Diabetes Prevention Program Feasibility Study of Breastfeeding Electronic Monitoring of Mom's Schedule 2.0

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Section I. Purpose, Background and Rationale

A. Specific Aims

In the proposed randomized controlled trial, we seek to determine the feasibility and efficacy of a combined breastfeeding, DPP-based program in a cohort of overweight/obese women to be followed during pregnancy through 3 months postpartum. Our trial will have two study arms: DPP plus breastfeeding (Tx1); and Usual Care (Tx2). Specific aims are:

Aim 1: Quantify interest in use of the DPP-lactation support app among target population. To accomplish this, we will: (1) measure research engagement including rates of screening, recruitment, and retention among users, especially rural and racially/ethnically diverse women; (2) assess barriers/facilitators to enrollment/retention through surveys and semi-structured in-depth interviews or focus groups; and (3) evaluate intervention uptake, delivery, and adherence via tracking/measuring use of the app.

Aim 2: Measure weight loss and duration of lactation through 3 months postpartum among target population. To accomplish this, we will measure pre-pregnancy weight, weight at study entry, weight immediately prior to and after delivery, and weight at specific postpartum time points. Lactation and infant feeding practices will be measured at similar postpartum time points.

B. Background and Significance

Between 1987 and 2020, U.S. pregnancy-related mortality tripled, from 7.2[1] to 23.8[2] maternal deaths per 100,000 live births with women of color, low-income and rural women at particularly increased risk of pregnancy-related death.[3,4] Increasing trends in obesity contribute to severe maternal morbidity and mortality. In 2019, nearly 3 in 10 U.S. women had pre-pregnancy obesity (PPOB).[5]

PPOB is a major risk factor for gestational diabetes mellitus (GDM) affecting 7-9% of pregnant women, particularly those with advanced maternal age, low socio-economic status, and women who self-identify as being non-White.[6] Women with GDM and comorbid conditions such as PPOB experience adverse pregnancy outcomes[7-9] including pre-eclampsia,[9-11] emergency cesarean section,[10,12] maternal prenatal depressive symptoms,[13] pregnancy hyperglycemia,[13] and reduced lactation.[14] Further, women with GDM have a seven-fold risk of developing type 2 diabetes mellitus (T2DM) later in life compared to women without GDM.[15,16]

Lactation is a critical element of postpartum care management. Women who lactate have a lower incidence of T2DM[17-20] and reduced postpartum weight.[21-23] To optimize these benefits, the World Health Organization (WHO) [24] and the American Academy of Pediatrics (AAP)[25,26] recommend exclusive breastfeeding for the first six months of life along with introduction of complementary foods at six months while continuing human milk for up to two years and beyond. About 83% of U.S. women attempt lactation, but only 56% continue to provide human milk with formula supplementation at six months and only 25% provide human milk exclusively at six months.[27]

Implementation of lifestyle change programs such as the national Diabetes Prevention Program (DPP) can reverse negative effects from PPOB[28-31] and reduce postpartum weight.[32,33] The DPP, through counseling on effective diet, exercise, and behavior modification, is associated with a reduced risk of developing T2DM by 58%[34,35] and is shown to be effective for preventing diabetes in women with a history of GDM.[36] Yet, access to evidence-based weight management programs that include lactation support remain limited. We posit that a significant number of medically underserved women will elect to participate in DPP-like interventions that include lactation support, if available. Clearly, technology-assisted DPP-like interventions show clinically meaningful weight loss.[37,38] Extended with lactation support, these programs have still unrealized potential to expand access to medically underserved communities.

To date, there are no studies that have coupled the DPP with bi-directional digital lactation support delivered to pregnant, medically underserved populations with overweight or obesity. The proposed study seeks to narrow the gap in knowledge by implementing a DPP-based intervention coupled with bi-directional lactation support for pregnant women at risk for pregnancy-related morbidity and mortality through an easily accessible mobile health (mHealth) application (app).

C. Preliminary Studies

I led and completed two pilot studies in southwest rural Kansas: (1) a health assessment of the obstetrical population (completed in April 2015), and (2) a follow-up focus group study with the same population (completed in May 2016). The purpose of the assessment was to learn about the health behaviors of rural pregnant women. Two local hospitals and one federally qualified rural health center participated in the assessment. Our sample consisted of 177 rural pregnant women. Key findings indicated that the majority of women were Hispanic (50.3%), 18-25 years old (48.6%), high school educated (51.2%) , WIC enrolled (51.7%), and earned < $25,000/year (54.2%).[39] The majority were overweight (28.1%) or obese (26.2%) *prior* to pregnancy.[39] Additionally, the majority engaged in no daily exercise (72.6%) and nearly one-third (30.5%) reported having an immediate family member who was diagnosed or treated for diabetes or cardiovascular disease.[39]

These results demonstrate significant diabetes risk factors during and after pregnancy. Subsequently, in follow-up to the assessment, I led and completed a focus group study to gain in-depth information from this same population on what they would value in a health promotion program. Findings indicated limited availability of programs that focus on exercise, diet, and breastfeeding support during and after pregnancy. Further, I published three additional studies relevant to the proposed project.[40-42] Each of these studies focused on health behaviors among urban versus rural WIC enrolled women in Kansas and helped our research team understand the prenatal and postnatal needs of at-risk populations in Kansas.

The electronic Monitoring Of Mom's Schedule 1.0 study (eMOMS^{TM}) was a feasibility, three-arm, multi-center randomized controlled trial (NCT04021602) examining lifestyle changes modelled after the Diabetes Prevention Program (DPP) and lactation (LC) support alone, and in combination. eMOMS 1.0 was created to quantify intervention uptake, and measure weight and

lactation duration.[43] The intervention was delivered by a professionally trained certified health coach (HC) using Facebook.

At baseline, participants averaged 13.0 (±2.5) weeks gestation, mean pre-pregnancy BMI of 29.7 (±3.0). With 5,000 bootstrapped samples, mean weight retention from baseline to 6 months postpartum was: 8.9 lbs. (3.6, 13.7) for DPP+LC+HC; 8.1 lbs. (-4.0, 21.7) for DPP+HC; and 16.5 lbs. (9.1, 25.5) for the health coaching only (HCO) group. Mean lactation duration was: 11.3 weeks (1.3, 21.2); 14.9 weeks (9.9, 20.0); and 16.7 weeks (9.4, 23.3) for each group respectively (our primary outcomes paper is currently under review with the Journal of Human Lactation and until this publication is finalized, study findings will remain preliminary).

Between September 2019 and May 2021, 100 individuals were screened, 47 were eligible, and 35 were randomized resulting in a 35% enrollment rate. Of those, 26 completed the intervention resulting in a 74% retention rate. Intervention completers were slightly older and entered the study earlier in pregnancy compared to non-completers. Completers were more likely to be first-time mothers, resided in urban areas, had higher educational attainment, and were slightly more racially and ethnically diverse. A majority of providers reported willingness to participate, believed the study aligned with their organization's mission, and were satisfied with using iPads for screening. Lessons learned to guide recruitment success include use of: (1) designated research staff in combination with physician support; and (2) user-friendly technology to help mitigate time burden on physicians and their staff.[44]

Additionally, feedback from study participants on their experiences was obtained. Of the 26 individuals who completed the eMOMS 1.0 study, 24 consented to a semi-structured, telephone interview using open-ended questions. Interviews were completed between October 2020 and May 2021. Data were analyzed using an exploratory, inductive thematic analysis. Participants' mean age was 27.5 (± 5.4) years and mean pre-pregnancy BMI was 29.5 kg/m(2) (± 2.7). The majority (71%) were non-Hispanic White and 54% had a high school education/some college. Based on specific areas of inquiry, the following themes emerged: convenience of online program access using Facebook, importance of health coach's support and online interaction, positivity toward improving one's health, increased consciousness of health behaviors, diverse lactation educational needs, importance of educational materials on depression, and grief over the loss of birth expectations during COVID-19.[45] In summary, study results show that lifestyle changes and health coaching positively impact postpartum weight retention and lactation duration.

D. Rationale for Proposed Study

Risk factors for diabetes are well documented.[46-50] Maternal obesity in particular increases the risk of negative health outcomes for mother[51-56] and child,[57-62] including the propensity for women to retain excessive postpartum weight leading to obesity in subsequent pregnancies.[63-66] Less is known about protective factors relevant to diabetes though evidence suggests that longer duration of breastfeeding among women with a history of GDM is associated with lower incidence of developing type 2 diabetes up to two years after pregnancy.[19,20,67,68] Breastfeeding also appears to lower maternal postpartum weight[21,69,70] and facilitates the resetting of maternal metabolism after pregnancy.[71] The Diabetes Prevention

Program (DPP) is associated with a reduced risk of developing diabetes by 58%[72] and there is evidence to support the use of this efficacious program in reducing postpartum weight.[32,33] Despite these findings, no studies prior to eMOMS 1.0 have used a DPP-enhanced version delivered using an mHealth app that includes intensive breastfeeding counseling and support for overweight and obese women. Given that overweight and obese women at risk for GDM are also less likely to start and continue breastfeeding,[60,73-75] it is critical that interventions for reducing GDM risk also include breastfeeding support that is uniquely tailored to the needs of this population. *This is where the current proposal narrows the gap and contributes to the body of knowledge about reducing diabetes risk factors during and after pregnancy in an underserved population with scarce healthcare resources available.*

E. Impact of Proposed Study

The proposed project will inform future intervention efforts that aim to reduce diabetes risk factors during and after pregnancy and to increase breastfeeding, thereby improving short- and long-term maternal and child health outcomes. The immediate impact will be to reduce diabetes risk factors among a high-risk population and inform interventions aimed at reducing these risk factors and decreasing disproportionate morbidity. Its ultimate potentially high public health impact is GDM and type 2 diabetes prevention among a racially and ethnically diverse, at-risk population.

