because it's just a talking session, but you know, knowledge is power when it comes down to it." The third theme was that the intervention helped women decide how they wanted to feed their infant and/or supported the feeding decision they had already made. Some women indicated they had already decided how they wanted to feed their baby prior to the intervention. One woman stated, "the program solidified what I wanted to do, because I already had that plan in mind (to breastfeed) but, this gave me a roadmap of how to do it." The final theme was that women were positive about their GBPC experience but provided constructive feedback. One mom stated "I

loved the way it was set up." Another said "I thought it was super informative." Two primary concerns were lack of connectivity and engagement, which in turn made conversation more difficult for some women. Women indicated they wanted at least one in-person meeting to build rapport with group members. Women also wanted additional visuals to augment the phone calls such as videos or web links and to have calls recorded so they could listen to them later.

Six Month Follow-Up

Thematic analysis of the structured interviews conducted at six months postpartum revealed five themes. The first theme was that, women retained a positive perception of the intervention after having a baby and starting their infant feeding journey. The intervention was particularly helpful for breastfeeding, but also for introducing solids. One woman stated, "It gave me the confidence to get started on the right foot." Another mom stated, "I really felt comfortable going into breastfeeding." Several women had not started solid foods yet to give adequate feedback on how the intervention helped or needed improvement. The second theme was that women used their participant manuals after the baby arrived. In regard to the use of the manual postpartum one mom stated, "If I was having an issue with latching or if I was having a problem I knew exactly where to find it and it was super simplified, and it told me exactly what I needed to know." The last three themes discussed potential improvements to the program. The third theme was that after the women had the chance to implement the information they learned, they had some specific suggestions on information they felt would benefit the program, particularly regarding breastfeeding. This included additional information on initiating breastfeeding in the hospital, breastfeeding and going back to work, latching, pumping, the use of nipple shields, and supply problems. The fourth theme was that women, regardless of if they were successful at breastfeeding or not, indicated they wished the program had encompassed

both the prenatal and postpartum time period, so sessions and group support continued after the baby arrived. One woman stated, “it should continue on to when you are actually doing (breastfeeding and introducing solids) so that you can get real time advice and feedback.” The final theme was from women who were not able to meet their goals. They felt the intervention was helpful but wished there was additional support in the postpartum period. One woman stated “The phone calls helped but they were not (enough). I needed someone in the room to help guide me.”

5.5 Discussion

The purpose of this pilot project was to determine if a PBLI delivered via GBPC was effective at increasing rates of exclusive breastfeeding and any breastfeeding up to six months. Additional aims included reducing the introduction of solids prior to four months, understanding the difference in feeding progression between groups, and determining if the intervention was feasible and acceptable to participants. Overall, the study found no difference in breastfeeding rates (initiation, any breastfeeding, or exclusive breastfeeding) at any time point. There was no difference in rates of early introduction of solids or feeding progression between groups. As a pilot project, this study was not powered to detect statistical differences between groups. As such, it is not surprising that no significant differences were found. Despite the lack of statistical difference, the rates of breastfeeding that we found can be used to help inform future interventions. Overall, the intervention was found to be feasible, acceptable, and beneficial by participants.

5.5.1 Breastfeeding

Our results are similar to a study by Schreck et al. [98] who found a prenatal intervention alone was ineffective at improving breastfeeding continuation. Attendance at a postpartum

support group was required to see higher rates of continuation. Our results confirm that women need and want additional support in the postpartum period. Women who struggled to meet their breastfeeding goals wanted postpartum meetings or access to "real time" advice after the baby arrived to help troubleshoot specific concerns. A future intervention to improve breastfeeding rates with a combination of prenatal education and postpartum support that is adequately powered is warranted.

5.5.2 Introduction of Solids

This is the first randomized controlled trial to examine the effect of an educational intervention delivered in the prenatal period on rates of early introduction of solids (prior to four months). No between group difference was found for the timing of solid introduction. In both the usual care and intervention, only one infant in each group received solids before four months. These rates are surprisingly low, accounting for only 5% of the group. Previous research indicates rates of early introduction of solids to be 24.3% in exclusively breastfed infants, 50.2% in mixed-fed infants, and 52.7% in exclusively formula fed infants [6]. These results may be explained in part by the characteristics of our sample. According to Hendricks et al. [138] introducing solids prior to four months is associated with younger maternal age, being African American, living in a household below 185% federal poverty level, and having less than a college education. Our sample consisted of women in their late twenties (mean 26 years old SD: 4.3 years), white, educated, and 53.7% reporting a household income above $75,000.

5.5.3 Maternal perception of the intervention

Despite no difference in rates of breastfeeding or early introduction of solids, women indicated the program either helped them decide how to feed their baby or supported the decision they had already made. The intervention also made them feel more prepared and confident.

