Diabetes Prevention Program Feasibility Study of Breastfeeding

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Section I. Purpose, Background and Rationale

A. Specific Aims and Hypotheses

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 6 months postpartum. Our trial will have three study arms: DPP plus breastfeeding (Tx1); DPP Only (Tx2); and Usual Care (Tx3). Specific aims are:

Aim 1: Test the efficacy of Tx1 to improve 6-month postpartum weight loss among women with a BMI ≥ 25. We will measure maternal height and weight at baseline; weight at delivery and 6 months postpartum.
Hypothesis 1: Women in Tx1 will have greater weight loss postpartum compared to women in Tx2 and Tx3.

Aim 2: Test the efficacy of Tx1 to improve 6-month postpartum mean blood glucose (HbA1c) and mean arterial blood pressure among women with a BMI ≥ 25. We will measure HbA1c and mean arterial blood pressure at baseline, delivery, and 6 months postpartum.
Hypothesis 2: Women in Tx1 will have better HbA1c and mean arterial blood pressure postpartum compared to women in Tx2 and Tx3.

Aim 3: Test the efficacy of Tx1 to increase any breastfeeding through 6 months postpartum among women with a BMI ≥ 25. We will measure any breastfeeding continuance at week 1, 3, and 6 postpartum, and at 3 and 6 months.
Hypothesis 3: Women in Tx1 will breastfeed longer compared to women in Tx2 and Tx3.

B. Background and Significance

Gestational diabetes mellitus (GDM) affects between 6%[1-3] to 20%[2,4] of pregnant women in the United States. Overweight and obesity are a major risk factor for GDM[5-9] and also considered an independent risk factor for other adverse health outcomes.[10-15] Women with a history of GDM have at least a seven-fold increased risk of developing type 2 diabetes mellitus (T2DM) compared to women who do not have GDM.[16,17] Gestational diabetes is associated with increased maternal and neonatal morbidity and mortality.[18-29] Complications of GDM are further increased for rural women who often experience limited access to obstetrical healthcare services,[30-33] leading to poor birth outcomes[34-36] and reduced breastfeeding rates.[37]

Against this background, we completed a pilot health assessment in a rural southwest Kansas community with an alarming number of high-risk pregnancies complicated by gestational diabetes, 11% vs. 6% nationally.[2] Half of respondents were Hispanic of low socio-economic status.[38] During pregnancy, three-quarters of women were overweight/obese, did not exercise, and had a family history of diabetes.[38] Further, findings from a qualitative follow-up study within this same community indicated that women had limited access to health promotion programs and breastfeeding services.

Rural communities with limited availability of health promotion programs and potentially high rates of chronic disease face a myriad of problems. First, diabetes is associated with adverse health outcomes for mother and child. Women with GDM are at increased risk for pregnancy and delivery complications — including preeclampsia,[18-22] cesarean section,[18,19,22,23] pregnancy-induced hypertension,[20,23,28] preterm birth,[19,20] shoulder dystocia,[18,20,24] and macrosomia[18,20,22-27,29] — leading to increased maternal and neonatal morbidity and mortality.[18,24,29,39] Infants born to mothers with GDM are more likely to have neonatal hypoglycemia,[26,40] hyperinsulinemia,[26,40] and are at greater risk for developing metabolic syndrome,[41] diabetes,[42] and obesity during childhood/adolescence.[43-45] Second, having a pregnancy complicated with GDM and residing in a rural location is particularly challenging due to limited access and availability of healthcare services.[46-51] Specifically, rural pregnant women have a higher likelihood of low birth-weight babies and pre-term delivery,[30,34-36] high smoking rates,[37,52] and reduced breastfeeding rates.[37] Due to geographic barriers, high rates of chronic disease including obesity, and limited availability of health promotion programs coupled with a demonstrated need for health behavior change, it becomes important to test an intervention during the prenatal and postnatal period among this at-risk population. This period is particularly conducive to behavior change because: (1) women are more likely to modify their behavior to benefit their children, (2) behavior change interventions are most successful in the short term, and (3) effective interventions that start during pregnancy are more likely to be sustained after birth, thereby reducing the risk of retaining excess weight and maternal obesity.[53,54]

Given the demonstrated need for health behavior change, it is worthwhile to test the use of an intervention during the prenatal and postnatal period. The Diabetes Prevention Program (DPP) is associated with a reduced risk of developing T2DM by 58% through counseling on effective

diet, exercise, and behavior modification.[55] There is also evidence to support the use of this efficacious program in reducing postpartum weight.[56,57] Further, recent evidence suggests that longer duration of breastfeeding is associated with lowering T2DM incidence,[58-61] reducing maternal postpartum weight,[62-64] and resetting maternal metabolism after pregnancy.[65] Breastfeeding also protects against breast cancer,[66] ovarian cancer,[67,68] and T2DM.[69,70] Despite these findings, no studies have addressed the role of intensive breastfeeding support combined with an efficacious weight loss program to reduce postpartum weight, thereby reducing progression to T2DM after pregnancy.