This project's impact is to provide strategies to improve human lactation and to reduce diabetes risk factors among women with overweight and obesity. Together, we expect to have a positive impact on improving access and delivery of an efficacious weight management program to pregnant populations, thereby decreasing disproportionate maternal morbidity and mortality, which is of significant importance to the National Institutes of Health. Our proposed research is expected to have a positive impact on improving access and delivery of efficacious weight management programs to pregnant populations using an mHealth application, thereby decreasing disproportionate maternal morbidity and mortality, which is of the highest priority to the Office of Research on Women's Health and the National Institute of Child Health and Human Development.

F. Justification for Project

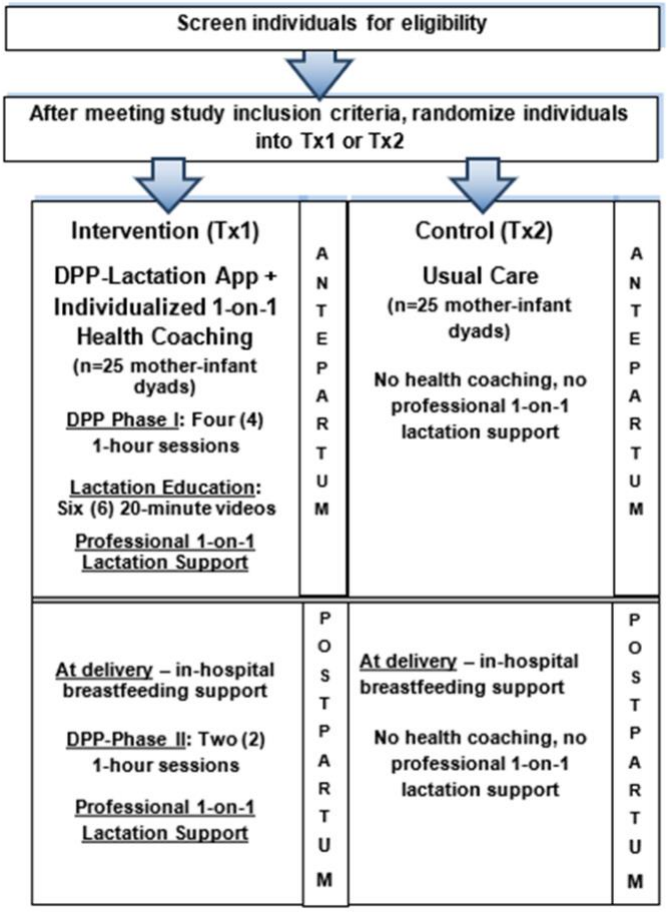
Risk factors for diabetes are well documented,[46-50] but less is known about some factors that attenuate the risk for GDM. Recent studies support the use of the Diabetes Prevention Program in reducing postpartum weight.[32,33] Moreover, emerging research suggests that longer duration of breastfeeding among women with a history of GDM decreases the likelihood of developing type 2 diabetes within two years after pregnancy.[19,20,67,68] However, no prior studies to eMOMS 1.0 have assessed the feasibility and efficacy of a DPP-based intervention that includes intensive breastfeeding counseling and support delivered using an mHealth app among racially and ethnically diverse reproductive-age rural women. Rural pregnant women in particular have decreased access to healthy foods and fewer options to engage in physical activity.[76-80] Furthermore, Hispanic women often supplement breastfeeding with formula, triggering decreased milk supply and early breastfeeding cessation.[81-83] The proposed research is

innovative because it represents a departure from what has been accomplished in the field thus far: *We seek to implement a combined breastfeeding, DPP-based intervention delivered using an mHealth app and determine its feasibility and efficacy as well as its effect on metabolic outcomes among an at-risk population.* Through examination of postpartum weight, breastfeeding behavior, and metabolic markers, results of the proposed project will inform the development of interventions to reduce diabetes risk factors during and after pregnancy. Furthermore, an efficacious approach toward promoting exercise, nutrition, and breastfeeding can be integrated into the continuum of healthcare services provided to racially and ethnically diverse, at-risk rural pregnant women.

Section II. Research Plan and Design

A. Study Design Overview

Figure 1. Study Design



This two-arm randomized controlled trial (RCT) will determine feasibility of the DPP mHealth app coupled with bi-directional lactation support, among a cohort of pregnant women with overweight and obesity (see Figure 1). Potential participants will be screened for inclusion/exclusion criteria. Upon recruitment during the 2nd or early 3rd trimester, eligible participants will be randomly assigned to either DPP-Lactation App (Tx1) or Usual Care (Tx2), and followed during pregnancy through 3 months postpartum. Usual care is described as obstetrical care that women with normal BMI receive and that is provided by the same provider. We will use a total sample of 50 pregnant women prior to accounting for dropouts. To evaluate the intervention's impact on the maternal-infant dyad, health indices will be monitored (see Table 4. Outcomes Measures, under Section III). Information gathered by this feasibility RCT will be used to develop a full scale RCT to assess if the DPP-lactation mHealth app (1) reduces postpartum weight retention, and (2) increases duration of lactation.

B. Duration of Study

It is anticipated that after receiving Institutional Review Board (IRB) approval, recruitment will begin Spring of 2024 and will continue through early Summer of 2024. We will recruit over a period of 3 months and the last follow-up with study participants will take place at 3 months postpartum. The trial will be completed over a 6 to 9-month period. Data collection and preliminary data analysis will take place as the trial runs. Final data analysis and dissemination of findings will take place following completion of the trial, during the final quarter of 2024 and/or first quarter of 2025.

C. Number of Participants

This IRB protocol pertains to the recruitment of eligible participants from one obstetrical clinic: Ascension Via Christi Hospitals Wichita, Inc. The state of Kansas lends itself for this study because of its stable population evidenced by minimum population migration between April 1, 2010, and April 1, 2020, compared to other comparable rural states (i.e., Iowa, Nebraska, Oklahoma)].[82]

Our Maternal-Fetal Medicine (MFM) specialist in Wichita, Dr. Michael Wolfe, sees a high volume of vulnerable patients with high-risk pregnancies, at an average of 123 patients per month, with an average pre-pregnancy BMI of 30.5 (personal communication, January 2022). In Wichita, 51% of its population is female, 17% is Hispanic followed by 10% non-Hispanic Black.[83] Dr. Wolfe's obstetrical clinic is affiliated with Ascension Via Christi Hospitals Wichita, Inc. located in Wichita, Kansas.

Based on our previous work, our recruitment target of women with BMI ≥25 will involve 15% non-Hispanic Black women, 25% Hispanic women, and 60% other race including non-Hispanic Whites. We anticipate meeting our recruitment goals through multiple approaches: (1) recommendations from physicians and staff; (2) social media; (3) targeted mailings; and (4) clinic posters and study brochures. We will recruit over a period of 3 months, planning to randomize 3-4 participants each week. Our goal is to randomize a total of 50 pregnant women (25 women in each study arm). Given an attrition rate of 20%, this will leave us with 40 women total (20 women in each study arm).

D. Subject Selection Criteria and Recruitment

We will actively recruit pregnant patients from Via Christi Hospitals Wichita, Inc. Rural hospitals and other various hospitals will be made aware of the study and refer patients to the eMOMS website. A website has been created containing the same information as the one-page flyer and study brochure that will be approved by the Institutional Review Board. We recruit participants into the study using two methods.

First, women will see flyers and brochures in their physician offices and will voluntarily go to the website and recruit themselves into the study. The website contains a link named "Do I qualify for eMOMS?" that interested women can use to recruit and screen themselves. If an interested participant meets eligibility, wants to participate, has all her questions answered, and electronically consents to participate using REDCap, then a study team member will contact her.

Second, Dr. Michael Wolfe, maternal fetal medicine specialist, sees pregnant women at the Wichita location, and he and his staff will actively assist with patient recruitment. Prior to a prenatal appointment, Dr. Wolfe will screen potential participants for inclusion criteria, and if he believes a participant meets inclusion criteria (see Table 1), then he will contact Dr. Jacobson and her research coordinator with the first and last name of the potential participant, and date/time of her prenatal appointment. During this prenatal appointment, Dr. Wolfe will familiarize a potential participant with the study's purpose. If the potential participant is interested in the study, then he will give her a study brochure and a hard copy of the consent form. Prior to using this study brochure, the brochure will be reviewed and approved by the Ascension Health Institutional Review Board (IRB). By providing the potential participant with a copy of the consent form, this will serve as the verbal consent script. After receiving a potential participant's name and appointment time from Dr. Wolfe, the research coordinator will follow up on-site to determine if the potential participant again meets study inclusion criteria, and if she does, the coordinator will screen if the potential participant meets study exclusion criteria at the same time (see Table 1). Before the research coordinator screens for inclusion and exclusion criteria, during this onsite visit, verbal consent will be obtained between the participant and the research coordinator, using the consent form as the verbal consent script, and then written e-consent will be obtained via REDCap at this same visit. Once the participant is enrolled in the study and over the course of her pregnancy develops one of the conditions mentioned under Exclusion (Table 1), then this will be reported to the Data and Safety Officer. It will then be decided in consultation with Dr. Wolfe if the participant will be able to continue participating in the study or if she will need to be dismissed.