Women offered constructive suggestions to improve future interventions including additional information on breastfeeding in the hospital, going back to work, latching, increasing supply, nipple shield use, and pumping. These suggestions support our findings that primary reasons for formula introduction were milk supply and latching concerns. Women also wanted more information on introducing solids as it was only discussed in one lesson. Specific feedback regarding what women liked and disliked about the introducing solids information was limited as several women had yet to utilize the information. Some women felt the introducing solids lesson was offered too soon as it was still too far in the future for the information to be relatable. Women consistently commented on having access to additional help for both breastfeeding and introducing solids in the postpartum period. Future studies should address maternal suggestions to further refine the intervention.

5.5.4 Intervention delivery method

To our knowledge, this is the first prenatal breastfeeding intervention delivered via GBPC. Previous studies found that traditional face to face interventions are effective, but they also present a higher cost and an increased number of barriers for participants [123]. Previous studies found delivering intervention information via technology to be feasible and effective [124]. For the present study, 85% (n=16) of the sample was compliant and the PBLI had high acceptability. In the usual care group, there was a 100% response rate at two weeks, 95% response rate at two months, and 86.3% response rate at both four and six months. The intervention group response rate was 100% at all time points. Women liked that the intervention was delivered remotely (including the remote delivery of surveys) allowing them to stay home and avoid travel concerns, the overall information that was provided, the structure of the program (including the comprehensive manual and homework), and being on the phone with a diverse

group of women going through a similar life stage. When asked, all women indicated they would participate in an intervention delivered via GBPC again. Additionally, they felt the GBPC was the optimal method of delivery for the intervention; however, there were concerns about a lack of engagement and connectivity and some women desired additional visuals such as video links. Women proposed options such as a single in-person meeting prior to the start of the intervention or a method such as video chat to improve rapport between women in the group and thus engagement.

In summary, GBPC, and more specifically the program format and content used for this study was an effective and acceptable method for intervention delivery and should be considered in future studies. Future studies should adjust the curriculum as suggested by participants and specifically add additional information on proper latch and maintaining an adequate milk supply throughout breastfeeding. An additional postpartum group component should be considered as this may be a vital component to improving breastfeeding rates. Finally, an effective technological method for improving breastfeeding rates and preventing the early introduction of solids that reduces both financial and participant barriers could drastically increase the number of women who received appropriate infant feeding information and improve infant and maternal health outcomes.

5.5.5 Strengths and Limitations

A strength is that an evaluation of maternal satisfaction of the intervention was completed to help guide future intervention development. This component was previously underreported in research [139]. Another strength is the high response rate and compliance to the study protocol. However, our study also had some limitations. For this study, we used maternal self-report for breastfeeding outcomes; however, previous research has shown this to be a reliable measure

[140]. Another limitation is the relative homogeneity of the group limiting generalizability. Further, women in both groups received lactation help in both the hospital and after discharge. We do not know what affect this may have had on their decision to continue breastfeeding. Another limitation is the small sample size and lack of power to detect significant results. A future study, with similar design, that is adequately powered is needed to determine the effect of a PBLI intervention delivered via GBPC on breastfeeding rates and introduction of solids.

5.6 Conclusions

Despite high initiation rates, women are discontinuing breastfeeding before recommended. Women overwhelmingly found the intervention beneficial and felt it gave them confidence and prepared them to breastfeed and introduce solids to their infant. Results from our pilot and feasibility study found that GBPC is an acceptable method of delivering a PBLI intervention for educating women on appropriate infant feeding. The intervention was not powered to detect statistically different results for breastfeeding rates. In the future, a larger, adequately powered study delivered via GBPC should be evaluated with a combination of prenatal education and postpartum support.