The American Academy of Pediatrics[71] and the World Health Organization[72] recommend breastfeeding for the first 6 months of life. In Kansas, 79%[73] of women with a BMI ≥ 25 start breastfeeding, and only 29%[73] still breastfeed with some supplementation (defined as "any breastfeeding") at 6 months postpartum. The Kansas rate for high BMI women of 29% is unacceptable and an urgent public health concern when compared to the 6-month breastfeeding rate for normal BMI Kansas women of 51% and the Healthy People 2020 goal of 61%.[74] 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 6 months postpartum. Our trial will have three study arms: DPP plus breastfeeding (Tx1); DPP Only (Tx2); and Usual Care (Tx3). A total sample of 60 pregnant women in their 1st or 2nd trimester with a BMI ≥ 25 will be recruited. Eligible participants are randomly assigned to a study arm (20 per arm).

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%).[38] The majority were overweight (28.1%) or obese (26.2%) *prior* to pregnancy, which increased to 34.4% and 41.6% respectively *during* pregnancy.[38] 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.[38] 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.[37,52,75] 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. These studies also provided me with

experience in collaborating with other researchers and with the process of publishing a manuscript in a high-impact professional journal.

D. Rationale for Proposed Study

Risk factors for diabetes are well documented.[5-9] Maternal obesity in particular increases the risk of negative health outcomes for mother[15,76-80] and child,[81-86] including the propensity for women to retain excessive postpartum weight leading to obesity in subsequent pregnancies.[87-90] 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.[58-61] Breastfeeding also appears to lower maternal postpartum weight[62-64] and facilitates the resetting of maternal metabolism after pregnancy.[65] The Diabetes Prevention Program (DPP) is associated with a reduced risk of developing diabetes by 58%[55] and there is evidence to support the use of this efficacious program in reducing postpartum weight.[56,57] Despite these findings, no studies have used a DPP-enhanced version 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,[84,91-93] 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.

F. Justification for Project

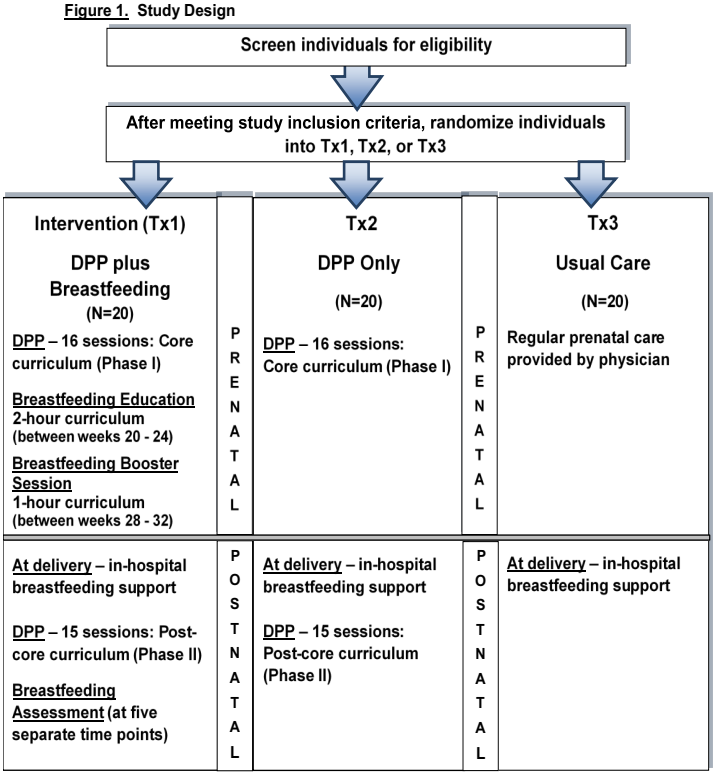
Risk factors for diabetes are well documented,[5-9] but less is known about some factors that attenuate the risk for GDM. Recent studies support the use of the Diabetes Prevention Program in reducing postpartum weight.[56,57] Moreover, emerging research suggests that longer duration of breastfeeding among women with a history of GDM decreases the likelihood of developing type 2 diabetes within two years after pregnancy.[58-61] However, no prior studies have assessed the feasibility and efficacy of a DPP-based intervention that includes intensive breastfeeding counseling and support 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.[94-98] Furthermore, Hispanic women often supplement breastfeeding with formula, triggering decreased milk supply and early breastfeeding cessation.[99-101] 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 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 is a three-arm pilot randomized controlled trial (RCT) to implement as well as determine the feasibility and efficacy of an intervention that is based on the Diabetes Prevention Program and includes intensive breastfeeding counseling and support among a cohort of overweight and obese pregnant women. Upon meeting eligibility criteria, participants will be randomly assigned to the DPP plus breastfeeding (intervention, Tx1), DPP Only (Tx2), or Usual Care (Tx3), and will be followed during pregnancy through 6 months postpartum. Participants in Tx1 will receive the DPP and targeted breastfeeding support during pregnancy through 6 months postpartum. Participants in Tx2 will receive the DPP only. Participants in Tx3 will receive care as usual. Usual care is described as obstetrical care that women with normal BMI receive and that is provided by the same provider (Dr. Michael Wolfe).