Table 1. Enrollment Criteria

Inclusion
1. Pregnant
2. In 2nd trimester or early in 3rd trimester
2. BMI ≥ 25 and < 35
3. At least 18 years old or older
4. Be able to read and understand English
5. Be able to learn and use a video platform
Exclusion
1. Pregnancy complications that require emergency care
2. Thyroid disease
3. Multiple gestation
4. Substance abuse within last 3 years
5. ART (Assisted Reproductive Technology) pregnancy
6. Current smoker
7. Prior bariatric surgery
8. In weight-loss program within 3 months of conception
9. BMI ≥ 35
10. Unable to attend intervention/follow-up visits
11. Unwilling to self-monitor data collection
12. Unable to complete intervention
13. Presence of any condition that limits walking
14. Presence of any condition that limits following diet recommendations
15. Pregnancies complicated with fetuses diagnosed with lethal malformations/conditions

If the participant meets enrollment criteria, then the research coordinator will schedule a virtual 30-minute orientation session, to complete study-related survey instruments, and to obtain her email address to provide her with informed consent materials for review. Participants are informed that they will earn incentives to continue and complete the study: (1) a $40 Amazon gift card and a pack of diapers at study entry, (2) a high-quality digital scale; and (3) a $50 gift card at study closure. Investigators will issue incentives in accordance with policies set forth by IRB (please refer to the heading titled "Self-Administered Surveys and Incentive to Participate" below for additional detail regarding participant incentives).

Our recruitment target of pregnant women with pre-pregnancy overweight or obesity will involve 15% non-Hispanic Black women, 25% Hispanic women, and 60% other race including non-Hispanic Whites. We anticipate meeting our recruitment goals through multiple approaches: (1) recommendations from physicians and staff; (2) social media;

(3) targeted mailings; and (4) clinic posters and study brochures. We will recruit over a period of 3 months, planning to randomize 3-4 participants each week. Our goal is to randomize a total of 50 pregnant women (25 women in each study arm). Given an attrition rate of 20%, this will leave us with 40 women total (20 women in each study arm). To reach vulnerable populations hesitant about engaging in research, we will use successful strategies from previous clinical trials with medically underserved populations.[84] We will work with trusted community organizations (see Letters of Support), engage/train staff who are culturally sensitive, and contact participants repeatedly.

E. Study Locations

Active recruitment will take place at Via Christi Hospitals Wichita, Inc. Doctors at other sites and community organizations in the Wichita area may refer their patients to this program but will not be assisting in active recruitment. We will have on-going support from the study location. The principal investigator, Dr. Jacobson, has a long-term collaborative partnership with Dr. Wolfe that has resulted in numerous conference presentations and/or publications. There will be additional rural sites interested in participating in this study. We have a strong letter of support from the Sunflower Health Network (SHN) whom we have partnered with on previous successful projects (see Appendix 1). The SHN consists of 26 Critical Access Hospitals (CAH) and associated rural clinics, 12 of which provide prenatal/obstetrical services across Kansas' rural and frontier counties. Most importantly, we will have ongoing support for Dr. Jacobson's work from Dr. Michael Wolfe, Maternal Fetal Medicine Specialist, who will see, screen, recruit, and provide clinical expertise to his patients (see letter of support, Appendix 2).

Location for affiliated obstetrical clinic above is as follows:

Via Christi Maternal Fetal Medicine Clinic
1515 South Clifton Avenue, Suite 130
Wichita, Kansas 67218

F & G. Methodology – Intervention, Study Procedures and Data Collection

The Intervention

Conceptual Model. We will use Social Cognitive Theory (SCT)[84,85] and Self-Determination Theory (SDT)[86,87] to guide program development and selection of measures. SCT stipulates that behavior modification results from the interaction between behavior change, cognition (self-efficacy, perception of barriers to lifestyle changes), and the environment (support), while modeling and reinforcement serve to encourage change. SDT is a broad-based theory of human motivation[88] that explains how intrinsic motivation can lead to improved eating and exercise patterns.[89] According to SDT, a person's increased intrinsic motivation to improve eating and exercise patterns should positively relate to self-efficacy and the ability to overcome barriers and solicit support. The DPP plus breastfeeding (Tx1) uses assignments, individualized goal setting, and shared problem-solving to increase mastery and goal achievement in incremental steps to

enhance self-regulatory skills. Using the Consolidated Framework for Implementation Research (CFIR), we will conduct a formative evaluation of the implementation of the DPP-lactation mHealth app employing a mixed-methods approach to assess implementation barriers and facilitators that influence program outcomes.[65] Specific constructs from the CFIR that are most relevant to the study setting will guide context, progress, and study results. [66,67] The RE-AIM framework [68,69] will also be used to assess Reach, Effectiveness, Adoption, Implementation, and Maintenance of the DPP-lactation app (see Approach section for additional detail).

Diabetes Prevention Program (DPP). The DPP will be administered in two phases by two (2) professionally trained and certified health coaches provided by Cappa Health (see Appendix 3). Phase I consists of a total of four sessions that will each be one hour long completed during pregnancy (see Table 2). Each of the four (4) sessions/modules of Phase I will be pre-recorded and archived on a secure, private mobile health application provided by Cappa Health. Prior to starting a DPP session, a participant will be sent a link to the REDCap database to complete a survey instrument. Only Dr. Jacobson, the database manager, the statistician, and the research coordinator will have access to this database.

Table 2. Intervention Content and Timeline

Prenatal (Core Curriculum)	
DPP Sessions - Phase I	**To be completed by or before**
Orientation - Welcome!	Study Entry
1 - Nutrition in Pregnancy	GW30
2 - Exercise while Pregnant, Sleep	GW32
3 - Mindfulness, Support, Stress Management	GW34
4 - Returning to Work: Lactation in Workplace	GW36
Lactation Sessions - Phase I	
1 - Importance of LC, Milk Composition, Anatomy	GW32
2 - Effective Latch and Positioning	
3 - Typical Feeding Session, Making Human Milk	GW34
4 - Formula, Hospital Expectations	
5 - Common Lactation Concerns	GW36
6 - Returning to Work: Pumping and Expressing	
Postnatal (Post-core Curriculum)	
DPP Sessions - Phase II	**To be completed by or before**
Orientation - Welcome Back!	PPW1
1 - Postpartum Nutrition, Weight Loss, Self-Care	PPW6
2 - Postpartum Physical Activity, Mindset, Stress	PPW9
Conclusion	PPW12

Note: All Phase I content will be completed between gestational week (GW) 24 and 36. The health coach will monitor participants' progress to ensure they complete content by GW36. All Phase II content will be completed by post-partum week (PPW) 12. Completion dates should be used as a guide, not as an exact completion date.

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icipants each week during
ipants will receive access

to the secure, private mobile health application provided by Cappa Health. They will be asked to complete each Phase I module on their own time, starting in the second/third trimester. To supplement their self-study of the curriculum, on a weekly basis, the health coach will follow up with each study participant via phone to check on progress. If participants do not make adequate progress, then the health coach will assess how much extra time the participant needs to complete a module, and will work with her one-on-one via Skype, FaceTime or Zoom if needed. Participants will complete Phase I by week 36 of pregnancy. Upon completion of Phase I and prior to delivery, participants are invited to attend a virtual focus group to talk about program experiences.

Phase II consists of a total of two sessions that will be completed after delivery (see Table 2). Each of the two (2) sessions/modules of Phase II will be pre-recorded and archived on the same secure, private mobile health application mentioned above. Participants will re-engage into Phase II within one week of delivery and with the same health coach as during Phase I. The same session completion format and procedure for progress will be followed as during pregnancy. Participants will complete Phase II by week 12 postpartum. Upon completion of Phase II, participants will be invited to a virtual focus group with other participants to talk about the program experiences. An 80% completion rate of each phase is considered successful completion of the intervention.

Breastfeeding. Additionally, participants in Tx1 will receive an educational session on breastfeeding (see Table 2). Participants in Tx2 will not receive breastfeeding education. The 2-hour breastfeeding session is pre-recorded into six (6) 15-20 minute sessions and archived on the same secure, private mobile health application as mentioned previously. Participants will have access to the first two lactation sessions by week 24 of pregnancy and they need to complete the remaining four sessions by week 36 of pregnancy. Each of the six lactation sessions is taught by the same International Board Certified Lactation Consultant (IBCLC).

At delivery, all participants will receive some type of lactation support in the hospital. However, only participants in Tx1 will receive one-on-one lactation support by the same health coach who also facilitates the DPP sessions. The health coaches are professionally trained Certified Breastfeeding Specialists (CBS). In doing so, they will assist the participants with any questions related to lactation. If a participant is having trouble breastfeeding and the health coach is having difficulty assessing or helping the participant, the health coach will contact the IBCLC-of-record. This person, Jolynn Dowling, is the same person who recorded the lactation curriculum and will provide assistance to and be a resource for the health coach only. The IBCLC will help the health coach answer questions, then the health coach will relay the information back to the participant. If the health coach or IBCLC deems more care necessary, the participant will be asked to bring their breastfeeding questions and problems to their primary care physician. The IBCLC will not have direct contact with the study participants, all information will be relayed through the health coach.