Figure 5.1 Consort Diagram

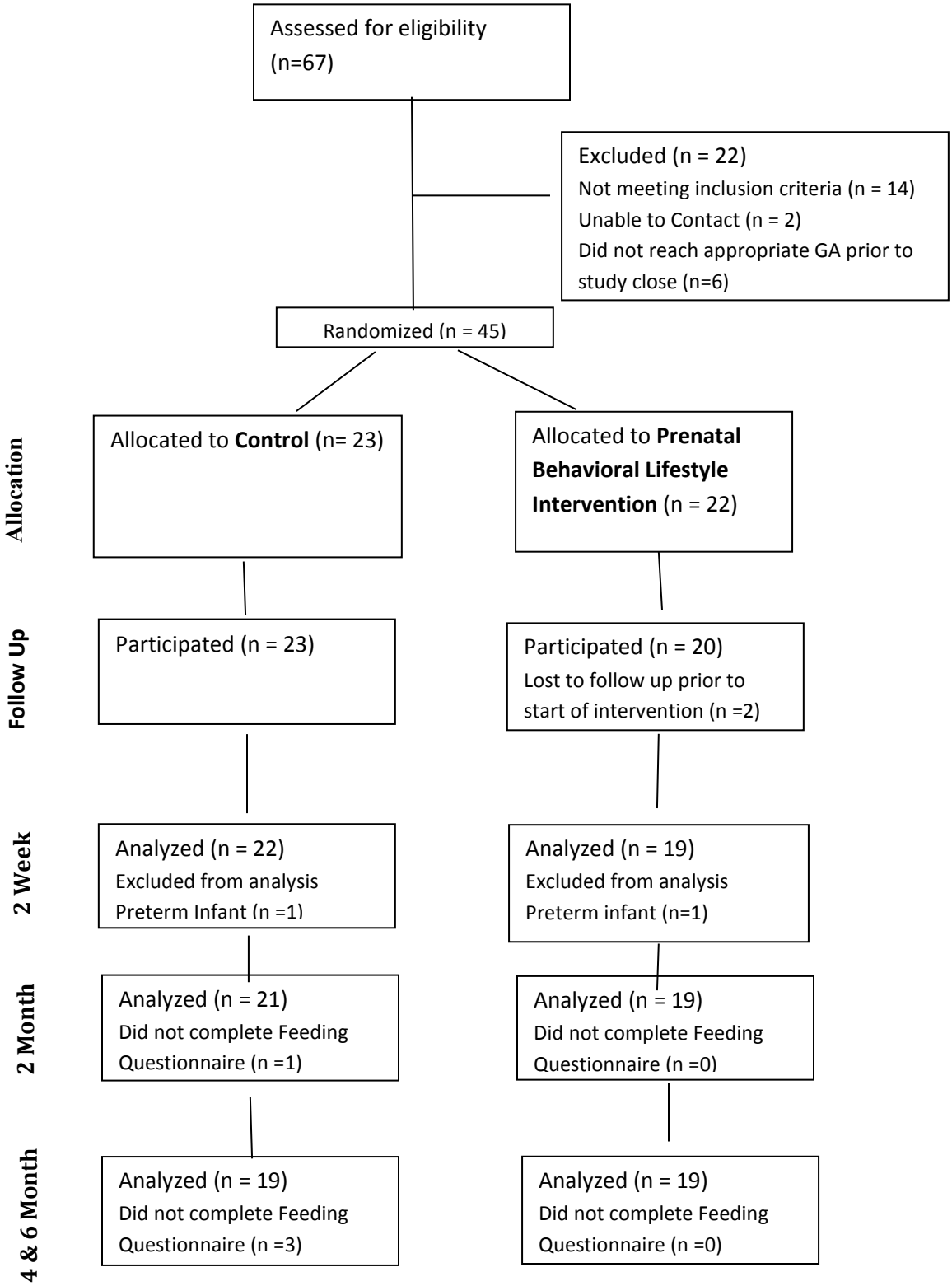

Figure 5.2 Rates of Initiation, Exclusive Breastfeeding, and Any Breastfeeding

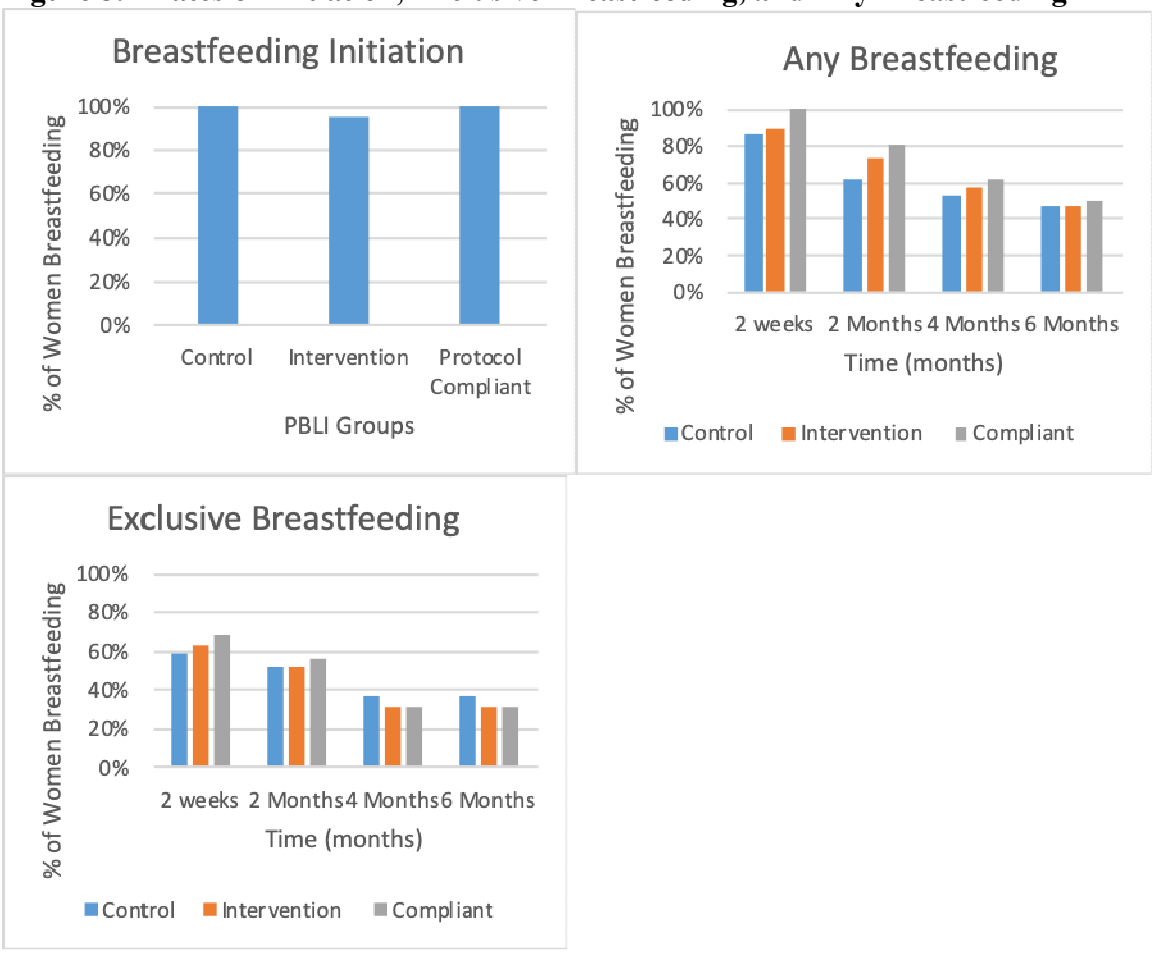

Figure 5.3 Overall duration of exclusive breastfeeding by treatment group

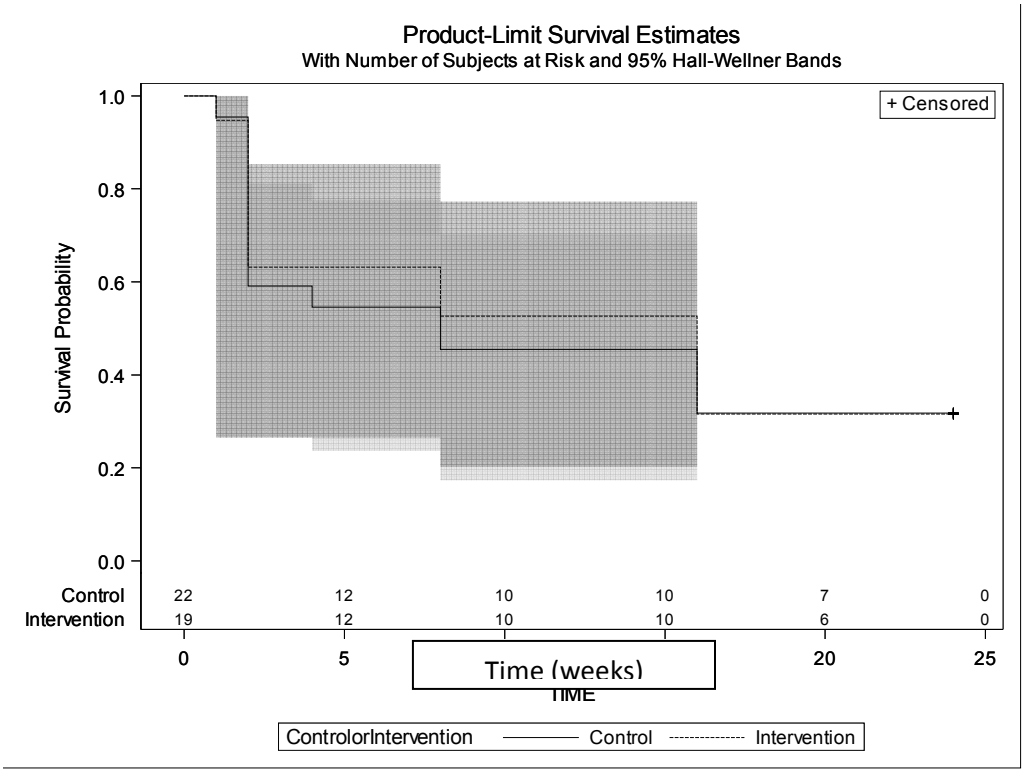

Figure 5.4 Overall time until introduction of solids by treatment group

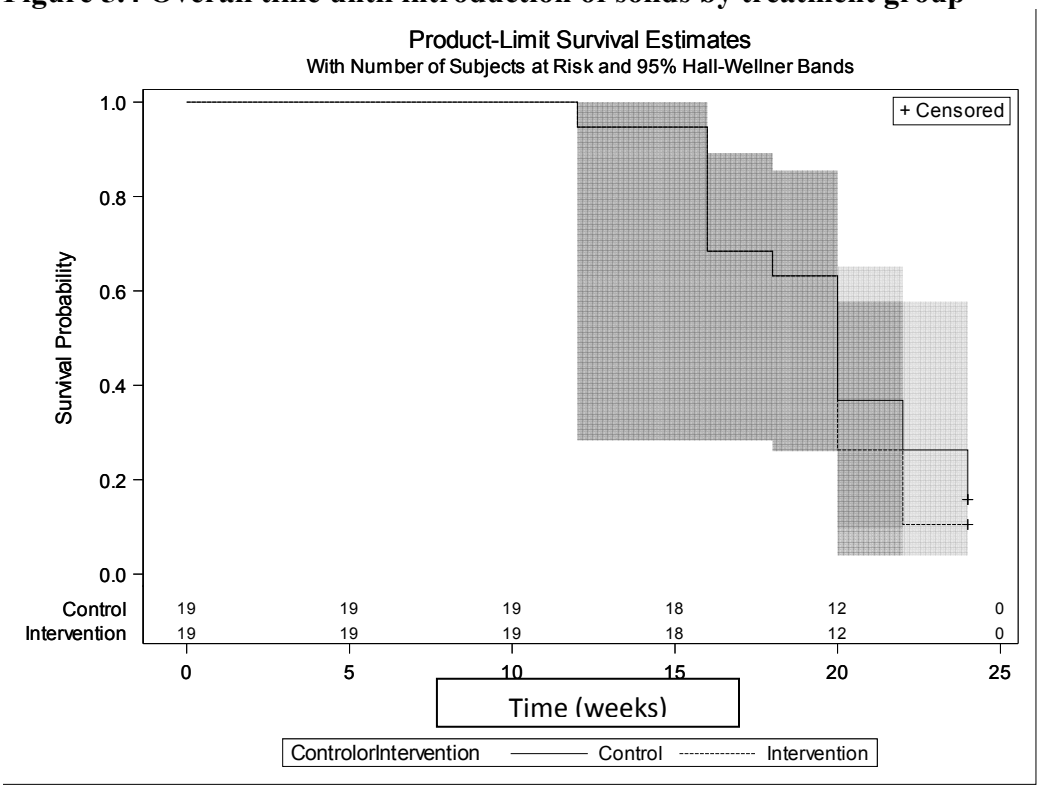

Table 5.1 Structured Interview Questions

Structured Interview Questions
Post Intervention Questions: *Overall* 1. What did you like about this program? 2. What did you dislike about this program? 3. Did the intervention help you determine how you wanted to feed your baby? *Calls* 1. Were the weekly group calls at a time you were generally available? 2. What did you like about the phone meetings and what did you not like about the phone meetings? 3. Was there anything about the calls that you would change? 4. Would you participate in another intervention using phone meetings? *Future* 1. What do you think we could do in order to make this program better? 