At recruitment and at study closure, participants will complete four survey instruments; each of which assesses women's knowledge of physical activity, nutrition, and breastfeeding (see appendices 1 through 4). Also, postpartum women will complete the Edinburgh Postnatal Depression Scale (EPDS, see appendix 5) and a study coordinator will assess postpartum women's breastfeeding experience with the Bristol Breastfeeding Assessment Tool (BBAT, see

appendix 6). Weight, mean blood glucose (HbA1c), mean arterial blood pressure, and glucose tolerance levels during pregnancy as well as initiation and duration of breastfeeding will be measured for all participants through 6 months postpartum.

B. Duration of Study

It is anticipated that after receiving Institutional Review Board (IRB) approval, recruitment will begin during the last quarter of 2019 and will continue through June of 2020. We will recruit over a period of 9 months and the last follow up with women will take place at 6 months postpartum. The trial will be completed over a 24-month period and will conclude during the second quarter of 2021. Data collection and preliminary data analysis will take place as the trial runs. Final data analysis and dissemination of findings will all take place following completion of the trial, during 2021 and 2022.

C. Number of Participants

This IRB protocol pertains to the recruitment of eligible participants from two obstetrical clinics: one clinic at Via Christi Health (VCH), a regional hospital in Wichita, and another clinic at Kearny County Hospital, a full-service hospital in rural southwest Kansas. About 45% (16,797) of Wichita's Hispanic population is female and of reproductive age,[102] and the VCH clinic sees a high volume of this at-risk population at an average of 123 pregnant patients per month, with an average pre-pregnancy BMI of 30.5 (personal communication by senior management staff at VCH on January 18, 2017). These socio-demographic and health data are similar to those of at-risk rural pregnant women in southwest Kansas who visit Kearny County Hospital (KCH) for prenatal and postnatal care. Dr. Michael Wolfe, maternal fetal medicine specialist, sees pregnant women at both of these locations (VCH and KCH), and he and his staff will actively assist with patient recruitment. Our goal is to randomize a total of 72 eligible participants (24 women in each study arm, which translates to 12 women from each recruitment site). Our recruitment target of overweight or obese pregnant women will involve 50% Hispanic women (who are English-speaking) and 50% other race including non-Hispanic whites. The population of pregnant women in southwest Kansas who deliver at Kearny County Hospital, Lakin, Kansas, is estimated to be 300 individuals, of which 75% (or 225 individuals) have a BMI ≥ 25 and < 35.

D. Subject Selection Criteria and Recruitment

We will recruit pregnant patients from two obstetrical clinics: one clinic at Via Christi Hospitals Wichita, Inc. (VCH), a regional hospital in Wichita, and another clinic at Kearny County Hospital, a full-service rural hospital located in Lakin, southwest Kansas. Dr. Michael Wolfe, maternal fetal medicine specialist, sees pregnant women at this location, and he and his staff will actively assist with patient recruitment. During the first 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 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 IRB at Via Christi Hospitals Wichita, Inc. By providing the potential

participant with a copy of the consent form, this will serve as the verbal consent script. Dr. Wolfe will also provide the potential participant's name and phone number to Dr. Jacobson and her research coordinator. After receiving a potential participant's name and phone number from Dr. Wolfe, the research coordinator will follow up with a phone call 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 during the same phone call (see Table 1). Before the research coordinator screens for inclusion and exclusion criteria, during this same phone call, 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. 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 1st trimester or early in 2nd trimester
2. BMI ≥ 25 and < 35
3. At least 18 years old or older
4. Be able to understand English
5. Must have a cell phone
6. Able to use Facebook
7. Able to use Skype, FaceTime or Zoom
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 call her again to assign her a time and place for the 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 $50 gift card at study entry, (2) a digital scale and pedometer at delivery, and (3) a gift up to $75 for baby at Walmart's baby registry 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 overweight or obese pregnant women will involve 50% Hispanic women (who are English-speaking) and 50% other race including non-Hispanic whites. We anticipate meeting our recruitment goals through multiple approaches. We will promote the study via targeted mailings and clinic posters. We will advertise and develop study materials in English only. We will recruit over a period of 9 months, planning to randomize 2-3 participants