Breastfeeding curriculum. The Kansas Breastfeeding Coalition, Inc. (KBC) in partnership with the Kansas Department of Health and Environment (KDHE) Bureau of Family Health (Title V Maternal and Child Health Services Program) created a 2-hour breastfeeding class for parents and parents-to-be. The curriculum aligns with nutritional requirements set by the U.S. Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and with parenting and maternity care practices of specific Kansas-based organizations such as the Kansas Infant Death and SIDS Network, Inc.[90] and the United Methodist Health Ministry Fund's High 5 for Mom & Baby.[91] Further, the curriculum is based on the Office on Women's Health "Your Guide to Breastfeeding."[92] The content of the 2-hour session will focus on the following areas: establishing and maintain a sufficient and safe breast milk supply, breast anatomy and physiology, maternal diet and lifestyle choices, prescription and non-prescription medications, infant stomach capacity, baby behavior feeding cues, breast milk expression, safe handling and storage of breast milk, returning to work, safe preparation of infant formula, biologically appropriate bottle feeding, and local community breastfeeding resources.

Potential survey participants will have the option of contacting researchers with any questions prior to completing the survey or prior to participating in the educational session, and will self-administer the survey if wanting to participate. Responses will be entered in REDCap for data analysis. All identifying information will be removed from the data prior to analysis. Research personnel will not have access to any identifying information contained in the survey.

Self-Administered Surveys and Incentive to Participate. At recruitment and at study closure, participants will complete seven survey instruments; each of which assesses women's physical activity, nutrition, mental health, maternal sleep, breastfeeding knowledge, and breastfeeding experience (see Appendices 4 through 12). Those randomized to Tx2 will complete all survey instruments and outcome measures, as are those randomized to the intervention (Tx1). All surveys will be self-administered (see Appendices 4 through 12) and are available in English. The pre- and post-survey instruments are identical. They will be administered electronically at baseline (at study entry) and at three months postpartum (see Table 4. Outcomes Measures, under Section III). Via email, the study coordinator will provide each participant with a REDCap link that provides electronic access to each survey. Informed consent will occur when the participant opens the survey. Participants will self-administer the survey and may stop at any time. Potential survey participants will have the option of contacting researchers with any questions prior to completing the survey. The survey instrument will be set up using REDCap and responses will be automatically entered and stored in REDCap for data analysis. All identifying information will be removed from the data prior to analysis. Research personnel will not have access to any identifying information contained in the survey.

At recruitment and at study closure 3 months postpartum, all participants will complete six pre- and post-survey instruments: (1) Questions on socio-demographic characteristics and health status (will only be asked at study entry/baseline) (Appendix 4); (2) Breastfeeding Knowledge (Appendix 5); (3) Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF)

(Appendix 6);[93-96] (4) Kaiser Physical Activity Survey (KPAS) (Appendix 7);[97,98] (5) the Eating At America's Table Study (EATS) Fruit & Vegetable Intake Screener[99-101] (Appendix 8); and (6) the Pittsburgh Sleep Quality Index (Appendix 9). Each instrument will take about 10-15 minutes to complete and participants are provided with adequate time (i.e., about 1 hour) to complete all surveys.

Additionally, recent evidence shows that higher BMI pregnant women may have an increased likelihood of depressive and anxiety symptoms.[102,103] Therefore, at specific timepoints (see Table 4. Outcome Measures, under Section III), all participants will complete the Edinburgh Postnatal Depression Scale (EPDS) (Appendix 10)[104-106] and the General Anxiety Disorder-7 (GAD-7) scale (Appendix 11).[107] Each scale takes about 5 minutes to complete. If a participant has an elevated score for depressive or anxiety symptoms, then the participant will be referred to The Village, a mental health clinic in Wichita, Kansas, or their own mental health care provider if the participant has one. Dr. Jacobson's research coordinator will ask the study participant if she can contact staff at The Village on her behalf and provide them with the participant's name and phone number. Licensed mental health therapists at The Village will then call the participant and attempt to schedule an appointment. Participants will sign a release form at consent allowing Dr. Jacobson and her team to follow up with The Village to record the rate at which participants are referred and attend at least one appointment.

Last, upon delivery and within 72 hours of hospital discharge, the participant will complete the Lactation Assessment Care Tool (LACT) (Appendix 12). The LACT identifies families at risk for breastfeeding difficulty and facilitates access to the most effective level of care.[108] All study survey instruments/scales are listed in Table 3.

Table 3. Survey Instruments

Study Instrument	Items Measured	No. of Items	Reliability	Populations Validated
Socio-Demographic Characteristics and Health Status	To collect data on the study sample.	24 items; multiple choice and select all that apply	Not yet performed.	Not yet performed.
Breastfeeding Knowledge Assessment	To assess knowledge of breastfeeding (44 items), to assess socio-demographic characteristics (6 items), to assess health status (7 items)	57 items; multiple choice, and Likert-type scale	Not yet performed.	Not yet performed.
Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF)	To assess levels of self-efficacy in postpartum women. BSES-SF has also been used with prenatal women.	14 items; 5-point Likert-type scale.	Cronbach's alpha = 0.97	Postpartum women at 1 week, 4 weeks, and 8 weeks.
Kaiser Physical Activity Survey (KPAS)	To assess multiple domains of physical activity and total physical activity in pregnant women.	38 items; 4 domains: household and family care activities, occupational activities, active living habits, participation in sports/exercise	Correlation coefficient for total activity: r = 0.84; correlation coefficient for multiple domains: r = 0.76 - 0.86	Pregnant women aged 18 to 47 years old.
Fruit & Vegetable Intake Screener (EATS)	To assess intake of fruits and vegetables.	10 items; with portion-size questions.	Correlation coefficient between test instrument and true intake: r = 0.51-0.67 Correlation coefficient between three screeners: r = 0.52 - 0.71	Men and women aged 20 to 70 years old.
Pittsburgh Sleep Quality Index (PSQI)	To assess levels of depression during the postpartum period.	10 items; 4 point scale and fill in the blank	Cronbach's alpha = 0.76 - 0.81	Antepartum and postpartum women.
Edinburgh Postnatal Depression Scale (EPDS)	To assess sleep quality.	10 items; 4 point scale	Sensitivity: 34-100% Specificity: 44-100% Positive likelihood ratios: 1.61-78	Antepartum and postpartum women.
Generalized Anxienty Disorder Scale (GAD-7)	To assess levels of general anxiety.	7 items; 4-point scale	Cronbach's alpha = 0.92 Sensitivity = 89% Specificity = 82%	Men and women aged 18 to 95 years old.
Lactation Assessment Care Tool (LACT)	To identify risk for breastfeeding difficulty and cessation	16 items; dichotomous scale	Not yet performed.	Not yet performed.

Each participant will receive a $40 gift card and a pack of diapers at consent, prior to delivery the participant will receive a digital scale, and upon completion of the study (at 3 months after birth), each participant will receive a $50 gift card. In summary, for participants randomized to either group: 1) DPP plus breastfeeding, or 2) Usual care, the total possible compensation is valued at approximately $140 including the following gift items: digital scale and accessories (valued at $35 in total), a $50 study closure gift card, a $40 study entry gift card, and a pack of diapers (valued at $11-15 each, depending on the size the mother chooses).

If a participant ends early prior to completing the study, then she will only receive the items for the program components that she completed.

Study payments are taxable income. Prior to distribution of gift items and after obtaining consent, a form 1099 will be provided to each participant for completion. This process is in accordance and in compliance with regulations set forth by the University of Kansas School of Medicine and the Internal Revenue Service if you receive $600 or more in a calendar year for participating in research studies.

Structured Focus Group Discussions. Upon completion of Phase I and prior to delivery, and at study closure, participants are invited to attend a virtual focus group discussion to provide feedback on their experience participating in the study. The purpose of this discussion is to obtain in-depth information about eMOMS^{TM} program content such as access and delivery of materials on breastfeeding, diet, physical activity, and other supportive services during and after pregnancy.

Study location and process - The virtual focus group discussions will take place via video call (i.e., Zoom technology) and are scheduled between Phase I completion and delivery, and within three months of completing Phase II. Dr. Jacobson or a team member will explain the purpose of the focus group and its voluntary nature immediately prior to the focus group discussion. Consent is obtained by requesting a participant's written signature at study entry and during her final eMOMS^{TM} visit at 3 months postpartum. The focus group discussion will take approximately 30-60 minutes. The session will be recorded and notes will be taken.

Risks when participating in the interview - Participation is completely voluntary and a participant may stop being in the discussion at any time. Participants have the opportunity to maintain anonymity by changing their name and keeping their camera off during the focus group; the only non-anonymous piece of this interview is their voice. Participation in the discussion will not harm a participant physically. Being in the focus group discussion will not affect a participant's continued or future medical care. The first potential risk for a participant is a possible loss of confidentiality; however, every effort will be made to preserve her privacy. Her name is not recorded during the discussion. Only Dr. Jacobson and the research coordinator listen to the recordings and have access to the transcripts of the focus group discussion. Second, if a participant becomes embarrassed or uncomfortable, she may stop participating in the discussion at any time. Participants are asked not to disclose any personal information.

Benefits when participating in the focus group discussion - To the individual, benefits to participate in this focus group discussion include a deeper understanding of what is important to her during and after pregnancy regarding physical activity, diet, breastfeeding and other supportive services. To the community or society, benefits to participate in the focus group discussion include an improved understanding of the importance of physical activity, diet and breastfeeding during and after pregnancy. Aggregate results of these focus group discussions are used to inform larger studies that will be designed to develop and implement health promotion interventions to improve health outcomes among reproductive age women.