2. Would you recommend this program to a friend? 3. For the future, instead of a phone meeting would you like to receive information in a different way such as a short video format, manual only, in person, etc.? **6 Month Follow up Questions:** *Overall* **1.** Do you feel the information you received on the phone calls was beneficial for breastfeeding your baby and introducing solids, if you have done that yet? **2.** What information that you received on the phone calls did you find most helpful while breastfeeding and introducing solids, if you have done that yet? **3.** Is there any information you did not receive during the phone calls that you wish you had received that would have made breastfeeding or introducing solids more successful? **4.** Did you use your participant handbook after baby arrived to look up information? **5.** Do you feel participating in the intervention helped you reach your breastfeeding goals? **6.** Any overall feedback that you would like to give?

Table 5.2. Maternal and Infant Characteristics

	Overall N=41	Usual care N=22	Intervention N=19	*P*-Value
Maternal				
Age (years)	26.2 ± 4.3	25.4 ± 4.5	27.3 ± 4.1	0.1
Pre-pregnancy BMI (kg/m^2)	27.3 ± 4.5	26.8 ± 4.4	27.9 ± 4.7	0.4
White Race n(%)	39 (95.1%)	21 (95.5%)	18 (94.7%)	1.0¥
Education n(%)				0.9¥
Less than High School	1 (2.4%)	1 (4.5%)	0 (0%)	
GED	3 (7.3%)	2 (9.1%)	1 (5.3%)	
High School	9 (22%)	4 (18.2%)	5 (26.3%)	
Vocational	1 (2.4%)	1 (4.5%)	0 (0%)	
Associates Degree	4 (9.8%)	3 (13.6%)	1 (5.3%)	
Undergraduate Degree	16 (39%)	8 (36.4%)	8 (42.1%)	
Graduate Degree	7 (17.1%)	3 (13.6%)	4 (21.1%)	
Married or Cohabitating n(%)	34 (82.9%)	17 (77.3%)	17 (89.5%)	0.4¥
Household Income n(%)				0.9
≤ $75,000	19 (46.3%)	10 (45.5%)	9 (47.4%)	
> $75,000	22 (53.7%)	12 (54.5%)	10 (52.6%)	
Parity, Primiparous n(%)	29 (70.7%)	15 (68.2%)	14 (73.7%)	0.7
Type of Delivery n(%)				1.0¥
Vaginal	32 (84.2%)	16 (84.2%)	16 (84.2%)	
Cesarean	6 (15.8%)	3 (15.8%)	3 (15.8%)	
Infant				
Gestational age (weeks)	39.47 ± 1.00	39.49 ± 0.78	39.46 ± 1.24	0.9
Female n(%)	30 (48.8%)	11 (50%)	9 (47.4%)	0.8
Birthweight (lbs)	7.80 ± 1.03	7.69 ± 1.00	7.93 ± 1.09	0.4
Values are % or mean ± SD ¥: Fisher's exact test				