each week, or 1-2 participants per site. Our goal is to randomize a total of 72 pregnant women (24 women in each study arm, 12 women per site). Given an attrition rate of 20%, this will leave us with 60 women total (20 women in each study arm, or 10 women per site in each study arm).

E. Study Locations

Recruitment will take place at two obstetrical clinics: 1) Via Christi Hospitals Wichita, Inc., Kansas, and 2) Kearny County Hospital, Lakin, Kansas. We will have on-going support from both hospitals. Michael Mullins, Senior Vice President, Ascension Healthcare and Laurie Labarca, Hospital President St. Joseph, Via Christi Hospitals Wichita, Inc. as well as Benjamin Anderson, Chief Executive Officer Kearny County Hospital, fully support Dr. Jacobson's work 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 6 months postpartum (see their letters of support, Appendix 7-8). Most importantly, we will have ongoing support for Dr. Jacobson's work from Dr. Michael Wolfe, Maternal Fetal Medicine Specialist, who sees pregnant women at both locations (see letter of support, Appendix 9).

Locations for each obstetrical clinic affiliated with the hospitals above are as follows:

Kearny County Hospital
500 East Thorpe Street
Lakin, Kansas 67860

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)[103,104] and Self-Determination Theory (SDT)[105,106] 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[107] that explains how intrinsic motivation can lead to improved eating and exercise patterns.[108] 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.

Diabetes Prevention Program (DPP). Dr. Jacobson and the research coordinator will administer the DPP in two phases. Phase I consists of a total of 16 sessions that will be completed during pregnancy (see Table 2). Two of the Phase I DPP sessions have been replaced with the Cooking Matters[47] curriculum: DPP session #2 has been replaced with creating a healthy home food environment, and DPP session #4 with incorporating more fruits, vegetables,

and whole grains into family meals. Cooking Matters empowers low-income families with the skills to cook healthy, affordable meals at home. Its curriculum uses the Dietary Guidelines for Americans[109] and MyPlate[71] as the foundation for basic nutrition guidelines. Each of the sixteen (16) sessions/modules of Phase I will be pre-recorded and archived on a secure, private group on Facebook. Only Tx1 and Tx2 participants, Dr. Jacobson and the research coordinator will have access to this Facebook group.

We will employ a "rolling" recruitment period of 9 months, meaning that each participant may be at different completion stages. During their first face-to-face orientation session, participants will receive access to the secure, private group on Facebook. They will be asked to complete each Phase I module on their own time, starting at week 19 of pregnancy. To supplement their self-study of the curriculum, on a weekly basis, the research coordinator will follow up with each study participant via phone to check on progress. If participants do not make adequate progress, then the coordinator will assess how much extra time the participant needs to complete a module, and will work with her face-to-face via Skype, FaceTime or Zoom if needed. Participants will complete Phase I by week 33 of pregnancy.

Phase II consists of a total of 15 sessions that will be completed after delivery (see Table 2). Two of the Phase II DPP sessions (sessions #4 and #5 respectively) have been modified with the Cooking Matters curriculum that (1) emphasizes planning/preparing for healthy, low-cost meals and (2) encourages mothers to make smart choices when food shopping. Each of the fifteen (15) sessions/modules of Phase II will be pre-recorded and archived on the same secure, private group on Facebook mentioned above. Only Tx1 and Tx2 participants, Dr. Jacobson and the research coordinator will have access to this Facebook group.

Participants will re-engage into the DPP with another face-to-face orientation session conducted by Dr. Jacobson at week 6 postpartum. The same session completion format and procedure for inadequate progress will be followed as during pregnancy. Participants will complete Phase II by week 20 postpartum. An 80% completion rate of each phase is considered successful completion of the intervention.