Confidentiality of records - Information collected for these focus group discussions is kept confidential and stored in an office with a lock and key. No one has access to information collected other than Dr. Jacobson. Research records may be reviewed by the Institutional Review Board of Ascension or other regulatory authorities. When the results of these focus group discussions are presented or published, participants are not identified by name. A participant may request a copy of the results of these focus group discussions when it is

completed. The University of Kansas School of Medicine record retention policy requires research records involving human subjects to be kept for at least 15 years so all data associated with this study is kept for at least 15 years.

Participation in the focus group discussion – A participant's participation is completely voluntary. She can decline to participate at any point during the focus group discussion. In giving consent, a participant states that her participation in the focus group is voluntary. She receives a copy of the consent form. If she refuses or wants to stop being in the focus group, there will be no penalty or loss of benefits to which she is otherwise entitled. To stop participating in the study, she needs to notify Dr. Jacobson prior to, during, or after the focus group discussion.

Contact person for questions - Before a participant signs the consent addendum form, Dr. Jacobson will answer all questions. A participant can speak with Dr. Jacobson if she has any more questions, suggestions, concerns or complaints before or after signing the consent addendum form. Dr. Jacobson's contact information is provided on the consent addendum: Dr. Jacobson can be reached at (316) 293-3484 or ljacobson@kumc.edu between the hours of 8 a.m. and 5 p.m., Monday through Friday.

Healthcare Provider and Clinic Staff Survey. At study closure, healthcare providers and clinic staff are invited to participate in a survey to provide feedback on their experience being involved in the eMOMS^{TM} program. The purpose of this survey is to assess the willingness of the healthcare providers and clinic staff to participate in eMOMS^{TM}, to obtain information on the screening and enrollment of pregnant women into the eMOMS^{TM} program from the perspective of healthcare providers and clinic staff, to understand the implementation of eMOMS ^{TM} from the perspective of healthcare providers and clinic staff, to get healthcare provider and clinic staff feedback on the program strengths and weakness, and to assess the demographics of healthcare providers and clinical staff.

Study location and process - The survey will be distributed online via REDCap once all participants have finished the eMOMS^{TM} program. A title page precedes the survey instrument that explains the purpose of the survey. Consent is obtained prior to starting the survey and is located at the bottom of the survey's title page. When a respondent consents to participate in the survey, he/she checks the box titled "I have had enough time to consider participating, have had all my questions answered, and I WOULD like to participate" located at the bottom of the survey's title page. After clicking on this box, a respondent will then proceed to the next screen that includes the first question of the survey. The survey takes approximately 10-15 minutes.

Risks when participating in the survey - Participation is completely voluntary and anonymous and a participant may stop the survey at any time. Participation in the survey will not harm a participant physically. Taking the survey will not affect a participant's continued or future medical care. The first potential risk for a participant is a possible loss of confidentiality;

however, every effort will be made to preserve their privacy. The participant's name is not recorded in the survey. Only Dr. Jacobson and her KU study team will have access to the survey responses. Participants are asked not to disclose any personal information.

Benefits when participating in the survey - To the individual, benefits to participate in this survey include a deeper understanding of what is happening at the healthcare provider and clinical staff perspective during the eMOMS™ program. To the community or society, benefits to participate in the survey include an improved understanding of how the healthcare providers and clinical staff are able to engage with the eMOMS™ intervention effectively to accomplish its intended goals. Aggregate results of these surveys are used to inform larger studies that will be designed to develop and implement health promotion interventions to improve health outcomes among reproductive age women.

Confidentiality of records – A potential risk of participating in the survey is a breach of confidentiality and loss of privacy. Privacy measures for participant responses to the survey are described below. Yet, to further address privacy, as well as to ensure confidentiality, the investigators will ensure the following measures are taken. All data obtained in the study will be kept confidential. The only parties having access to the data in the proposed study will be the Principal Investigator (Dr. Jacobson), Dr. Jacobson's research team, and the Institutional Review Board of record. Responses to the surveys will be maintained on the KUSM-W REDCap database. Only the necessary members of the research team will have access to the REDCap database. Research records may be reviewed by the Institutional Review Board of Ascension or other regulatory authorities. When the results of these surveys are presented or published, participants are not identified by name. A participant may request a copy of the results of these surveys when it is completed. The University of Kansas School of Medicine record retention policy requires research records involving human subjects to be kept for at least 15 years so all data associated with this study is kept for at least 15 years.

Participation in the survey – A respondent's participation is completely voluntary. He/she can decline to participate at any point during the survey. After consenting to participate in the survey by checking the box titled "I have had enough time to consider participating, have had all my questions answered, and I WOULD like to participate" located at the bottom of the survey's title page, a respondent will then proceed to the next screen that includes the first question of the survey. If a respondent refuses or wants to stop the survey, there will be no penalty or loss of benefits to which they are otherwise entitled. To stop participating in the survey, the participant can exit the survey at any time without submitting it.

Contact person for questions - Before a participant consents to participate, Dr. Jacobson and/or Mrs. Meeker will answer all questions. A participant can speak with Dr. Jacobson and/or Mrs. Meeker if he/she has any more questions, suggestions, concerns or complaints before or after consenting to participate in the survey. Dr. Jacobson's and Mrs. Meeker's contact information is provided on the title page of the survey instrument: Dr. Jacobson can be reached at (316) 293-

3484 or ljacobson@kumc.edu and Mrs. Meeker can be reached at (316) 293-2626 or smeeker@kumc.edu between the hours of 8 a.m. and 5 p.m., Monday through Friday.

Section III. Statistical Methods and Data Analysis

Study data will be managed using REDCap electronic data capture tools hosted at the University of Kansas School of Medicine – Wichita.[109] REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

All participant data will be captured and stored in REDCap. The only people who will have access to this data are Dr. Jacobson, the database manager, the statistician, and the research coordinator. Cleaned data will be downloaded into statistical software for analyses. Clinical data, sociodemographic characteristics, and measures for mother and baby will be summarized using descriptive statistics. Missing observations will be evaluated for type of missingness. Values missing completely at random or at random will be imputed. Analyses will be based on intention-to-treat principle. Test results will be considered statistically significant if $p<0.05$. SAS 9.4 (SAS/STAT Inst., Carry NC) will be used for all analyses.

Outcome Measures and Rationale for Outcome Measures. The expected outcomes of this study are (1) to quantify user interest; and (2) to measure weight retention and duration of lactation (see Table 4).

Table 4. Outcome Measures and Timeline for Data Collection

Domain	Procedure	Baseline	DPP-Lactation Phase 1		Delivery	Discharge	DPP-Lactation Phase 2					
			Immediately prior to birth				PP Day 7	PP Wk 3	PP Mon 1	PP Wk 6	PP Mon 2	PP Mon 3
Maternal Measures												
PhenX Toolkit	Tier 1 and Core Social Determinants of Health Questionnaires: Educational attainment, age, marital status, ethnicity and race, gender, biological sex, birthplace, current employment status, food insecurity, health insurance	X										
Medical History	Obstetric history, birth mode, blood glucose during pregnancy, routine vital signs, birth weight/length/head circumference	X			X							X
Anthropometrics	Maternal height and weight in clinic	X										
	Maternal weight (to derive body mass index)	X	X		X	X	X	X	X	X	X	X
Physical Activity and Dietary Intake	Kaiser Physical Activity Survey (KPAS) [97,98]	X										X
	Fruit and Vegetable Intake Screener (EATS) [99-101]	X										X
Mental Health Screening	Edinburgh Postnatal Depression Scale (EPDS) [104,106]	X										X
	Generalized Anxiety Disorder Scale (GAD-7) [107]	X										X
Maternal Sleep	Pittsburgh Sleep Quality Index (PSQI)	X										X
Infant Measures												
Growth	Infant weight, length, head circumference (per vaccination schedule by WHO) [110]				X	X	X	X	X	X	X	X
Feeding Practices*	Exclusive human milk feedings				X	X	X	X	X	X	X	X
	Supplemental infant feedings (i.e., formula, water, juice, etc.)				X	X	X	X	X	X	X	X
	Solid food feedings (i.e., cereal, baby food)				X	X	X	X	X	X	X	X
Lactation Assessment	Breastfeeding Self-Efficacy Scale – Short Form (BSES-SF) [93]	X										X
	Lactation knowledge survey	X										X
	Lactation Assessment Care Tool (LACT)					X						

*Note: Data on feeding practices are collected at these timepoints due to (1) congruent child-wellness visits to the primary care provider, and (2) having an established human milk supply and return-to-work by the parent at 3 and 6 weeks of life.

As this is a pilot trial, we will also collect the following data: number of women screened, number of women recruited and enrolled, number of participants who withdraw from the study and reasons for withdrawal, number of participants who complete the DPP protocol, and number of participants who complete the breastfeeding sessions. Upon recruitment into the study and at study closure, all participants will complete the BSES-SF, KPAS, EATS, PSQI, LACT, EPDS, and GAD-7 to assess differences in knowledge and self-efficacy toward breastfeeding, physical activity, mental health, maternal sleep, and nutrition. Table 4 shows a timeline for data collection in both study arms.