Table 5.3 Rates of Initiation, Exclusive Breastfeeding, and Any Breastfeeding

	Usual care n=22	Intervention n=19	*P*-Value	Protocol Compliant n=16	*P*-Value
BF Initiation					
	22 (100%)	18 (94.7%)	0.5 ¥	16 (100%)	-
Exclusive Breastfeeding					
2 weeks	13 (59.1%)	12 (63.2%)	0.79	11 (68.8%)	0.54
2 Months	11 (50%)	10 (52.6%)	0.87	9 (56.3%)	0.7
4 Months	7 (31.8%)	6 (31.6%)	0.98	5 (31.3%)	0.97
6 Months	7 (31.8%)	6 (31.6%)	0.98	5 (31.3%)	0.97
Any Breastfeeding					
2 Weeks	19 (86.4%)	17 (89.5%)	0.35¥	16 (100%)	0.25¥
2 Months	13 (61.9%)	14 (73.7%)	0.43	13 (81.3%)	0.28¥
4 Months	10 (52.6%)	11 (57.9%)	0.74	10 (62.5%)	0.56
6 Months	9 (47.4%)	9 (47.4%)	1.0	8 (50%)	0.88
Values are n(%) ¥: Fisher's exact test					

Table 5.4 Reasons for Introduction of Formula. Data are reported as n(%)

	2 Weeks n=16	2 Months n=20	4 Months n=25	6 Months n=25
Following Advice from HealthCare Provider	6 (37.5%)	4 (20.0%)	5 (20.0%)	5 (20.0%)
Following Advice from Family and Friends	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Breastfeeding was too Difficult	3 (18.8%)	3 (15.0%)	3 (12.0%)	4 (16.0%)
Baby Did Not Gain Enough Weight	4 (25.0%)	6 (30.0%)	5 (20.0%)	5 (20.0%)
Easier to Fit into Daily Routine	2 (12.5%)	7 (35.0%)	8 (32.0%)	9 (36.0%)
Allows Others to Feed Baby	2 (12.5%)	4 (20.0%)	6 (24.0%)	4 (16.0%)
My Plan was to Formula Feed	1 (6.3%)	1 (5.0%)	1 (4.0%)	1 (4.0%)
Other	8 (50.0%)	9 (40.0%)	16 (60.0%)	9 (36.0%)
	Supply (3) Latch (2) Mental Health (1) BF isn't always possible (1) No answer (1)	Supply (5) Poor Support (1) No answer (3)	Supply (8) Mental Health (2) No Answer (2) Refused to BF (1) Poor Support (1)	Supply (7) Mental Health (2) Refuse to BF/Weight loss (1)

CHAPTER 6

CONCLUSIONS

6.1 Summary of Findings

This is the first study to report when women are making their infant feeding decisions and the feasibility and acceptability of a PBLI delivered via GBPC to increase breastfeeding rates and the appropriate introduction of solids. Our results move the field forward by showing that women make their infant feeding decisions prior to pregnancy, requiring interventions to begin earlier. In addition, we know that an intervention delivered during pregnancy via GBPC is an acceptable and beneficial method of delivery. When comparing groups, we saw a trend toward increased breastfeeding rates in the intervention group, but no differences were seen at any time point. The trend decreased as the infants age increased, suggesting additional support is needed in the postpartum period. This study provided valuable information on what aspects of the intervention women liked and suggestions to inform a more effective future intervention.

Chapter 4 Maternal opinions on breastfeeding, introducing solids, and postpartum weight loss

The purpose of this study was to understand timing of and factors that influenced infant feeding decisions and barriers that women faced when breastfeeding, introducing solids, and losing weight postpartum to inform future interventions. We found women are making their infant feeding decisions prior to pregnancy. They faced a number of barriers when breastfeeding, introducing solids, and working to lose weight postpartum. Overall, women do not feel prepared to face these transitions after baby is delivered and indicated wanting basic and practical information offered to them both during pregnancy and after baby arrived.

Chapter 5 Impact of a Prenatal Group Based Phone Counseling Intervention on Breastfeeding Rates and the Introduction of Solid Foods: A Randomized, Controlled Pilot and Feasibility Trial

The purpose of this pilot randomized controlled trial was to evaluate the effectiveness of a PBLI delivered via GBPC on breastfeeding rates up to six months postpartum, rates of early

introduction of solids, infant feeding progression, and maternal compliance and acceptability of the intervention. No between group differences were found for rates of exclusive or any breastfeeding up to six months or for the introduction of solids prior to four months. Overwhelmingly, women found the intervention to be beneficial, providing increased preparedness and confidence prior to breastfeeding and introducing solids. Women preferred GBPC for intervention delivery but wanted additional visuals and follow up during the postpartum period. Results indicate the potential for a PBLI to improve breastfeeding rates. Additionally, feedback from women will allow for refinement of the current intervention and inclusion of a postpartum component that could further improve rates of breastfeeding.