Table 2. Timetable - Diabetes Prevention Program Sessions

Prenatal (Core Curriculum)		Postnatal (Post-core Curriculum)	
DPP Sessions - Phase I	Week of Pregnancy	DPP Sessions - Phase II	Week of Postpartum
1 - Orientation - Welcome!	18	1 - Orientation - Welcome Back!	6
2 - Cooking Matters (CM): Set a Healthy Example	19	2 - Fats: Saturated, Unsaturated, & Trans-Fats	7
3 - Eating Less Fat and Fewer Calories	20	3 - Food Preparation & Recipe Modification	8
4 - CM: Choosing Fruits, Vege's, Whole Grains	21	4 - Taking It One Meal at a Time, *CM: Planning*	9
5 - Move Those Muscles	22	5 - Variety and Balance, *CM: Shopping*	10
6 - Being Active - A Way of Life	23	6 - More Volume, Fewer Calories	11
7 - Tip the Calorie Balance	24	7 - Staying on Top of Physical Activity	12
8 - Take Charge of What's Around You	25	8 - Stepping Up to Physical Activity	13
9 - Problem Solving	26	9 - Long-term Maintenance	14
10 - Four Keys to Healthy Eating Out	27	10 - Holidays, Vacations, Special Events	15
11 - Talk Back to Negative Thoughts	28	11 - Preventing Relapse	16
12 - The Slippery Slope of Lifestyle Change	29	12 - Stress and Time Management	17
13 - Jump Start Your Activity Plan	30	13 - Heart Health	18
14 - Make Social Cues Work for You	31	14 - A Closer Look at Type 2 Diabetes	19
15 - You Can Manage Stress	32	15 - Looking Back and Looking Forward	20
16 - Ways to Stay Motivated	33		

Breastfeeding. Additionally, participants in Tx1 will receive an educational session on breastfeeding and will register for and participate in a professional peer support group (see Table 3). Participants in Tx2 and Tx3 will not receive breastfeeding education or register/participate in a professional peer support group. The 2-hour breastfeeding session is pre-recorded into four (4) 30-minute sessions and archived on the same secure, private Facebook group as mentioned previously. Participants will have access to all four breastfeeding sessions by week 24 of pregnancy and they need to complete all sessions by week 30 of pregnancy. The breastfeeding session will be taught by an 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 be provided with a breastfeeding assessment at day 3, day 10, week 3 and week 6, as well as months 2, 3 and 6 postpartum (see Table 3). The breastfeeding telephone assessment is modelled after the Bristol Breastfeeding Assessment Tool (BBAT)[110] (see Appendix 6) and used to improve an infant's positioning, attachment, sucking, and swallowing. During these telephone assessments, Dr. Jacobson's research coordinator will assess if mother and baby need breastfeeding support from a lactation professional. If the telephone assessment warrants an in-person visit, then the research coordinator will put mother and baby in contact with a lactation professional provided by the hospital.

Table 3. Breastfeeding Support for Women in Tx1 (Intervention Arm) Only

	Prenatal	Postnatal						
Intervention Components	Week 24 - 30	Day 3	Day 10	3 Weeks	6 Weeks	2 Months	3 Months	6 Months
Breastfeeding Education (2-hour curriculum)	X							
Breastfeeding Professional Peer Support	Participants initiate contact	Participants attend 2 to 4 sessions as needed						
Breastfeeding Telephone Assessment (15-20 minutes)		X	X	X	X	X	X	X

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.[111] and the United Methodist Health Ministry Fund's High 5 for Mom & Baby.[112] Further, the curriculum is based on the Office on Women's Health "Your Guide to Breastfeeding."[113] 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. All surveys will be self-administered (Appendix 1 through 5 – Survey Instruments) 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 six months postpartum (see Table 5 Data Collection). 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 6 months postpartum, <u>all</u> participants will complete four pre- and post-survey instruments: (1) Breastfeeding assessment, socio-demographic characteristics, and health status (sociodemographic and health status questions will only be asked at baseline, not at study closure) (Appendix 1); (2) Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) (Appendix 1);[114-117] (3) Kaiser Physical Activity Survey (KPAS) (Appendix 2);[118,119] and, (4) the Eating At America's Table Study (EATS) Fruit & Vegetable Intake Screener[120-122] (Appendix 3) supplemented with questions on fiber, added sugars, dairy, calcium, and meat from the Dietary Screener in the National Health and Nutrition Examination Survey (NHANES 2009-10) (Appendix 4).[123,124] 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 postnatal depression.[125,126] Therefore, at 6 weeks postpartum, all participants will complete the Edinburgh Postnatal Depression Scale (EPDS) (Appendix 5),[127-129] which takes about 5 minutes. Participants with an EPDS score of 10 or higher will be referred to a mental healthcare professional for further psychological evaluation. All study survey instruments are listed in Table 4.