Aim 1: **Quantify interest in use of the DPP-lactation support app among target population**. To accomplish this, we will: (1) measure research engagement including rates of screening, recruitment, and retention among users, especially rural and racially/ethnically diverse women; (2) assess barriers/facilitators to enrollment/retention through surveys and semi-structured in-depth interviews or focus groups; and (3) evaluate intervention uptake, delivery, and adherence via tracking/measuring use of the app.

Aim 2: **Measure weight loss and duration of lactation through 3 months postpartum among target population**. To accomplish this, we will measure pre-pregnancy weight, weight at study entry, weight immediately prior to and after delivery, and weight at specific postpartum time

points. Lactation and infant feeding practices will be measured at similar postpartum time points.

Sample Size and Randomization. The primary outcomes of interest are: (1) to quantify user interest; and (2) to measure weight loss and duration of lactation. Given an anticipated attrition rate of 20%, a total of 50 participants (25 per study arm) will be recruited. The results from this pilot study will be used in sample size estimation for a future study that is sufficiently powered to detect a clinically meaningful effect size. Due to the nature of this project being a feasibility study, the sample size in the proposed study is not based on providing adequate power to detect a clinically meaningful effect size across both study arms. Block randomization with block size of 5 participants will be employed. A sequence of 8 random integers will be generated using a computer algorithm. The first 4 integers of the sequence will be assigned to the DPP plus breastfeeding arm (Tx1); and the last 4 will be assigned to the usual care arm (Tx2). Blocks will be assigned to arms in the increasing order of sequence of integers generated. Study results will be used to determine sample size for a future large-scale RCT that is sufficiently powered to detect a clinically meaningful effect size.

Statistical Analysis. For baseline data characteristics, descriptive statistics will be reported as mean and standard deviation for continuous variables and as count and percentage for categorical variables. Depending on the distribution of the continuous variables, the Kruskal-Wallis test or ANOVA will be used to test for differences in continuous variables across the three arms. Chi-Square test of independence (or Fishers exact test if 25% of cells have counts less than 5) will be used to assess the association between categorical variables and the two arms. The analysis will be based on "intention-to-treat" principle. A two-sided alpha level of 0.05 will be used to determine statistical significance. A 95% confidence interval will also be reported. Consistent with procedures described by Guest et al.,[111] we will conduct an inductive thematic analysis to analyze qualitative data. Using Dedoose software, we will develop a codebook containing structural and thematic codes. Consensus will then be reached on emergent primary and sub-themes.

<u>Aim 1</u>: **Quantify interest in use of the DPP-lactation support app among target population**.

- Quantitative variables will be quoted as absolute numbers, rates, and relative frequencies. For quantitative variables, likelihood ratio chi-square and Fisher's exact tests will be conducted to test associations between variables. Quantitative data will be analyzed using procedures below.
- *Recruitment/Enrollment, Retention Rates (Primary Outcome for Aim 1)*. To compute recruitment rate, REDCap will track % contacted and % enrolled across week of pregnancy, maternal weight/age, rural/urban, and other disadvantaged categories. To compute retention rate, we will track % of intervention completers across the same categories, and compare characteristics of completers vs. non-completers.
- *Facilitators/Barriers to Research Engagement for Study Participants (Secondary Outcome for Aim 1)*. Participants will have an opportunity to participate in focus groups/interviews to

discuss program experiences. Individuals not completing the program will be provided the same opportunity.

- *Intervention Uptake, Delivery, Adherence (Tertiary Outcome for Aim 1)*. REDCap will track intervention uptake across each clinic. We will track participants' app use, time spent on each module, time spent with health coach, and other characteristics. Feasibility of screening/recruiting among providers will be assessed.

Aim 2: **Measure weight loss and duration of lactation through 3 months postpartum among target population**.

- Continuous data will be assessed for normal or skewed distributions. Descriptive statistics such as the mean, standard deviation, median and interquartile range (IQR) will be conducted to summarize outcome measures. To assess for potential bias and evaluate retention, those who complete the trial will be compared to non-completers. Further, Cochran-Mantel-Haenszel tests will be used to reveal associations between categorical/nominal variables after controlling for the strata variables.
- *Weight Loss*. We will measure maternal weight: at baseline, week 30, week 32, week 34 of pregnancy and day 3, day 10, week 3, week 6, month 2, and month 3 postpartum (see Table 4). Pre-pregnancy weight/height will be obtained from medical records.
- *Lactation*. At delivery, initiation of lactation will be measured (defined as starting lactation at birth). We will measure duration of *any* lactation (defined as predominant human milk with formula supplementation) and *exclusive* lactation (defined as human milk exclusively), at specific timepoints (see Table 4). We will also measure formula supplementation when this is first introduced, and quantity/frequency of feedings.

Missing data. Owing to the design of the study and non-transient nature of the study population, we anticipate few to none missing observations. Missing observations will be evaluated for type of missingness. Values missing completely at random or at random will be imputed. Depending on the proportion of missingness, complete case analysis (less than 5% missing) or the multiple imputation method will be used to impute missing data. For longitudinal response (postpartum weight measurements), the last observation will be carried forward to impute the missing response. Results based on imputed data will be compared to findings from complete case analysis, to assess the effect of missingness on study findings.

Comparison of scores on the Breastfeeding Knowledge Assessment, BSES-SF, KPAS, EATS, and PSQI. The Breastfeeding Assessment is based on 44 questions. Cronbach's alpha will be used to test the internal consistency of the data. The "difference in Breastfeeding Assessment scores between recruitment and at study closure" in both study arms will be assessed using the multiple linear regression approach. The model will be adjusted for the effect of age, race/ethnicity, level of education, annual household income, family history of diabetes, pre-diabetes status, and parity. The BSES-SF score is based on 14 questions and ranges from 14 to 70 points. Cronbach's alpha will be used to test the internal consistency of the data. The "difference in BSES scores between recruitment and at study closure" across both study arms

will be assessed using the multiple linear regression approach. The model will be adjusted for the effect of age, race/ethnicity, level of education, annual household income, family history of diabetes, pre-diabetes status, and parity. The KPAS score comprises of 38 questions that are distributed sequentially but non-uniformly across four sections and measure household and family care activities (household index); occupational activities (occupational index); active living habits (active living index); and participation in sports and exercise (sports and exercise index). For each section, Cronbach's alpha will be used to test the internal consistency of the data. For each index of physical activity, "difference/change between recruitment and at study closure" across both study arms will be assessed using the multiple linear regression approach after adjusting for the effect of the previously stated covariates. The EATS survey consists of 10 questions and the PSQI consists of 10 questions. For each question, counts and percentages will be reported for participants at recruitment and at study closure across both study arms.
For each survey item, count and percentages will be reported. The difference in scores for each survey instrument across both study arms will be assessed using a multiple linear regression approach adjusted for the effects of demographic and health status variables.

Section IV. Patient Protections and Methods to Minimize Risk

A. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

The focus of this research is to implement and determine the feasibility and efficacy of an intervention that is based on the Diabetes Prevention Program (DPP) and includes intensive breastfeeding support and counseling in a cohort of overweight or obese pregnant women to be followed during pregnancy through 6 months postpartum. Study participants will be pregnant women who reside in or near Wichita or northwest rural Kansas. Participants are eligible if they meet study inclusion criteria. This is a randomized controlled pilot study with two study arms. Participants will be randomized to each arm of the study by computer. Participants in Tx1 will receive the DPP plus breastfeeding, and participants in Tx2 will receive usual care. Usual care consists of (1) the same obstetrical care that pregnant women with normal body mass index (BMI) receive, and (2) obstetrical care that is provided to pregnant women by the same provider (Dr. Michael Wolfe). Total enrollment for the proposed study will be 50 pregnant female participants.

Participants are actively recruited from an obstetrical clinic at Via Christi Hospitals Wichita, Inc., a regional medical center located in Wichita, Kansas. Participants must be women 18 years old or older, pregnant, with a BMI ≥ 25 and <35, and able to read and understand English. Eligible participants will be recruited during the 2nd trimester or early during the 3rd trimester. General study exclusions include women who have pregnancy complications that require emergency care, have thyroid disease, have multiple gestation, had substance abuse within last 3 years, have an ART (Assisted Reproductive Technology) pregnancy, are a current smoker, had prior bariatric surgery, have been in a weight-loss program within 3 months of conception, have a BMI ≥ 35, are unable to attend intervention/follow-up visits, are unwilling to

self-monitor data collection, are unable to complete the intervention, have a presence of any condition that limits walking, have a presence of any condition that limits following diet recommendations, or have a pregnancy complicated with a fetus diagnosed with lethal malformations/conditions.

Vulnerable populations in this study might include economically/educationally disadvantaged persons. Some pregnant women may be economically and/or educationally disadvantaged based on their demographic profile. We especially want to accommodate these individuals as our study's focus is on measuring postpartum weight and breastfeeding behaviors among an at-risk ethnically and racially diverse, overweight and obese pregnant population.