6.2 Discussion

6.2.1 Comparison with Other Studies

Chapter 4 Maternal opinions on breastfeeding, introducing solids, and postpartum weight loss

Several studies have looked at maternal characteristics related to early breastfeeding cessation and reasons for early breastfeeding cessation [67-71, 74]. Our results aligned with previous studies and found milk supply problems, latching issues, and nipple pain as primary barriers to successful breastfeeding. None of these studies assessed what information women would have wanted to help overcome these barriers. One previous qualitative study looked at information gaps experienced by breastfeeding mothers [78]. Identified information gaps included milk supply, feeding frequency, latch, nipple care, and practical advice to address breastfeeding concerns. Our study confirmed these results. However, our study expanded current knowledge by addressing the type of information women wanted to overcome barriers, when women wanted this information given, and how they wanted it delivered. We found that women wanted information earlier, during the second or third trimester of pregnancy, in addition to

postpartum. In addition, this is the first study to report that women are making their infant feeding decisions prior to pregnancy.

The barriers women face during breastfeeding often prevent women from meeting breastfeeding recommendations and self-established breastfeeding goals. One study evaluated whether a woman met her own breastfeeding goals regardless of meeting infant feeding recommendations. Odom et al. [67] found that 60% of women did not meet self-established breastfeeding goals. Our results were similar and found that 40% of women did not meet self-established goals.

A review by Dewy et al. [118] suggested that numerous complementary feeding interventions occur in developing countries to address growth stunting, infectious illnesses, and micronutrient deficiencies. These results have little applicability to the US because these conditions are not common, but instead, obesity is a primary health concern. A recent review by Arikpo et al. [119] found educational interventions are effective for improving the timing of introducing solids foods; however, they did not address what information mothers would want included in an intervention. Our results provide specific information on what education women want to receive in an intervention and when they want to receive it.

Chapter 5 Impact of a Prenatal Group Based Phone Counseling Intervention on Breastfeeding Rates and the Introduction of Solid Foods: A Randomized, Controlled Pilot and Feasibility Trial

A review conducted to assess interventions to improve breastfeeding rates at six months indicated the majority of interventions occur in the postpartum period [81]. The most successful interventions were substantial in length and involved peer support or a lactation consultant. Despite these interventions, breastfeeding rates remain low and a lack of prenatal education is a barrier to improved rates [77, 88]. Prenatal education is associated with improved rates of

breastfeeding initiation [89]. A review of prenatal breastfeeding education interventions concluded that peer support, formal breastfeeding education, and the use of lactation consultants may increase breastfeeding duration [90]. One pilot randomized controlled trial looked at the effect of a breastfeeding intervention on breastfeeding self-efficacy, duration, and exclusivity [141]. They collected qualitative data on the feasibility and acceptability of the intervention. As a pilot, the trial was not powered to detect significant between group differences, however, they did see increased rates of breastfeeding self-efficacy, duration, and exclusivity at four and eight weeks postpartum. Further, most women indicated the intervention was beneficial. They found exclusive rates of breastfeeding at two months were 45.2% in the usual care group and 50.8 % in the intervention. In comparison, our study found at two months similar results with 50% of women in the usual care group exclusively breastfeeding and 52.6% of women in the intervention exclusively breastfeeding. Our study also had high compliance and was both feasible and beneficial to participants. In addition, our study expanded upon this intervention by offering educational information earlier and offering all sessions via GBPC.

Another prenatal breastfeeding intervention offered education sessions with a lactation consultant at standard prenatal care visits. They found no differences in continued breastfeeding at six months for women who only received the prenatal intervention [98]. However, in a cohort of women who also participated in a postpartum support group, increased rates of continued breastfeeding at six months were found. Our results are similar as we found no differences in exclusive breastfeeding at six months and women who struggled with breastfeeding indicated that they needed additional support in the postpartum period to be successful.

Previous estimates of early introduction of solid foods range from 24.3% to 52.7%, depending on feeding method [6]. Our study found less than 5% of women introduced solids

prior to four months. These results could be explained by our population, which had very few characteristics associated with mothers who are at risk for introducing solid foods too early [138]. A recent review by Arikpo et al. [119] found that educational interventions improved the timing of solid food introduction. Most educational interventions to improve timing of introducing solids occurred in the postpartum period. To our knowledge this is the first prenatal educational intervention with a targeted goal of reducing early introduction of solids. Mothers provided positive feedback regarding learning about introducing solids in the prenatal period, but our study did not find a problem with early introduction of solids.

6.2.2 Clinical Implications

6.2.2.1 Timing of Maternal Feeding Decisions and Desired Information

In the chapter 4 group interviews we discovered that women are deciding how they want to feed their infant prior to pregnancy. This is clinically relevant because it indicates interventions need to begin sooner. Interventions aimed at a mother's intent to breastfeed, and thus initiation, should begin during pregnancy and possibly pre-conception. Waiting until baby has arrived is too late. Women also indicated that they felt unprepared to breastfeed, introduce solids, and lose weight in the postpartum period. They want breastfeeding information given during pregnancy and also appreciated anticipatory guidance on introducing solids and losing postpartum weight during pregnancy. Mothers wanted information on solids thoroughly reviewed by their pediatrician at the standard four month well child check. Overall, women wanted breastfeeding information that included basic information on breastfeeding, difficulties they may experience and how to handle them, and where to find additional support. Specifically, women wanted guidance on the proper use of a nipple shield, guidance on exclusive pumping, how often to feed baby, hunger cues, latching techniques, and how to get in touch with a

lactation consultant. Information on introducing solids included feeding problems such as constipation or picky eating, appropriate weight gain and growth expectations, allergies, and baby led weaning.