Table 4. Survey Instruments

Study Instrument	Items Measured	No. of Items	Reliability	Populations Validated
Breastfeeding Knowledge Assessment, Socio-demographic Characteristics, and Health Status	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.	Crohnbach'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.
Selected items from the Dietary Screener Questionnaire (NHANES 2009-10)	To assess intake of fiber, added sugars, dairy, calcium, and meat.	Up to 6 selected items on fiber, added sugars, dairy, calcium and meat; DSQ has a total of 26 items.	Not yet performed.	Not yet performed.
Edinburgh Postnatal Depression Scale (EPDS)	To assess levels of depression during the postpartum period.	10 items	Sensitivity: 34-100% Specificity: 44-100% Positive likelihood ratios: 1.61-78	Antepartum and postpartum women.

Each participant will receive a $50 gift card at consent, after she will deliver her baby, the participant will receive a digital scale and a pedometer, and upon completion of the study (at 6 months after birth), each participant may select a gift up to $75 for their baby from their baby registry at Walmart. . In summary, for participants randomized to any of the three groups: 1) DPP plus breastfeeding, or 2) DPP only, or 3) Usual care, the total possible compensation is valued at $187.50 including the following gift items: digital scale (valued at $50 each), pedometer (valued at $12.50 each), baby gift at Walmart (valued at $75 each), and a $50 gift card.

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.

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.[19] 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.

Outcome Measures and Rationale for Outcome Measures. The expected outcomes of this study are (1) to increase postpartum weight loss; (2) to improve HbA1c and mean arterial blood pressure; and (3) to increase any breastfeeding. 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 women who withdraw from the study and reasons for withdrawal, number of women who complete the DPP protocol, and number of women who complete the breastfeeding sessions. Upon recruitment into the study and at study closure, all participants will complete the BSES-SF, KPAS, EATS, and selected items from the DSQ NHANES 2009-10 to assess differences in knowledge and self-efficacy toward breastfeeding, physical activity, and nutrition. Table 5 shows a timeline for data collection in all three study arms.

Aim 1: Test the efficacy of Tx1 to improve 6-month postpartum weight loss among women with a BMI ≥ 25. Hypothesis 1: Women in Tx1 will have greater weight loss postpartum compared to women in Tx2 and Tx3. We will measure maternal height and weight as outlined in Table 5 below. We will measure weight loss at the same time points as any breastfeeding because this will allow meaningful comparisons among the study arms.

Aim 2: Test the efficacy of Tx1 to improve 6-month postpartum mean blood glucose (HbA1c) and mean arterial blood pressure among women with a BMI ≥ 25. Hypothesis 2: Women in Tx1 will have better HbA1c and mean arterial blood pressure postpartum compared to women in Tx2 and Tx3. We will measure mean blood glucose and mean arterial blood pressure ((systolic blood pressure +2 [41]/3)) as outlined in Table 5 below. We will also collect baseline data on glucose tolerance levels during pregnancy.

Aim 3: Test the efficacy of Tx1 to increase any breastfeeding through 6 months postpartum among women with a BMI ≥ 25. Hypothesis 3: Women in Tx1 will breastfeed longer compared to women in Tx2 and Tx3. At delivery, breastfeeding initiation will be measured (see Table 5). This is defined as starting breastfeeding immediately after delivery. We

will also measure the duration of any breastfeeding (defined as predominant breast milk with some formula supplementation) as outlined in Table 5 below. Further, we will measure exclusivity of breastfeeding (defined as exclusive breast milk without supplementation unless medically necessary), formula supplementation, and solid foods. We will measure formula and solid food at the time that they were first introduced as well as quantity and frequency of feedings.

Table 5. Timeline: Data Collection for All Study Participants

	Prenatal					Postnatal					
Measurements	**Baseline**	**Week 24**	**Week 28**	**Week 32**	**Week 36**	**Delivery**	**1 Week**	**3 Weeks**	**6 Weeks**	**3 Months**	**6 Months**
Breastfeeding Knowledge, demographics, health status	X										X
Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF)	X										X
Kaiser Physical Activity Survey (KPAS)	X										X
Fruit & Vegetable Intake Screener (EATS)	X										X
Selected items from DSQ (NHANES 2009-10)	X										X
Mother's Weight (lbs)	X					X	X	X	X	X	X
Mother's Height (inches)	X										
Glucose tolerance	X										
Mother's HbA1c	X										X
Mother's Mean Arterial Blood Pressure	X					X					X
Baby's Weight (kg)						X	X	X	X	X	X
Baby's Height (gm)						X	X	X	X	X	X
Breastfeeding Initiation at Delivery						X					
Breastfeeding Duration (any and exclusive)							X	X	X	X	X
Formula Supplementation						X	X	X	X	X	X
Solid Foods							X	X	X	X	X

Sample Size and Randomization. The primary outcomes of interest are: (1) postpartum weight loss; (2) HbA1c and mean arterial blood pressure; and (3) breastfeeding duration. A total of 60 participants (20 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 the three study arms. Block randomization with block size of 5 participants will be employed. A sequence of 12 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; the next 4 integers will be assigned to the DPP only arm; and the last 4 will be assigned to the usual care arm. Blocks will be assigned to arms in the increasing order of sequence of integers generated.