We will obtain approval from the Ascension Health Institutional Review Board (IRB). With the active assistance of Dr. Wolfe, maternal fetal medicine specialist at VCH, Dr. Jacobson and her research coordinator will recruit each participant for the study. All members of the research team involved in consenting and enrolling participants have successfully completed institutional Human Subjects training.

b. <u>Sources of materials</u>

Research material obtained from participants will include: socio-demographic data (i.e. age, race/ethnicity, income, education level, etc.), breastfeeding self-efficacy, breastfeeding knowledge, physical activity level, dietary assessment, maternal sleep, level of postpartum symptoms of depression and anxiety, weight, height, mean arterial blood pressure, blood glucose tolerance level during pregnancy, breastfeeding initiation, breastfeeding duration, use of formula, and solid food. All data are based on validated questionnaires (except for the Breastfeeding Knowledge Assessment questionnaire), and activity and nutrition monitoring as required by the DPP protocol. The validated measures that will be used are the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF), the Kaiser Physical Activity Survey (KPAS), the Fruit and Vegetable Intake Screener (EATS), the Pittsburgh Sleep Quality Index (PSQI), the Edinburgh Postnatal Depression Scale (EDPS), the Generalized Anxiety Disorder scale (GAD-7), and the Lactation Assessment Care Tool (LACT). These validated survey instruments will be administered at baseline (=study entry) and at study closure (=3 months postpartum) except for the LACT which will be administered within 72 hours of hospital discharge after giving birth. At delivery and through the 3-month postpartum period, we will also obtain the infant's height and weight via healthcare records. Further, at delivery, we will measure if the mother starts breastfeeding and we will measure how long she will continue breastfeeding through 3 months postpartum.

All behavioral assessments/surveys will be completed in a private room without the researcher present. All DPP orientation sessions and breastfeeding classes will take place at Via Christi Health, or if the participant choses to do this virtually, it will take place at their location of choice. Collected data will be stored on a secure drive backed up on a nightly basis by the Information Technology (IT) department at KUSM-W. Identification numbers will be assigned

to each participant at the time of initial survey completion. All hard-copy and data files will be labelled according to participant number. Only the research team (Dr. Jacobson, the statistician, the database manager, and the research coordinator) will have access to information regarding demographic and medical information and identification number for each participant. All other data collected throughout the duration of the study will be kept in locked cabinets and on a secure server within the University of Kansas School of Medicine-Wichita. Data used for analysis will be de-identified and accessible only by the research team. A log will be kept of all data collection and analysis steps completed for each participant.

c. Potential risks

Participants will undergo an intervention that is educational. Participants will share education on exercise and diet and will then apply these concepts in their daily functioning. During the study, participants' weight and height will be measured to determine BMI. During pregnancy, the breastfeeding component of the proposed intervention is highly visual and interactive. An International Board Certified Lactation Consultant (IBCLC) will demonstrate proper breastfeeding techniques and strategies. After delivery, participants will have access to the health coach who is also a Certified Breastfeeding Specialist (CBS) through 3 months postpartum. The IBCLC will be a resource for the CBS; however, the IBCLC will not have direct contact with the study participant, only the health coach/CBS has direct contact with the participant. There are no known risks of subjects participating in an educational intervention. All data will be kept anonymous and in a locked file cabinet in a locked office. All data will be entered into a computer; electronic data will be on a secure server at KUSM-W that is backed up on a nightly basis by the IT department at KUSM-W.

A potential risk of participating in the study is a breach of confidentiality and loss of privacy. Privacy measures for participant responses to the questionnaires are described below. Yet, to further address privacy, as well as to ensure confidentiality, the investigators will ensure the following measures are taken. All data obtained in the study will be kept confidential. The only parties having access to the data in the proposed study will be the Principal Investigator (Dr. Jacobson), Dr. Jacobson's research team, and the Institutional Review Board of record. Hardcopies of completed participant questionnaires will be locked in a secure file cabinet in the PI's office. Responses to the surveys and the clinical information obtained will be maintained on the KUSM-W REDCap database. Only the necessary members of the research team will have access to the REDCap database.

Participants have the opportunity to post, comment, or like a post in the "Community" section of the mobile phone application. If a participant posts, comments, or likes a post in this section, their anonymity may be forfeited; however, they have the option to opt for a nickname or a pseudonym if they do not want their legal name displayed.

Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

Participants will be recruited from the obstetrical clinic located at Via Christi Hospitals Wichita, Inc., a regional medical center located in Wichita, Kansas. We will use printed flyers, posters, and word-of-mouth advertising to recruit potential participants. Prior to using these recruitment materials, Ascension Health Institutional Review Board (IRB) at will review and approve these materials. Dr. Michael Wolfe, a maternal fetal medicine specialist at Via Christi Hospitals Wichita, Inc., will make the initial contact with a potential participant during her prenatal visit. Prior to this prenatal appointment, Dr. Wolfe will screen potential participants for inclusion criteria, and if he believes a participant meets inclusion criteria (see Table 1), then he will contact Dr. Jacobson and her research coordinator with the first and last name of the potential participant, and date/time of her prenatal appointment. During this prenatal appointment, if Dr. Wolfe believes a potential participant meets inclusion criteria, then he will familiarize her with the nature and purpose of the study. If the potential participant is interested in the study, then he will give her a study brochure and a hard copy of the consent form. After receiving a potential participant's name and phone number from Dr. Wolfe, the research coordinator will follow up with a phone call or meet with the interested participant in-person in an on-site, private conference room immediately after their prenatal appointment to determine if the potential participant again meets study inclusion criteria. If she does, the coordinator will screen if the potential participant meets study exclusion criteria during the same phone call or during this same in-person on-site visit (see Table 1). Before the research coordinator screens for inclusion and exclusion criteria, during this same phone call or during this same in-person on-site visit, verbal consent will be obtained between the participant and the research coordinator, using the consent form as the verbal consent script, and then written e-consent will be obtained via REDCap at the orientation session. When a participant is recruited on-site, then the in-person visit between the participant and the research coordinator is considered to be the orientation session. If a participant is recruited through a brochure, website, flyer, word of mouth, or by other means, the research coordinator will schedule a call with the potential participant.

If the participant meets all study criteria and the participant is contacted via telephone and not in-person on-site, then the research coordinator will provide her with a time and place for the DPP's orientation session and to complete study-related survey instruments. The research coordinator will also verify the participant's email address to provide her with informed consent materials for review. Study procedures will be explained verbally by the PI and in writing at the time of survey completion and, again, at the DPP's orientation session. All subjects participating in the study will consent to participate as evidenced by signing an informed e-consent form via REDCap immediately prior to commencement of the orientation session. Subjects will be informed that they are free to withdraw their consent at any time during the study with no penalty.

Written informed e-consent will be obtained via REDCap from each participant prior to completing the first questionnaire. A verbal explanation of the study will be provided in addition to the written explanation included in the consent form. Potential participants will be encouraged to ask questions concerning the study. After reading the consent form, participants will be asked to provide a verbal summary of the study as they understand it. This will be used to assess the participant's understanding of the study. If potential participants are able to understand, remember, and verbalize the main aspects of the study, it will be assumed that they have the capacity to consent. Participants will be informed that they can withdraw from the study at any time by contacting research personnel. When consent is withdrawn, participation in the study will be terminated and no additional data will be collected or used for analysis. All patients will receive a copy of their signed consent form. The original signed consent forms will be kept in a locked file cabinet in a secure data storage room in Dr. Jacobson's office area, which can only be accessed with a key.

b. Protection Against Risk

All information we obtain throughout the study will be kept confidential. The risks associated with the study are minimal. No adverse events are anticipated with this study, but procedures will be in place to monitor the study using the scientific protocol provided and approved by the Institutional Review Board of record. Participants experiencing any adverse effects from participating in this study will be directed to the PI. Action will be taken to direct the study participant to the appropriate resources.

Information collected throughout the course of the study will be de-identified of Protected Health Information (PHI) and will only be accessed by research staff directly involved with the study. Researchers believe there is less than minimal risk regarding economic risks and legal risks pertaining to this study. However, the risks associated with this project are considerably reasonable in comparison to the potential benefits from the study.

c. Adverse Events

In the case an adverse event was to occur due to study procedures, the principal investigator, Dr. Jacobson, will assume responsibility for reporting and documenting any complications. All adverse events will be recorded, and the necessary documents will be completed. The principal investigator and/or the project coordinator will notify the IRB within the appropriate time frame. The investigators and project coordinator are responsible for complying with any reporting requirement of the reviewing IRB.

A uniquely tailored intervention such as the one proposed may not be enough to support pregnant participants with severe obesity and thus, we will only recruit women whose BMI is ≥25 and <35. Given our previous work, we do not anticipate any problems enrolling pregnant participants. Last, we are aware that instruments in this study have been validated, but not specifically for medically underserved pregnant populations.

If an adverse event should occur, the participant will have the opportunity to withdraw from the study. Dr. Wolfe will be available for consultation should an adverse event happen. Throughout the study, we will be monitoring for issues related to safety of participants as well as privacy of data. Should an adverse event occur, the research team will document the event. The following information will be monitored throughout the study: number of participants screened and enrolled, drop-outs, and serious and non-serious adverse events. This data, with the exception of serious adverse events, will be reported every 12-months. Because no serious adverse events are anticipated in this study, any such events will be immediately reported to the Institutional Review Board of record. If the severity of an adverse event requires emergency medical attention, appropriate providers/staff will be contacted to provide medical attention. To assess participant safety even further, we will have a Data and Safety Officer in place. Dr. Brian Brost has agreed and is confirmed as the Data and Safety Officer for our study. Brian Brost, MD, is professor in the Department of Obstetrics and Gynecology, University of Kansas School of Medicine-Kansas City, Mailstop 2028 (Wescoe Pavilion 3000), 3901 Rainbow Boulevard, Kansas City, KS 66160. Dr. Brosts's email: bbrost@kumc.edu, Main phone: 913.588.6259 or 913.588.6200.