In the chapter 5 PBLI, we used the information obtained from the group interviews presented and developed a PBLI that was delivered via GBPC. Women found the intervention to be acceptable and highly beneficial. Women liked the program format and were in favor of the accompanying manual, diversity of experiences represented by the group, having an expert available, and the comprehensiveness of the information they received. They also appreciated not traveling to attend the program and having a designated hour set aside to learn. A primary concern was a lack of engagement during phone sessions, which will need to be addressed in future interventions. Suggestions included meeting at least one time face to face to improve rapport between participants, having some type of social media group (Facebook, skype, etc) so women could connect better, and making the information less didactic and more relational.

Overall, women felt unprepared to breastfeed their infant and introduce solids. Offering a PBLI delivered via GBPC is beneficial for building maternal confidence for feeding their infant. Future interventions should take maternal suggestions into consideration and encompass both the prenatal and postpartum period.

6.2.2.2 Breastfeeding

We found no between group differences in rates of any breastfeeding or exclusive breastfeeding at any time point. When comparing groups, there was a trend toward higher breastfeeding rates at all time points for women who were compliant to the intervention, attending at least four GBPC sessions. Clinically, this implies that the intervention needs to remain highly accessible with minimal participant burden to encourage participation in the

intervention. Keeping the intervention technologically based, with the possible addition of a social media group or one in-person meeting to improve rapport, will reduce barriers to participation. Due to low rates of exclusive breastfeeding and women's feedback that additional support was needed after baby arrived, we feel the intervention should encompass both the prenatal and postpartum period. In addition, more information should be included on breastfeeding in the hospital, milk supply, latching, going back to work, etc. In summary, the PBLI was beneficial, but the information should be fine-tuned and extended into the postpartum period to improve overall rates of exclusive and any breastfeeding.

6.2.2.3 Introduction of Solid Foods

No between group differences were found in rates of early introduction of solids. Overall, women in both groups introduced solids appropriately. Qualitatively, we found that women felt information on introducing solids in the postpartum period was beneficial and it made them feel more prepared. However, women indicated they wanted additional support in the postpartum period so they could access "real time" advice. Despite no differences in rates of early solid introduction, it is clinically important to provide women with information about introducing solids in both the prenatal and postpartum period to improve maternal preparedness and satisfaction.

6.2.3 Strengths and Limitations

6.2.3.1 Strengths

Our study had several strengths. First, in both chapters we implemented qualitative measures to help understand barriers women face and how to improve future interventions. This information is vital to aid in the development of interventions that women find beneficial and effective. Additionally, our study had high response rates and protocol compliance. In the PBLI,

the usual care group response rates at two weeks was a 100%, 95% at two months, and 86.3% at four and six months. The intervention group response rate was 100% at all time points. Most women in the intervention (n=16, 85%) were compliant to the intervention protocol and completed four or more GBPC sessions.

6.2.3.2 Limitations

Our study also had limitations. The sample size was small (n=11 for Group Interviews and n=41 for the PBLI). In the PBLI, our small sample size limited our ability to detect significant differences in breastfeeding rates. However, as a pilot feasibility trial, this was expected. In the group interviews, there was a lack of participant diversity (age, parity, etc.) which reduce the breadth of feedback we received in relation to barriers women face and what information women wanted to overcome the barriers, and how they want information delivered. In the PBLI, the sample was homogenous which limits generalizability of our findings.

6.3 Future Directions

A future study with a similar design and larger sample size is warranted to detect significant differences. In addition, the intervention needs further refinement to include participant suggestions. This includes waiting to start the intervention until closer to the middle or end of the second trimester, the addition of information review at the beginning of each lesson, added links and visuals in the participant manual, and the addition of a postpartum component. Future studies should also collect data on maternal method of feeding more frequently. This will aid in comparing breastfeeding rates to national and state rates at three months and six months and present a narrower timing of breastfeeding cessation to help understand when additional education or support is needed. In regard to introducing solids, feeding questionnaires and structured interviews should be administered past six months to allow

mothers time to practice introducing solids and have relevant feedback on how the intervention helped. In addition, offering this intervention to a population at risk for early introduction of solids (i.e., formula fed or formula/breastfed) may show a greater benefit as previous research found that mode of feeding is related to early introduction of solids [6].

6.4 Conclusions

Mothers discontinue breastfeeding earlier than recommended despite high rates of initiation. This innovative randomized, controlled pilot and feasibility trial suggests a PBLI delivered via GBPC may improve breastfeeding rates and empower mothers to feel more successful at both breastfeeding and introducing solids. Valuable qualitative information was gained to help refine the current intervention. A future intervention should incorporate both prenatal and postpartum components to maximize the effect on breastfeeding rates, introducing solids, and maternal satisfaction.

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