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 three 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.

Aim 1: **Test the efficacy of Tx1 to improve 6-month postpartum weight loss among women with a BMI ≥ 25.** The outcome of interest is 6 month postpartum weight loss measured across the three arms. Weight will be measured at delivery, and at weeks 1, 3, and 6 postpartum and at 3 months (13 weeks) and 6 months (26 weeks) postpartum. The difference in postpartum weight (weight loss) between two consecutive time points will be computed. Thus, each participant has 5 postpartum weight loss values based on weight measurements at 6 different time points. We will use the generalized estimating equation approach to compare weight loss in the DPP plus breastfeeding arm (Tx1) with weight loss in the DPP only (Tx2) and usual care (Tx3) arms, as well as weight loss between Tx2 and Tx3. The working correlation matrix will be specified after assessing the data. The model will be adjusted for the effect of age, race/ethnicity, level of education, annual household income, family history of diabetes, baseline weight, pre-diabetes status, and parity.

Aim 2: Test the efficacy of Tx1 to improve 6-month postpartum mean blood glucose (HbA1c) and mean arterial blood pressure among women with a BMI ≥ 25. The outcome of interest is mean blood glucose (HbA1c) and mean arterial blood pressure ((systolic blood pressure +2 (diastolic blood pressure)/3)) measured at baseline, delivery, and at 6 months postpartum across the three arms. We will use a multiple linear regression approach to compare HbA1c in Tx1 with HbA1c in Tx2 and Tx3, as well as HbA1c between Tx2 and Tx3. 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, parity, and baseline weight. The difference in mean blood arterial pressure at 6 months postpartum will also be assessed using a separate multiple linear regression approach after adjusting for the same covariates listed previously.

Aim 3: **Test the efficacy of Tx1 to increase any breastfeeding through 6 months postpartum among women with a BMI ≥ 25.** The outcome of interest is breastfeeding through 6 months postpartum; it will be measured at delivery, and at weeks 1, 3, and 6 postpartum and at 3 months (13 weeks) and 6 months (26 weeks) postpartum. The risk of stopping "6 month postpartum breastfeeding" in Tx1 relative to Tx2 and Tx3 will be estimated using Zou's modified Poisson regression approach.[130] The outcome in Zou's modified Poisson regression is binary, and it does not take into account the time until which any breastfeeding was done before stopping. However, it provides an interpretation-friendly estimate of the probability of stopping "6 month postpartum breastfeeding." Additionally, the Cox Ph model will be used to compare the risk (hazard) of stopping breastfeeding across each study arm. Unlike Zou's modified Poisson approach, the Cox model takes into account the time of breastfeeding. Any participants who are lost to follow-up will be treated as censored events and participants who stop

breastfeeding during the follow-up are the events of interest. In addition, participants who performed any breastfeeding until 6 months will be treated as administratively censored events. The model will be adjusted for the same covariates listed above under Aims #1 and #2.

Missing data. Owing to the design of the study and non-transient nature of the study population, we anticipate few to none missing observations. Any missing observation that can be attributed to either attrition or nonresponse will be considered missing at random. 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 Assessment, BSES-SF, KPAS, EATS, and selected items from the DSQ. 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" across all three 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 all three 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 all three 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 up to 6 questions will be selected from the DSQ. For each question, counts and percentages will be reported for participants at recruitment and at study closure across all three study arms.

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 and in or near Lakin, Kansas. Participants are eligible if they meet study inclusion criteria. This is a randomized controlled pilot study with three study arms. Participants will be randomized to each arm of the study by computer. Participants in Tx1 will receive the DPP plus breastfeeding, participants in Tx2 will receive the DPP only, and participants in Tx3 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 60 pregnant female participants.

Participants are recruited from an obstetrical clinic at Via Christi Hospitals Wichita, Inc., a regional medical center located in Wichita, Kansas, and Kearny County Hospital, a critical access full-spectrum rural hospital, in Lakin, 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 1st trimester or early during the 2nd 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, breastfeeding behaviors, HbA1c and blood pressure among an at-risk ethnically and racially diverse, overweight and obese pregnant population.