B. Potential Benefits of the Proposed Research to the Subjects and Others

The potential benefit of this study is to determine if a combined breastfeeding, DPP-based intervention reduces postpartum weight, increases lactation duration, among an at-risk population with a BMI ≥ 25. This is an innovative way to address nutrition, physical activity, weight, and breastfeeding in one intervention that is modeled after the evidence-based Diabetes Prevention Program and could be integrated into the continuum of healthcare services provided to culturally, diverse at-risk pregnant women. Results of the proposed intervention will inform the development of interventions aimed at reducing diabetes risk factors and potential progression to type 2 diabetes after pregnancy among at-risk women. The overall impact of this project will be to reduce diabetes risk factors among a high-risk population and inform interventions aimed at reducing these risk factors thereby decreasing disproportionate morbidity. Moreover, study results will add significant knowledge to the field of diabetes prevention and related behavioral health interventions and strategies to improve maternal and child health outcomes. Although the randomization process will not be performed by a clinician, instead it will be generated by a computer system, participants may still have concerns about bias (who receives the treatment versus who receives the control). We will inform them that, regardless of group assignment, they will continue to receive routine care from their maternal fetal medicine specialist.

C. Importance of the Knowledge to be Gained

Knowledge to be gained from this study is whether a combined breastfeeding, DPP-based intervention reduces diabetes risk factors among an at-risk population. Results of this study will enhance current intervention efforts that aim to reduce diabetes risk factors and potential progression to diabetes during and after pregnancy and improve breastfeeding thereby improving maternal and child health outcomes. An intervention that starts during pregnancy and extends

beyond pregnancy has a high likelihood of success because during this time period, women are more inclined to change their behavior to benefit their children leading to reduced risk of retaining excess weight and a possible subsequent healthier pregnancy. The knowledge, methodologies, and strategies obtained from this study will be of importance to the submission of a larger research grant such as an R01with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) that will involve a longitudinal study with a larger sample size of high-risk, ethnically and racially diverse Kansas women and their children to assess if a combined breastfeeding, DPP-based program reduces maternal risk for diabetes and impedes the cycle of obesity as a diabetes risk factor among families. The R01 is a Research Project Grant and is the original and historically oldest grant mechanism used by the National Institutes of Health (NIH). The R01 provides support for health-related research and development based on the mission of the NIH. An R01 can be investigator-initiated or can be solicited via a Request for Applications by the NIH. The R01 is an award made to support a discrete, specified, circumscribed project to be performed by the named investigators in an area representing the investigators' specific interest and competencies, based on the mission of the NIH. It is believed that the minimal risk involved in the proposed study is reasonable considering that it could lead to more effective ways to reduce diabetes risk factors among at-risk populations with a greater burden of disease and risk for related health complications. The proposed pilot study will be the first to use an intensive breastfeeding, DPP-based program to reduce diabetes risk factors among a vulnerable, at-risk population.

E. Privacy and Confidentiality

This is an educational intervention utilizing identified pre- and post-surveys. The privacy and confidentiality of potential participants will be maintained as all study data will be protected and only study personnel have access.

Only the listed investigators and their designated staff will have access to the surveys and study data. The University of Kansas School of Medicine-Wichita IRB, the US Department of Health and Human Services, the Office of Human Research Protections, and other government and regulatory bodies as required by law may have access to these research data. Information technology protections and firewalls are in place at all study facilities and will protect the electronic data stored at each facility. Secure email will be used to transfer documents between investigators. The database (participant identifiers removed) will be encrypted and password-protected when sent through secure email between investigators.

F. Waiver of Documentation of Consent

A Waiver of Documentation of Consent is <u>not</u> requested for this study. This study presents no more than minimal risk to study participants as the information obtained is not sensitive in nature, and if inadvertently released should not be injurious to the participants, either financially, legally, or personally. Surveys will not ask for a participant's name, medical record number, birthdate, social security number, or any other protected health information. However, it is critical that the pre- and post-surveys, along with data on individual weight loss and length

of breastfeeding are linked to the same individual to assess health outcomes. Therefore, research personnel will seek informed written consent and the process for obtaining written consent is outlined previously under Item B. Adequacy of Protection Against Risks, Item A. Recruitment and Informed Consent.

G. Adherence to Study Protocol

Protocol adherence is the primary responsibility of the principal investigator. The co-investigators will serve to support protocol adherence efforts and maintain an understanding of all protocol details. Protocol amendments, revisions, deviations will be promptly reported to the IRB.

H. Secure and Maintain IRB Approval at All Sites

IRB approval will include all the study locations listed previously. All protocol deviations, amendments, revisions, and continuing review reports will be promptly compiled and reviewed by the principal investigator and co-investigators and provided to the IRB. All research within the scope of this project will be conducted under IRB policies and guidelines.

I. Obtain IRB Approvals Prior to Implementing Changes to Protocol

The principal investigator and co-investigators wish to assure the IRB that any amendments to the protocol or supporting documents will be submitted for approval prior to implementation; problems associated with the research will be reported in accordance with IRB policies.

J. Modifications to Study Protocol and Oversight

Each review will consider whether or not the study should continue without change, be modified, or be terminated. Recommendations regarding modification of the design and conduct of the study might include:

1. Modification of the study protocol based upon review of the safety data;
2. Optional approaches when the incidence of primary study outcomes is substantially less than expected such as recommendations to extend study site;
3. Corrective actions regarding the study site.
4. To assess participant safety, we will have a Data and Safety Officer in place.

The principal investigator and co-investigators will provide oversight, supervision and monitoring of the data collection and will insure integrity of the data which will ultimately ensure subject confidentiality.

K. Monitoring Unanticipated Problems

The principal investigator, Lisette Jacobson, will assume responsibility for:

1. Data quality, completeness, and timeliness;
2. Adherence to the protocol;

3. Factors that might affect the study outcome or compromise the confidentiality of the trial data (such as protocol deviations).

The principal investigator will consult with the research team/co-investigators regarding protocol revisions and amendments before adopting such changes. The IRB will be notified of any problems during the conduct of this study.

L. Ensure General Coordination of Study Conduct

The principal investigator agrees to accept responsibility for the scientific conduct of this study and for the rights and welfare of human subjects. General oversight of the coordination of this study will be provided by the principal investigator.

M. Record Retention

All other study related documents (protocols, databases, IRB documents, surveys) will be retained for fifteen (15) years from the data of initial IRB approval and will be kept in the principal investigator's office (University of Kansas School of Medicine - Wichita) under lock and key at the conclusion of this study. At the time of document disposal, documents will be shredded according to KUMC Research Institute Record Retention guidelines. The University of Kansas School of Medicine record retention policy requires research records involving human subjects to be kept for at least 15 years so all data associated with this study will be kept for at least 15 years.

Section V. Results, Source of Funding, and Study Timeline

A. Dissemination of Results

The findings of this study will be submitted to peer reviewed public health and diabetes prevention journals (i.e. American Journal of Public Health, Diabetes, Diabetes Care, Diabetes Obesity and Metabolism, Health Education and Behavior, Maternal Child Health Journal, etc.), and may be presented at conferences (i.e. Society of Behavioral Medicine, American Public Health Association, American Diabetes Association, National Rural Health Association, research forums, ACOG, district meetings, obstetrical updates, etc.). The IRB will be notified at time of continuing review of the research project. Additionally, findings will be used in the future to obtain grant funding and for future intervention development.

B. Source of Funding

This study is funded by the National Institute of General Medical Sciences (NIGMS) in collaboration with the National Heart, Lung and Blood Institute (NHLBI), under award number 5P20GM144269-02S2.

C. Study Timeline (tentative)

The following timeline is suggested for study completion.

Suggested Timeframe	Completed Objective/Goals
October 2023 – November 2023	IRB protocols, preliminary work including hiring of research coordinator, and working with clinical staff at hospital site
November 2024 – March 2024	Finalize planning for participant recruitment
March - May 2024	Start recruitment (rolling recruitment over a 3-month period)
March 2024 – November 2024	Intervention, data collection, preliminary data analysis
November 2024	Intervention/trial closes
November 2024 – December 2024	Final data analysis, manuscript completion, dissemination of findings, preparation for R01 submission
January - February 2025	R01 submission

Section VI. Attachments/Appendices:

1. Appendix 1 – Letter of Support from the Sunflower Health Network
2. Appendix 2 – Letter of Support from Dr. Michael Wolfe
3. Appendix 3 – Cappa Health Service Agreement
4. Appendix 4 – Questions to obtain information on socio-demographic characteristics and health status (these data will only be collected at study entry)
5. Appendix 5 – Survey Instrument: Breastfeeding Knowledge
6. Appendix 6 – Survey Instrument: Breastfeeding Self-Efficacy Scale-Short From (BSES-SF)
7. Appendix 7 – Survey Instrument: Kaiser Physical Activity Survey (KPAS)
8. Appendix 8 – Survey Instrument: Eating at America's Table Study (EATS) Fruit and Vegetable Intake Screener
9. Appendix 9 – Survey Instrument: Pittsburgh Sleep Quality Index (PSQI)
10. Appendix 10 – Survey Instrument: Edinburgh Postnatal Depression Scale (EPDS)
11. Appendix 11 – Survey Instrument: General Anxiety Disorder (GAD-7)
12. Appendix 12 – Survey Instrument: Lactation Assessment Care Tool (LACT)

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