We will obtain approval from the Institutional Review Board (IRB) at the University of Kansas School of Medicine-Wichita (KUSM-W), Via Christi Hospitals Wichita, Inc. (VCH), and Kearny County Hospital (KCH). Via Christi Hospitals Wichita, Inc. and Kearny County Hospital are agreeable to allow Dr. Jacobson and her research team access to use their patient population to recruit study participants. With the active assistance of Dr. Wolfe, maternal fetal medicine specialist at both hospitals, Dr. Jacobson and her research team 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. Sources of materials

Research material obtained from participants will include: socio-demographic data (i.e. age, race/ethnicity, income, education level, etc.), breastfeeding self-efficacy, physical activity level, dietary assessment, level of postpartum depression, weight, height, HbA1c, 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 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 Dietary Screener Questionnaire (NHANES 2009-10), and the Edinburgh Postnatal Depression Scale (EDPS). These validated survey instruments will be administered at baseline (=study entry) and at study closure (=6 months postpartum). At delivery and through the 6 month postpartum period, we will also obtain the infant's height and weight. Further, at delivery, we will measure if the mother will start breastfeeding and we will measure how long she will continue breastfeeding through 6 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 Kearny County Hospital (depending on the residence of the study participant). Data collected 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 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, HbA1c and mean arterial blood pressure will be measured. 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 an IBCLC up to 6 months postpartum. 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 insure 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.

B. Adequacy of Protection Against Risks

a. <u>Recruitment and Informed Consent</u>

Participants will be recruited from the obstetrical clinic located at Via Christi Hospitals Wichita, Inc., a regional medical center located in Wichita, Kansas, and at Kearny County Hospital, a critical access full-spectrum rural hospital, in Lakin, Kansas. We will use printed flyers, posters and word-of-mouth advertising to recruit potential participants. Prior to using these recruitment materials, IRB at Via Christi Hospitals Wichita, Inc. will review and approve these materials. Dr. Michael Wolfe, Via Christi Hospitals Wichita, Inc. and Kearny County Hospital's maternal fetal medicine specialist, will make the initial contact with a potential participant during her first prenatal visit and screen for inclusion criteria. 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 paper copy of the consent form. Prior to using this study brochure, the brochure will be reviewed and approved by the IRB at Via Christi Hospitals Wichita, Inc. By providing the potential participant with a copy of the consent form, this will serve as the verbal consent script.

Then, Dr. Wolfe will provide Dr. Jacobson and her research coordinator the potential participant's contact information (i.e., participant name, email address, telephone number). 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 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 were 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.

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. Paige Geiger has agreed and is confirmed as the Data and Safety Officer for our study. Paige Geiger, PhD, is a full professor in the Department of Molecular and Integrative Physiology, University of Kansas School of Medicine-Kansas City, Mailstop 3043, 3901 Rainbow Boulevard, Kansas City, KS 66160.

C. 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 breastfeeding, and improves mean blood glucose (HbA1c) and mean arterial blood pressure, among an at-risk population with a BMI ≥ 25. This is an innovative way to address 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.

D. 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 not 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, HbA1c, mean arterial blood pressure 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 will be funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), grant number 1K01DK113048-01A1.

C. Study Timeline (tentative)

The following timeline is suggested for study completion.

Suggested Timeframe	Completed Objective/Goals
September 2018 – December 2018	IRB protocols, preliminary work including hiring of research coordinator, and working working with clinical staff at both hospital sites
January 2019 – August 2019	Finalize planning for participant recruitment
September 2019	Start recruitment (rolling recruitment over a 9 month period)
September 2019 – September 2021	Intervention, data collection, preliminary data analysis
September 2021	Intervention/trial closes
September 2021 – December 2022	Final data analysis, manuscript completion, dissemination of findings, preparation for R01 submission
January 2023 – September 2023	R01 submission

Section VI. Attachments/Appendices:

1. Appendix 1 – Survey Instrument, Breastfeeding Self-Efficacy Scale-Short From (BSES-SF) and Breastfeeding Knowledge Assessment (the Breastfeeding Knowledge assessment includes questions regarding socio-demographic data and health status data; these data will only be collected at study entry)
2. Appendix 2 – Survey Instrument, Kaiser Physical Activity Survey (KPAS)
3. Appendix 3 – Survey Instrument, Eating at America's Table Study (EATS) Fruit and Vegetable Intake Screener
4. Appendix 4 – Selected survey items (6) from the "Dietary Screener Questionnaire" (NHANES 2009-10)
5. Appendix 5 – Survey Instrument, Edinburgh Postnatal Depression Scale (EPDS)
6. Appendix 6 – Bristol Breastfeeding Assessment Tool (BBAT)
7. Appendix 7 – Letter of Support from Via Christi
8. Appendix 8 – Letter of Support from Kearny County Hospital
9. Appendix 9 – Letter of Support from Dr. Michael Wolfe

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